# ACTEMRA IV (S)

#### **Products Affected**

• Actemra INJ 200MG/10ML, 400MG/20ML, 80MG/4ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Actemra therapy. Systemic Juvenile Idiopathic arthritis (SJIA) (Initial): Diagnosis of active SJIA. Trial and failure, contraindication, or intolerance to one NSAID or systemic glucocorticoid. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of active PJIA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Actemra therapy. RA, SJIA, PJIA (Initial, reauth): Patient is not receiving Actemra in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]. Cytokine Release Syndrome (CRS) Risk due to CAR T-cell Therapy: Patient will receive or is receiving chimeric antigen receptor (CAR) T-cell immunotherapy [i.e., Kymriah (tisagenlecleuce), Yescarta (axicabtagene ciloleucel)].
Age Restrictions	N/A
Prescriber Restrictions	RA, SJIA, PJIA (Initial): Prescribed by or in consultation with a rheumatologist. CRS Risk due to CAR T-cell Therapy: Prescribed by or in consultation with an oncologist or hematologist.
Coverage Duration	RA, SJIA, PJIA (Initial, reauth): 12 months. CRS risk due to CAR T-cell therapy: 2 months
Other Criteria	RA, SJIA, PJIA (Reauth): Documentation of positive clinical response to Actemra therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# **ACTIMMUNE (S)**

#### **Products Affected**

• Actimmune

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of one of the following: 1) Chronic granulomatous disease (CGD), or 2) severe malignant osteopetrosis (SMO).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# ADAGEN (S)

#### **Products Affected**

• Adagen

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Excluded if patient has severe thrombocytopenia
Required Medical Information	Adenosine deaminase (ADA) deficiency: Diagnosis of ADA deficiency in a patient with severe combined immunodeficiency disease (SCID) AND patient is not a suitable candidate for, or who has failed, bone marrow transplantation, hematopoietic stem cell transplant, or gene therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# ADCIRCA (S)

#### **Products Affected**

- Adcirca
- Tadalafil TABS 20MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# ADDERALL XR (S)

#### **Products Affected**

• Amphetamine/dextroamphetamine CP24

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# ADEMPAS (S)

#### **Products Affected**

• Adempas

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH AND PAH is symptomatic AND One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. Chronic thromboembolic pulmonary hypertension (CTEPH) (Initial): One of the following: A) Both of the following: 1) Diagnosis of inoperable or persistent/recurrent CTEPH and 2) CTEPH is symptomatic OR B) Patient is currently on any therapy for the diagnosis of CTEPH.
Age Restrictions	N/A
Prescriber Restrictions	PAH, CTEPH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH, CTEPH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH, CTEPH (Reauth): Documentation of positive clinical response to therapy.

# **AFINITOR (S)**

#### **Products Affected**

• Afinitor

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC): Diagnosis of SEGA associated with TSC that requires therapeutic intervention but patient is not a candidate for curative surgical resection. Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma AND trial and failure, contraindication, or intolerance to SUTENT (sunitinib) or NEXAVAR (sorafenib).  Neuroendocrine tumors of pancreatic origin (pNET): Diagnosis of progressive pNET that are unresectable, locally advanced, or metastatic. Renal angiomyolipoma: Diagnosis of renal angiomyolipoma and TSC AND Patient does not require immediate surgery. Breast Cancer: Patient is a postmenopausal woman AND Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer AND trial and failure, contraindication, or intolerance to FEMARA (letrozole) or ARIMIDEX (anastrozole) AND Afinitor will be used in combination with AROMASIN (exemestane). Neuroendocrine tumors of gastrointestinal (GI) or lung origin: Diagnosis of progressive, well-differentiated, nonfunctional NET of GI or lung origin AND patient has unresectable, locally advanced or metastatic disease.
Age Restrictions	N/A
Prescriber Restrictions	All Indications: Prescribed by or in consultation with an oncologist
Coverage Duration	All Indications: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

# **AFINITOR DISPERZ (S)**

#### **Products Affected**

• Afinitor Disperz

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Subependymal Giant Cell Astrocytoma (SEGA): Diagnosis of SEGA associated with tuberous sclerosis complex (TSC) that requires therapeutic intervention but patient is not a candidate for curative surgical resection. TSC-associated partial-onset seizures: Diagnosis of TSC-associated partial-onset seizures. Used as adjunctive therapy.
Age Restrictions	N/A
Prescriber Restrictions	SEGA: Prescribed by or in consultation with an oncologist. TSC-associated partial-onset seizures: Prescribed by or in consultation with a neurologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# **ALDURAZYME (S)**

#### **Products Affected**

• Aldurazyme

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Mucopolysaccharidosis I: confirmed diagnosis of Hurler and Hurler-Scheie forms of Mucopolysaccharidosis I (MPS I), OR confirmed diagnosis of Scheie form of Mucopolysaccharidosis I (MPS I) who have moderate to severe symptoms.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# **ALECENSA (S)**

#### **Products Affected**

Alecensa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): A) Diagnosis of metastatic NSCLC AND B) Patient has anaplastic lymphoma kinase (ALK)-positive disease as detected with an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# ALIQOPA (S)

#### **Products Affected**

• Aliqopa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Relapsed Follicular Lymphoma: Diagnosis of relapsed follicular lymphoma AND patient has received at least two prior systemic therapies.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# ALPHA-1 PROTEINASE INHIBITOR, NON-PREFERRED (S)

#### **Products Affected**

- Aralast Np
- Glassia

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency: All of the following: A) Patient has an alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency AND B) Diagnosis of emphysema AND C) One of the following: 1) Patient has a high risk phenotype: PiZZ, PiZ(null), or Pi(null)(null) OR 2) Patient has serum alpha-1 antitrypsin concentrations of less than 11 µM/L (80 mg/dL), AND D) One of the following: FEV1 level is between 30% and 65% of predicted OR the patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment, AND E) Trial and failure, or intolerance to Prolastin-C.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# ALPHA-1 PROTEINASE INHIBITOR, PROLASTIN (S)

#### **Products Affected**

- Prolastin-c
- Zemaira

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency: All of the following: A) Patient has an alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency AND B) Diagnosis of emphysema AND C) One of the following: 1) Patient has a high risk phenotype: PiZZ, PiZ(null), or Pi(null)(null) OR 2) Patient has serum alpha-1 antitrypsin concentrations of less than 11 µM/L (80 mg/dL) AND D) One of the following: FEV1 level is between 30% and 65% of predicted OR the patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# **ALUNBRIG (S)**

#### **Products Affected**

• Alunbrig

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC. Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility. Trial and failure or intolerance to Xalkori (crizotinib).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# AMPYRA (S)

#### **Products Affected**

- Ampyra
- Dalfampridine Er

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS) (initial): Diagnosis of MS. Physician confirmation that patient has difficulty walking (eg, timed 25 foot walk test). One of the following: expanded disability status scale (EDSS) score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured).
Age Restrictions	N/A
Prescriber Restrictions	MS (Initial): Prescribed by or in consultation with a neurologist.
Coverage Duration	MS (Initial): 6 months. (Reauth): 12 months.
Other Criteria	MS (Reauth): Physician confirmation that the patient's walking improved with Ampyra therapy. One of the following: EDSS score less than or equal to 7, or not restricted to using a wheelchair (if EDSS is not measured).

Members Health Insurance Company Date Effective: November 1, 2018

# ANADROL-50(S)

#### **Products Affected**

• Anadrol-50

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Anemia (initial): Diagnosis of anemia caused by deficient red cell production AND trial and failure or intolerance to standard therapies for anemia (i.e., erythropoiesis-stimulating agents, immunosuppressants) AND Treatment will not replace other supportive measures (e.g., transfusion, correction of iron, folic acid, vitamin B12 or pyridoxine deficiency, antibacterial therapy, corticosteroids).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial and reauth: 12 months
Other Criteria	Anemia (reauth): patient has experienced an objective improvement in anemia (e.g., increased hemoglobin, increased reticulocyte count, reduction/elimination for need of blood transfusions)

# ANDROXY (S)

#### **Products Affected**

• Androxy

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Hypogonadism (HG) (Initial): Diagnosis (dx) of HG in a male patient at birth. 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Delayed puberty (DP): Dx of DP in males at birth. Breast cancer (BC): Dx for the palliative treatment of inoperable BC in females at birth. Gender Identity Disorder (GID) (off-label): Dx of GID. Patient is a female-to-male transsexual.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC, GID: 12 mo. DP: 6 mo.
Other Criteria	HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

Members Health Insurance Company Date Effective: November 1, 2018

# APOKYN (S)

#### **Products Affected**

• Apokyn INJ 30MG/3ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	PD (Initial): Patient is using Apokyn with any 5-HT3 antagonist (eg, ondansetron, granisetron, dolasetron, palonosetron, alosetron)
Required Medical Information	Parkinson's disease (PD) (Initial): Diagnosis of advanced PD. Patient is experiencing acute intermittent hypomobility (defined as "off" episodes characterized by muscle stiffness, slow movements, or difficulty starting movements). Patient is receiving Apokyn in combination with other medications for the treatment of PD (e.g., carbidopa/levodopa, pramipexole, ropinirole, benztropine, etc.).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PD (Initial, reauth): 12 months
Other Criteria	PD (Reauth): Patient is benefiting from therapy (eg, patient had an improvement in motor function).

Prior Authorization Criteria Members Health Insurance Company Date Effective: November 1, 2018

# ARANESP (S)

#### **Products Affected**

Aranesp Albumin Free INJ 100MCG/0.5ML, 100MCG/ML, 10MCG/0.4ML, 150MCG/0.3ML, 200MCG/0.4ML, 200MCG/ML, 25MCG/0.42ML, 25MCG/ML, 300MCG/0.6ML, 300MCG/ML, 40MCG/0.4ML, 40MCG/ML, 500MCG/ML, 60MCG/0.3ML, 60MCG/ML Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with chemo (Initial): Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS. CKD (init, reauth), Chemo (init), MDS (init): Verify iron evaluation for adequate iron stores.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CKD (Init): 6 mo. CKD (reauth): 12 mo. Chemo(init, reauth): 3 mo. MDS: (init) 3 mo,(reauth) 12 mo.
Other Criteria	Subject to ESRD review. CKD (Reauth): Dx of CKD. Most recent or average (avg) Hct over 3 mo is 33% or less OR most recent or avg Hgb over 3 months is 11 g/dL or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less.

Members Health Insurance Company

Date Effective: November 1, 2018

Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Off-label uses (except MDS): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%.

Members Health Insurance Company Date Effective: November 1, 2018

# **ARCALYST (S)**

#### **Products Affected**

• Arcalyst

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Cryopyrin-Associated Periodic Syndromes (CAPS) (Initial): Diagnosis of CAPS, including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS). The medication will not be used in combination with another biologic.
Age Restrictions	CAPS (Initial): 12 years of age or older
Prescriber Restrictions	CAPS (Initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist.
Coverage Duration	CAPS (initial, reauth): 12 months
Other Criteria	CAPS (Reauth): Patient has experienced disease stability or improvement in clinical symptoms while on therapy as evidence by one of the following: A) improvement in rash, fever, joint pain, headache, conjunctivitis, B) decreased number of disease flare days, C) normalization of inflammatory markers (CRP, ESR, SAA), D) corticosteroid dose reduction, OR E) improvement in MD global score or active joint count.

Members Health Insurance Company Date Effective: November 1, 2018

# ARZERRA (S)

#### **Products Affected**

• Arzerra

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Refractory chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Disease is refractory to both fludarabine and alemtuzumab. Previously untreated CLL: Diagnosis of CLL. Patient is previously untreated for CLL. Patient is not an appropriate candidate for fludarabine-based therapy. Used in combination with chlorambucil. Recurrent or progressive Chronic Lymphocytic Leukemia (CLL): Diagnosis of chronic lymphocytic leukemia (CLL). Disease is recurrent or progressive. Arzerra is used for an extended treatment for patients who are in complete or partial response after at least two lines of therapy. Relapsed Chronic Lymphocytic Leukemia (CLL): Diagnosis of CLL. Disease has relapsed. Used in combination with fludarabine and cyclophosphamide.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# AUBAGIO (S)

#### **Products Affected**

• Aubagio

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# **AURYXIA (S)**

#### **Products Affected**

• Auryxia

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Exclude if used for iron deficiency anemia in chronic kidney disease (CKD) not on dialysis.
Required Medical Information	Hyperphosphatemia in chronic kidney disease: Diagnosis of hyperphosphatemia. Patient has chronic kidney disease (CKD). Patient is on dialysis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# AUSTEDO (S)

#### **Products Affected**

• Austedo

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chorea associated with Huntington's disease (initial): Diagnosis of Chorea associated with Huntington's disease. Tardive dyskinesia (initial): Diagnosis of moderate to severe tardive dyskinesia. One of the following: 1) Patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication or 2) Patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication.
Age Restrictions	N/A
Prescriber Restrictions	Huntington's disease chorea (initial): Prescribed by a neurologist. Tardive dyskinesia (initial): Prescribed by or in consultation with a neurologist or psychiatrist.
Coverage Duration	initial: 3 months, Reauth: 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to Austedo therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# BAVENCIO (S)

#### **Products Affected**

• Bavencio

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Merkel Cell Carcinoma (MCC): Diagnosis of metastatic Merkel cell carcinoma. Urothelial Carcinoma (UC): Diagnosis of locally advanced or metastatic urothelial carcinoma. One of the following: 1) Patient has disease progression during or following platinum-containing chemotherapy, OR 2) Patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy
Age Restrictions	MCC: Patient is 12 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

Members Health Insurance Company Date Effective: November 1, 2018

# **BELEODAQ** (S)

#### **Products Affected**

• Beleodaq

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Peripheral T-cell lymphoma (PTCL): Diagnosis of PTCL. Trial and failure, contraindication, or intolerance to at least one prior therapy (e.g., conventional chemotherapy).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# BENLYSTA (S)

#### **Products Affected**

• Benlysta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Systemic lupus erythematosus (SLE) (init): Diagnosis of active SLE. Autoantibody positive (ie, anti-nuclear antibody [ANA] titer greater than or equal to 1:80 or anti-dsDNA level greater than or equal to 30 IU/mL). Currently receiving at least one standard of care treatment for active SLE (eg, antimalarials [eg, Plaquenil (hydroxychloroquine)], corticosteroids [eg, prednisone], or immunosuppressants [eg, methotrexate, Imuran (azathioprine), CellCept (mycophenolate mofetil)]).
Age Restrictions	N/A
Prescriber Restrictions	SLE (init): Prescribed by or in consultation with a rheumatologist
Coverage Duration	SLE (init, reauth): 6 months
Other Criteria	SLE (reauth): Documentation of positive clinical response to Benlysta therapy

Members Health Insurance Company Date Effective: November 1, 2018

# **BENZODIAZEPINES (S)**

#### **Products Affected**

- Alprazolam TABS
- Alprazolam Er
- Alprazolam Xr
- Chlordiazepoxide Hcl
- Estazolam
- Lorazepam CONC
- Lorazepam INJ 2MG/ML, 4MG/ML
- Lorazepam TABS
- Lorazepam Intensol
- Temazepam

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	For alprazolam only: concomitant use with ketoconazole or itraconazole.
Required Medical Information	Verify the medication is being used for an FDA-approved diagnosis or compendia-supported indication.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# BERINERT (S)

#### **Products Affected**

• Berinert

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Firazyr, Kalbitor, or Ruconest).
Age Restrictions	N/A
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# **BLINCYTO (S)**

#### **Products Affected**

• Blincyto

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL): Diagnosis of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia/acute lymphoblastic lymphoma.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Subject to Part B vs. Part D review. Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# **BORTEZOMIB** (S)

#### **Products Affected**

• Bortezomib

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma (MM): Diagnosis of MM. Mantle cell lymphoma (MCL): Diagnosis of MCL AND patient has received at least one prior therapy for MCL.
Age Restrictions	N/A
Prescriber Restrictions	MM, MCL: Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# **BOSULIF (S)**

#### **Products Affected**

• Bosulif

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic myelogenous/myeloid leukemia (CML): Diagnosis of Philadelphia chromosome-positive (Ph+) CML.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company

Date Effective: November 1, 2018

# BOTOX (S)

#### **Products Affected**

• Botox

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Neuromuscular Disorders (init): Strabismus, blepharospasm associated with dystonia (eg, benign essential blepharospasm), treatment of upper or lower limb spasticity, VII cranial nerve disorders (hemifacial spasms), cervical dystonia Hyperhidrosis(HH): (Init) Dx of primary axillary HH. Score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS) or skin maceration with secondary infection. Migraine:(Init) Dx of chronic migraines (greater than or equal to 15 migraine headache days per month with headache lasting 4 hours a day or longer). TF/C/I to prophylactic therapy with at least two of the following agents, each given for a trial of at least two months: antidepressants [ie, Effexor (venlafaxine)], antiepileptics [ie, Depakote/Depakote ER (divalproex sodium), Topamax (topiramate)], beta-blockers [eg, atenolol, Inderal (propranolol), nadolol, timolol, Toprol XL (metoprolol)] Achalasia:(Init) High risk of complication from or failure to pneumatic dilation or myotomy, or prior dilation caused esophageal perforation, or patient has an epiphrenic diverticulum or hiatal hernia. Anal Fissure (AF)(Init): Dx of chronic AF. At least 2 months of either nocturnal pain and bleeding or postdefecation pain. Chronic Back Pain (CBP):(Init) Dx of low back pain lasting greater than or equal to six months. Urinary incont (UI):(init) Neurogenic detrusor overactivity associated with a neurologic condition (eg, spinal cord injury [SCI], multiple sclerosis) or detrusor sphincter dyssynergia with SCI. Overactive bladder (OAB): (init) Dx of OAB. One of the following symptoms: urge urinary incontinence, urgency, frequency.
Age Restrictions	N/A
Prescriber Restrictions	Migraine (Initial): Prescribed by a neurologist or pain specialist. CBP (Initial): Prescribed by a neurologist, neurosurgeon, orthopedist, or pain specialist. UI, OAB (initial): Prescribed by a neurologist, neurosurgeon, or urologist.
Coverage Duration	Achalasia: 6moCBP:1 tx(series of injxs)UI:3mo(1 dose,200units)Other:3mo
Other Criteria	UI, OAB, CBP, Neuromuscular Disorders:(Reauth) Confirmed improvement in symptoms with initial Botox treatment. At least 3 months have or will have elapsed since the last treatment with Botox HH:(Reauth) At least a 2-point improvement in HDSS. Migraine:(Reauth) Reduction in

Date Effective: November 1, 2018

headache frequency or intensity. Confirmation of decreased utilization of pain medications (eg, narcotic analgesics, NSAIDs) or triptans, or a reduction in the number of ER visits. Achalasia:(Reauth) Documentation of improvement or reduction in symptoms of achalasia (ie, dysphagia, regurgitation, chest pain). At least 6 months have or will have elapsed since last series of injections AF: (Reauth) Incomplete healing of fissure or recurrence of fissure. Improved symptoms with prior treatment with Botox.

Members Health Insurance Company Date Effective: November 1, 2018

# CABOMETYX (S)

## **Products Affected**

• Cabometyx

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. RCC is advanced.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# CALQUENCE (S)

## **Products Affected**

• Calquence

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Mantle Cell Lymphoma: Diagnosis of mantle cell lymphoma (MCL) AND patient has received at least one prior therapy for MCL
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# CAPRELSA (S)

## **Products Affected**

• Caprelsa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Thyroid Cancer: Diagnosis of medullary thyroid cancer (MTC)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with oncologist or endocrinologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# CARISOPRODOL (S)

## **Products Affected**

• Carisoprodol TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication. If the patient is 65 years of age or older, the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# CAYSTON (S)

## **Products Affected**

• Cayston

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Cystic fibrosis (CF) (Initial, Reauth): Diagnosis of CF AND Patient has evidence of Pseudomonas aeruginosa in the lungs
Age Restrictions	CF (Initial): 7 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	CF (Initial, reauth): 12 months
Other Criteria	CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations)

Members Health Insurance Company Date Effective: November 1, 2018

# CERDELGA (S)

## **Products Affected**

• Cerdelga

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Gaucher disease (Initial): Diagnosis of Gaucher disease type 1. Patient is an extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) of cytochrome P450 enzyme (CYP) 2D6 as detected by an FDA-cleared test.
Age Restrictions	Gaucher disease (initial): 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Gaucher disease (initial, reauth): 12 months
Other Criteria	Gaucher disease (Reauth): Patient's condition has not progressed, as defined by ALL of the following: A) Hemoglobin level decreased greater than 1.5 g/dL from baseline, AND B) Platelet count decreased greater than 25% from baseline, AND C) Spleen volume increased greater than 25% from baseline, AND D) Liver volume increased greater than 20% from baseline.

Members Health Insurance Company Date Effective: November 1, 2018

# **CEREZYME (S)**

## **Products Affected**

• Cerezyme

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Gaucher disease: Diagnosis of type 1 Gaucher disease. Patient has evidence of symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Gaucher disease: 12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# CHOLBAM (S)

## **Products Affected**

• Cholbam

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Bile acid synthesis disorders due to single enzyme defects (BAS) (initial): diagnosis of a bile acid synthesis disorder due to a single enzyme defect. Peroxisomal disorders (PD) (initial): All of the following: 1) diagnosis of peroxisomal disorder, 2) patient exhibits at least one of the following: a) liver disease (eg, jaundice, elevated serum transaminases), OR b) steatorrhea, OR c) complications from decreased fat-soluble vitamin absorption (eg, poor growth), AND 3) Cholbam will be used as an adjunctive treatment.
Age Restrictions	N/A
Prescriber Restrictions	All uses (initial): Prescribed by a hepatologist, medical geneticist, pediatric gastroenterologist, OR other specialist that treats inborn errors of metabolism.
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	All uses (reauth): documentation of positive clinical response to Cholbam therapy

## **CHORIONIC GONADOTROPIN (S)**

- Chorionic Gonadotropin INJ
- Novarel
- Pregnyl W/diluent Benzyl Alcohol/nacl

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Prepubertal Cryptorchidism: Diagnosis of prepubertal cryptorchidism not due to anatomical obstruction. Male Hypogonadotropic Hypogonadism (MHH) (initial): Diagnosis of male hypogonadism secondary to pituitary deficiency, and low testosterone (below normal reference value provided by the physician's laboratory) and one of the following: a) low LH (below normal reference value provided by the physician's laboratory) or b) low FSH (below normal reference value provided by the physician's laboratory).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prepubertal Cryptorchidism: 6 wks. MHH (initial, reauth): 12 months.
Other Criteria	Excluded if used to promote fertility. MHH (Reauth): Documentation of positive clinical response to therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## CICLOPIROX (S)

- Ciclodan SOLN
- Ciclopirox Nail Lacquer

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	All of the following: 1) Patient does not have dermatophytomas or lunula (matrix) involvement, 2) one of the following: a) Diagnosis of onychomycosis of the toenails, OR b) Diagnosis of onychomycosis of the fingernails, 3) Diagnosis of onychomycosis has been confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c) histology, 4) If toenail onychomycosis, patient has mild to moderate disease involving at least 1 great toenail, AND 5) Trial and inadequate response, intolerance or hypersensitivity to oral terbinafine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	48 weeks.
Other Criteria	N/A

Members Health Insurance Company

Date Effective: November 1, 2018

# CIMZIA (S)

- Cimzia
- Cimzia Starter Kit

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA, initial): Diagnosis (dx) of moderately to severely active RA. TF/C/I to Enbrel and Humira, or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Cimzia therapy. Crohn's Disease (CD, initial): Dx of moderately to severely active CD. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), Azathioprine (Imuran), Corticosteroid (eg, prednisone, methylprednisolone), Methotrexate (Rheumatrex, Trexall). TF/C/I to Humira OR for continuation of prior Cimzia therapy. Psoriatic Arthritis (PsA, initial): Dx of active PsA. TF/C/I to Cosentyx and either Humira or Enbrel OR for continuation of prior Cimzia therapy. Ankylosing Spondylitis (AS, initial): Dx of active AS. TF/C/I to Enbrel and Humira, or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Cimzia therapy. Plaque Psoriasis (initial): Dx of moderate to severe plaque psoriasis. TF/C/I to Cosentyx AND either Humira or Enbrel OR for continuation of prior Cimzia therapy.
Age Restrictions	N/A
Prescriber Restrictions	CD (init): Prescribed by or in consultation with a gastroenterologist. RA, AS (init): Prescribed by or in consultation with a rheumatologist. PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.
Coverage Duration	RA, PsA, AS, Plaque psoriasis (init,reauth): 12 mos. CD (init): 16 wks. (reath): 12 mos.
Other Criteria	Reauthorization (all indications): Documentation of positive clinical response to Cimzia therapy. All indications (initial and reauth): Patient is not receiving Cimzia in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab), Orencia (abatacept)].

Members Health Insurance Company Date Effective: November 1, 2018

# CINRYZE (S)

#### **Products Affected**

• Cinryze

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For prophylaxis against HAE attacks. For continuation of prior therapy or Trial and failure, contraindication, or intolerance of one of the following: 17-alpha alkylated androgen (eg, danazol, oxandrolone) or antifibrinolytics (eg, aminocaproic acid, tranexamic acid).
Age Restrictions	N/A
Prescriber Restrictions	HAE (prophylaxis, treatment): Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# COMETRIQ (S)

## **Products Affected**

• Cometriq

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Medullary thyroid cancer (MTC): Diagnosis of Metastatic MTC.
Age Restrictions	N/A
Prescriber Restrictions	MTC: Prescribed by or in consultation with an oncologist/hematologist or endocrinologist.
Coverage Duration	All uses: 12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## CORLANOR (S)

## **Products Affected**

• Corlanor

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic heart failure (CHF) (initial): Diagnosis of CHF with NYHA Class II, III, or IV symptoms. Left ventricular ejection fraction less than or equal to 35%. Patient is in sinus rhythm with a resting heart rate of greater than or equal to 70 BPM and has been hospitalized for worsening HF in the previous 12 months. Trial and failure, intolerance, or contraindication to maximally tolerated doses of at least one beta-blocker with proven mortality benefit (i.e., carvedilol, bisoprolol, sustained-release metoprolol) AND trial and failure, intolerance, or contraindication to maximally tolerated doses of an ACE inhibitor or ARB.
Age Restrictions	N/A
Prescriber Restrictions	CHF (initial): Prescribed by or in consultation with a cardiologist
Coverage Duration	CHF (initial, reauth): 12 months
Other Criteria	CHF (reauth): patient does not have contraindications/exclusions to therapy.

# COSENTYX (S)

- Cosentyx
- Cosentyx Sensoready Pen

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) OR Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) or Humira (adalimumab), OR for continuation of prior Cosentyx therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: Trial and failure, contraindication, or intolerance to Enbrel (etanercept) or Humira (adalimumab), OR for continuation of prior Cosentyx therapy. All indications (Initial, reauth): Patient is not receiving Cosentyx in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].
Age Restrictions	N/A
Prescriber Restrictions	Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. AS (Initial): Prescribed by or in consultation with a rheumatologist.
Coverage Duration	All indications (Initial, reauth): 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to Cosentyx therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# COTELLIC (S)

## **Products Affected**

• Cotellic

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable or metastatic melanoma. Patient has a BRAF V600E or V600K mutation as detected by an FDA-approved test (e.g., cobas 4800 BRAF V600 Mutation Test) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Used in combination with vemurafenib.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# CRINONE (S)

## **Products Affected**

• Crinone

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	All indications: Excluded if for fertility uses.
Required Medical Information	Secondary amenorrhea: Diagnosis of secondary amenorrhea (the absence of menses in women who have already started menstruation who are not pregnant, breastfeeding, or in menopause).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

## CYRAMZA (S)

#### **Products Affected**

• Cyramza

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Gastric cancer: All of the following: 1) diagnosis of one of the following: a) gastric adenocarcinoma, OR b) gastro-esophageal junction (GEJ) adenocarcinoma, AND 2) disease is one of the following: a) locally advanced, OR b) metastatic, AND 3) disease has progressed on or after one of the following first-line therapies: a) fluoropyrimidine-containing chemotherapy (eg, fluorouracil, capecitabine), OR b) platinum-containing chemotherapy (eg, cisplatin, carboplatin, oxaliplatin). Non-small cell lung cancer: All of the following: 1) diagnosis of metastatic non-small cell lung cancer, AND 2) used in combination with docetaxel, AND 3) disease has progressed on or after platinum-based chemotherapy (eg, cisplatin, carboplatin, oxaliplatin). Metastatic colorectal cancer (mCRC): 1) Diagnosis of metastatic CRC AND 2) Patient had disease progression on or after prior therapy with bevacizumab, oxaliplatin, and a fluoropyrimidine.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# CYSTARAN (S)

## **Products Affected**

• Cystaran

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Cystinosis: Diagnosis of cystinosis, confirmed by elevated leukocyte cystine levels (LCL), genetic analysis of the CTNS gene or corneal cystine crystal accumulation AND Patient is concomitantly receiving treatment with oral cysteamine
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# DACOGEN (S)

## **Products Affected**

• Decitabine

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Myelodysplastic syndrome (MDS): Diagnosis of myelodysplastic syndrome.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

DAKLINZA (S)

## **Products Affected**

• Daklinza

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. For genotype 1, ONE of the following: 1) Patient has had a trial and failure, contraindication or intolerance to both of the following: a) Harvoni or Epclusa AND b) Mavyret OR 2) For continuation of prior Daklinza therapy. For genotype 1 liver transplant recipient, ONE of the following: 1) Patient has had a trial and failure, contraindication or intolerance to Harvoni OR Mavyret OR 2) For continuation of prior Daklinza therapy. For genotype 2 or 3 (except liver transplant recipients), ONE of the following: 1) Patient has had a trial and failure, contraindication or intolerance to one of the following: Epclusa or Mavyret OR 2) For continuation of prior Daklinza therapy. For genotype 2 or 3 liver transplant recipients without cirrhosis, ONE of the following: 1) Patient has had a trial and failure, contraindication or intolerance to Mavyret OR 2) For continuation of prior Daklinza therapy. For genotype 2 or 3 liver transplant recipients with decompensated cirrhosis, ONE of the following: 1) Patient has had a trial and failure, contraindication or intolerance to Epclusa OR 2) For continuation of prior Daklinza therapy. All: One of the following: 1) Patient has not failed a prior HCV NS5A-containing regimen (eg, Daklinza) OR 2) patient has failed prior therapy with an NS5A-containing regimen AND submission of medical records (eg, chart notes) documenting that the patient does not have NS5A inhibitor resistance-associated variants detected using commercially available assays. All: One of the following: 1) requested daily dosage is less than 90 mg OR 2) both of the following: requested daily dosage is equal to 90 mg and patient is concomitantly receiving a moderate CYP3A inducer (eg, bosentan, dexamethasone, efavirenz, etravirine, modafinil).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
Coverage Duration	12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

## DALIRESP (S)

## **Products Affected**

• Daliresp

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD): (Initial) Diagnosis of moderate to very severe COPD. Patient has chronic bronchitis. Trial and failure, intolerance, or contraindication to two prior therapies for COPD.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	COPD (init, reauth): 12 months
Other Criteria	COPD (reauth): Documentation of positive clinical response to Daliresp therapy.

## DARAPRIM (S)

## **Products Affected**

• Daraprim

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Toxoplasmosis: 1) Patient is using Daraprim for the treatment of toxoplasmic encephalitis, secondary prophylaxis of toxoplasmic encephalitis, or treatment of congenital toxoplasmosis OR 2) Patient is using Daraprim for the primary prophylaxis of toxoplasmic encephalitis, patient has experienced intolerance to prior prophylaxis with trimethoprim-sulfamethoxazole (TMP-SMX), and one of the following: patient has been re-challenged with TMP-SMX using a desensitization protocol and is still unable to tolerate, or evidence of life-threatening reaction to TMP-SMX in the past (eg, toxic epidermal necrolysis, Stevens-Johnson syndrome). Malaria: Patient is using Daraprim for the treatment of acute malaria or chemoprophylaxis of malaria. Patient does not have megaloblastic anemia due to folate deficiency. The provider acknowledges that Daraprim is not recommended by the Centers for Disease Control and Prevention (CDC) for the treatment and/or prophylaxis of malaria.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an infectious disease specialist
Coverage Duration	12 months
Other Criteria	Toxoplasmosis only: Approve for continuation of prior therapy.

# DARZALEX (S)

## **Products Affected**

• Darzalex

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Relapsed/Refractory Multiple Myeloma (MM): Diagnosis of MM. One of the following: A) Patient has received at least three prior treatment regimens which included both a proteasome inhibitor (eg, bortezomib [Velcade], carfilzomib [Kyprolis]) and an immunomodulatory agent (eg, lenalidomide [Revlimid], thalidomide [Thalomid]) or patient is double-refractory to a proteasome inhibitor and an immunomodulatory agent. OR B) Patient has received at least one prior therapy. Darzalex will be used in combination with either 1) lenalidomide and dexamethasone or 2) bortezomib and dexamethasone. OR C) Both of the following: used in combination with both pomalidomide and dexamethasone, AND patient has received at least two prior therapies including lenalidomide and a proteasome inhibitor (e.g., bortezomib [Velcade], carfilzomib [Kyprolis]). Newly Diagnosed Multiple Myeloma: Newly diagnosed multiple myeloma, patient is ineligible for autologous stem cell transplant and used in combination with all of the following: bortezomib, melphalan, and prednisone.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

## **DEFERASIROX (S)**

- Exjade
- Jadenu
- Jadenu Sprinkle

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic Iron Overload Due to Blood Transfusions (Initial): Diagnosis of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Patient has a baseline ferritin level more than 1,000 mcg/L. Patient has required the transfusion of at least 100 mL/kg packed red blood cells. Myelodysplastic Syndrome (MDS) (Initial): Diagnosis of MDS. Patient has Low or Intermediate-1 disease or is a potential transplant patient. Patient has received more than 20 red blood cell transfusions. Chronic iron overload due to non-transfusion-dependent thalassemia (NTDT) (Initial): Diagnosis of chronic iron overload due to NTDT. Liver iron concentration (LIC) 5 milligrams of iron per gram of liver dry weight (mg Fe/g dw) or higher. Serum ferritin level greater than 300 mcg/L.
Age Restrictions	Iron Overload Due to Blood Transfusions (initial): 2 years of age or older. NTDT (initial): 10 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Iron Overload Due to Blood Transfusions, MDS (initial, reauth):12 mo. NTDT (initial, reauth): 6mo.
Other Criteria	Iron Overload Due to Blood Transfusions, MDS (Reauth): Patient experienced a reduction from baseline in serum ferritin level or LIC. NTDT (Reauth): Patient has LIC 3 mg Fe/g dw or higher. Patient experienced a reduction from baseline in serum ferritin level or LIC.

## **DEXMETHYLPHENIDATE (S)**

- Dexmethylphenidate Hcl
- Dexmethylphenidate Hcl Er

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

## **DEXTROAMPHETAMINE (S)**

- Dexedrine TABS
- Dextroamphetamine Sulfate SOLN
- Dextroamphetamine Sulfate TABS
- Dextroamphetamine Sulfate Er

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# **DUPIXENT (S)**

#### **Products Affected**

• Dupixent

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Atopic dermatitis (initial): Diagnosis of moderate to severe atopic dermatitis. Trial and failure, contraindication, or intolerance to one medium to high potency topical corticosteroid. One of the following: A) Trial and failure or intolerance to Elidel (pimecrolimus) topical cream, unless the patient is not a candidate for Elidel therapy (e.g., immunocompromised, severe atopic dermatitis), B) Trial and failure or intolerance to tacrolimus topical ointment, unless the patient is not a candidate for tacrolimus ointment therapy (e.g., immunocompromised).
Age Restrictions	Initial: Age 18 years of age or older
Prescriber Restrictions	Initial: Prescribed by or in consultation with one of the following: dermatologist, allergist/immunologist.
Coverage Duration	12 months
Other Criteria	Atopic dermatitis (reauth): Documentation of a positive clinical response to Dupixent therapy (e.g., reduction in body surface area involvement, reduction in pruritus severity)

Members Health Insurance Company Date Effective: November 1, 2018

## ELAPRASE (S)

#### **Products Affected**

• Elaprase

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Hunter Syndrome (Mucopolysaccharidosis II (MPS II))
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# EMFLAZA (S)

## **Products Affected**

• Emflaza

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of Duchenne muscular dystrophy (DMD) AND Patient has received genetic testing for a mutation of the dystrophin gene AND One of the following: A) Documentation of a confirmed mutation of the dystrophin gene or B) Muscle biopsy confirmed an absence of dystrophin protein AND Patient has had a trial and failure or intolerance to prednisone or prednisolone AND Dose will not exceed 0.9 milligrams per kilogram of body weight once daily
Age Restrictions	Initial: 5 years of age or older
Prescriber Restrictions	Initial: Prescribed by or in consultation with a neurologist who has experience treating children
Coverage Duration	12 months
Other Criteria	Reauthorization: Patient has experienced a benefit from therapy (e.g., improvement or preservation of muscle strength) AND Dose will not exceed 0.9 milligrams per kilogram of body weight once daily

Members Health Insurance Company Date Effective: November 1, 2018

# EMPLICITI (S)

## **Products Affected**

• Empliciti

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma: Diagnosis of multiple myeloma. Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# ENBREL (S)

- Enbrel
- Enbrel Mini
- Enbrel Sureclick

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Failure, contraindication, or intolerance to one disease-modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Polyarticular Juvenile Idiopathic Arthritis (PJIA) (Initial): Diagnosis of moderately to severely active PJIA. Trial and failure, contraindication, or intolerance to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. Trial and failure, contraindication, or intolerance to two NSAIDs. All indications (Initial, reauth): Patient is not receiving Enbrel in combination with a biologic DMARD [eg, Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)].
Age Restrictions	N/A
Prescriber Restrictions	RA (Initial), PJIA (Initial), AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist. Plaque Psoriasis (Initial): Prescribed by or in consultation with a dermatologist.
Coverage Duration	All indications (Initial, reauth): 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to Enbrel therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# ENDARI (S)

## **Products Affected**

• Endari

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Sickle cell disease (initial): Diagnosis of sickle cell disease. Used to reduce acute complications of sickle cell disease. One of the following: (a) Patient is using Endari with concurrent hydroxyurea therapy, OR (b) Patient has a contraindication or intolerance to hydroxyurea. Patient has had 2 or more painful sickle cell crises within the past 12 months.
Age Restrictions	N/A
Prescriber Restrictions	Sickle cell disease (initial): Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	Sickle cell disease (initial, reauth): 12 months
Other Criteria	Sickle cell disease (reauth): Documentation of positive clinical response to Endari therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# ENTYVIO (S)

#### **Products Affected**

• Entyvio

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Ulcerative Colitis (UC) (init): Diagnosis (Dx) of moderately to severely active UC. Trial and failure, contraindication, or intolerance (F/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), aminosalicylates [eg, mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)], azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone). F/C/I to one tumor necrosis factor (TNF) inhibitor [eg, Humira (adalimumab), infliximab]. Crohn's Disease (CD) (init): Dx of moderately to severely active CD. F/C/I to one of the following medications: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). F/C/I to one TNF inhibitor [eg, Humira (adalimumab), infliximab]. UC, CD (init, reauth): Patient is not receiving Entyvio in combination with Tysabri (natalizumab), or a TNF inhibitor [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab), infliximab].
Age Restrictions	N/A
Prescriber Restrictions	UC, CD (init): Prescribed by or in consultation with a gastroenterologist
Coverage Duration	UC, CD (init): 14 weeks. UC, CD (reauth): 12 months.
Other Criteria	UC, CD (reauth): Documentation of positive clinical response to Entyvio therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# EPCLUSA (S)

#### **Products Affected**

• Epclusa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. Diagnosis of chronic hepatitis C virus. Patient is not receiving Epclusa in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir), Olysio (simeprevir)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
Coverage Duration	12 to 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline.
Other Criteria	N/A

Members Health Insurance Company

Date Effective: November 1, 2018

# **EPOETIN ALFA (S)**

#### **Products Affected**

• Procrit

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Anemia with Chronic Kidney Disease (CKD) (Initial): Diagnosis (Dx) of CKD. Anemia by lab values (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. One of the following: a) both of the following: Patient is on dialysis, patient is without ESRD OR b) all of the following: patient is not on dialysis, the rate of hemoglobin decline indicates the likelihood of requiring a red blood cell (RBC) transfusion, and reducing the risk of alloimmunization and/or other RBC transfusion-related risks is a goal. Anemia with HIV (Initial): Anemia by lab values (Hgb less than 12 g/dL or Hct less than 36%) collected within 30 days of request. Serum erythropoietin level less than or equal to 500 mU/mL. Receiving zidovudine therapy or dx of HIV. Anemia with chemo (Initial):Other causes of anemia have been ruled out. Anemia by lab values (Hct less than 30%, Hgb less than 10 g/dL) collected within the prior 2 weeks of request. Cancer is a non-myeloid malignancy. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 mos, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. Preoperative for reduction of allogeneic blood transfusion: Patient is scheduled to undergo elective, non-cardiac, non-vascular surgery. Hgb is greater than 10 to less than or equal to 13 g/dL. Patient is at high risk for perioperative transfusions. Patient is unwilling or unable to donate autologous blood pre-operatively. Anemia in hepatitis C virus (HCV)-infected pts due to ribavirin in combination with interferon or peg-interferon (Initial): Dx of HCV infection. Anemia by labs (Hct less than 30% or Hgb less than 10 g/dL) collected within 30 days of request. Patient is receiving ribavirin and one of the following: interferon alfa or peginterferon alfa. Anemia in Myelodysplastic Syndrome (MDS) (Initial): Dx of MDS. Serum erythropoietin level is 500 mU/mL or less, or dx of transfusion-dependent MDS.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CKD,HIV(Init):6mo. CKD,HIV(reauth):12mo. Chemo,HCV(all):3mo. MDS:(init) 3mo,(reauth)12mo. Preop:1mo.

#### Other Criteria

Subject to ESRD review. CKD (Reauth): Dx of CKD. Most recent or average (avg) Hct over 3 months is 33% or less OR most recent or avg Hgb over 3 months is 11 g/dL or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. HIV (Reauth): Most recent or avg Hct over 3 months is below 36% or most recent or avg Hgb over 3 months is below 12 g/dl. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pretreatment level. Chemo (Reauth): Anemia by lab values (Hgb less than 10 g/dl or Hct less than 30%) collected within the prior 2 weeks of request. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Patient is concurrently on chemo, or will receive concomitant chemo for a minimum of 2 months, or anemia is caused by cancer chemo. Will not be approved if patient is not receiving cancer chemotherapy. HCV (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. If patient has demonstrated response to therapy, authorization will be issued for the full course of ribavirin therapy. MDS (Reauth): Most recent or avg Hct over 3 months is 36% or less, OR most recent or avg Hgb over 3 months is 12 g/dl or less. Decrease in the need for blood transfusion or Hgb increased by 1 g/dL or more from pre-treatment level. Off-label uses (except MDS): Will not be approved if patient has Hgb greater than 10 g/dL or Hct greater than 30%. CKD (init, reauth), HIV (init), Chemo (init), Preop, MDS (init), HCV (init): Verify iron evaluation for adequate iron stores.

### **EPOPROSTENOL (S)**

#### **Products Affected**

- Epoprostenol Sodium
- Veletri

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH (Initial): 6 months. (Reauth): 12 months
Other Criteria	Subject to Part B vs D review. PAH (Reauth): Documentation of positive clinical response to therapy.

Members Health Insurance Company

Date Effective: November 1, 2018

# ERBITUX (S)

#### **Products Affected**

• Erbitux

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Head and Neck Cancer: Diagnosis of locally or regionally advanced squamous cell head and neck cancer and used in combination with radiation therapy, or diagnosis of recurrent or metastatic squamous cell head and neck cancer and 1 of the following: trial and failure, contraindication or intolerance to platinum-based chemotherapy, or used in combination with 1 of the following: cisplatin (Platinol AQ), carboplatin (Paraplatin), cisplatin (Platinol AQ) plus 5-FU (Adrucil), or carboplatin (Paraplatin) plus 5-FU (Adrucil). Colorectal Cancer: Diagnosis of metastatic carcinoma of the colon or rectum. One of the following: Used in combination with either FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan), OR trial and failure, contraindication or intolerance to irinotecan-based chemotherapy, oxaliplatin-based chemotherapy, or intensive therapy (eg, FOLFOX or FOLFIRI), OR used as monotherapy in patients not appropriate for intensive therapy. Tumor expresses wild-type KRAS gene and wild type NRAS gene. Non-Small Cell Lung Cancer (NSCLC): Diagnosis of recurrent or metastatic NSCLC stage IIIB or IV. One of the following: Used in combination with vinorelbine (Navelbine) and cisplatin (Platinol AQ), OR used as a single-agent for continuation maintenance therapy and Erbitux was given first-line with chemotherapy. Epidermal growth factor receptor (EGFR) expression by immunohistochemistry.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months.
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# **ERIVEDGE (S)**

#### **Products Affected**

• Erivedge

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Basal cell carcinoma: One of the following: A) Diagnosis of metastatic basal cell carcinoma OR B) Both of the following: 1) Diagnosis of locally advanced basal cell carcinoma AND 2) One of the following: a) Disease recurred following surgery or b) Patient is not a candidate for surgery and radiation.
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

### ERLEADA (S)

#### **Products Affected**

• Erleada

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Non-metastatic castration-resistant prostate cancer (NM-CRPC): Diagnosis of non-metastatic, castration-resistant (chemical or surgical) prostate cancer. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog OR 2) Patient received a bilateral orchiectomy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

Members Health Insurance Company Date Effective: November 1, 2018

# ESBRIET (S)

#### **Products Affected**

• Esbriet

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Idiopathic pulmonary fibrosis (IPF) (initial): Both of the following: 1) diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity), AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF, AND 2) not used in combination with Ofev (nintedanib).
Age Restrictions	N/A
Prescriber Restrictions	IPF (initial): Prescribed by a pulmonologist
Coverage Duration	initial, reauth: 12 months
Other Criteria	IPF (reauth): Documentation of positive clinical response to Esbriet therapy

Members Health Insurance Company Date Effective: November 1, 2018

# **EXONDYS 51 (S)**

### **Products Affected**

• Exondys 51

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Initial: Diagnosis of Duchenne muscular dystrophy (DMD). Documentation of a confirmed mutation of the dystrophin gene amenable to exon 51 skipping. Patient is ambulatory. Initial/Reauth: Exondys 51 dosing for DMD is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 30 mg/kg infused once weekly.
Age Restrictions	N/A
Prescriber Restrictions	(initial, reauth): Prescribed by or in consultation with a neurologist who has experience treating children
Coverage Duration	Initial: 6 months, Reauth: 12 months
Other Criteria	Reauth: One of the following: 1) All of the following: Patient has been on therapy for less than 12 months, patient is maintaining ambulatory status, and patient is tolerating therapy, OR 2) All of the following: Patient has been on therapy for 12 months or more, Patient is maintaining ambulatory status, patient has experienced a benefit from therapy (e.g., disease amelioration compared to untreated patients), and patient is tolerating therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# EYLEA (S)

#### **Products Affected**

• Eylea

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of one of the following: A) Neovascular (wet) age-related macular degeneration OR B) Macular edema following retinal vein occlusion, OR C) Diabetic macular edema OR D) Diabetic retinopathy in patients with diabetic macular edema
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

### FABRAZYME (S)

#### **Products Affected**

• Fabrazyme INJ 35MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Fabry Disease: Diagnosis of Fabry disease.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Fabry Disease: 12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# FARYDAK (S)

#### **Products Affected**

• Farydak

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple Myeloma (MM): Diagnosis of MM. Used in combination with both of the following: Velcade (bortezomib) and dexamethasone. Patient has received at least two prior treatment regimens which included both of the following: Velcade (bortezomib) and an immunomodulatory agent [eg, Revlimid (lenalidomide), Thalomid (thalidomide)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company

Date Effective: November 1, 2018

# FASENRA (S)

#### **Products Affected**

• Fasenra

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Severe asthma (initial): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by a baseline blood eosinophil level greater than or equal to 150 cells per microliter. One of the following: 1) Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids within the past 12 months, OR 2) Any prior intubation for an asthma exacerbation, OR 3) Prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) High-dose inhaled corticosteroid (ICS) [e.g., greater than 500 mcg fluticasone propionate equivalent/day] and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline], OR b) One maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)]
Age Restrictions	Initial: Patient is 12 years of age or older
Prescriber Restrictions	Initial/Reauth: Prescribed by or in consultation with a pulmonologist or allergy/immunology specialist
Coverage Duration	12 months
Other Criteria	Reauth: Documentation of a positive clinical response (e.g., reduction in exacerbations). Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications: a) Both of the following: i) inhaled corticosteroid (ICS) and ii) additional asthma controller medication [e.g., leukotriene receptor antagonist, longacting beta-2 agonist (LABA), theophylline], OR b) A combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)]

### FENTANYL (S)

#### **Products Affected**

• Fentanyl Citrate Oral Transmucosal

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids: Morphine sulfate at doses of greater than or equal to 60 mg/day, Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# FERRIPROX (S)

#### **Products Affected**

• Ferriprox

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Transfusional iron overload due to thalassemia syndromes (Initial): Patient has a diagnosis of transfusional iron overload due to thalassemia syndromes. Absolute neutrophil count (ANC) greater than 1.5 x 109/L. One of the following: A) Patient has failed prior chelation therapy (e.g., Exjade) [failure defined as serum ferritin greater than 2,500 mcg/L] OR B) Patient has a contraindication or intolerance to Desferal (deferoxamine) or Exjade (deferasirox).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	All uses (reauth): Patient has experienced greater than or equal to 20% decline in serum ferritin levels from baseline. ANC greater than 0.5 x 109/L.

Members Health Insurance Company Date Effective: November 1, 2018

### FIRAZYR (S)

#### **Products Affected**

• Firazyr

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Kalbitor, or Ruconest).
Age Restrictions	N/A
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# FIRMAGON (S)

#### **Products Affected**

• Firmagon

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of advanced or metastatic prostate cancer.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# FOLOTYN (S)

#### **Products Affected**

• Folotyn

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Peripheral T-cell lymphoma: Diagnosis of relapsed or refractory PTCL
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company

Date Effective: November 1, 2018

# FORTEO (S)

#### **Products Affected**

• Forteo INJ 600MCG/2.4ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Postmenopausal Osteoporosis or osteopenia or men with primary or hypogonadal osteoporosis or osteopenia: One of the following: Set I) Both of the following: A) Diagnosis of osteoporosis defined as bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND B) either 1) patient has a history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) patient has a trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia (denosumab)), or Set II) Both of the following: A) Diagnosis of osteopenia defined by bone mineral density (BMD) T-score of between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site), AND B) One of the following: 1) patient has a history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or 2) both of the following: i) Trial and failure, contraindication, or intolerance to at least one prior osteoporosis therapy (e.g., alendronate, risedronate, zoledronic acid, Prolia (denosumab) and ii) One of the following FRAX 10-year probabilities: a) Major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or b) Hip fracture is 3% or more in the U.S., or the country-specific threshold in other countries or regions. Treatment duration of parathyroid hormones [e.g., Forteo (teriparatide), Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime. Glucocorticoid-Induced Osteoporosis: See Other Criteria section.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All indications: 24 months, max 2 years of therapy.
Other Criteria	Glucocorticoid-Induced Osteoporosis: Diagnosis of glucocorticoid-induced osteoporosis. History of prednisone or its equivalent at a dose of greater than or equal to 5mg/day for greater than or equal to 3 months. One of the following: A) BMD T score of -2.0 or less based on BMD measurements from lumbar spine (at least two vertebral bodies), hip

(femoral neck, total hip), or radius (one-third radius site) or B) Both of the following: 1) BMD T score between -1.0 and -2.0 (BMD T-score greater than -2.0 and less than or equal to -1.0) based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) and 2) either history of one of the following fx resulting from minimal trauma (vertebral compression fx, fx of the hip, or fx of the distal radius) or trial and failure, contraindication, or intolerance (TF/C/I) to one bisphosphonate [e.g., Fosamax (alendronate)] or C) Both of the following: 1) history of one of the following fractures resulting from minimal trauma (vertebral compression fx, fx of the hip, or fx of the distal radius) and 2) TF/C/I to one bisphosphonate [e.g., Fosamax (alendronate)]. Treatment duration of parathyroid hormones [e.g., Forteo (teriparatide), Tymlos (abaloparatide)] has not exceeded a total of 24 months during the patient's lifetime.

# GAMASTAN S/D (S)

#### **Products Affected**

- Gamastan
- Gamastan S/d

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).
Required Medical Information	Immune globulin is being used intramuscularly. The immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Patient requires immunization for hepatitis A, measles, rubella, or varicella.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months (Approve one dose only)
Other Criteria	Subject to Part B vs D review.

Members Health Insurance Company Date Effective: November 1, 2018

# GATTEX (S)

#### **Products Affected**

• Gattex

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Short Bowel Syndrome (SBS) (Initial) Diagnosis of SBS. Patient is dependent on parenteral nutrition/intravenous (PN/IV) support for at least 12 consecutive months.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	SBS (Init): 6 months. SBS (Reauth): 12 months.
Other Criteria	SBS (Reauth): Documentation of positive clinical response to Gattex therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# GAZYVA (S)

#### **Products Affected**

• Gazyva

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Used in combination with chlorambucil. Patient is previously untreated for CLL. Follicular lymphoma (FL): Diagnosis of FL. Patient has relapsed after or is refractory to a rituximab-containing regimen. Both of the following: Used in combination with bendamustine and followed by Gazyva monotherapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# GILENYA (S)

### **Products Affected**

• Gilenya

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# GILOTRIF (S)

#### **Products Affected**

• Gilotrif

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): A) Diagnosis of advanced or metastatic (stage IIIB or IV) NSCLC AND B) One of the following: 1) Both of the following: a) Tumors have non-resistant epidermal growth factor (EGFR) mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility AND b) GILOTRIF will be used as first-line treatment, OR 2) All of the following: a) disease progressed after platinum-based chemotherapy and b) squamous NSCLC
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **GLATIRAMER ACETATE (S)**

#### **Products Affected**

- Copaxone INJ 40MG/ML
- Glatiramer Acetate
- Glatopa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# GLEEVEC (S)

#### **Products Affected**

• Imatinib Mesylate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	For adults 18 years of age or older, One of the following: A) Diagnosis of Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) AND Patient is found to be Ph+ or BCR-ABL positive as detected by bone marrow cytogenetics, FISH or PCR OR B) Ph+ acute lymphoblastic leukemia (ALL) OR C) Gastrointestinal stromal tumor (GIST) AND one of the following: 1) Patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST, OR 2) Patient had resection of c-KIT (CD117) positive GIST and imatinib will be used as adjuvant therapy OR D) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic OR E) Hypereosinophilic syndrome or chronic eosinophilic leukemia OR F) Myelodysplastic syndrome (MDS) or myeloproliferative disease associated with platelet-derived growth factor receptor gene re-arrangements OR G) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutational status unknown. For Pediatric patients younger than 18 years of age, One of the following: A) Diagnosis of Ph+ CML that is newly diagnosed in the chronic phase OR B) Diagnosis of newly diagnosed Ph+ALL.
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	All uses: 12 months
Other Criteria	All uses: Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# GOCOVRI (S)

#### **Products Affected**

• Gocovri

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Parkinson's disease (PD) (initial): Diagnosis of Parkinson's disease, patient is experiencing dyskinesia, patient is receiving levodopa-based therapy.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with a neurologist
Coverage Duration	12 months
Other Criteria	Parkinson's Disease (reauthorization): Documentation of positive clinical response to Gocovri therapy (e.g., decreased "off" periods or decreased "on" time with troublesome dyskinesia)

### **GROWTH HORMONE (S)**

#### **Products Affected**

- Genotropin
- Genotropin Miniquick
- Nutropin Aq Nuspin 10
- Nutropin Aq Nuspin 20
- Nutropin Aq Nuspin 5
- Nutropin Aq Pen

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	PGHD(initial):less than 4mo w/GD,or hx neonatal hypoglycemia assoc w/pituitary dz,or panhypopituitarism dx,or all of the following: PGHD dx [confrmd by ht (utilizing age and gender grwth charts related to ht) documented(doc) by ht more than 2.0SD below midparental ht or more than 2.25SD below population(pop) mean (below 1.2 percentile for age and gender),or grwth velocity more than 2SD below mean for age and gender, or delayed skeletal maturation more than 2SD below mean for age and gender (eg,delayed more than 2yrs compared w/chronological age)]. PWS(reauth):evidence of positive response to tx(eg,incr in total LBM, decr in fat mass) and expetd adult ht not attained and doc of expetd adult ht goal. GFSGA(initial):SGA dx based on catchup grwth failure in 1st 24mo of life using 0-36mo grwth chart confrmd by birth wt or length below 3rd percentile for gestational age(more than 2SD below pop mean) and ht remains at or below 3rd percentile (more than 2SD below pop mean). TS,NS(initial):ped grwth failure dx assoc w/TS w/doc female w/bone age less than 14yrs, or NS and ht below 5th percentile on grwth charts for age and gender. SHOX(initial):ped grwth failure dx w/SHOX gene deficiency confirmed by genetic testing. GFCRI(initial): ped grwth failure dx assoc w/CRI. ISS(initial):ISS dx, diagnostic eval excluded other causes assoc w/short stature(eg GHD, chronic renal insufficiency), doc ht at or below -2.25SD score below corresponding mean ht for age and gender, doc grwth velocity less than 25th percentile for bone age. PGHD,NS,SHOX,GFCRI,ISS (initial): doc male w/bone age less than 16yrs or female w/bone age less than 14yrs. PGHD,GFSGA,TS/NS,SHOX,GFCRI,ISS(reauth):expctd adult ht not attained and doc of expctd adult ht goal.
Age Restrictions	N/A
Prescriber Restrictions	PGHD, PWS, GFSGA, TS/NS, SHOX, AGHD, TPAP, IGHDA, ISS: prescribed by endocrinologist. GFCRI: prescribed by endocrinologist or nephrologist
Coverage Duration	All indications (initial, reauth): 12 months
Other Criteria	Trial and failure or intolerance to Genotropin and Nutropin (no prerequisites needed for Genotropin and Nutropin). AGHD(initial):dx of

AGHD with clin records supporting dx of childhood-onset GHD, or adultonset GHD w/clin records doc hormone deficiency d/t hypothalamicpituitary dz from organic or known causes (eg,damage from surgery, cranial irradiation, head trauma, subarachnoid hemorrhage) and pt has 1GH stim test (insulin tolerance test [ITT], arginine/GHRH.glucagon,arginine) to confirm adult GHD w/peak GH values ([ITT at or below 5mcg/L],[GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2],[glucagon at or below 3mcg/L],[Arg at or below 0.4mcg/L]) or doc deficiency of 3 anterior pituitary hormones (prolactin, ACTH, TSH, FSH/LH) and IFG-1/somatomedinC below age and gender adjstd nrml range as provided by physicians lab. AGHD.IGHDA(reauth):monitoring as demonstrated by doc w/in past 12mo of IGF-1/somatomedinC level. TransitionPhaseAdolescent Pts(TPAP)(initial): attained expctd adult ht or closed epiphyses on bone radiograph, and doc high risk of GHD d/t GHD in childhood (from embryopathic/congenital defects, genetic mutations, irreversible structural hypothalamic-pituitary dz, panhypopituitarism, or deficiency of 3 anterior pituitary hormones: ACTH, TSH, prolactin, FSH/LH), w/IGF-1/somatomedinC below age and gender adj nrml range as provided by physicians lab, or pt does not have low IGF-1/somatomedinC and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT,GHRH+ARG,ARG,glucagon) after d/c of tx for at least 1mo w/peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L], or at low risk of severe GHD(eg d/t isolated and/or idiopathic GHD) and d/c GH tx for at least 1mo, and pt has 1 GH stim test (ITT, GHRH+ARG, ARG, glucagon) after d/c of tx for at least 1mo w/corresponding peak GH value [ITT at or below 5mcg/L], [GHRH+ARG at or below 11mcg/L if BMI less than 25kg/m2, at or below 8mcg/L if BMI at or above 25 and below 30kg/m2, or at or below 4mcg/L if BMI at or above 30kg/m2], [glucagon at or below 3mcg/L], [Arg at or below 0.4mcg/L]. TPAP(reauth): evidence of positive response to therapy (eg,incr in total lean body mass, exercise capacity or IGF-1 and IGFBP-3). IGHDA(initial):doc GHD by failure to produce peak serum GH greater than 5 mcg/L after 2 provocative pharmacol stim tests(insulin,L-ARG,glucagon).

# H.P. ACTHAR GEL (S)

#### **Products Affected**

• H.p. Acthar

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Infantile Spasm (West Syndrome): Diagnosis of infantile spasms (West Syndrome). Multiple Sclerosis (MS): Acute exacerbations of MS. Rheumatic disorders: As adjunctive therapy for short-term administration in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis. Collagen diseases: During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematous, systemic dermatomyositis (polymyositis). Dermatologic diseases: Severe erythema multiforme, Stevens-Johnson syndrome. Allergic states: Serum sickness. Ophthalmic diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa, such as: keratitis, iritis and iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation. Respiratory diseases: Symptomatic sarcoidosis. Edematous state: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus. All indications except for infantile spasms: Trial and failure, contraindication, or intolerance to treatment with two corticosteroids.
Age Restrictions	Infantile spasms: less than 2 years old
Prescriber Restrictions	Infantile Spasm, MS: neurologist. Rheumatic disorder, collagen disease: rheumatologist. Dermatologic: dermatologist. Allergic state: allergist, immunologist. Ophthalmic disease: optometrist, ophthalmologist. Respiratory diseases: pulmonologist. Edematous state: nephrologist, rheumatologist.
Coverage Duration	Infantile Spasms: 4 weeks. MS: 3 weeks. All other FDA-approved uses: 3 months.
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# HAEGARDA (S)

### **Products Affected**

• Haegarda

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Prophylaxis of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For prophylaxis against HAE attacks. For continuation of prior therapy or trial and failure, contraindication, or intolerance to one of the following: 17-alpha alkylated androgen (e.g., danazol, oxandrolone) or antifibrinolytics (e.g., aminocaproic acid, tranexamic acid).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# HALAVEN (S)

#### **Products Affected**

• Halaven

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer: Diagnosis of recurrent or metastatic breast cancer. Previous treatment with both of the following: one anthracycline [eg, doxorubicin, Ellence (epirubicin)] and one taxane [eg, paclitaxel, Taxotere (docetaxel)]. Liposarcoma: Diagnosis of unresectable or metastatic liposarcoma. Previous treatment with one anthracycline-containing regimen.
Age Restrictions	N/A
Prescriber Restrictions	All Uses: prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# HARVONI (S)

#### **Products Affected**

• Harvoni

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. ALL (including patients with genotype 5 or 6 infection AND decompensated cirrhosis): A) Diagnosis of chronic hepatitis C (CHC) virus AND B) Patient is not receiving Harvoni in combination with another HCV direct acting antiviral agent [eg, Sovaldi (sofosbuvir), Olysio (simeprevir)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
Coverage Duration	12 to 24 wks. Criteria will be applied consistent with current AASLD/IDSA guideline
Other Criteria	N/A

# HERCEPTIN (S)

### **Products Affected**

• Herceptin

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-overexpressing breast cancer. One of the following treatment regimens: a) As adjuvant treatment, b) metastatic disease and one of the following: 1) used in combination with a taxane (eg, docetaxel, paclitaxel), or 2) used as a single agent in a patient who has received one or more chemotherapy regimens for metastatic disease, or c) used in combination with Perjeta (pertuzumab). Gastric Cancer: Diagnosis of HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma (locally advanced, recurrent, or metastatic). Used in combination with one of the following treatment regimens: a) Adrucil (5-fluorouracil), or b) Platinol (cisplatin) and Xeloda (capecitabine).
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# HETLIOZ (S)

### **Products Affected**

• Hetlioz

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Non-24-Hour Sleep-Wake Disorder (Non-24) (initial): Both of the following: 1) Diagnosis of non-24-hour sleep-wake disorder (also known as free-running disorder, free-running or non-entrained type circadian rhythm sleep disorder, or hypernychthemeral syndrome), AND 2) patient is totally blind (has no light perception).
Age Restrictions	N/A
Prescriber Restrictions	Non-24 (initial): Prescribed by or in consultation with a specialist in sleep disorders or neurologist
Coverage Duration	Non-24 (initial): 6 mo. (reauth): 12 mo
Other Criteria	Non-24 (reauth): Documentation of positive clinical response to Hetlioz therapy.

Date Effective: November 1, 2018

### **HRM - ANTIHISTAMINES**

- Cyproheptadine Hcl TABS
- Dexchlorpheniramine Maleate SYRP
- Hydroxyzine Hcl INJ
- Hydroxyzine Hcl SYRP
- Hydroxyzine Hcl TABS 10MG, 25MG
- Hydroxyzine Hydrochloride TABS 50MG
- Hydroxyzine Pamoate CAPS
- Meclizine Hcl TABS
- Phenadoz
- Phenergan SUPP
- Promethazine Hcl INJ
- Promethazine Hcl SUPP
- Promethazine Hcl SYRP
- Promethazine Hcl TABS
- Promethazine Hcl Plain
- Promethazine Hydrochloride TABS 50MG
- Promethegan

Members Health Insurance Company

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

### **HRM - ANTIHYPERTENSIVE AGENTS**

- Guanfacine Hcl
- Methyldopa TABS 250MG, 500MG
- Methyldopa/hydrochlorothiazide

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) unless alternative(s) is/are inappropriate or would not be applicable for the indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Requires trial of at least one Non-HRM alternative: Low dose thiazide or a second generation calcium channel blocker OR ACE inhibitor, ARB, beta-blocker or combination product based on specific chronic conditions

### **HRM - ANTIPARKINSON AGENTS**

- Benztropine Mesylate TABS
- Trihexyphenidyl Hcl TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

### **HRM - ANTIPSYCHOTICS**

#### **Products Affected**

• Thioridazine Hcl TABS 100MG, 10MG, 25MG, 50MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) unless alternative(s) is/are inappropriate or would not be applicable for the indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Applies to New Starts only. Requires trial of at least one Non-HRM alternative: haloperidol, atypical antipsychotic

### **HRM - ANTISPASMODICS**

- Atropine Sulfate INJ 8MG/20ML
- Dicyclomine Hcl CAPS
- Dicyclomine Hcl INJ
- Dicyclomine Hcl ORAL SOLN
- Dicyclomine Hydrochloride TABS
- Diphenatol
- Diphenoxylate/atropine TABS
- Scopolamine
- Transderm-scop

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# HRM - CARDIOVASCULAR, ANTI-ARRHYTHMICS

- Digitek TABS 0.25MG
- Digox TABS 250MCG
- Digoxin INJ 0.25MG/ML
- Digoxin SOLN
- Digoxin TABS 250MCG
- Disopyramide Phosphate CAPS
- Lanoxin TABS 187.5MCG
- Norpace Cr

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# **HRM - DEMENTIA AGENTS**

#### **Products Affected**

• Ergoloid Mesylates TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) unless alternative(s) is/are inappropriate or would not be applicable for the indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Requires trial of at least one Non-HRM alternative: donepezil, galantamine, rivastigmine, memantine

# HRM - ENDOCRINE

- Megestrol Acetate SUSP
- Megestrol Acetate TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Applies to New Starts only.

Members Health Insurance Company Date Effective: November 1, 2018

# HRM - ENDOCRINE, MENEST

### **Products Affected**

• Menest

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of therapy.

Date Effective: November 1, 2018

# HRM - ENDOCRINE, ORAL AND TRANSDERMAL

# **ESTROGENS AND PROGESTINS**

- Amabelz
- Climara Pro
- Divigel
- Elestrin
- Estradiol ORAL TABS 0.5MG, 1MG, 2MG
- Estradiol PTTW
- Estradiol PTWK
- Estradiol/norethindrone Acetate
- Estropipate TABS
- Fyavolv
- Jevantique Lo
- Jinteli
- Lopreeza
- Mimvey
- Mimvey Lo
- Norethindrone Acetate/ethinyl Estradiol TABS 2.5MCG; 0.5MG, 5MCG; 1MG
- Premarin TABS 0.3MG, 0.45MG, 0.625MG, 0.9MG, 1.25MG
- Premphase
- Prempro

Members Health Insurance Company

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication. Breast cancer (formulary estradiol tablet and Premarin): Dx of breast cancer. Disease is metastatic. Used for palliative treatment. Prostatic carcinoma (formulary estradiol tablet and Premarin): Dx of advanced androgen-dependent carcinoma of the prostate. Used for palliative treatment.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Breast cancer and prostatic carcinoma (formulary estradiol tablet and Premarin): Approve for continuation of therapy.

### **HRM - PAIN MEDICATIONS**

- Butalbital/acetaminophen
- Butalbital/aspirin/caffeine CAPS
- Cephadyn
- Indomethacin CAPS
- Ketorolac Tromethamine INJ 15MG/ML, 300MG/10ML, 30MG/ML
- Ketorolac Tromethamine TABS
- Marten-tab
- Tencon TABS 325MG; 50MG
- Vanatol Lq

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# **HRM - PAROXETINE**

- Paroxetine Hcl
- Paroxetine Hcl Er
- Paxil SUSP

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Applies to New Starts only.

# HRM - PHENOBARBITAL, PENTOBARBITAL

- Pentobarbital Sodium INJ
- Phenobarbital ELIX 20MG/5ML
- Phenobarbital TABS 100MG, 15MG, 16.2MG, 30MG, 32.4MG, 60MG, 64.8MG, 97.2MG
- Phenobarbital Sodium INJ 130MG/ML, 65MG/ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Verify the medication is being used for an FDA-approved diagnosis AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of therapy.

# **HRM - PLATELET INHIBITORS**

#### **Products Affected**

• Ticlopidine Hcl

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) unless alternative(s) is/are inappropriate or would not be applicable for the indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Requires trial of at least one Non-HRM alternative: clopidogrel, Aggrenox

# **HRM - SEDATIVE HYPNOTIC AGENTS**

- Zaleplon
- Zolpidem Tartrate TABS
- Zolpidem Tartrate Er

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) when used longer than 90 days and wishes to proceed with the originally prescribed medication AND intended duration of therapy will be verified.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# HRM - SKELETAL MUSCLE RELAXANTS

- Chlorzoxazone TABS
- Cyclobenzaprine Hcl TABS 10MG, 5MG
- Methocarbamol TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# **HRM - SULFONYLUREAS**

- Glyburide TABS
- Glyburide Micronized
- Glyburide/metformin Hcl

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA) unless alternative(s) is/are inappropriate or would not be applicable for the indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication.
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Requires trial of at least one Non-HRM alternative: glimepiride, glipizide

Members Health Insurance Company Date Effective: November 1, 2018

### HRM - TCA

- Amitriptyline Hcl TABS
- Amoxapine
- Chlordiazepoxide/amitriptyline
- Clomipramine Hcl CAPS
- Desipramine Hcl TABS
- Doxepin Hcl CAPS
- Doxepin Hcl CONC
- Imipramine Hcl TABS 25MG, 50MG
- Imipramine Hydrochloride TABS 10MG
- Nortriptyline Hcl CAPS
- Nortriptyline Hcl SOLN
- Perphenazine/amitriptyline
- Protriptyline Hcl
- Trimipramine Maleate CAPS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The drug is being prescribed for an FDA-approved indication AND the prescribing physician has been made aware that the requested drug is considered a high risk medication for elderly patients (age 65 years and older) and wishes to proceed with the originally prescribed medication .
Age Restrictions	PA applies to patients 65 years or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Applies to New Starts only.

Members Health Insurance Company

Date Effective: November 1, 2018

# HUMIRA (S)

- Humira
- Humira Pediatric Crohns Disease Starter Pack
- Humira Pen
- Humira Pen-cd/uc/hs Starter
- Humira Pen-ps/uv Starter

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Trial and failure, contraindication, or intolerance (TF/C/I) to one disease modifying antirheumatic drug (DMARD) [eg, methotrexate (Rheumatrex/Trexall), Arava (leflunomide), Azulfidine (sulfasalazine)]. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. TF/C/I to one of the following DMARDs: Arava (leflunomide) or methotrexate (Rheumatrex/Trexall). Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe chronic plaque psoriasis. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. TF/C/I to two NSAIDs. Crohn's Disease (CD) (Initial): Diagnosis of moderately to severely active CD. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall), or failure (ie, lost response) or intolerance to infliximab. Ulcerative Colitis (UC) (Initial): Diagnosis of moderately to severely active UC. TF/C/I to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol, Pentasa, Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Hidradenitis suppurativa (Initial): Diagnosis of moderate to severe hidradenitis suppurativa (ie, Hurley Stage II or III). Uveitis (initial): Diagnosis of noninfectious uveitis, classified as intermediate, posterior, or panuveitis. All indications (initial, reauth): Patient is not receiving Humira in combination with a biologic DMARD [eg, Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept)].
Age Restrictions	N/A
Prescriber Restrictions	RA, AS, JIA (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque Psoriasis, HS (Initial): Prescribed by or in consultation with a dermatologist. CD, UC (Initial): Prescribed by or in consultation with a gastroenterologist. Uveitis (initial): Prescribed by or in consultation with an ophthalmologist or rheumatologist.
Coverage Duration	UC (Initial): 12 wks. UC (reauth): 12 mo. All other indications (initial, reauth): 12 mo.

Members Health Insurance Company

Date Effective: November 1, 2018

#### **Other Criteria**

RA, JIA, PsA, Plaque psoriasis, AS, CD, Hidradenitis suppurativa (HS), Uveitis (Reauth): Documentation of positive clinical response to Humira therapy. UC (Reauth): For patients who initiated Humira therapy within the past 12 weeks: Documentation of clinical remission or significant clinical benefit by eight weeks (Day 57) of therapy OR For patients who have been maintained on Humira therapy for longer than 12 weeks: Documentation of positive clinical response to Humira therapy.

# HYDROXYPROGESTERONE (S)

#### **Products Affected**

• Hydroxyprogesterone Caproate INJ 1.25GM/5ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	All uses (initial): Pregnant patients.
Required Medical Information	Amenorrhea: Diagnosis of primary or secondary amenorrhea.  Amenorrhea is due to hormonal imbalance in the absence of organic pathology (e.g., submucous fibroids or uterine cancer) Secretory endometrium and desquamation: Used for production of secretory endometrium and desquamation in patients with endometrial disorder. Adenocarcinoma: Diagnosis of Stage III or IV adenocarcinoma of the uterine corpus. Estrogen production test: Used for the testing of endogenous estrogen production.
Age Restrictions	N/A
Prescriber Restrictions	Adenocarcinoma (initial): Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# **IBRANCE (S)**

### **Products Affected**

• Ibrance

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer: Diagnosis of breast cancer. Disease is a)advanced or metastatic, b) hormone-receptor (HR)-positive, and c) human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) used in combination with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane) and patient is a postmenopausal woman, OR b) both of the following: used in combination with Faslodex (fulvestrant) and disease has progressed following endocrine therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# ICLUSIG (S)

### **Products Affected**

• Iclusig

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic myelogenous leukemia: Diagnosis of chronic myelogenous leukemia AND One of the following: A) Trial and failure, resistance, relapse, contraindication, or intolerance to at least TWO other tyrosine kinase inhibitors (i.e., Gleevec [imatinib], Sprycel, Tasigna, and Bosulif) or B) Patient has the T315I mutation. Acute Lymphoblastic Leukemia: Diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) AND One of the following: A) Trial and failure, resistance relapse, contraindication, or intolerance to at least TWO other FDA-approved tyrosine kinase inhibitors (i.e., Gleevec [imatinib], Sprycel), or B) Patient has the T315I mutation.
Age Restrictions	All Uses: 18 years of age or older
Prescriber Restrictions	All Uses: Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	All uses: 12 months
Other Criteria	All uses: Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# **I**DHIFA (S)

### **Products Affected**

• Idhifa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Acute Myeloid Leukemia (AML): Diagnosis of AML. Disease is relapsed or refractory. Patient has an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test (e.g., Abbott RealTime IDH2 assay) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# ILARIS (S)

### **Products Affected**

• Ilaris

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Periodic Fever Syndromes (Cryopyrin-Associated Periodic Syndromes (CAPS), Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), Familial Mediterranean Fever (FMF)). (Initial) Diagnosis of one of the autoinflammatory Periodic Fever Syndromes: CAPS (including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS)), TRAPS, HIDS/MKD, or FMF, AND The medication will not be used in combination with another biologic agent. Systemic juvenile idiopathic arthritis (sJIA) (Initial): Diagnosis of active sJIA AND The medication will not be used in combination with another biologic
Age Restrictions	SJIA (initial): 2 years of age or older
Prescriber Restrictions	Periodic Fever Syndromes (CAPS, TRAPS, HIDS/MKD, FMF) (initial): Prescribed by or in consultation with an immunologist, allergist, dermatologist, rheumatologist, neurologist or other medical specialist
Coverage Duration	All indications (initial, reauth): 12 months
Other Criteria	Periodic Fever Syndrome (CAPS, TRAPS, HIDS/MKD, FMF) ((Reauth) and SJIA (Reauth): Documentation of positive clinical response to therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# **IMBRUVICA (S)**

### **Products Affected**

• Imbruvica

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Mantle cell lymphoma (MCL): Diagnosis of MCL AND patient has relapsed or is refractory to at least one prior therapy for the treatment of MCL. Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Waldenstrom's macroglobulinemia: Diagnosis of Waldenström's macroglobulinemia/lymphoplasmacytic lymphoma. Small lymphocytic lymphoma (SLL): Diagnosis of SLL. Marginal zone lymphoma (MZL): Diagnosis of MZL AND patient has received at least one prior anti-CD20-based therapy for MZL [e.g., Rituxan (rituximab), Zevalin (ibritumomab), Gazyva (obinutuzumab, etc.)]. Chronic graft versus host disease (cGVHD): Diagnosis of cGVHD AND trial and failure of one or more lines of systemic therapy (e.g., corticosteroids, mycophenolate).
Age Restrictions	N/A
Prescriber Restrictions	All uses (except chronic graft versus host disease): Prescribed by or in consultation with an oncologist or hematologist. Chronic graft versus host disease: Prescribed by or in consultation with a hematologist, oncologist, or physician experienced in the management of transplant patients.
Coverage Duration	All Uses: 12 months
Other Criteria	All Uses: Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# **IMFINZI (S)**

#### **Products Affected**

• Imfinzi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Urothelial carcinoma: 1) Diagnosis of locally advanced or metastatic urothelial carcinoma AND 2) One of the following: a) Patient has experienced disease progression during or following platinum-containing chemotherapy OR b) Patient has experienced disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Non-Small Cell Lung Cancer (NSCLC): 1) Diagnosis of NSCLC AND 2) Disease is stage III and unresectable AND 3) Disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

Members Health Insurance Company Date Effective: November 1, 2018

## **INCRELEX (S)**

### **Products Affected**

• Increlex

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Insulin-like Growth Factor-1 (IGF-1) deficiency (initial): Diagnosis of severe primary IGF-1 deficiency. Height standard deviation score of -3.0 or less. Basal IGF-1 standard deviation score of -3.0 or less. Normal or elevated growth hormone (GH). GH gene deletion (initial): Diagnosis of GH gene deletion in patients who have developed neutralizing antibodies to GH.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with a pediatric endocrinologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	(Reauth): Evidence of positive response to therapy.

Prior Authorization Criteria Members Health Insurance Company

Date Effective: November 1, 2018

## INFLECTRA (S)

### **Products Affected**

• Inflectra

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Dx of moderately to severely active CD or FCD. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. Rheumatoid arthritis (RA) (initial): Diagnosis (Dx) of moderately to severely active RA. Ankylosing spondylitis (AS) (initial): Dx of active AS. Psoriatic arthritis (PsA) (initial): Dx of active PsA. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. CD, FCD (initial): Trial and failure, contraindication or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). UC (initial): TF/C/I to one of the following conventional therapies: corticosteroids, aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine/Sulfazine)], azathioprine (Imuran), 6-mercaptopurine (Purinethol). RA (initial): Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), or TF/C/I to methotrexate. AS (initial): TF/C/I to two or more NSAIDs. All indications (initial): One of the following: 1) Trial and failure or intolerance to Remicade or 2) For continuation of prior Inflectra therapy. All indications (Initial): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)].
Age Restrictions	N/A
Prescriber Restrictions	RA, AS: Prescribed or recommended by a rheumatologist. PsA: Prescribed or recommended by rheumatologist or dermatologist. Crohn's Disease, Fistulizing Crohn's Disease, UC: Prescribed or recommended by a gastroenterologist. Plaque Psoriasis: Prescribed or recommended by a dermatologist.
Coverage Duration	All indications (initial, reauth): 12 months
Other Criteria	Reauthorization for all indications: Documentation of positive clinical response to infliximab therapy. All indications (re-auth): Excluded if patient is receiving infliximab in combination with a Biologic Disease

Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)].

Members Health Insurance Company Date Effective: November 1, 2018

## INGREZZA (S)

### **Products Affected**

• Ingrezza

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Tardive Dyskinesia (initial): Diagnosis of moderate to severe tardive dyskinesia. One of the following: a) patient has persistent symptoms of tardive dyskinesia despite a trial of dose reduction, tapering, or discontinuation of the offending medication OR b) patient is not a candidate for a trial of dose reduction, tapering, or discontinuation of the offending medication.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with a neurologist or psychiatrist.
Coverage Duration	Initial: 3 months, Reauth: 12 months
Other Criteria	Tardive Dyskinesia (reauth): Documentation of positive clinical response to Ingrezza therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## INLYTA (S)

### **Products Affected**

• Inlyta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Renal cell cancer (RCC): Diagnosis of RCC. One of the following: (1) disease has relapsed or (2) both of the following: medically or surgically unresectable tumor and diagnosis of stage IV disease.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## INTRON A (S)

- Intron A
- Intron A W/diluent INJ 10MU

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Diagnosis of chronic hepatitis C, patient without decompensated liver disease, patient has not previously been treated with interferon, and one of the following - 1) used in combination with ribavirin or 2) contraindication or intolerance to ribavirin. Metastatic renal cell carcinoma (RCC): diagnosis of metastatic RCC, used in combination with Avastin (bevacizumab). Other: diagnosis of condylomata acuminata (genital or perianal), diagnosis of hairy cell leukemia, diagnosis of AIDS-related Kaposi's sarcoma, diagnosis of malignant melanoma, diagnosis of Stage III or IV follicular Non-Hodgkin's Lymphoma, as maintenance therapy for the treatment of multiple myeloma.
Age Restrictions	N/A
Prescriber Restrictions	RCC: Prescribed by or in consultation with an oncologist.
Coverage Duration	HepB, HepC: 48 wks. Condylomata acuminata (genital or perianal): 6 wks. Other: 12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## IRESSA (S)

## **Products Affected**

• Iressa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of metastatic NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

## **ISOTRETINOIN (S)**

- Amnesteem
- Claravis
- Isotretinoin CAPS
- Myorisan
- Zenatane

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Acne (initial): Diagnosis of acne. Trial and failure, contraindication or intolerance to an adequate trial (at least 6 weeks) on both of the following conventional therapy regimens: a) topical retinoid or retinoid-like agent [eg, Retin-A/Retin-A Micro (tretinoin)] AND b) combination therapy with benzoyl peroxide and one of the following: 1) oral antibiotic [eg, Ery-Tab (erythromycin), Minocin (minocycline)] OR 2) topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl peroxide/erythromycin)].
Age Restrictions	N/A
Prescriber Restrictions	Acne (Initial): Prescribed by a dermatologist
Coverage Duration	Acne (initial, reauth): 5 months
Other Criteria	Acne (reauth): One of the following: A) After more than 2 months off therapy, persistent or recurring severe recalcitrant nodular acne is still present, OR B) the total cumulative dose is less than 150 mg/kg (will be approved up to a total of 150 mg/kg).

Members Health Insurance Company Date Effective: November 1, 2018

## ISTODAX (S)

- Istodax
- Istodax (overfill)
- Romidepsin

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Patient has tried and had an inadequate response, intolerance or contraindication to at least one prior therapy (eg, retinoids, corticosteroids). Peripheral T-cell lymphoma (PTCL): Diagnosis of PTCL. Patient has tried and had an inadequate response, intolerance or contraindication to at least one prior therapy (eg, conventional chemotherapy such as CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone), Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin), HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone) alternating with high-dose methotrexate and cytarabine).
Age Restrictions	N/A
Prescriber Restrictions	CTCL, PTCL: Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company

Date Effective: November 1, 2018

## IVIG(S)

- Bivigam
- Carimune Nanofiltered INJ 12GM, 6GM
- Flebogamma Dif
- Gammagard Liquid
- Gammagard S/d Iga Less Than 1mcg/ml
- Gammaked
- Gammaplex
- Gamunex-c
- Octagam
- Privigen

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Privigen only: Hyperprolinemia. Octagam only: Allergy to corn. Gammaplex only: Hereditary intolerance to fructose. Infants for whom sucrose or fructose tolerance has not been established.
Required Medical Information	Initial: Immune globulin (Ig) will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. For IVIG – Ig is being used intravenously (IV) AND One of the following diagnoses: [A] Primary Immunodeficiency 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). [B] Secondary Acquired Antibody Deficiency 1) B-cell chronic lymphocytic leukemia with an Ig level less than 500 mg/dL OR history of recurrent bacterial infections. 2) HIV infection with an Ig level less than 400 mg/dL OR Patient has active bleeding or a platelet count less than 10 x 109/L. 3) Multiple myeloma in plateau phase and patient has hypogammaglobulinemia. [C] Hematological Autoimmune Disorders 1) Acquired (pure) red cell aplasia (PRCA) that is immunologic and patient had a trial and failure, contraindication, or intolerance (TF/C/I) to a corticosteroid and an immunosuppressant (i.e., cyclophosphamide, cyclosporine) OR patient has viral PRCA caused by parvovirus B19. 2) Fetal alloimmune thrombocytopenia. 3) Hemolytic disease of the newborr and the patient has established hyperbilirubinemia. 4) Idiopathic thrombocytopenic purpura and patient had a TF/C/I to a corticosteroid OR a platelet count less than 30,000 cells/mm3. 5) Post-transfusion purpura. Continued in Other Criteria Section.
Age Restrictions	HIV (initial): patient is less than or equal to 12 years of age.
Prescriber Restrictions	All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on immune globulin therapy (e.g., immunologist, hematologist, neurologist, etc.).

Coverage Duration	4 months: Solid organ transplant. 12 months: all other diagnoses.
Other Criteria	[D] Neuromuscular Autoimmune Disorders 1) Chronic inflammatory demyelinating polyneuropathy. 2) Guillain-Barré syndrome. 3) Inflammatory myopathies (dermatomyositis and polymyositis) AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, methotrexate, cyclosporine A, cyclophosphamide, or tacrolimus). 4) Lambert-Eaton myasthenic syndrome AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (e.g., azathioprine). 5) Multifocal motor neuropathy. 6) Myasthenia gravis with severe exacerbations or myasthenic crises AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., azathioprine, cyclosporine, cyclophosphamide, or mycophenolate mofetil). 7) Stiff person syndrome AND Patient had a TF/C/I to at least 2 standard therapies (i.e., benzodiazepines, muscle relaxants, or anti-convulsants). [E] Other Disorders 1) Autoimmune blistering disease AND Patient had a TF/C/I to a corticosteroid AND an immunosuppressant (i.e., cyclophosphamide, dapsone, methotrexate, azathioprine, or mycophenolate mofetil). 2) Kawasaki syndrome. 3) Solid organ transplan and IVIG is being used for CMV prophylaxis, or patient is a kidney transplant recipient and has donor specific antibodies, or patient has steroid-resistant rejection and had a TF/C/I to standard therapies. For SCIG (Gamunex-C, Gammagard Liquid, Gammaked only)- Immune globulin is being used subcutaneously AND One of the following PI diagnoses: 1) Common variable immunodeficiency. 2) Congenital agammaglobulinemia (X-linked or autosomal recessive). 3) Severe combined immunodeficiencies. 4) Wiskott-Aldrich syndrome. OR 5) Other PI with an immunologic evaluation including IgG levels below the

normal laboratory value for the patient's age at the time of diagnosis and patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine). All products: Subject to Part B vs. Part D review. For non-oncology renewal, the patient has experienced an objective improvement on

immune globulin therapy and the immune globulin will be administered at

the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## JAKAFI (S)

### **Products Affected**

• Jakafi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Myelofibrosis: Diagnosis of primary myelofibrosis, OR post- polycythemia vera myelofibrosis, OR post-essential thrombocythemia myelofibrosis. Polycythemia vera: Diagnosis of polycythemia vera, AND trial and failure, contraindication, or intolerance to hydroxyurea.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	Myelofibrosis, Polycythemia vera: 12 months.
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## **JEVTANA (S)**

### **Products Affected**

Jevtana

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Diagnosis of castration-resistant metastatic prostate cancer AND patient has been previously treated with a docetaxel-containing regimen AND patient is receiving concurrent prednisone
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Prior Authorization Criteria Members Health Insurance Company

Date Effective: November 1, 2018

## **JUXTAPID (S)**

### **Products Affected**

• Juxtapid

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Homozygous familial hypercholesterolemia (HoFH) (initial): Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the following: 1) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. Patient has been receiving at least 12 consecutive weeks of ONE LDL-C lowering prescription therapy and will continue to receive an LDL-C lowering prescription therapy. Trial and failure after 12 consecutive weeks or intolerance to Repatha therapy. One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: LDL-C greater than or equal to 100 mg/dL with ASCVD OR LDL-C greater than or equal to 130 mg/dL without ASCVD. Not used in combination with Kynamro (mipomersen). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient is not pregnant. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests. Patient is not concomitantly on moderate or strong CYP 3A4 inhibitors (eg, clarithromycin).
Age Restrictions	N/A
Prescriber Restrictions	HoFH (initial, reauth): Prescribed by a cardiologist, endocrinologist, or lipid specialist.
Coverage Duration	HoFH (initial): 6 months. (reauth): 12 months
Other Criteria	HoFH (reauthorization): Patient continues to receive statin at the maximally tolerated dose (or other LDL-C lowering prescription therapy if patient is unable to take a statin). Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pretreatment baseline (ie, prior Juxtapid therapy) while on Juxtapid therapy. Not used in combination with Kynamro (mipomersen). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9)

inhibitor. Patient is not pregnant. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests. Patient is not concomitantly on moderate or strong CYP 3A4 inhibitors (eg, clarithromycin).

Members Health Insurance Company Date Effective: November 1, 2018

# KADCYLA (S)

### **Products Affected**

• Kadcyla

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: A) Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive recurrent or metastatic breast cancer AND B) Patient has been previously treated with Herceptin (trastuzumab) and a taxane (eg, docetaxel, paclitaxel).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# KALBITOR (S)

### **Products Affected**

• Kalbitor

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Firazyr, or Ruconest).
Age Restrictions	12 years of age or older
Prescriber Restrictions	HAE: Prescribed by an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# KALYDECO (S)

### **Products Affected**

• Kalydeco

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Cystic Fibrosis (CF) (Initial): Diagnosis of cystic fibrosis. Patient has one of the following mutations on at least one allele in the cystic fibrosis transmembrane conductance regulator gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA)-approved facility: A455E, A1067T, D110E, D110H, D579G, D1152H, D1270N, E56K, E193K, E831X, F1052V, F1074L, G178R, G551D, G551S, G1069R, G1244E, G1349D, K1060T, L206W, P67L, R74W, R117C, R117H, R347H, R352Q, R1070Q, R1070W, S549N, S549R, S945L, S977F, S1251N, S1255P, 711+3A-G, 2789+5G-A, 3272-26A-G, or 3849+10kbC-T.
Age Restrictions	CF (Initial): 2 years of age or older
Prescriber Restrictions	CF (Initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).

Members Health Insurance Company Date Effective: November 1, 2018

## KANUMA (S)

#### **Products Affected**

• Kanuma

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Lysosomal acid lipase deficiency: Diagnosis of lysosomal acid lipase deficiency (LAL-D). Diagnosis was confirmed by an enzymatic blood (e.g., dried blood spot test) or genetic test.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism, gastroenterologist, or lipidologist
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

## **KEVEYIS (S)**

### **Products Affected**

• Keveyis

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Periodic paralysis (Initial): Diagnosis of one of the following: Primary hyperkalemic periodic paralysis, Primary hypokalemic periodic paralysis, or Paramyotonia Congenita with periodic paralysis
Age Restrictions	N/A
Prescriber Restrictions	All uses (Initial): Prescribed by or in consultation with a neurologist
Coverage Duration	All uses (Initial): 3 months. (Reauth): 12 months
Other Criteria	All uses (Reauth): Documentation of positive clinical response to Keveyis therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## KEVZARA (S)

#### **Products Affected**

• Kevzara

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (initial): Diagnosis of moderately to severely active RA. One of the following: a) Trial and failure, contraindication, or intolerance (TF/C/I) to both Enbrel (etanercept) and Humira (adalimumab), b) or attestation demonstrating a trial may be inappropriate, OR c) For continuation of prior Kevzara therapy. (Initial, Reauth): Patient is not receiving Kevzara in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with a rheumatologist
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	RA (reauth): Documentation of positive clinical response to Kevzara therapy.

Prior Authorization Criteria Members Health Insurance Company Date Effective: November 1, 2018

# **KEYTRUDA (S)**

### **Products Affected**

• Keytruda

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis (dx) of melanoma and disease is unresectable or metastatic. Non-Small Cell Lung Cancer (NSCLC): Dx of metastatic NSCLC. One of the following: A) Tumors express high PD-L1 [Tumor Proportion Score (TPS) greater than or equal to 50%] as determined by an FDA-approved test, absence of epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations, and used as first-line treatment. OR B) Tumors express PD-L1 [Tumor Proportion Score (TPS) greater than or equal to 1%] as determined by an FDA-approved test, patient had a trial and failure, contraindication, or intolerance to platinum-containing therapy (eg, cisplatin, carboplatin), AND one of the following: 1) absence of EGFR mutation or ALK rearrangement, OR 2) both of the following: presence of EGFR or ALK genomic tumor aberrations AND trial and failure, contraindication, or intolerance to FDA-approved therapy for these aberrations [e.g., Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib), Xalkori (crizotinib)]. OR C) Both of the following: prescribed medication is being used for first line treatment in patients with nonsquamous NSCLC AND prescribed medication is being used in combination with pemetrexed and carboplatin. Recurrent or metastatic head and neck squamous cell carcinoma (HNSCC): Patient has a diagnosis of recurrent or metastatic HNSCC AND patient has disease progression on or after platinum-containing therapy. Classical Hodgkin lymphoma: Diagnosis of classical Hodgkin lymphoma AND One of the following: A) disease is refractory or B) disease has relapsed after 3 or more prior lines of therapy. Primary Mediastinal Large B-Cell Lymphoma (PMBCL): Dx of PMBCL. One of the following: A) disease is refractory, or B) disease has relapsed after 2 or more prior lines of therapy.
Age Restrictions	N/A
Prescriber Restrictions	cHL, PMBCL: Prescribed by or in consultation with a hematologist/oncologist. All Other Uses:Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months.

#### Other Criteria

Urothelial Carcinoma: Dx of locally advanced or metastatic urothelial carcinoma AND one of the following: 1) Patient is not eligible for cisplatin-containing chemotherapy and tumors express PD-L1 (Combined Positive Score [CPS] greater than or equal to 10), 2) Disease progression during or following platinum-containing chemotherapy, or 3) Disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Microsatellite Instability-High Cancer (MSI-H): One of the following: 1) Dx of unresectable or metastatic, MSI-H or mismatch repair deficient solid tumors AND disease progression following prior treatment AND patient has no satisfactory alternative treatment options, OR 2) Dx of unresectable or metastatic, MSI-H or mismatch repair deficient colorectal cancer AND patient has experienced progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Gastric Cancer: Dx of gastric or gastroesophageal junction adenocarcinoma AND disease is locally advanced, recurrent, or metastatic AND tumors express PD-L1 (Combined Positive Score [CPS] greater than or equal to 1) as determined by an FDA-approved test AND disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy AND HER2/neu-targeted therapy if the patient is HER2/neu positive. Cervical Cancer (CC): Dx of CC. Disease is recurrent or metastatic. Disease progression on or after chemotherapy. Tumor(s) express PD-L1 (CPS greater than or equal to 1) as determined by an FDA-approved test. All Indications: Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## KINERET (S)

### **Products Affected**

• Kineret

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Kineret therapy. Neonatal-Onset Multisystem Inflammatory Disease (NOMID) (initial): Diagnosis of NOMID AND dx of NOMID has been confirmed by one of the following: NLRP-3 (nucleotide-binding domain, leucine rich family (NLR), pyrin domain containing 3] gene (also known as Cold-Induced Auto-inflammatory Syndrome-1 [CIAS1]) mutation OR evidence of active inflammation including both of the following: clinical symptoms (eg, rash, fever, arthralgia) and elevated acute phase reactants (eg, ESR, CRP). All Uses (initial, reauth): Patient is not receiving Kineret in combination with a biologic disease modifying antirheumatic drug (DMARD) [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].
Age Restrictions	N/A
Prescriber Restrictions	RA (initial): Prescribed by or in consultation with a rheumatologist. NOMID (initial): Prescribed by or in consultation with allergist/immunologist or rheumatologist or pediatrician.
Coverage Duration	All Uses (initial, reauth): 12 months
Other Criteria	All Uses (Reauth): Documentation of positive clinical response to Kineret therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# KISQALI (S)

### **Products Affected**

• Kisqali

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: A) Both of the following: 1) Kisqali is used in combination with an aromatase inhibitor [(e.g., Femara (letrozole)] and 2) One of the following: a) patient is a pre/perimenopausal woman or b) patient is a postmenopausal woman OR B) Both of the following: 1) Used in combination with Faslodex (fulvestrant) and 2) patient is a postmenopausal woman.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by on in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

## KISQALI-FEMARA PACK (S)

- Kisqali Femara 200 Dose
- Kisqali Femara 400 Dose
- Kisqali Femara 600 Dose

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis of advanced or metastatic breast cancer. Patient is a postmenopausal woman. Cancer is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

Members Health Insurance Company Date Effective: November 1, 2018

# KORLYM (S)

### **Products Affected**

• Korlym

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Cushing's syndrome (Initial): Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). Diagnosis of either type 2 diabetes mellitus or diagnosis of glucose intolerance. Patient has either failed surgery or patient is not a candidate for surgery. Patient is not pregnant.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Initial, reauth: 6 months
Other Criteria	Reauthorization: Documentation of one of the following: patient has improved glucose tolerance while on Korlym therapy or patient has stable glucose tolerance while on Korlym therapy.

# KRYSTEXXA (S)

### **Products Affected**

• Krystexxa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Initial, reauth: Excluded if patient has diagnosis of glucose-6-phosphate dehydrogenase (G6PD) deficiency.
Required Medical Information	Gout (initial): Diagnosis of severe chronic gout. Patient has tried and had an inadequate response (defined as one of the following symptoms of treatment failure gout: a) greater than or equal to 3 flares in previous 18 months, b) greater than or equal to 1 gout tophus or c) gouty arthritis) to two of the following conventional therapies: allopurinol, febuxostat, probenecid or colchicine. Patient will NOT receive concurrent use of oral urate-lowering agents (i.e. Uloric). Patient will receive premedication with antihistamines and corticosteroids.
Age Restrictions	Gout (initial): 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Gout (initial, reauth): 12 months
Other Criteria	Gout (reauth): Serum urate level has decreased since initiating therapy. Clinical improvement in the signs and symptoms of gout (e.g., decrease in tophi size or frequency of gouty flares per year from baseline or improvement in chronic arthropathy or quality of life).

Members Health Insurance Company Date Effective: November 1, 2018

# KUVAN (S)

### **Products Affected**

• Kuvan

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Phenylketonuria (PKU) (initial): Diagnosis of PKU. Patient will have blood Phe levels measured after 1 week of therapy (new starts to therapy only) and periodically for up to 2 months of therapy to determine response.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	PKU (Init): 2 months (Reauth): 12 months
Other Criteria	PKU (reauth): Patient has had an objective response to therapy, defined as a 30% or greater reduction in phenylalanine (Phe) blood levels from baseline. Patient will continue to have blood Phe levels measured periodically during therapy.

Prior Authorization Criteria Members Health Insurance Company

Date Effective: November 1, 2018

## KYNAMRO (S)

### **Products Affected**

• Kynamro

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Homozygous familial hypercholesterolemia (HoFH) (initial):Submission of medical records (eg, chart notes, laboratory values) documenting diagnosis of HoFH as confirmed by one of the following: a) genetic confirmation of 2 mutations in the LDL receptor, ApoB, PCSK9, or LDL receptor adaptor protein 1 (ie, LDLRAP1 or ARH), or b) both of the following: 1) either untreated LDL-C greater than 500 mg/dL or treated LDL-C greater than 300 mg/dL AND 2) either xanthoma before 10 years of age or evidence of heterozygous FH in both parents. Patient has been receiving at least 12 consecutive weeks of ONE LDL-C lowering prescription therapy and will continue to receive an LDL-C lowering prescription therapy. Trial and failure after 12 consecutive weeks or intolerance to Repatha therapy. One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 30 days: LDL-C greater than or equal to 100 mg/dL with ASCVD OR LDL-C greater than or equal to 130 mg/dL without ASCVD. Not used in combination with Juxtapid (lomitapide). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient does not have moderate or severe hepatic impairment (ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests.
Age Restrictions	N/A
Prescriber Restrictions	HoFH (initial, reauth): Prescribed by a cardiologist, endocrinologist, or lipid specialist.
Coverage Duration	HoFH (initial): 6 months. (reauth): 12 months
Other Criteria	HoFH (reauthorization): Patient continues to receive statin at the maximally tolerated dose (or other LDL-C lowering prescription therapy if patient is unable to take a statin). Submission of medical records (eg, laboratory values) documenting a sustained LDL-C reduction from pretreatment baseline (ie, prior Juxtapid therapy) while on Kynamro therapy. Not used in combination with Juxtapid (lomitapide). Not used in combination with a proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor. Patient does not have moderate or severe hepatic impairment

(ie, Child-Pugh category B or C) or active liver disease including unexplained persistent abnormal liver function tests.

Members Health Insurance Company Date Effective: November 1, 2018

# Kyprolis (s)

### **Products Affected**

• Kyprolis

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple Myeloma (MM): Diagnosis of MM. Disease is relapsed or refractory. Patient has received at least one prior therapy for MM.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## LARTRUVO (S)

#### **Products Affected**

• Lartruvo

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Soft Tissue Sarcoma (STS): Diagnosis of STS. All of the following: A) One of the following: 1) Disease is not amenable to curative treatment with radiotherapy or 2) Disease is not amenable to curative treatment with surgery AND B) Used in combination with doxorubicin for the first 8 cycles of treatment
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

## LEMTRADA (S)

#### **Products Affected**

• Lemtrada

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses). One of the following: 1) Patient has not been previously treated with alemtuzumab, and patient had trial and failure following a trial for at least 4 weeks, or intolerance or contraindication to 2 of the following: interferon beta-1a (Avonex or Rebif), interferon beta-1b (Betaseron, Extavia), glatiramer acetate (Copaxone or Glatopa), dimethyl fumarate (Tecfidera), teriflunomide (Aubagio), fingolimod (Gilenya), peginterferon beta-1a (Plegridy), natalizumab (Tysabri), or 2) Patient has previously received treatment with alemtuzumab, and at least 12 months have or will have elapsed since the first treatment with alemtuzumab, and patient has not already received the FDA-recommended lifetime limit of two (2) treatment courses of alemtuzumab. Patient is not receiving alemtuzumab in combination with another disease modifying agent (eg, interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, or teriflunomide).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	MS: 12 months, max 2 yrs of therapy.
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

### LENVIMA (S)

- Lenvima 10 Mg Daily Dose
- Lenvima 12mg Daily Dose
- Lenvima 14 Mg Daily Dose
- Lenvima 18 Mg Daily Dose
- Lenvima 20 Mg Daily Dose
- Lenvima 24 Mg Daily Dose
- Lenvima 4 Mg Daily Dose
- Lenvima 8 Mg Daily Dose

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Differentiated thyroid cancer (DTC): Diagnosis of DTC. Disease is locally recurrent or metastatic. Patient has symptomatic or progressive disease. Disease is refractory to radioactive iodine treatment. Renal Cell Carcinoma (RCC): Diagnosis of advanced RCC following one prior antiangiogenic therapy. Used in combination with everolimus.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## LETAIRIS (S)

### **Products Affected**

• Letairis

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH (Initial): 6 months. PAH (Reauth): 12 months
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

Members Health Insurance Company

Date Effective: November 1, 2018

# LEUKINE (S)

### **Products Affected**

• Leukine INJ 250MCG

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Bone marrow/stem cell transplant (BMSCT): One of the following: 1) patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by autologous or allogeneic BMT, OR 2) for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis, OR 3) for peripheral stem cell transplant (PSCT) patients who have received myeloablative chemotherapy. Acute myeloid leukemia (AML): patients with AML following induction or consolidation chemotherapy, AND age greater than or equal to 55 years. Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) patient is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) patient receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN (SPFN): Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia, AND 2) patients with a history of FN or dose-limiting event during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) Patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Treatment of FN (off-label): Both of the following: 1) patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia, AND 2) patients with FN at high risk for infection-associated complications. Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist except HIVN: Prescribed by or in consultation with a hematologist/oncologist or infectious disease specialist
Coverage Duration	BMSCT, AML, CFN, SPFN, NDDC:3mo or duration of tx. HIVN:6mo. FN (treatment), ARS:1 mo.

Members Health Insurance Company

Date Effective: November 1, 2018

Other Criteria	HIV-related neutropenia (HIVN)(off-label): Patients infected with HIV, and ANC less than or equal to 1000 (cells/mm^3).

Members Health Insurance Company Date Effective: November 1, 2018

## LIDODERM (S)

#### **Products Affected**

• Lidocaine PTCH

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of post-herpetic neuralgia
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

### LONSURF (S)

#### **Products Affected**

• Lonsurf

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Colorectal Cancer: Diagnosis of metastatic colorectal cancer AND trial and failure, contraindication, or intolerance to at least one component in the following: fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (e.g., FOLFOX, FOLFIRI, FOLFOXIRI) AND trial and failure, contraindication, or intolerance to at least one anti-VEGF therapy (e.g., Avastin) AND One of the following: A) patient has KRAS wild-type tumors and trial and failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Vectibix, Erbitux) OR Patient has KRAS mutant tumors.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## LOTRONEX (S)

#### **Products Affected**

• Alosetron Hydrochloride

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Severe Diarrhea-Predominant Irritable Bowel Syndrome (IBS) in Women (initial): All of the following: 1) diagnosis of severe diarrhea-predominant IBS, 2) symptoms for at least 6 months, 3) female patient, AND 4) trial and failure, contraindication, or intolerance to an antidiarrheal agent [eg, loperamide].
Age Restrictions	Initial: 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	IBS (initial): 12 weeks. IBS (reauth): 6 mo.
Other Criteria	IBS (reauthorization): Symptoms of IBS continue to persist, AND documentation of positive clinical response to Lotronex therapy.

Members Health Insurance Company Date Effective: November 1, 2018

### **LUMIZYME-MYOZYME (S)**

- Lumizyme
- Myozyme

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Pompe disease: Diagnosis of Pompe disease [acid alpha-glucosidase (GAA) deficiency].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# LUPANETA PACK (S)

#### **Products Affected**

• Lupaneta Pack

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Endometriosis (initial): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID or one oral contraceptive. Trial and failure, contraindication, or intolerance to Lupron Depot (7.5 mg, 22.5 mg, 30 mg, and 45 mg).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Endomet (init, reauth): 6 months
Other Criteria	Endometriosis (reauthorization): Patient is experiencing recurrence of symptoms after an initial course of therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## LUPRON (S)

#### **Products Affected**

• Leuprolide Acetate INJ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range.
Age Restrictions	N/A
Prescriber Restrictions	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
Coverage Duration	CPP (initial, reauth), Prostate CA: 12 months
Other Criteria	Approve for continuation of prior therapy.

### **LUPRON DEPOT (S)**

- Lupron Depot (1-month)
- Lupron Depot (3-month)
- Lupron Depot (4-month)
- Lupron Depot (6-month)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer (7.5 mg, 22.5 mg, 30 mg, 45 mg): Diagnosis of advanced or metastatic prostate cancer. Endometriosis (3.75 mg, 11.25 mg) (initial): Diagnosis of endometriosis. One of the following: Patient has had surgical ablation to prevent recurrence, or trial and failure, contraindication, or intolerance to one NSAID and one oral contraceptive. Uterine Leiomyomata (UL) (3.75 mg, 11.25 mg): a) For use prior to surgery to reduce size of fibroids to facilitate a surgical procedure (eg, myomectomy, hysterectomy) OR b) all of the following: treatment of anemia, anemia is caused by uterine leiomyomata (fibroids), and for use prior to surgery.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Prostate CA: 12 mo. Endomet (init, reauth):6mo. UL (anemia):3 mo (fibroids):4 mo
Other Criteria	Approve for continuation of prior therapy.

## **LUPRON DEPOT PED (S)**

- Lupron Depot-ped (1-month)
- Lupron Depot-ped (3-month)

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range.
Age Restrictions	N/A
Prescriber Restrictions	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
Coverage Duration	CPP (init, reauth): 12 months
Other Criteria	CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.

Members Health Insurance Company Date Effective: November 1, 2018

### LYNPARZA (S)

#### **Products Affected**

• Lynparza CAPS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Ovarian Cancer: Diagnosis of advanced ovarian cancer. Presence of deleterious or suspected deleterious germline BRCA-mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility. Trial and failure, contraindication, or intolerance to three or more prior lines of chemotherapy (e.g., paclitaxel with cisplatin).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Date Effective: November 1, 2018

## LYNPARZA TABLET (S)

### **Products Affected**

• Lynparza TABS

Date Effective: November 1, 2018

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Ovarian cancer, advanced disease with known or suspected BRCA mutation with 3 or more prior lines of chemotherapy: Diagnosis of advanced ovarian cancer. Presence of deleterious or suspected deleterious germline BRCA-mutations as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility. Trial and failure, contraindication, or intolerance to three or more prior lines of chemotherapy (e.g., paclitaxel with cisplatin). Maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of one of the following: recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin). Breast cancer: Diagnosis of metastatic breast cancer. Presence of a deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility. Disease is human epidermal growth factor receptor 2 (HER2)-negative. Patient has been previously treated with chemotherapy (e.g., anthracycline, taxane) in the neoadjuvant, adjuvant, or metastatic setting. One of the following: a) Disease is hormone receptor (HR)-positive and one of the following: i) patient has been treated with prior endocrine therapy or ii) patient is considered an inappropriate candidate for endocrine therapy.
Age Restrictions	N/A
Prescriber Restrictions	All indications: Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

### MAKENA (S)

- Hydroxyprogesterone Caproate INJ 250MG/ML
- Makena

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Preterm birth prophylaxis: Patient had a previous singleton (single offspring) spontaneous preterm birth. Patient is having a singleton pregnancy. Therapy will be started between 16 weeks, 0 days and 20 weeks, 6 days of gestation. Therapy will be continued until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.
Age Restrictions	N/A
Prescriber Restrictions	Preterm birth prophylaxis: Prescribed by a specialist in obstetrics and gynecology
Coverage Duration	Preterm birth prophylaxis: 21 weeks
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

### MARINOL (S)

#### **Products Affected**

• Dronabinol

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Nausea and Vomiting Associated with Cancer Chemotherapy (CINV): Patient is receiving cancer chemotherapy. Trial and failure, contraindication, or intolerance to one 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). Trial and failure, contraindication, or intolerance to one of the following: Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Zyprexa (olanzapine). AIDS anorexia: Diagnosis of anorexia with weight loss in patients with AIDS. Patient is on antiretroviral therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CINV: 6 months. AIDS anorexia: 3 months.
Other Criteria	Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B when patient is receiving cancer chemotherapy.

Members Health Insurance Company Date Effective: November 1, 2018

## MAVYRET (S)

### **Products Affected**

• Mavyret

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
Coverage Duration	8 to 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guideline
Other Criteria	N/A

# MEKINIST (S)

#### **Products Affected**

• Mekinist

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Tafinlar (dabrafenib). Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Tafinlar (dabrafenib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic ATC. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Tafinlar (dabrafenib).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### METADATE ER-RITALIN SR (S)

- Metadate Er TBCR 20MG
- Methylphenidate Hcl Sr
- Methylphenidate Hydrochloride Er TBCR 10MG, 20MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# **METHOTREXATE INJECTION (S)**

### **Products Affected**

• Rasuvo

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	(initial): Both of the following: 1) One of the following diagnoses: a) Severe, active rheumatoid arthritis, OR b) active polyarticular juvenile idiopathic arthritis, OR c) severe psoriasis, AND 2) trial and failure or intolerance to oral methotrexate.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	(initial, reauth): 12 months
Other Criteria	(reauth): Documentation of positive clinical response to therapy.

## **METHYLIN CHEW (S)**

#### **Products Affected**

• Methylphenidate Hydrochloride CHEW

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

### **METHYLPHENIDATE (S)**

- Methylphenidate Hydrochloride SOLN
- Methylphenidate Hydrochloride TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD), OR c) diagnosis of narcolepsy as confirmed by a sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible)
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

### METHYLPHENIDATE ER (S)

- Methylphenidate Hydrochloride CD
- Methylphenidate Hydrochloride Er CP24
- Methylphenidate Hydrochloride Er CPCR 20MG, 30MG, 40MG
- Methylphenidate Hydrochloride Er TB24
- Methylphenidate Hydrochloride Er TBCR 18MG, 27MG, 36MG, 54MG, 72MG
- Methylphenidate Hydrochloride Er (la)
- Relexxii
- Ritalin La CP24 10MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	One of the following: a) diagnosis of attention deficit hyperactivity disorder (ADHD), OR b) diagnosis of attention deficit disorder (ADD)
Age Restrictions	PA applies to members 19 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

## MIRVASO (S)

#### **Products Affected**

• Mirvaso

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Rosacea (init): Diagnosis of rosacea. Patient has moderate to severe persistent (nontransient) facial erythema.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Rosacea (init, reauth): 12 months
Other Criteria	Rosacea (reauth) Documentation of positive clinical response to Mirvaso therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## Mozobil (s)

#### **Products Affected**

Mozobil

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Hematopoietic Stem Cell (HSC) Mobilization: Patient with non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM) who will be undergoing autologous HSC transplantation. Used in combination with granulocyte-colony stimulating factor (G-CSF).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	One course of therapy up to 4 days
Other Criteria	N/A

### Ms Inteferons (s)

- Avonex
- Avonex Pen
- Betaseron
- Extavia
- Plegridy
- Plegridy Starter Pack
- Rebif
- Rebif Rebidose
- Rebif Rebidose Titration Pack
- Rebif Titration Pack

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

## MYALEPT (S)

#### **Products Affected**

• Myalept

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Lipodystrophy (initial): Diagnosis of congenital or acquired generalized lipodystrophy AND Patient is refractory to current standards of care for lipid and diabetic management AND One or more of the following metabolic abnormalities are present: A) Insulin resistance (defined as requiring more than 200 units per day), B) Hypertriglyceridemia, or C) Diabetes
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an endocrinologist
Coverage Duration	Initial and reauth: 12 months
Other Criteria	Lipodystrophy (reauth): Patient has experienced an objective response to therapy, such as A) Sustained reduction in hemoglobin A1c (HbA1c) level from baseline OR B) Sustained reduction in triglyceride (TG) levels from baseline

Members Health Insurance Company Date Effective: November 1, 2018

### MYLOTARG (S)

#### **Products Affected**

• Mylotarg

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Acute myeloid leukemia (AML): One of the following diagnoses: Newly diagnosed AML or relapsed/refractory (R/R) AML. Disease is CD33-positive.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

### NAGLAZYME (S)

#### **Products Affected**

• Naglazyme

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Mucopolysaccharidosis (MPS VI): Diagnosis of MPS VI (Maroteaux- Lamy Syndrome)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	MPS VI: 12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# NATPARA (S)

#### **Products Affected**

• Natpara

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Hypocalcemia (Initial): Diagnosis of hypocalcemia due to chronic hypoparathyroidism. NATPARA is not being used in the setting of acute post-surgical hypoparathyroidism. Patient does not have a known calcium-sensing receptor mutation. Patient has a documented parathyroid hormone concentration that is inappropriately low for the level of calcium, recorded on at least two occasions within the previous 12 months. Patient has been optimized on adequate doses of oral calcium (more than 2,000 mg daily) and vitamin D (calcitriol at least 1 microgram/day) supplementation. Patient has normal thyroid-stimulating hormone concentrations if not on thyroid hormone replacement therapy (or if on therapy, the dose had to have been stable for greater than or equal to 3 months). Patient has normal magnesium and serum 25-hydroxyvitamin D concentrations. Creatinine clearance is at least 30 mL/min on two separate measurements, or greater than 60 mL/min (one measurement) with an accompanying serum creatinine concentration of less than 1.5 mg/dL. NATPARA will be used as an adjunct to calcium and vitamin D.
Age Restrictions	N/A
Prescriber Restrictions	Hypocalcemia (Initial): Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Initial: 4 months. Reauth: 12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# NERLYNX (S)

### **Products Affected**

• Nerlynx

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Breast cancer: Diagnosis (dx) of early stage breast cancer. Disease is human epidermal growth factor receptor 2 (HER2)-positive. Patient has received adjuvant Herceptin (trastuzumab)-based therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

# NEULASTA (S)

#### **Products Affected**

- Neulasta
- Neulasta Onpro Kit

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Primary prophylaxis of chemotherapy-induced febrile neutropenia (CFN): One of the following: 1) patient is receiving chemotherapy regimens associated with a greater than 20% incidence of FN, OR 2) both of the following: a) patient receiving chemotherapy regimen associated with 10-20% incidence of FN, AND b) one or more risk factors associated with chemotherapy-induced infection, FN, or neutropenia. Secondary prophylaxis of FN: Both of the following: 1) patients receiving myelosuppressive anticancer drugs associated with neutropenia, AND 2) patients with a history of FN or dose-limiting event during a previous course of chemotherapy. Neutropenia associated with dose-dense chemotherapy (NDDC): One of the following: 1) patient is receiving National Cancer Institute's Breast Intergroup, INT C9741 dose dense chemotherapy protocol for primary breast cancer, OR 2) patient is receiving a dose-dense chemotherapy regimen for which the incidence of FN is unknown. Treatment of FN (off-label): Both of the following: 1) patients who have received or are receiving myelosuppressive anticancer drugs associated with neutropenia, AND 2) patients with FN at high risk for infection-associated complications. Acute radiation syndrome (ARS): Patient was/will be acutely exposed to myelosuppressive doses of radiation (hematopoietic subsyndrome of ARS).
Age Restrictions	N/A
Prescriber Restrictions	All uses: Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	FN (treatment), ARS: 1 mo. CFN, NDDC, FN (prophylaxis): 3 mo or duration of tx.
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# NEXAVAR (S)

#### **Products Affected**

• Nexavar

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of RCC. One of the following: Relapsed disease OR both medically/surgically unresectable tumor and dx of Stage IV disease. Hepatocellular carcinoma (HCC): Diagnosis of HCC. One of the following: patient has metastatic disease, or patient has extensive liver tumor burden, or patient is inoperable by performance status or comorbidity (local disease or local disease with minimal extrahepatic disease only), or disease is unresectable. Differentiated thyroid carcinoma (DTC): Diagnosis of DTC (ie, follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma). One of the following: locally recurrent disease or metastatic disease. One of the following: patient has symptomatic disease or patient has progressive disease. Disease is refractory to radioactive iodine (RAI) treatment. Medullary thyroid carcinoma (MTC): Diagnosis of MTC. One of the following: 1) Disease is progressive or 2) Patient has symptomatic disease. Trial and failure, contraindication, or intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib).
Age Restrictions	N/A
Prescriber Restrictions	DTC, MTC: Prescribed by or in consultation with an oncologist. RCC: Prescribed by or in consultation with one of the following: oncologist or nephrologist. HCC: Prescribed by or in consultation with one of the following: an oncologist, hepatologist, or gastroenterologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# NINLARO (S)

#### **Products Affected**

• Ninlaro

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma: Diagnosis of multiple myeloma. Used in combination with Revlimid (lenalidomide) and dexamethasone. Patient has received at least one prior therapy for multiple myeloma [eg, Revlimid (lenalidomide), Thalomid (thalidomide), Velcade (bortezomib)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### NON-PREFERRED TIRF (S)

#### **Products Affected**

- Abstral
- Fentora TABS 100MCG, 200MCG, 400MCG, 600MCG, 800MCG
- Lazanda

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	For the management of breakthrough cancer pain. Patient is currently taking a long-acting opioid around the clock for cancer pain. Patient must have at least a one week history of ONE of the following medications to demonstrate tolerance to opioids: Morphine sulfate at doses of greater than or equal to 60 mg/day, Fentanyl transdermal patch at doses greater than or equal to 25 µg/hr, Oxycodone at a dose of greater than or equal to 30 mg/day, Oral hydromorphone at a dose of greater than or equal to 8 mg/day, Oral oxymorphone at a dose of greater than or equal to 25 mg/day, or an alternative opioid at an equianalgesic dose (e.g., oral methadone greater than or equal to 20 mg/day). Trial and failure or intolerance to generic fentanyl lozenge.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Pain specialist, Oncologist, Hematologist, Hospice care specialist, or Palliative care specialist.
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# NORTHERA (S)

#### **Products Affected**

• Northera

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Neurogenic orthostatic hypotension (NOH) (init): Diagnosis of symptomatic NOH. NOH is caused by one of the following conditions: primary autonomic failure (eg, Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, non-diabetic autonomic neuropathy. Trial and failure, contraindication, or intolerance to one of the following agents: fludrocortisone acetate, midodrine.
Age Restrictions	N/A
Prescriber Restrictions	NOH (init): Prescribed by or in consultation with a cardiologist, neurologist, or nephrologist
Coverage Duration	NOH (init): 1 month (reauth): 12 months
Other Criteria	NOH (reauth): Documentation of positive clinical response to therapy

# **NOVANTRONE (S)**

#### **Products Affected**

• Mitoxantrone Hcl INJ 2MG/ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis (dx) of one of the following: secondary progressive MS: gradually worsening disability with or without superimposed relapses, progressive relapsing MS: progression of disability from the onset with superimposed relapses, or worsening relapsing-remitting MS: neurological status remains significantly abnormal in between MS relapses. Disease progression despite one of the following therapies: Avonex, Aubagio, Betaseron, Copaxone/Glatopa, Extavia, Gilenya, Lemtrada, Ocrevus, Plegridy, Rebif, Tecfidera, Tysabri, Zinbryta. Left ventricular ejection fraction (LVEF) greater than or equal to 50%. Neutrophil count greater than or equal to 1500 cell/mm^3. Lifetime cumulative dose less than 140 mg/m^2. Prostate Cancer (PC): Dx of advanced hormone-refractory (castration-resistant) PC. Used in combination with corticosteroids (eg, prednisone, methylprednisolone). LVEF greater than or equal to 50%. Neutrophil count greater than or equal to 1500 cell/mm^3. Acute Non-Lymphocytic Leukemia (ANLL): Dx of ANLL (eg, myelogenous, promyelocytic, monocytic, and erythroid). Used in combination with other medications used for the treatment of ANLL. LVEF greater than or equal to 50%.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All Uses: 6 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# NPLATE (S)

#### **Products Affected**

• Nplate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic immune (idiopathic) thrombocytopenic purpura (ITP): All of the following: A) Diagnosis of relapsed/refractory chronic ITP for greater than 6 months. AND B) Baseline platelet count is less than 50,000/mcL. AND C) Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. AND D) One of the following: 1) Patient had an insufficient response, intolerance, contraindication to corticosteroids or immune globulin OR 2) Patient had an inadequate response or contraindication to splenectomy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ITP (initial, reauth): 12 months
Other Criteria	ITP (reauth): After at least 4 weeks of therapy at the maximum weekly dose (10 mcg/kg) the platelet count increased to a sufficient level to avoid clinically important bleeding.

Members Health Insurance Company

Date Effective: November 1, 2018

# NUCALA (S)

#### **Products Affected**

• Nucala

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Severe asthma (init): Diagnosis of severe asthma. Asthma is an eosinophilic phenotype as defined by one of the following: baseline peripheral blood eosinophil levels are greater than or equal to 150 cells/microliter or peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months. Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids within the past 12 months or Patient has had any prior intubation for an asthma exacerbation or Patient has had a prior asthma-related hospitalization within the past 12 months. Patient is currently being treated with both a high-dose inhaled corticosteroid (ICS) [eg, greater than 500 mcg fluticasone propionate equivalent/day] and an additional asthma controller medication [eg, leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline] or one maximally-dosed combination ICS/LABA product [eg, Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)], unless there is a contraindication or intolerance to these medications. Eosinophilic Granulomatosis with Polyangiitis (EGPA) (init): Diagnosis of EGPA. Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy). Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone).
Age Restrictions	Severe asthma (init): Age greater than or equal to 12 years
Prescriber Restrictions	Severe asthma (init): Prescribed by or in consultation with a pulmonologist or allergy/immunology specialist. EGPA (init): Prescribed by or in consultation with a pulmonologist, rheumatologist or allergist/immunologist.
Coverage Duration	Severe asthma (init, reauth): 12 months. EGPA (init, reauth): 12 months
Other Criteria	Severe asthma (reauth): Documentation of positive clinical response (eg, reduction in exacerbations). Patient is currently being treated with both a inhaled corticosteroid (ICS) and an additional asthma controller medication [eg, leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline] or a combination ICS/LABA product [eg, Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol),

Date Effective: November 1, 2018

Symbicort (budesonide/formoterol)], unless there is a contraindication or intolerance to these medications. EGPA (reauth): Documentation of positive clinical response to therapy (e.g., increase in remission time).

Members Health Insurance Company Date Effective: November 1, 2018

# NULOJIX (S)

#### **Products Affected**

• Nulojix

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Kidney transplant: The medication is being used for prevention of kidney transplant organ rejection AND The patient is immune to the Epstein-Barr virus (i.e. EBV seropositive) AND The patient is prescribed concurrent therapy with mycophenolate and corticosteroids
Age Restrictions	Kidney transplant: 18 years of age or older
Prescriber Restrictions	Kidney transplant: Prescriber is experienced in immunosuppressive therapy and management of transplant patients
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# NUPLAZID (S)

#### **Products Affected**

• Nuplazid

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Parkinson's disease psychosis: Diagnosis of Parkinson's disease. Patient has at least one of the following: hallucinations or delusions.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# OCALIVA (S)

### **Products Affected**

• Ocaliva

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Primary Biliary Cholangitis (PBC) (initial): Diagnosis of PBC (aka primary biliary cirrhosis). One of the following: a) patient has failed to achieve an alkaline phosphatase (ALP) level of less than 1.67 times the upper limit of normal (ULN) after at least 12 consecutive months of treatment with ursodeoxycholic acid (UDCA) (e.g., Urso, Urso Forte, ursodiol) AND used in combination with UDCA, OR b) contraindication or intolerance to UDCA. Patients with moderate to severe hepatic impairment (Child-Pugh class B or C) will be subject to a quantity limit of 5 mg or 10 mg twice weekly (MDD = 0.34).
Age Restrictions	N/A
Prescriber Restrictions	PBC (initial): Prescribed by or in consultation with a hepatologist or gastroenterologist.
Coverage Duration	PBC (initial): 6 months, (reauth): 12 months
Other Criteria	PBC (reauthorization): Submission of medical records (eg, laboratory values) documenting a reduction in ALP level from pre-treatment baseline (ie, prior Ocaliva therapy) while on Ocaliva therapy. Patients with moderate to severe hepatic impairment (Child-Pugh class B or C) will be subject to a quantity limit of 5 mg or 10 mg twice weekly (MDD = 0.34).

Members Health Insurance Company

Date Effective: November 1, 2018

# OCREVUS (S)

#### **Products Affected**

• Ocrevus

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Relapsing forms of multiple sclerosis (initial): Diagnosis of a relapsing form of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses). One of the following: a) Trial and failure following a trial for at least 4 weeks, or intolerance, or contraindication to two of the following: interferon beta-1a (e.g., Avonex, Rebif, Plegridy), interferon beta-1b (e.g., Betaseron, Extavia), glatiramer acetate (e.g., Copaxone, Glatopa), dimethyl fumarate (Tecfidera), teriflunomide (Aubagio), fingolimod (Gilenya), natalizumab (Tysabri), daclizumab (Zinbryta), OR b) Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their multiple sclerosis, OR c) For continuation of prior Ocrevus therapy. Primary progressive MS (initial): Diagnosis of primary progressive multiple sclerosis (PPMS). All indications (initial): Not used in combination with another disease-modifying therapy for MS (e.g., interferon beta preparations [e.g., Betaseron, Rebif, etc.], glatiramer acetate [e.g., Copaxone, Glatopa], teriflunomide [Aubagio], dimethyl fumarate [Tecfidera], fingolimod [Gilenya], daclizumab [Zinbryta], or natalizumab [Tysabri]). Not used in combination with another B-cell targeted therapy (e.g., rituximab [Rituxan], belimumab [Benlysta], ofatumumab [Arzerra]). Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone). Hepatitis B virus (HBV) screening has been performed.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All indications (initial, reauth): 12 months
Other Criteria	All indications (reauth): Documentation of positive clinical response to Ocrevus therapy. Not used in combination with another disease-modifying therapy for MS (e.g., interferon beta preparations [e.g., Betaseron, Rebif, etc.], glatiramer acetate [e.g., Copaxone, Glatopa], teriflunomide [Aubagio], dimethyl fumarate [Tecfidera], fingolimod [Gilenya], daclizumab [Zinbryta], or natalizumab [Tysabri]). Not used in combination with another B-cell targeted therapy (e.g., rituximab

Date Effective: November 1, 2018

[Rituxan], belimumab [Benlysta], ofatumumab [Arzerra]). Not used in combination with another lymphocyte trafficking blocker (e.g., alemtuzumab [Lemtrada], mitoxantrone).

Members Health Insurance Company Date Effective: November 1, 2018

# ODOMZO(S)

### **Products Affected**

• Odomzo

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Basal cell carcinoma: Diagnosis of locally advanced basal cell carcinoma AND One of the following: 1) Cancer has recurred following surgery or radiation therapy or 2) Patient is not a candidate for surgery or radiation therapy
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# OFEV (S)

#### **Products Affected**

• Ofev

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Idiopathic pulmonary fibrosis (IPF) (initial): Both of the following: 1) diagnosis of IPF as documented by all of the following: a) exclusion of other known causes of interstitial lung disease (ILD) (eg, domestic and occupational environmental exposures, connective tissue disease, drug toxicity) AND b) one of the following: i) in patients not subjected to surgical lung biopsy, the presence of a usual interstitial pneumonia (UIP) pattern on high-resolution computed tomography (HRCT) revealing IPF or probable IPF, OR ii) in patients subjected to a lung biopsy, both HRCT and surgical lung biopsy pattern revealing IPF or probable IPF, AND 2) not used in combination with Esbriet (pirfenidone).
Age Restrictions	N/A
Prescriber Restrictions	IPF (initial): Prescribed by a pulmonologist
Coverage Duration	Initial, reauth: 12 months
Other Criteria	IPF (reauth): Documentation of positive clinical response to Ofev therapy.

# **OLUMIANT (S)**

### **Products Affected**

• Olumiant

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR F40.2 for specific phobia diagnostic criteria), OR for continuation of prior Olumiant therapy. Patient is not receiving Olumiant in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine) or with other janus kinase inhibitors (e.g., Xeljanz).
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with a rheumatologist.
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Reauth: Documentation of positive clinical response to Olumiant therapy. Patient is not receiving Olumiant in combination with a potent immunosuppressant (e.g., azathioprine, cyclosporine) or with other janus kinase inhibitors (e.g., Xeljanz).

Members Health Insurance Company Date Effective: November 1, 2018

### OLYSIO (S)

#### **Products Affected**

• Olysio

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. Both of the following: A) Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of chronic hepatitis C (CHC) virus AND B) Patient is without decompensated liver disease (defined as Child-Pugh Class B or C). For Olysio plus peginterferon and ribavirin: One of the following: 1) Diagnosis of genotype 1a infection AND patient does not have the NS3 Q80K polymorphism OR 2) Diagnosis of genotype 1b infection OR 3) Diagnosis of genotype 4 infection. One of the following: 1) Trial and failure, intolerance or contraindication to both of the following: a) Harvoni OR Epclusa and b) Mavyret, or 2) for continuation of prior Olysio therapy. All Olysio plus Sovaldi therapy: One of the following: 1) Trial and failure, intolerance, or contraindication to both of the following: a) Harvoni OR Epclusa and b) Mavyret, 2) Both of the following: Trial and failure of a NS5A containing regimen (e.g., Harvoni, Epclusa, Zepatier) and patient has NS5A inhibitor resistant-associated variants detected using commercially available assays, or 3) for continuation of prior Olysio therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
Coverage Duration	12 to 24 wks. Criteria will be applied consistent with current AASLD/IDSA guideline
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# ONMEL (S)

#### **Products Affected**

• Onmel

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	All of the following: 1) Diagnosis of onychomycosis of the toenail as confirmed by one of the following: a) positive potassium hydroxide (KOH) preparation, OR b) culture, OR c) histology, AND 2) patient has had a trial and inadequate response, intolerance or hypersensitivity to oral terbinafine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A

Members Health Insurance Company

Date Effective: November 1, 2018

# OPDIVO (S)

#### **Products Affected**

• Opdivo

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis (dx) of melanoma and one of the following: a) disease is unresectable, or b) disease is metastatic, or c) Opdivo will be used in the adjuvant setting following complete resection of Stage IIIB/C or Stage IV disease. Non-small cell lung cancer (NSCLC): Dx of NSCLC, disease is metastatic, trial and failure, contraindication, or intolerance (TF/C/I) to platinum-based chemotherapy (eg, cisplatin, carboplatin), and one of the following: 1) absence of epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) rearrangement, OR 2) presence of EGFR or ALK genomic tumor aberrations AND TF/C/I to FDA-approved therapy for these aberrations [e.g., Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib), Xalkori (crizotinib)]. Renal cell carcinoma (RCC): Dx of RCC. Disease is advanced, relapsed, or Stage IV disease that is surgically unresectable. One of the following: A) TF/C/I to at least one anti-angiogenic or tyrosine kinase inhibitor therapy (eg, Inlyta [axitinib], Votrient [pazopanib], Sutent [sorafenib], Nexavar [sunitinib]) or B) All of the following: 1) intermediate- or poor-prognosis risk, 2) previously untreated disease, and 3) used in combination with Yervoy (ipilimumab). Classical Hodgkin Lymphoma (cHL): Dx of cHL. One of the following: A) Patient has had relapse or progression after autologous hematopoietic stem cell transplantation and Adcetris (brentuximab vedotin), OR B) Patient has had relapse or progression after 3 or more lines of systemic therapy that includes autologous HSCT, OR C) Used as palliative therapy and patient is greater than 60 years of age. Head and Neck Squamous Cell Carcinoma (HNSCC): Dx of recurrent or metastatic HNSCC. Patient has disease progression on or after platinum-containing therapy.
Age Restrictions	Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer: Patient is 12 years of age or older.
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months.
Other Criteria	Urothelial Carcinoma: Diagnosis of urothelial carcinoma. Disease is locally advanced or metastatic. One of the following: Patient has disease

Date Effective: November 1, 2018

progression during or following platinum-containing chemotherapy OR Patient has disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer: Dx of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (CRC). Patient has experienced progression following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Hepatocellular Carcinoma (HCC): Dx of HCC AND previously treated with Nexavar (sorafenib). All indications: Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# **OPSUMIT (S)**

#### **Products Affected**

• Opsumit

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

# ORENCIA IV (S)

#### **Products Affected**

• Orencia INJ 250MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. All indications (Initial): One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Orencia therapy. All indications (Initial, reauth): Patient is not receiving Orencia in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].
Age Restrictions	N/A
Prescriber Restrictions	RA, JIA (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	All indications (Initial, reauth): 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to Orencia therapy.

### ORENCIA SC (S)

#### **Products Affected**

- Orencia INJ 125MG/ML, 50MG/0.4ML, 87.5MG/0.7ML
- Orencia Clickject

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid Arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Juvenile Idiopathic Arthritis (JIA) (Initial): Diagnosis of moderately to severely active polyarticular JIA. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. All indications (Initial): One of the following: Trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Orencia therapy. Patient is not receiving Orencia in combination with a biologic disease modifying antirheumatic drug (DMARD) [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].
Age Restrictions	N/A
Prescriber Restrictions	RA, JIA (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	All indications (Initial, reauth): 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to Orencia therapy. Patient is not receiving Orencia in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

Members Health Insurance Company Date Effective: November 1, 2018

### **ORENITRAM (S)**

### **Products Affected**

• Orenitram

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# ORKAMBI (S)

### **Products Affected**

• Orkambi TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Cystic Fibrosis (CF) (Initial): Diagnosis of CF. Patient is homozygous for the F508del mutation in the CF transmembrane conductance regulator (CFTR) gene as detected by an FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments-approved facility.
Age Restrictions	CF (Initial): Patient is 6 years of age or older
Prescriber Restrictions	CF (Initial): Prescribed by or in consultation with a specialist affiliated with a CF care center or pulmonologist
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	CF (Reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations)

Members Health Insurance Company Date Effective: November 1, 2018

### OTEZLA (S)

### **Products Affected**

• Otezla TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Psoriatic arthritis (PsA, initial): Diagnosis of active PsA. Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. PsA, plaque psoriasis (initial): Trial and failure, contraindication, or intolerance to both Humira and Enbrel, or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Otezla therapy.
Age Restrictions	N/A
Prescriber Restrictions	PsA (init): Prescribed by or in consultation with a dermatologist or rheumatologist. Plaque psoriasis (init): Prescribed by or in consultation with a dermatologist.
Coverage Duration	Initial, Reauth: 12 months
Other Criteria	Reauthorization (all indications): Documentation of positive clinical response to Otezla therapy.

### OXANDRIN (S)

### **Products Affected**

• Oxandrolone TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Promote weight gain (initial): Medication will be used as an adjunct therapy to promote weight gain AND One of the following: Extensive surgery, Chronic infections, Severe trauma, Failure to gain or maintain at least 90% of ideal body weight without definite pathophysiologic reasons. Counterbalance protein catabolism (initial): Oxandrin will be used to counterbalance protein catabolism associated with chronic corticosteroid administration. Bone pain (initial): Diagnosis of bone pain associated with osteoporosis.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	bone pain (initial, reauth): 1 month. Others (initial, reauth): 3 months
Other Criteria	All diagnoses (reauth): patient has experienced an objective improvement (i.e. weight gain, increase in lead body mass, or reduction in muscle pain/weakness)

Members Health Insurance Company Date Effective: November 1, 2018

# PEGASYS (S)

#### **Products Affected**

- Pegasys
- Pegasys Proclick

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic hepatitis B: Diagnosis of chronic hepatitis B infection, and patient is without decompensated liver disease. Chronic Hepatitis C: Criteria will be applied consistent with current AASLD-IDSA guidance
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HepB: 48 wks. HepC: Initial: 28 wks. Reauth: 20 wks.
Other Criteria	N/A

### **PEG-INTRON (S)**

#### **Products Affected**

- Pegintron
- Peg-intron INJ 120MCG/0.5ML, 150MCG/0.5ML, 80MCG/0.5ML
- Peg-intron Redipen
- Peg-intron Redipen Pak 4 INJ 120MCG/0.5ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic Hepatitis C:Criteria will be applied consistent with current AASLD-IDSA guidance
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HepC: Initial: 28 wks. Reauth: 20 wks.
Other Criteria	HepC (reauth): patient has an undetectable HCV RNA at week 24, additional treatment weeks of peginterferon are required to complete treatment regimen, and patient has not exceeded 48 wks of therapy with peginterferon.

### PENNSAID (S)

#### **Products Affected**

• Diclofenac Sodium TRANSDERMAL SOLN 1.5%

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Initial, reauth: History of severe allergic-type reactions after taking aspirin or other non-steroidal anti-inflammatory (NSAIDs), including urticaria and asthma (aspirin-sensitive asthma).
Required Medical Information	Osteoarthritis of the knees (initial): Diagnosis of osteoarthritis of the knees and diclofenac will not be used in the treatment of peri-operative pain in the setting of coronary artery bypass graft surgery. Patient meets one of the following: 1) Treatment failure with at least two prescription strength oral non-steroidal anti-inflammatory drugs (NSAIDs) OR 2) Documented swallowing disorder OR 3) History of peptic ulcer disease/gastrointestinal bleed OR 4) Patient is older than 65 years of age with one additional risk factor for gastrointestinal adverse events (e.g. use of anticoagulants, chronic corticosteroids).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Osteoarthritis of the knees (reauth): Patient has experienced a response to therapy (e.g., improvement in pain symptoms of osteoarthritis).

Members Health Insurance Company Date Effective: November 1, 2018

# PERJETA (S)

#### **Products Affected**

• Perjeta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Metastatic breast cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic breast cancer. One of the following: a) patient has not received prior anti-HER2 therapy or chemotherapy for metastatic disease AND used in combination with Herceptin (trastuzumab) and a taxane (eg, docetaxel, paclitaxel), OR b) patient was previously treated with chemotherapy and Herceptin (trastuzumab) without Perjeta AND used in combination with Herceptin (trastuzumab). Non-metastatic breast cancer: One of the following diagnoses: HER2-positive early stage breast cancer, HER2-positive locally advanced breast cancer, or HER2-positive inflammatory breast cancer. Used in combination with both Herceptin (trastuzumab) and chemotherapy. Early Breast Cancer Adjuvant Treatment: Diagnosis of HER2-positive early breast cancer. Patient is at high risk of recurrence. Used in combination with both of the following: Herceptin (trastuzumab) and chemotherapy.
Age Restrictions	N/A
Prescriber Restrictions	All Uses: Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# POMALYST (S)

#### **Products Affected**

• Pomalyst

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple Myeloma (MM): Diagnosis of MM. Used in combination with dexamethasone. Patient has received two prior therapies, including Revlimid (lenalidomide) and a proteasome inhibitor [eg, Velcade (bortezomib) or Kyprolis (carfilzomib)] or has a contraindication or intolerance to Revlimid and proteasome inhibitors. Patient has experienced disease progression on or within 60 days of completion of last therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## PORTRAZZA (S)

### **Products Affected**

Portrazza

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): All of the following: A) Diagnosis of metastatic squamous NSCLC AND B) Portrazza will be used in combination with gemcitabine and cisplatin AND C) Portrazza will be used as first-line treatment.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company

Date Effective: November 1, 2018

# PRALUENT (S)

### **Products Affected**

• Praluent

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Initial: One of the following diagnoses: A) Heterozygous familial hypercholesterolemia (HeFH) as confirmed by one of the following: (1) Submission of medical records (MR) (e.g., chart notes, laboratory values) documenting assessment of patient using Dutch Lipid Clinic Network diagnostic criteria with a cumulative score greater than or equal to 9 points (ie, definite FH), (2) both of the following: a) One of the following: i) Presence of tendinous xanthomas and/or arcus cornealis in first degree relative, or second degree relative, ii) Family history (hx) of myocardial infarction (MI) in first-degree relative less than 60 years of age, iii) Family hx of MI in second-degree relative less than 50 years of age, iv) Family hx of LDL-C greater than 190 mg/dL in first- or second-degree relative, v) Family hx of FH in first- or second-degree relative, AND b) Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult, (3) Submission of MR (e.g., chart notes, laboratory values) documenting genetic confirmation of a mutation in the LDL receptor, ApoB, or PCSK9, or (4) Untreated/pre-treatment LDL-C greater than 190 mg/dL in an adult AND submission of MR (e.g., chart notes, laboratory values) documenting presence of tendinous xanthoma in patient or arcus cornealis before age 45. OR B) Atherosclerotic cardiovascular disease (ASCVD) as confirmed by acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin. One of the following: set A) Both of the following: a)One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 120 days: (1) LDL-C greater than or equal to 100 mg/dL with ASCVD.
Age Restrictions	N/A
Prescriber Restrictions	Initial, reauth: Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist
Coverage Duration	Initial: 6 months. Reauth: 12 months
Other Criteria	Set A (continued, initial): AND b) One of the following: (1) Patient (pt) has been receiving at least 12 consecutive weeks of one high-intensity

(HI) statin therapy (tx) and will continue to receive a HI statin [ie. atorvastatin 40-80 mg, Crestor (rosuvastatin) 20-40 mg] at maximally tolerated dose, OR (2) Both of the following: A) Pt is unable to tolerate HI statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), AND B) One of the following: a) Pt has been receiving at least 12 consecutive weeks of one moderate-intensity or low-intensity statin tx and will continue to receive a MODERATE-INTENSITY or LOW-INTENSITY statin [ie, atorvastatin 10-20 mg, Crestor (rosuvastatin) 5-10 mg, simvastatin 10-40 mg, pravastatin 10-80 mg, lovastatin 20-40 mg, Lescol XL (fluvastatin XL) 80 mg, fluvastatin 20-40 mg, or Livalo (pitavastatin) 1-4 mg] at maximally tolerated dose, OR b) Pt is unable to tolerate moderate-intensity or low-intensity statin as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times upper limit of normal [ULN]), OR (3) Submission of MR documenting pt has a labeled contraindication to all statins, OR (4) Pt has experienced rhabdomyolysis or muscle symptoms with statin treatment with CK elevations greater than 10 times ULN on one statin tx. OR set B) Both of the following: a) One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 120 days: (1) LDL-C b/t 70 and 99 mg/dL with ASCVD. (2) LDL-C b/t 100 and 129 mg/dL without ASCVD. AND b) Both of the following: (1) One of the following: i) Pt has been receiving at least 12 consecutive weeks of one maximally-tolerated statin tx and will continue to receive a statin at maximally tolerated dose, ii) pt is unable to tolerate statin tx as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times ULN, iii) Submission of MR documenting patient has a labeled contraindication to all statins, or iv) Pt has experienced rhabdomyolysis or muscle symptoms with statin tx with CK elevations greater than 10 times ULN on one statin tx and (2) Pt has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) tx as adjunct to maximally tolerated statin tx OR Pt has a history of contraindication or intolerance to ezetimibe. Reauth: Pt continues to receive statin at the maximally tolerated dose (unless pt has documented inability to take statins). Submission of MR (eg, chart notes, lab values) documenting LDL-C reduction while on Praluent therapy. Initial, reauth: Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor.

Members Health Insurance Company Date Effective: November 1, 2018

# PROCYSBI (S)

### **Products Affected**

• Procysbi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Nephropathic cystinosis: Diagnosis of nephropathic cystinosis, confirmed by elevated leukocyte cystine levels (LCL) or genetic analysis of the CTNS gene AND Trial and failure or intolerance to therapy with Cystagon (immediate-release cysteamine bitartrate).
Age Restrictions	1 year of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

# PROMACTA (S)

### **Products Affected**

• Promacta

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic immune (idiopathic) thrombocytopenic purpura (ITP) (initial): Diagnosis of relapsed/refractory chronic ITP for greater than 6 months. Baseline platelet count is less than 50,000/mcL. Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding. One of the following: A) Trial and failure, intolerance, contraindication to corticosteroids or immune globulin OR B) Trial and failure or contraindication to splenectomy. Chronic hepatitis C (initial): Diagnosis of chronic hepatitis C. Patient has thrombocytopenia defined as platelets less than 90,000/mcL for initiation (pre-treatment) of interferon therapy. Severe aplastic anemia (initial): Diagnosis of severe aplastic anemia. Patient has a platelet count less than 30,000/mcL. Trial and failure, intolerance, or contraindication to immunosuppressive therapy with antithymocyte globulin and cyclosporine.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ITP (init, reauth): 12mo. HepC: 9wks (init), 24wks (reauth). Aplas anemia (init, reauth): 16wks.
Other Criteria	ITP (reauth): After at least 4 weeks of therapy at the maximum weekly dose (10 mcg/kg), the platelet count increased to a sufficient level to avoid clinically important bleeding. Hepatitis C (reauth): Platelets less than 75,000/mcL for maintenance of optimal interferon-based therapy. Aplastic anemia (reauth): Patient has experienced an increase in platelet count.

Members Health Insurance Company

Date Effective: November 1, 2018

## Provigil (s)

### **Products Affected**

• Modafinil

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Obstructive sleep apnea/hypopnea syndrome (OSAHS) (Initial): Diagnosis (dx) of OSAHS defined by one of the following: 15 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), or both of the following: 5 or more obstructive respiratory events per hour of sleep confirmed by a sleep study (unless prescriber provides justification confirming that a sleep study is not feasible), and 1 of the following symptoms: unintentional sleep episodes during wakefulness, daytime sleepiness, unrefreshing sleep, fatigue, insomnia, waking up breath holding/gasping/choking, loud snoring, or breathing interruptions during sleep. Shift-work sleep disorder (SWSD) (Initial):Dx of SWSD confirmed by symptoms of excessive sleepiness or insomnia for at least 3 months, which is associated with a work period (usually night work) that occurs during the normal sleep period, or sleep study demonstrating loss of a normal sleep-wake pattern (ie, disturbed chronobiologic rhythmicity). No other medical condition or medication accounts for the symptoms. Narcolepsy (initial): Dx of narcolepsy as confirmed by sleep study (unless prescriber provides justification confirming that a sleep study is not feasible). MS Fatigue (initial): Dx of multiple sclerosis (MS). Patient is experiencing fatigue. Depression (initial): Treatment-resistant depression defined as diagnosis of major depressive disorder (MDD) or bipolar depression, AND trial and failure, contraindication, or intolerance to at least two antidepressants from different classes (eg, SSRIs, SNRIs, bupropion). Used as adjunctive therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	OSAHS/MS/dep(init), SWSD (init,reauth): 3 mo.OSAHS/dep(reauth): 12mo. MS (reauth): 6mo. Other: 12mo
Other Criteria	OSAHS (Reauth): Documentation of positive clinical response to prior therapy. SWSD (Reauth): Documentation of positive clinical response to prior therapy. Patient still requires treatment for SWSD. Narcolepsy (reauth): Documentation of positive clinical response to prior therapy. MS

Fatigue (reauth): Patient is experiencing relief of fatigue with modafinil therapy. Idiopathic Hypersomnia (reauth): Documentation of positive clinical response to modafinil therapy. Depression (reauth): Documentation of positive clinical response to modafinil therapy. Used as adjunctive therapy.

Members Health Insurance Company Date Effective: November 1, 2018

### PULMOZYME (S)

#### **Products Affected**

• Pulmozyme

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Cystic Fibrosis (CF) (Initial, Reauth): Diagnosis of CF
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CF (initial, reauth): 12 months
Other Criteria	Part B vs D determination applies. CF (reauth): Patient is benefiting from treatment (i.e. improvement in lung function [forced expiratory volume in one second (FEV1)], decreased number of pulmonary exacerbations).

### QUALAQUIN (S)

#### **Products Affected**

• Quinine Sulfate CAPS 324MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Malaria: Diagnosis of uncomplicated malaria. One of the following: 1) Treatment in areas of chloroquine-sensitive malaria, and trial and failure, contraindication, or intolerance to chloroquine or hydroxychloroquine, OR 2) Treatment in areas of chloroquine-resistant malaria. Not used for the treatment or prevention of nocturnal leg cramps.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	7 days
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

## RADICAVA (S)

#### **Products Affected**

• Radicava

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Amyotrophic lateral sclerosis (ALS) (initial): Submission of medical records (e.g., chart notes, previous medical history, diagnostic testing including: imaging, nerve conduction studies, laboratory values) to support a diagnosis of "definite" or "probable" ALS per the revised El Escorial diagnostic criteria. Patient has scores of greater than or equal to 2 in all items of the ALS Functional Rating Scale-Revised (ALSFRS-R) criteria at the start of treatment. Patient has a percent forced vital capacity (%FVC) of greater than or equal to 80% at the start of treatment.
Age Restrictions	N/A
Prescriber Restrictions	ALS (initial): Prescribed by or in consultation with a neurologist.
Coverage Duration	(Initial and reauth): 6 months
Other Criteria	ALS (reauthorization): Documentation of a benefit from therapy (e.g., slowing in the decline of functional abilities), and Patient is not depenent on invasive ventilation or tracheostomy.

Members Health Insurance Company Date Effective: November 1, 2018

### RAVICTI (S)

### **Products Affected**

• Ravicti

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Urea cycle disorders (UCDs) (Initial): Diagnosis of UCDs.
Age Restrictions	UCDs (Initial): Age greater than or equal to 2 months
Prescriber Restrictions	N/A
Coverage Duration	UCDs (Initial, reauth): 12 months
Other Criteria	UCDs (reauth): Documentation of positive clinical response to Ravicti therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## **RELISTOR (S)**

#### **Products Affected**

• Relistor INJ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Opioid-induced constipation (OIC) (Initial): Diagnosis of OIC. Patient has used opioid medication for a minimum of 4 weeks. Patient is experiencing fewer than 3 bowel movements in a week or no bowel movement for longer than 2 days. One of the following: A) Patient has chronic non-cancer pain, or chronic pain related to prior cancer or its treatment AND patient had a trial and failure, contraindication, or intolerance to Amitiza (lubiprostone), OR B) Patient is receiving palliative care for an advanced illness or pain caused by active cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	OIC (initial, reauth): 4 months
Other Criteria	OIC (Reauth): Diagnosis of OIC. One of the following: A) Patient has chronic non-cancer pain, or chronic pain related to prior cancer or its treatment, OR B) Both of the following: Patient is receiving palliative care for an advanced illness or pain caused by active cancer AND Patient has responded to therapy (e.g., increase in bowel movements).

# **RELISTOR TABLETS (S)**

### **Products Affected**

• Relistor TABS

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Opioid-induced constipation (OIC) (non-cancer pain, initial): Diagnosis of OIC. Patient has chronic non-cancer pain, or chronic pain related to prior cancer or its treatment. Patient has used an opioid medication for a minimum of 4 weeks. Patient is experiencing fewer than 3 bowel movements in a week or no bowel movement for longer than 2 days. Trial and failure, contraindication, or intolerance to Amitiza (lubiprostone).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	OIC (Reauth): Diagnosis of OIC. Patient has chronic non-cancer pain, or chronic pain related to prior cancer or its treatment. Documentation of a positive clinical response to Relistor therapy (e.g., increase in bowel movements).

Members Health Insurance Company

Date Effective: November 1, 2018

## REMICADE (S)

### **Products Affected**

• Remicade

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (Initial): Diagnosis (Dx) of moderately to severely active CD or FCD. Failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex/Trexall). Ulcerative colitis (UC) (Initial): Dx of moderately to severely active UC. Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine, Imuran (azathioprine), corticosteroid (eg, prednisone, methylprednisolone), aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), Dipentum (olsalazine), Azulfidine (sulfasalazine)]. Rheumatoid arthritis (RA) (Initial): Dx of moderately to severely active RA. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), OR TF/C/I to methotrexate (Rheumatrex/Trexall). Ankylosing spondylitis (AS) (Initial): Dx of active AS. TF/C/I to two NSAIDs. Psoriatic arthritis (PsA) (Initial): Dx of active PsA. Plaque psoriasis (Initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. Sarcoidosis (initial): TF/C/I to one immunosuppressant [eg, methotrexate (Rheumatrex/Trexall), cyclophosphamide, or azathioprine (Imuran)] AND TF/C/I to one corticosteroid (eg, prednisone). All indications (Initial): Patient is not receiving Remicade in combination with a biologic DMARD [eg, Enbrel (etanercept), Rituxan (rituximab), Orencia (abatacept), Kineret (anakinra)].
Age Restrictions	N/A
Prescriber Restrictions	CD, FCD, UC (Initial): Prescribed by or in consultation with a gastroenterologist. RA, AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with rheumatologist or dermatologist. Plaque Psoriasis (Initial): Prescribed by or in consultation with a dermatologist. Sarcoidosis (Initial): Prescribed by or in consultation with a pulmonologist, dermatologist, ophthalmologist.
Coverage Duration	All indications (initial, reauth): 12 months

#### **Other Criteria**

Reauthorization for all indications: Documentation of positive clinical response to infliximab therapy. All indications (re-auth): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)].

Members Health Insurance Company Date Effective: November 1, 2018

## REMODULIN (S)

#### **Products Affected**

• Remodulin

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	Subject to Part B vs. D Review. PAH (Reauth): Documentation of positive clinical response to therapy.

Members Health Insurance Company

Date Effective: November 1, 2018

## RENFLEXIS (S)

### **Products Affected**

• Renflexis

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Crohn's Disease (CD) and Fistulizing Crohn's Disease (FCD) (initial): Diagnosis (Dx) of moderately to severely active CD or FCD. Ulcerative colitis (UC) (initial): Dx of moderately to severely active UC. Rheumatoid arthritis (RA) (initial): Dx of moderately to severely active RA. Ankylosing spondylitis (AS) (initial): Dx of active AS. Psoriatic arthritis (PsA) (initial): Dx of active PsA. Plaque psoriasis (initial): Dx of chronic severe (ie, extensive and/or disabling) plaque psoriasis. Reauthorization for all indications: Documentation of positive clinical response to infliximab therapy.
Age Restrictions	N/A
Prescriber Restrictions	RA, AS (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a rheumatologist or dermatologist. CD, FCD, UC (initial): Prescribed by or in consultation with a gastroenterologist. Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist.
Coverage Duration	All indications (Initial, reauth): 12 months
Other Criteria	CD, FCD (initial): Trial and failure, contraindication or intolerance (TF/C/I) to one of the following conventional therapies: 6-mercaptopurine (Purinethol), azathioprine (Imuran), corticosteroids (eg, prednisone, methylprednisolone), methotrexate (Rheumatrex, Trexall). UC (initial): TF/C/I to one of the following conventional therapies: corticosteroids, aminosalicylate [eg, mesalamine (Asacol/Pentasa/Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine/Sulfazine)], azathioprine (Imuran), 6-mercaptopurine (Purinethol). RA (initial): Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), or TF/C/I to methotrexate. AS (initial): TF/C/I to two or more NSAIDs. All indications (initial): One of the following: 1) Trial and failure or intolerance to Remicade or 2) For continuation of prior Renflexis therapy. All indications (Initial and reauth): Excluded if patient is receiving infliximab in combination with a Biologic Disease Modifying Antirheumatic Drug (DMARD) [eg, Enbrel (etanercept), Orencia (abatacept), Rituxan (rituximab), Kineret (anakinra), Cimzia (certolizumab)].

### REPATHA (S)

#### **Products Affected**

- Repatha
- Repatha Pushtronex System
- Repatha Sureclick

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	HeFH/ASCVD (init): One of the following dx: HeFH as confirmed by one of the following: (1) Submission (Sub) of medical records (MR) (e.g., chart notes, lab values) Documenting assessment of patient (pt) using Dutch Lipid Clinic Network diagnostic criteria w/a cum.score greater than or equal to 9 points (ie, definite FH), or (2)both of the following: a) One of the following: i)Presence of tendinous xanthomas and/or arcus cornealis in 1st degree relative, or 2nd degree relative, ii) Family history (hx) of MI in 1st degree relative less than 60 yo, iii) Family hx of MI in 2nd degree relative less than 50 yo, iv) Family hx of LDL greater than 190 mg/dL in 1st or 2nd degree relative, v) Family hx of FH in 1st or 2nd degree relative, AND b) Untreated/pre-treatment LDL greater than 190 in an adult, or (3) Sub of MR (e.g., chart notes, lab values) documenting gen confirmation of a mutation in the LDL receptor, ApoB, or PCSK9, or (4) Untreated/pre-treatment LDL greater than 190 in an adult AND sub of MR (e.g., chart notes, lab values) documenting presence of tendinous xanthoma in pt or arcus cornealis before age 45. OR B)ASCVD as confirmed by ACS, hx of MI, stable or unstable angina, coronary or other arterial revascularization, stroke,TIA, or peripheral arterial disease presumed to be of atherosclerotic origin. HoFH (initial): Sub of MR (eg, chart notes, lab values) documenting dx of HoFH as confirmed by one of the following: (1) Gen confirmation of 2 mutations in LDL receptor, ApoB, PCSK9, or LDLRAP1 or ARH, or (2) either untreated LDL greater than 500 or treated LDL greater than 300, AND either xanthoma before 10 yo or evidence of HeFH in both parents. HeFH/ASCVD (init): One of the following: set A) Both of the following: a)One of the following LDL values while on max tolerated lipid-lowering regimen w/in the last 120 days: (1) LDL greater than or equal to 100 w/ ASCVD, or (2) LDL greater than or equal to 130 w/o ASCVD.
Age Restrictions	N/A
Prescriber Restrictions	HeFH/ASCVD/HoFH (init, reauth): Prescribed by or in consultation with a cardiologist, endocrinologist, or lipid specialist
Coverage Duration	HeFH/ASCVD/HoFH (init): 6 mon.HeFH/ASCVD/HoFH (reauth): 12 mon.

#### Other Criteria

Set A (continued, initial): AND b)One of the following: (1) Pt has been receiving at least 12 consecutive wks of one max-tolerated statin tx and will continue to receive a statin at max tolerated dose, or (2) Pt is unable to tolerate statin as evidenced by intolerable and persistent (ie, more than 2 wks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times ULN), or (3) Sub of MR documenting pt has a labeled contraindication to all statins, or (4) Pt has experienced rhabdomyolysis or muscle symptoms with statin tx with CK elevations greater than 10 times ULN on one statin tx. OR set B) Both of the following: a) One of the following LDL-C values while on maximally tolerated lipid-lowering regimen within the last 120 days: (1) LDL-C b/t 70 and 99 mg/dL with ASCVD. (2) LDL-C b/t 100 and 129 mg/dL without ASCVD. AND b) Both of the following: (1) One of the following: i) Pt has been receiving at least 12 consecutive weeks of one maximally-tolerated statin tx and will continue to receive a statin at maximally tolerated dose, ii) pt is unable to tolerate statin tx as evidenced by intolerable and persistent (ie, more than 2 weeks) myalgia (muscle symptoms without CK elevations) or myositis (muscle symptoms with CK elevations less than 10 times ULN, iii) Sub of MR documenting pt has a labeled contraindication to all statins, or iv) Pt has experienced rhabdomyolysis or muscle symptoms with statin tx with CK elevations greater than 10 times ULN on one statin tx and (2) Pt has been receiving at least 12 consecutive weeks of ezetimibe (Zetia) tx as adjunct to maximally tolerated statin tx OR Pt has a history of contraindication or intolerance to ezetimibe. HoFH (initial): Pt is receiving other lipidlowering tx (e.g., statin, ezetimibe).HeFH/ASCVD (reauth): Pt continues to receive statin at the max tolerated dose (unless pt has documented inability to take statins). HoFH (reauth): Pt continues to receive other lipid-lowering tx (e.g., statin, ezetimibe). HeFH/ASCVD/HoFH (reauth): Sub of MR (eg, chart notes, lab values) documenting LDL-C reduction while on Repatha tx. HeFH/ASCVD/HoFH (Initial, reauth): Not used in combination with another PCSK9 inhibitor. HoFH (Initial, reauth): Not used in combination with Juxtapid (lomitapide) or Kynamro (mipomersen).

Members Health Insurance Company Date Effective: November 1, 2018

### REVATIO (S)

#### **Products Affected**

- Revatio SUSR
- Sildenafil INJ
- Sildenafil TABS 20MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH. For formulary sildenafil citrate injection only (Initial): Patient is unable to take oral medications. For Revatio oral suspension only (initial): One of the following: A) Intolerance to generic Revatio tablets, OR B) Patient is unable to ingest a solid dosage form (e.g., an oral tablet or capsule) due to one of the following: age, oral-motor difficulties, or dysphagia.
Age Restrictions	N/A
Prescriber Restrictions	PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	PAH (Reauth): Documentation of positive clinical response to therapy

Members Health Insurance Company Date Effective: November 1, 2018

### REVLIMID (S)

#### **Products Affected**

• Revlimid

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma (MM): Diagnosis of MM. Either used as 1) combination therapy with dexamethasone, or 2) maintenance therapy following autologous hematopoietic stem cell transplantation (auto-HSCT). Myelodysplastic syndromes (MDS): Patient has transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with a deletion. Mantle cell lymphoma (MCL): Diagnosis of MCL. Disease has relapsed, refractory, or progressed after at least one prior therapy (eg, bortezomib, bendamustine, cladribine, rituximab).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# RILUTEK (S)

### **Products Affected**

• Riluzole

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Amyotrophic lateral sclerosis (ALS): Diagnosis of amyotrophic lateral sclerosis (ALS)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	ALS: 12 months
Other Criteria	N/A

Members Health Insurance Company

Date Effective: November 1, 2018

# RITUXAN (S)

### **Products Affected**

• Rituxan

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Rheumatoid Arthritis (RA) (init): Patient is not receiving Rituxan in combination with a biologic DMARD [eg, Enbrel (etanercept), Orencia (abatacept), Kineret (anakinra)].
Required Medical Information	Non-Hodgkin's Lymphoma (NHL): As first-line treatment of diffuse large B-cell, CD20-positive, NHL in combination with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) or other anthracycline-based chemotherapy regimens, or as first-line treatment of follicular, CD20-positive, B-cell NHL in combination with chemotherapy, or as a single-agent maintenance therapy for the treatment of follicular, CD20-positive, B-cell NHL in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, or for the treatment of low-grade, CD20-positive, B-cell NHL in patients with stable disease following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/prednisone) chemotherapy or who achieve a partial or complete response following first-line treatment with CVP (cyclophosphamide, vincristine, prednisolone/prednisone) chemotherapy, or diagnosis of relapsed or refractory, low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma. Rheumatoid Arthritis (RA) (init): Concurrently on or contraindication, or intolerance to methotrexate. Trial and failure, contraindication, or intolerance (TF/C/I) to a TNF antagonist (eg, adalimumab, etanercept, infliximab). Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): Patient is concurrently on glucocorticoids (eg, prednisone). Immune or idiopathic thrombocytopenic purpura (ITP): TF/C/I to one of the following: corticosteroids, immunoglobulins, or splenectomy. Documented platelet count of less than 50x10^9 /L. Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Pemphigus Vulgaris (PV): Diagnosis of moderate to severe PV.
Age Restrictions	N/A
Prescriber Restrictions	ITP: Prescribed by or in consultation with a hematologist or oncologist. RA: Prescribed by or in consultation with a rheumatologist. WG, MPA: Prescribed by or in consultation with a nephrologist, pulmonologist, or rheumatologist. PV: Prescribed by or in consultation with a dermatologist
Coverage Duration	All uses except RA, WG, MPA: 12 mos. RA: 3 months. WG, MPA: 3 months only.

Members Health Insurance Company

Date Effective: November 1, 2018

Other Criteria
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Members Health Insurance Company Date Effective: November 1, 2018

## RUBRACA (S)

### **Products Affected**

• Rubraca

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Ovarian cancer: Diagnosis of ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. One of the following: 1) Both of the following: a) Presence of deleterious BRCA mutation as detected by an FDA-approved diagnostic test (e.g., FoundationFocus CDxBRCA Assay) or performed at a Clinical Laboratory Improvement Amendments-approved facility and b) Trial and failure, contraindication, or intolerance to two or more chemotherapies (e.g., cisplatin, carboplatin), OR 2) Both of the following: a) Disease is recurrent and b) Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

Members Health Insurance Company Date Effective: November 1, 2018

## RUCONEST (S)

#### **Products Affected**

• Ruconest

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Treatment of hereditary angioedema (HAE) attacks: Diagnosis of HAE. For the treatment of acute HAE attacks. Not used in combination with other approved treatments for acute HAE attacks (eg, Berinert, Firazyr, or Kalbitor).
Age Restrictions	N/A
Prescriber Restrictions	HAE: Prescribed by or in consultation with an immunologist, allergist, or rheumatologist
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# RYDAPT (S)

#### **Products Affected**

• Rydapt

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Acute Myeloid Leukemia (AML): Newly diagnosed acute myeloid leukemia (AML), FMS-like tyrosine kinase 3 (FLT3) mutation-positive as detected by a U.S. Food and Drug Administration (FDA)-approved test, used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with Associated Hematological Neoplasm (SM-AHN), Mast Cell Leukemia (MCL): Diagnosis of one of the following: aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).
Age Restrictions	N/A
Prescriber Restrictions	All indications: Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

Members Health Insurance Company Date Effective: November 1, 2018

### SABRIL (S)

#### **Products Affected**

- Sabril
- Vigabatrin
- Vigadrone

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Complex Partial Seizures (CPS): For use as adjunctive therapy. Failure, contraindication, or intolerance to two formulary anticonvulsants [eg, Lamictal (lamotrigine), Depakene (valproic acid), Dilantin (phenytoin)]. Infantile Spasms (IS): Diagnosis of infantile spasms.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

### **SANDOSTATIN (S)**

### **Products Affected**

• Octreotide Acetate

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) History of failure to surgical resection and/or pituitary irradiation OR B) patient is not a candidate for surgical resection or pituitary irradiation AND Trial and failure or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All Uses (Initial and reauth): 12 months
Other Criteria	Acromegaly (reauth): Patient has had a clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): patient has improvement in number of diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (reauth): patient has improvement in number of diarrhea episodes.

## SANDOSTATIN LAR (S)

### **Products Affected**

• Sandostatin Lar Depot

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Acromegaly (initial): Diagnosis of acromegaly AND One of the following: A) Failure to surgical resection and/or pituitary irradiation OR B) patient is not a candidate for surgical resection or pituitary irradiation AND Trial and failure or intolerance to a dopamine agonist (e.g., bromocriptine or cabergoline) at maximally tolerated doses AND Patient had a trial of short-acting octreotide and responded to and tolerated therapy. Carcinoid tumor (initial): Diagnosis of metastatic carcinoid tumor requiring symptomatic treatment of severe diarrhea or flushing episodes AND Patient had a trial of short-acting octreotide and responded to and tolerated therapy. Vasoactive peptide tumor (initial): Diagnosis of vasoactive intestinal peptide tumor requiring treatment of profuse watery diarrhea AND Patient had a trial of short-acting octreotide and responded to and tolerated therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All Uses (Initial and reauth): 12 months
Other Criteria	Acromegaly (reauth): Patient has had a clinical response to therapy (e.g., reduction or normalization of IGF-1/GH level for same age and sex, reduction in tumor size). Carcinoid tumor (reauth): patient has improvement in number of diarrhea or flushing episodes. Vasoactive intestinal peptide tumor (reauth): patient has improvement in number of diarrhea episodes.

Members Health Insurance Company Date Effective: November 1, 2018

## SCIG (S)

#### **Products Affected**

- Cuvitru
- Hizentra
- Hyqvia

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	All uses (initial, reauth): Contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication). Patient does not have hyperprolinemia.
Required Medical Information	Initial: Immune globulin will be administered at the minimum effective dose and appropriate frequency for the prescribed diagnosis. Medication is being used subcutaneously. One of the following FDA-approved or literature supported diagnoses: 1) Common variable immunodeficiency (CVID), OR 2) Congenital agammaglobulinemia (X-linked or autosomal recessive), OR 3) Severe combined immunodeficiencies (SCID), OR 4) Wiskott-Aldrich syndrome, OR 5) Other primary immunodeficiency with an immunologic evaluation including IgG levels below the normal laboratory value for the patient's age at the time of diagnosis and the patient lacks an adequate response to protein and polysaccharide antigens (i.e., tetanus toxoid or diphtheria toxoid and pneumovax or HiB vaccine).
Age Restrictions	N/A
Prescriber Restrictions	All uses (initial, reauth): Prescribed by or in consultation with a physician who has specialized expertise in managing patients on SCIG therapy (e.g., immunologist, hematologist, neurologist, etc.).
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Subject to Part B vs. Part D review. All uses (reauth): Patient has experienced an objective improvement on immune globulin therapy and the immune globulin will be administered at the minimum effective dose (by decreasing the dose, increasing the frequency, or implementing both strategies) for maintenance therapy.

### SEROSTIM (S)

#### **Products Affected**

• Serostim INJ 4MG, 5MG, 6MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	HIV wasting (Initial): Diagnosis of HIV-associated wasting syndrome or cachexia, and one of the following: unintentional weight loss greater than 10% over the last 12 months, or unintentional weight loss greater than 7.5% over the last 6 months, or loss of 5% body cell mass (BCM) within 6 months, or body mass index (BMI) less than 20 kg/m2, or patient is male and has BCM less than 35% of total body weight (TBW) and BMI less than 27 kg/m2, or patient is female and has BCM less than 23% of TBW and BMI less than 27 kg/m2. Nutritional evaluation since onset of wasting first occurred. Anti-retroviral tx has been optimized to decrease the viral load. Patient has not had weight loss as a result of other underlying treatable conditions (eg, depression, mycobacterium avium complex, chronic infectious diarrhea, or malignancy with the exception of Kaposi's sarcoma limited to skin or mucous membranes). Patient has tried and had an inadequate response or intolerance to dronabinol or megestrol acetate.
Age Restrictions	N/A
Prescriber Restrictions	Initial, Reauth: Prescribed by or in consultation with an infectious disease specialist.
Coverage Duration	Initial: 3 months, Reauth: 6 months
Other Criteria	HIV wasting (reauth): Evidence of positive response to therapy. One of the following targets or goals has not been achieved: weight, BCM, BMI. Patient is currently receiving treatment with antiretrovirals.

Members Health Insurance Company Date Effective: November 1, 2018

### SIGNIFOR (S)

#### **Products Affected**

• Signifor

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Cushing's disease (initial): Diagnosis of Cushing's disease AND failure to or patient is not a candidate for pituitary surgery.
Age Restrictions	Initial: 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	Initial: 3 months. Reauth: 12 months.
Other Criteria	Cushing's disease (reauth): a clinically meaningful reduction in 24-hour urinary free cortisol levels or improvement in signs or symptoms of the disease

# SIGNIFOR LAR (S)

#### **Products Affected**

• Signifor Lar

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Acromegaly (initial): Diagnosis of acromegaly AND failure to surgery or patient is not a candidate for surgery
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial: 6 months. Reauth: 12 months.
Other Criteria	Acromegaly (reauth): patient's growth hormone (GH) level or insulin-like growth factor 1 (IGF-1) level for age and gender has normalized/improved

Members Health Insurance Company Date Effective: November 1, 2018

# SILIQ (S)

#### **Products Affected**

• Siliq

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication, or intolerance to both Cosentyx (secukinumab) and either Enbrel (etanercept) or Humira (adalimumab), OR for continuation of prior Siliq therapy. Patient is not receiving Siliq in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].
Age Restrictions	N/A
Prescriber Restrictions	Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist.
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Plaque psoriasis (Reauth): Documentation of positive clinical response to Siliq therapy. Patient is not receiving Siliq in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

### SIMPONI ARIA (S)

#### **Products Affected**

• Simponi Aria

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. One of the following: Receiving concurrent therapy with methotrexate (Rheumatrex/Trexall), OR trial and failure, contraindication, or intolerance (TF/C/I) to methotrexate (Rheumatrex/Trexall). One of the following: trial and failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Psoriatic Arthritis (PsA) (Initial): Diagnosis of active PsA. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior therapy. Ankylosing Spondylitis (AS) (Initial): Diagnosis of active AS. One of the following: TF/C/I to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR for continuation of prior Simponi therapy. All indications (initial): Patient is not receiving Simponi Aria in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)].
Age Restrictions	N/A
Prescriber Restrictions	RA, AS (Initial): Prescribed by or in consultation with a rheumatologist. PsA (Initial): Prescribed by or in consultation with a rheumatologist or dermatologist.
Coverage Duration	RA (Initial, reauth): 12 months
Other Criteria	All Indications (Reauth): Documentation of positive clinical response to Simponi therapy. Patient is not receiving Simponi Aria in combination with a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)].

Members Health Insurance Company Date Effective: November 1, 2018

### **SIMVASTATIN (S)**

#### **Products Affected**

• Simvastatin TABS 80MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has been taking simvastatin 80 mg per day chronically (12 months or more) and no evidence of muscle toxicity/myopathy (eg, muscle pain, muscle tenderness, muscle weakness) on simvastatin 80 mg per day.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# SOLIRIS (S)

### **Products Affected**

• Soliris

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	(initial): One of the following diagnoses: atypical hemolytic uremic syndrome (aHUS) OR paroxysmal nocturnal hemoglobinuria (PNH). The patient has received a meningococcal vaccination at least two weeks prior to the initiation of therapy with Soliris (eculizumab).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	(Reauth): Documentation of positive clinical response to Soliris therapy.

## **SOMATULINE DEPOT (S)**

#### **Products Affected**

• Somatuline Depot

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Acromegaly: Diagnosis of acromegaly AND One of the following: A) Failure to one of the following: surgery or radiotherapy, OR B) not a candidate for one of the following: surgery or radiotherapy. Gastroenteropancreatic neuroendocrine tumors (GEP-NETs): Diagnosis of unresectable, well- or moderately-differentiated, locally advanced or metastatic GEP-NETs. Carcinoid syndrome (120mg/0.5mL): Diagnosis of carcinoid syndrome. Used to reduce the frequency of short-acting somatostatin analog rescue therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All Indications: 12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

### **SOMAVERT (S)**

#### **Products Affected**

• Somavert

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Acromegaly (initial): Diagnosis of acromegaly AND Failure to surgery and/or radiation therapy and/or other medical therapies (such as dopamine agonists [e.g., bromocriptine, cabergoline]) unless patient is not a candidate for these treatment options AND trial and failure or intolerance to generic octreotide (a somatostatin analogue)
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial and reauth: 12 months
Other Criteria	Acromegaly (reauth): Patient has experienced an objective response to therapy (biochemical control, decrease or normalization of IGF-1 levels).

Members Health Insurance Company

Date Effective: November 1, 2018

## SOVALDI (S)

#### **Products Affected**

• Sovaldi

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. For genotype (GT) 1 patients, Sovaldi plus Olysio: Patient is without decompensated liver disease (defined as Child-Pugh Class B or C). All GT1 (except Sovaldi plus Olysio therapy, or Sovaldi plus Daklinza therapy in liver transplant (tx) patients) and GT4: 1) trial and failure, intolerance or contraindication (TF/I/C) to both of the following: a) Harvoni OR Epclusa and b) Mavyret therapy OR 2) For continuation of prior Sovaldi therapy. For GT2 (except liver tx patients, or pediatric patients 12 years of age and older or weighing at least 35 kg) or GT3 patients (except pediatric patients 12 years of age and older or weighing at least 35 kg), using Sovaldi plus ribavirin: TF/I/C to a) Epclusa OR Mavyret OR b) for continuation of prior Sovaldi therapy. All Sovaldi plus Olysio therapy: one of the following: 1) TF/I/C to both of the following: a) Harvoni OR Epclusa and b) Mavyret OR 2) both of the following: a) trial and failure of a NS5A-containing regimen (e.g., Harvoni, Epclusa, OR Zepatier) AND b) the patient has NS5A inhibitor resistant-associated variants detected using commercially available assays, OR 3) For continuation of prior Sovaldi plus Olysio therapy.(continued in Other Criteria)
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
Coverage Duration	12 to 48 wks. Criteria will be applied consistent with current AASLD/IDSA guideline
Other Criteria	All Sovaldi plus Daklinza therapy: One of the following: 1) Patient has not failed a prior HCV NS5A-containing regimen (eg, Daklinza) therapy, OR 2) patient has failed prior therapy with an NS5A-containing regimen AND submission of medical records (eg, chart notes) documenting that the patient does not have NS5A inhibitor resistance-associated variants detected using commercially available assays. For GT2 and GT3 (except liver tx patients) patients, using Sovaldi plus Daklinza: TF/I/C to Epclusa OR Mavyret, OR for continuation of prior Sovaldi therapy. For GT2 or 3 liver tx recipients without cirrhosis, ONE of the following: 1) Patient has

Date Effective: November 1, 2018

had a TF/I/C to Mavyret OR 2) For continuation of prior Daklinza therapy. For GT2 or 3 liver tx recipients with decompensated cirrhosis, ONE of the following: 1) Patient has had a TF/I/C to Epclusa OR 2) For continuation of prior Daklinza therapy. For GT1 liver tx patients using Sovaldi plus Daklinza, TF/I/C to a) Harvoni OR Mavyret OR b) continuation of prior Sovaldi therapy.

Members Health Insurance Company Date Effective: November 1, 2018

### SPORANOX (S)

#### **Products Affected**

- Itraconazole CAPS
- Itraconazole SOLN
- Sporanox SOLN

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	One of the following: 1) patient has a systemic fungal infection (e.g., aspergillosis, histoplasmosis, blastomycosis), OR 2) patient is resistant to topical antifungal treatment and has one of the following diagnoses: a) tinea corporis (ringworm), OR b) tinea cruris (jock itch), OR c) tinea pedis (athlete's foot), OR d) tinea capitis (scalp ringworm), OR e) pityriasis versicolor, OR 3) all of the following: a) patient has a diagnosis of onychomycosis confirmed by one of the following (CAPSULE ONLY): i) positive potassium hydroxide (KOH) preparation, OR ii) culture, OR iii) histology, AND b) patient has had a trial and inadequate response, intolerance or hypersensitivity to oral terbinafine, OR 4) patient has a diagnosis of candidiasis (esophageal or oropharyngeal) that is refractory to treatment with fluconazole (ORAL SOLUTION ONLY).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	systemic fungal infxn:6mo.(candidiasis,fingernail onycho.):1 mo.(toenail onycho, other):3mo.
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

### SPRYCEL (S)

#### **Products Affected**

• Sprycel

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Philadelphia chromosome positive/BCR ABL positive (Ph+/BCR ABL+) chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL+ CML. Ph+/BCR ABL+ acute lymphoblastic leukemia (ALL): Diagnosis of Ph+/BCR ABL+ ALL.
Age Restrictions	N/A
Prescriber Restrictions	All Uses: Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	All Uses: 12 months
Other Criteria	All Uses: Approve for continuation of prior therapy.

### STELARA (IV) (S)

#### **Products Affected**

• Stelara INJ 130MG/26ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of moderately to severely active Crohn's disease. One of the following: a) trial and failure, contraindication, or intolerance to Humira (adalimumab), or (b) trial and failure, contraindication, or intolerance to treatment with at least one immunomodulator or corticosteroid [e.g., Purinethol (6-mercaptopurine), Imuran (azathioprine), Sandimmune (cyclosporine A), Prograf (tacrolimus), MTX (methotrexate)]. Patient is not receiving Stelara in combination a biologic DMARD [eg, Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].
<b>Age Restrictions</b>	N/A
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	One time
Other Criteria	Stelara is to be administered as an intravenous induction dose. Stelara induction dosing is in accordance with the United States Food and Drug Administration approved labeled dosing for Crohn's Disease: 260 mg for patients weighing 55 kg or less, 390 mg for patients weighing more than 55 kg to 85 kg, or 520 mg for patients weighing more than 85 kg.

Members Health Insurance Company Date Effective: November 1, 2018

### STIVARGA (S)

#### **Products Affected**

• Stivarga

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Metastatic colorectal cancer (mCRC): All of the following: 1) diagnosis of mCRC, AND 2) trial and failure, contraindication or intolerance to fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, AND 3) trial and failure, contraindication or intolerance to an anti-VEGF therapy (e.g. Avastin [bevacizumab]), AND 4) one of the following: a) KRAS mutation, OR b) both of the following: KRAS wild-type and trial and failure, contraindication or intolerance to an anti-EGFR therapy [e.g. Vectibix (panitumumab), Erbitux (cetuximab)]. Gastrointestinal stromal tumor (GIST): All of the following: 1) diagnosis of locally advanced, unresectable or metastatic GIST, AND 2) trial and failure, contraindication or intolerance to both of the following: a) Gleevec (imatinib mesylate), AND b) Sutent (sunitinib malate). Hepatocellular Carcinoma (HCC): Diagnosis of HCC. Trial and failure or intolerance to Nexavar (sorafenib tosylate).
Age Restrictions	N/A
Prescriber Restrictions	mCRC, GIST: Prescribed by or in consultation with an oncologist. HCC: Prescribed by or in consultation with an oncologist, hepatologist, or gastroenterologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## STRENSIQ (S)

#### **Products Affected**

• Strensiq

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Hypophosphatasia: Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia AND for patients requesting the 80 mg/0.8 mL vial only: Patient's weight is greater than or equal to 40 kg
Age Restrictions	N/A
Prescriber Restrictions	Hypophosphatasia: Prescribed by or in consultation with a specialist experienced in the treatment of inborn errors of metabolism or endocrinologist
Coverage Duration	Hypophosphatasia: 12 months
Other Criteria	N/A

## SUPPRELIN LA (S)

#### **Products Affected**

• Supprelin La

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Central Precocious Puberty (CPP) (initial): Diagnosis of CPP (idiopathic or neurogenic). Early onset of secondary sexual characteristics in females less than age 8 or males less than age 9. Advanced bone age of at least one year compared with chronologic age. One of the following: a) patient has undergone gonadotropin-releasing hormone agonist (GnRHa) testing AND Peak luteinizing hormone (LH) level above pre-pubertal range, or b) patient has a random LH level in the pubertal range.
Age Restrictions	N/A
Prescriber Restrictions	CPP (initial, reauth): Prescribed by or in consultation with a pediatric endocrinologist.
Coverage Duration	CPP (init, reauth): 12 months
Other Criteria	CPP (reauthorization): LH levels have been suppressed to pre-pubertal levels.

Members Health Insurance Company Date Effective: November 1, 2018

## SUTENT (S)

### **Products Affected**

• Sutent

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma: Diagnosis of advanced or metastatic renal cell carcinoma. Gastrointestinal stromal tumor (GIST): Diagnosis of GIST after disease progression on or intolerance to Gleevec (imatinib). Pancreatic neuroendocrine tumors: Diagnosis of progressive, well-differentiated pancreatic neuroendocrine tumor that is unresectable locally advanced or metastatic disease. Adjuvant treatment of renal cell carcinoma: Diagnosis of renal cell carcinoma (RCC). Used as adjuvant therapy. Patient is at high risk of recurrent RCC following nephrectomy.
Age Restrictions	N/A
Prescriber Restrictions	All Indications: Prescribed by or in consultation with an oncologist
Coverage Duration	All Indications: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy

Members Health Insurance Company Date Effective: November 1, 2018

### SYLATRON (S)

#### **Products Affected**

• Sylatron

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of melanoma with microscopic or gross nodal involvement AND The prescribed medication will be used as adjuvant therapy within 84 days of definitive surgical resection, including complete lymphadenectomy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

Members Health Insurance Company Date Effective: November 1, 2018

## SYLVANT (S)

#### **Products Affected**

• Sylvant

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multicentric Castleman's disease (MCD) (Initial): Diagnosis of MCD. Patient is human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.
Age Restrictions	N/A
Prescriber Restrictions	MCD (Initial): Prescribed by or in consultation with hematologist/oncologist or rheumatologist.
Coverage Duration	MCD (initial, reauth): 6 months
Other Criteria	MCD (reauth): Documentation of positive clinical response to Sylvant therapy. Patient is HIV negative and HHV-8 negative.

Members Health Insurance Company Date Effective: November 1, 2018

### SYMDEKO (S)

#### **Products Affected**

• Symdeko

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Initial: 1)Diagnosis of cystic fibrosis. 2) One of the following: Patient is homozygous for the F508del mutation as detected by a FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA) -approved facility OR Patient has one of the following mutations on at least one allele in the CF transmembrane conductance regulator (CFTR) gene as detected by FDA-cleared cystic fibrosis mutation test or Clinical Laboratory Improvement Amendments (CLIA) -approved facility: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3A-G, E831X, S945L, S977F, F1052V, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G-A, 3272-26A-G, 3849+10kbC-T.
Age Restrictions	Patient is 12 years of age or older
Prescriber Restrictions	Initial: Prescribed by or in consultation with pulmonologist or specialist affiliated with a CF care center
Coverage Duration	12 months
Other Criteria	Reauth: Documentation of a positive clinical response to Symdeko (tezacaftor/ivacaftor) therapy (e.g., improvement in lung function or decreased number of pulmonary exacerbations)

Members Health Insurance Company Date Effective: November 1, 2018

### SYMLIN (S)

#### **Products Affected**

- Symlinpen 120
- Symlinpen 60

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	One of the following diagnoses: A) Type 1 diabetes OR B) Type 2 diabetes.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Prior Authorization Criteria Members Health Insurance Company Date Effective: November 1, 2018

### SYNAGIS (S)

#### **Products Affected**

• Synagis INJ 100MG/ML, 50MG/0.5ML

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient will use palivizumab for immunoprophylaxis of respiratory syncytial virus (RSV) during the peak months of infection in the patient's geographic region AND Patient meets one of the following criteria: 1) Infants born at 28 weeks, six days gestation or earlier and who are younger than 12 months of age at the start of the RSV season OR 2) Diagnosis of chronic lung disease of prematurity, born before 32 weeks, 0 days gestation, received greater than 21% oxygen for at least the first 28 days after birth, and one of the following: a) 12 months of age or younger at the start of the RSV season OR b) greater than 12 months of age to 24 months of age at the start of the RSV season and received medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) within 6 months before the start of the second RSV season. OR 3) Patient is 12 months of age or younger at the start of the RSV season and has one of the following: a) acyanotic heart failure that will require a cardiac surgical procedure and the patient is receiving medication to control congestive heart failure, OR b) moderate to severe pulmonary hypertension OR c) cyanotic heart defect. OR 4) patient is younger than 24 months of age and will or has undergone a cardiac transplantation during the RSV season. OR 5) Patient is 12 months of age or younger at the start of the RSV season with a congenital abnormality or neuromuscular disorder and has an impaired ability to clear secretions from the upper airway due to an ineffective cough. OR 6) Patient is younger than 24 months of age with a lymphocyte count below the normal range for patient's age and has received or will receive a solid organ transplant, hematopoietic stem cell transplant recipient, or chemotherapy during the RSV season.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a pediatric specialist (i.e., pulmonologist, neonatologist, neurologist, cardiologist, pediatric intensivist, or infectious disease specialist).
Coverage Duration	12 months
Other Criteria	Approve 5 doses based on patient body weight for all other indications.

Members Health Insurance Company Date Effective: November 1, 2018

## SYNDROS (S)

#### **Products Affected**

• Syndros

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Nausea and Vomiting Associated with Cancer Chemotherapy (CINV): Patient is receiving cancer chemotherapy. Trial and failure, contraindication, or intolerance (TF/C/I) to a 5HT-3 receptor antagonist (eg, Anzemet [dolasetron], Kytril [granisetron], or Zofran [ondansetron]). TF/C/I to one of the following: Compazine (prochlorperazine), Decadron (dexamethasone), Haldol (haloperidol), Zyprexa (olanzapine). AIDS anorexia: Diagnosis of anorexia with weight loss in patients with AIDS. Patient is on antiretroviral therapy.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	CINV: 6 months. AIDS anorexia: 3 months.
Other Criteria	Subject to Part B vs. Part D review. CINV: Approve for continuation of therapy for treatment covered under Part B when patient is receiving chemotherapy.

Members Health Insurance Company Date Effective: November 1, 2018

### SYNRIBO (S)

#### **Products Affected**

• Synribo

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic myelogenous leukemia (CML): Diagnosis of CML in the chronic or accelerated phase AND Patient has tried and has had resistance, relapse, inadequate response, intolerance or is contraindicated to TWO tyrosine kinase inhibitors (i.e., Gleevec [imatinib], Sprycel, Tasigna, and Bosulif, Iclusig)
Age Restrictions	CML: 18 years of age or older
Prescriber Restrictions	CML: Prescribed by or in consultation with a hematologist/oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

# TAFINLAR (S)

### **Products Affected**

• Tafinlar

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Adjuvant Treatment for Melanoma: Diagnosis of melanoma. Cancer is BRAF V600E or V600K mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Involvement of lymph nodes following complete resection. Used as adjunctive therapy. Medication is used in combination with Mekinist (trametinib). Non-small Cell Lung Cancer (NSCLC): All of the following: diagnosis of metastatic non-small cell lung cancer AND cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA) AND medication is used in combination with Mekinist (trametinib). Anaplastic Thyroid Cancer (ATC): Diagnosis of locally advanced or metastatic anaplastic thyroid cancer. Cancer is BRAF V600E mutant type as detected by an FDA-approved test (THxID-BRAF Kit) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Cancer may not be treated with standard locoregional treatment options. Medication is used in combination with Mekinist (trametinib).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## TAGRISSO (S)

#### **Products Affected**

• Tagrisso

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC. One of the following: 1) Tumors are positive for epidermal growth factor receptor (EGFR) exon 19 deletions, OR 2) Tumors are positive for EGFR exon 21 L858R mutations, OR 3) Both of the following: a) Tumors are positive for EGFR T790M mutation and b) The patient has experienced disease progression on or after one of the following EGFR Tyrosine Kinase Inhibitors (TKIs): Gilotrif (afatinib), Iressa (gefitinib), Tarceva (erlotinib).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## TALTZ (S)

#### **Products Affected**

• Taltz

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: Trial and failure, contraindication, or intolerance to both Cosentyx (secukinumab) and either Enbrel (etanercept) or Humira (adalimumab), OR for continuation of prior Taltz therapy. Psoriatic Arthritis (PsA) (initial): Diagnosis of active PsA. One of the following: Trial and failure, contraindication, or intolerance to Cosentyx (secukinumab), OR for continuation of prior Taltz therapy. All indications (initial): Patient is not receiving Taltz in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].
Age Restrictions	N/A
Prescriber Restrictions	Plaque Psoriasis (initial): Prescribed by or in consultation with a dermatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist.
Coverage Duration	Initial, reauth: 12 months
Other Criteria	All indications (Reauth): Documentation of positive clinical response to Taltz therapy. Patient is not receiving Taltz in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)].

Members Health Insurance Company Date Effective: November 1, 2018

# TARCEVA (S)

#### **Products Affected**

• Tarceva

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of locally advanced or metastatic (Stage III or IV) NSCLC AND Patient has known active epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutation as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility. Pancreatic Cancer: Diagnosis of locally advanced, unresectable, or metastatic pancreatic cancer AND TARCEVA will be used in combination with gemcitabine.
Age Restrictions	N/A
Prescriber Restrictions	All Indications: Prescribed by or in consultation with an oncologist
Coverage Duration	All Indications: 12 months
Other Criteria	All Indications: Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## TARGRETIN (S)

#### **Products Affected**

- Bexarotene
- Targretin GEL

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Cutaneous T-Cell Lymphoma (CTCL): Diagnosis of CTCL. Trial and failure, contraindication, or intolerance to at least one prior therapy (including skin-directed therapies [eg, corticosteroids {ie, clobetasol, diflorasone, halobetasol, augmented betamethasone dipropionate}] or systemic therapies [eg, interferons]).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# TASIGNA (S)

#### **Products Affected**

• Tasigna

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Philadelphia chromosome positive/BCR ABL positive (Ph+/BCR ABL+) chronic myelogenous leukemia (CML): Diagnosis of Ph+/BCR ABL+ CML
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## TAVALISSE (S)

#### **Products Affected**

• Tavalisse

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic Idiopathic Thrombocytopenic Purpura (ITP) (initial): Diagnosis of chronic immune ITP or relapsed/refractory ITP. Baseline platelet count is less than 30,000/mcL. Trial and failure, contraindication, or intolerance to at least one of the following: corticosteroids, immunoglobulins, splenectomy, thrombopoietin receptor agonists (e.g., Nplate, Promacta), or Rituxan (rituximab). Patient's degree of thrombocytopenia and clinical condition increase the risk of bleeding.
Age Restrictions	N/A
Prescriber Restrictions	ITP (initial): Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	ITP (initial, reauth): 12 months
Other Criteria	ITP (reauth): Documentation of positive clinical response to Tavalisse therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding.

## **TECENTRIQ (S)**

#### **Products Affected**

• Tecentriq

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Urothelial Carcinoma: Diagnosis of locally advanced or metastatic urothelial carcinoma. One of the following: A) Both of the following: Tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells [IC] covering greater than or equal to 5% of the tumor area), as determined by an FDA-approved test (e.g., Ventana PD-L1 Assay) and Patient is not eligible for cisplatin-containing chemotherapy, B) Patient is not eligible for any platinum-containing chemotherapy regardless of PD-L1 status, C) Patient has disease progression during or following any platinum-containing chemotherapy, OR D) Patient has disease progression within 12 months of neoadjuvant or adjuvant chemotherapy. Non-Small Cell Lung Cancer: All of the following: A) Diagnosis of metastatic non-small cell lung cancer (NSCLC), and B) Patient has disease progression during or following platinum-containing chemotherapy, and C) One of the following: 1) Patient does not have epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) rearrangement OR 2) Both of the following: patient has an EGFR mutation AND trial and failure, contraindication, or intolerance to at least one anti-EGFR therapy (e.g., Gilotrif [afatinib], Iressa [gefitinib], Tarceva [erlotinib]) OR 3) Both of the following: patient has ALK rearrangement AND trial and failure, contraindication, or intolerance to at least one ALK inhibitor (e.g., Xalkori [crizotinib]).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 Months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# TECFIDERA (S)

- Tecfidera
- Tecfidera Starter Pack

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# TECHNIVIE (S)

# **Products Affected**

• Technivie

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	All of the following: A) Criteria will be applied consistent with current AASLD/IDSA guideline, AND B) Patient is not receiving Technivie in combination with another HCV direct acting antiviral agent [eg, Harvoni (ledipasvir-sofosbuvir), Sovaldi (sofosbuvir), Olysio (simeprevir)], AND C) ONE of the following: Trial and failure, intolerance, or contraindication to a) Harvoni OR Epclusa and b) Mavyret, OR for continuation of prior Technivie therapy.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
Coverage Duration	12 wks. Criteria will be applied consistent with current AASLD/IDSA guideline
Other Criteria	N/A

Date Effective: November 1, 2018

# **TESTOSTERONE (S)**

- Androderm PT24 2MG/24HR, 4MG/24HR
- Androgel GEL 20.25MG/1.25GM, 40.5MG/2.5GM
- Androgel Pump GEL 1.62%
- Testosterone GEL 1.62%, 20.25MG/1.25GM, 40.5MG/2.5GM
- Testosterone SOLN
- Testosterone Cypionate INJ
- Testosterone Pump GEL 1.62%
- Testosterone Topical Solution

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Gender Identity Disorder or Gender Dysphoria (GID/GD) (off-label): Dx of GID/GD. Patient is a female-to-male transsexual.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HG(init): (New to T tx:6 mo. New to plan and cont T tx:12 mo), (reauth): 12 mo. GID/GD: 12 mo.
Other Criteria	HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

# **TESTOSTERONE ENANTHATE (S)**

### **Products Affected**

• Testosterone Enanthate INJ

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Hypogonadism (HG) (Initial): Diagnosis (dx) of HG AND male patient at birth AND one of the following: 1) Two pre-treatment serum total testosterone (T) levels less than reference range for the lab OR 2) Both of the following: a) Has a condition that may cause altered sex-hormone binding globulin (SHBG) (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and b) one pre-treatment calculated free or bioavailable T level less than 5 ng/dL (0.17 nmol/L) or less than reference range for the lab, OR 3) History of bilateral orchiectomy, panhypopituitarism, or a genetic disorder known to cause HG (eg, congenital anorchia, Klinefelter's syndrome). Delayed puberty (DP): Dx of DP AND male patient at birth. Breast cancer (BC): Dx of inoperable BC AND used for palliative treatment AND female patient at birth. Gender Identity Disorder or Gender Dysphoria (GID/GD) (off-label): Dx of GID/GD. Patient is a female-to-male transsexual.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	HG(init): (New to T tx:6 mo. Cont T tx:12 mo), (reauth): 12 mo. BC, GID/GD: 12 mo. DP: 6 mo.
Other Criteria	HG (Reauth): 1) Total serum T level within or below the normal limits of the reporting lab, or 2) Total serum T level outside of upper limits of normal for the reporting lab and the dose is adjusted, OR 3) Has a condition that may cause altered SHBG (eg, thyroid disorder, HIV disease, liver disorder, diabetes, obesity), and one of the following: Calculated free or bioavailable T level within or below the normal limits of the reporting lab, or calculated free or bioavailable T level outside of upper limits of normal for the reporting lab and the dose is adjusted.

Members Health Insurance Company Date Effective: November 1, 2018

# THALOMID (S)

### **Products Affected**

• Thalomid

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma (MM): Diagnosis of MM. Used in combination with dexamethasone, unless the patient has an intolerance to steroids. Erythema nodosum leprosum (ENL): Diagnosis of moderate to severe ENL with cutaneous manifestations. Thalomid is not used as monotherapy if moderate to severe neuritis is present.
Age Restrictions	N/A
Prescriber Restrictions	MM: Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# THYROGEN (S)

### **Products Affected**

• Thyrogen

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient requires Blood Tg testing or Radioiodine ablation of remnant thyroid tissue after a thyroidectomy. One of the following: 1) Patient is unable to tolerate thyroid hormone withdrawal (i.e., intolerable hypothyroid symptoms), OR 2) Thyroid hormone withdrawal is medically contraindicated (i.e., exacerbation of comorbid conditions), OR 3) Patient had inadequate thyroid stimulating hormone (TSH) response to thyroid hormone withdrawal, OR 4) Patient has an undetectable Tg on thyroid hormone suppressive therapy, to exclude the diagnosis of residual or recurrent thyroid cancer.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# TOPICAL RETINOID (S)

- Avita
- Tretinoin CREA
- Tretinoin GEL
- Tretinoin Microsphere
- Tretinoin Microsphere Pump

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	One of the following: Acne: Diagnosis of acne.
Age Restrictions	PA applies to members 26 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# TRELSTAR (S)

- Trelstar
- Trelstar Mixject

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Diagnosis of advanced or metastatic prostate cancer. Trial and failure, contraindication, or intolerance to Lupron Depot (7.5 mg, 22.5 mg, 30 mg, and 45 mg).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# TREMFYA (S)

### **Products Affected**

• Tremfya

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Plaque psoriasis (Initial): Diagnosis of moderate to severe plaque psoriasis. One of the following: set A) 1) Trial and failure, contraindication, or intolerance (TF/C/I) to Enbrel (etanercept) or Humira (adalimumab) AND 2) TF/C/I to Cosentyx (secukinumab), OR set B) for continuation of prior Tremfya therapy. Patient is not receiving Tremfya in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab pegol), Simponi (golimumab)].
Age Restrictions	N/A
Prescriber Restrictions	Plaque psoriasis (Initial): Prescribed by or in consultation with a dermatologist.
Coverage Duration	Plaque psoriasis (Initial, reauth): 12 months
Other Criteria	Plaque psoriasis (Reauth): Documentation of positive clinical response to Tremfya therapy. Patient is not receiving Tremfya in combination with a biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab pegol), Simponi (golimumab)].

Members Health Insurance Company Date Effective: November 1, 2018

# TYKERB (S)

### **Products Affected**

• Tykerb

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer: Diagnosis of human epidermal growth factor receptor 2 (HER2)-positive metastatic or recurrent breast cancer. Used in combination with one of the following: Herceptin (trastuzumab), Xeloda (capecitabine), or aromatase inhibitors [eg, Aromasin (exemestane), Femara (letrozole), Arimidex (anastrazole)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

# TYMLOS (S)

## **Products Affected**

• Tymlos

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient is a postmenopausal woman. Either of the following: set I) diagnosis of osteoporosis defined as bone mineral density (BMD) T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) AND one of the following: a) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm or b) trial and failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia (denosumab)), or set II) diagnosis of osteopenia defined as BMD T-score between -1.0 and -2.5 in the lumbar spine, femoral neck, total hip, or radius (one-third radius site) and one of the following: a) history of low-trauma fracture of the hip, spine, proximal humerus, pelvis, or distal forearm, or b) both of the following: history of failure, contraindication, or intolerance to one osteoporosis treatment (e.g., alendronate, risedronate, zoledronic acid, Prolia [denosumab]) and one of the following FRAX (Fracture Risk Assessment Tool) 10-year probabilities: major osteoporotic fracture at 20% or more in the U.S., or the country-specific threshold in other countries or regions, or hip fracture is 3% or more in the U.S., or the country-specific threshold in other countries or regions. Treatment duration of parathyroid hormones (Forteo, Tymlos (abaloparatide)) has not exceeded a total of 24 months during the patient's lifetime.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	24 months
Other Criteria	N/A

Members Health Insurance Company

Date Effective: November 1, 2018

# Tysabri (s)

### **Products Affected**

• Tysabri

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple Sclerosis (MS): Diagnosis of a relapsing form of MS (eg, relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses). One of the following: 1) Trial and failure, contraindication, or intolerance (TF/C/I) to one of the following: Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone or Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Ocrevus (ocrelizumab), Plegridy (peginterferon beta-1a), Rebif (interferon beta-1a), Tecfidera (dimethyl fumarate), or Zinbryta (daclizumab), 2) Patient is not a candidate for any of the drugs listed as prerequisites due to the severity of their MS, or 3) For continuation of prior therapy. Patient is not taking Tysabri in combination with another MS agent [eg, Aubagio (teriflunomide), Avonex (interferon beta-1a), Betaseron (interferon beta-1b), Copaxone (glatiramer acetate), Glatopa (glatiramer acetate), Extavia (interferon beta-1b), Gilenya (fingolimod), Lemtrada (alemtuzumab), Rebif (interferon beta-1a), or Tecfidera (dimethyl fumarate)]. Crohn's Disease (CD) (initial): Diagnosis of moderate to severe CD with evidence of inflammation (eg, elevated C-reactive protein [CRP], elevated erythrocyte sedimentation rate, presence of fecal leukocytes). Inadequate response or intolerance to one of the following conventional therapies: corticosteroids, 6-mercaptopurine (6MP [Purinethol], azathioprine (Imuran), methotrexate, aminosalicylates (eg, sulfasalazine, mesalamine, olsalazine). Inadequate response or intolerance to a TNF-inhibitor (eg, Cimzia [certolizumab pegol], Humira [adalimumab], Remicade [infliximab]). CD (initial and reauth): Patient is not taking Tysabri in combination with an immunosuppressant (eg, 6-MP, azathioprine, cyclosporine, or methotrexate) or a TNF-inhibitor (eg, Enbrel [etanercept], Humira [adalimumab], or Remicade [infliximab]).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	MS: 12mo. CD (Init): 3 mo. CD (Reauth): 6 mo if not on steroids. Otherwise, 3 mo.

Members Health Insurance Company

Date Effective: November 1, 2018

Other Criteria	CD (reauth): Diagnostic and/or clinical documentation (eg, improved disease activity index) that indicates patient has experienced clinical benefit from receiving (induction) Tysabri therapy by week 12.
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Members Health Insurance Company Date Effective: November 1, 2018

# Tyvaso(s)

- Tyvaso
- Tyvaso Refill
- Tyvaso Starter

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH: Initial: 6 months. Reauth: 12 months.
Other Criteria	Subject to Part B vs D review. PAH (Reauth): Documentation of positive clinical response to therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# UPTRAVI (S)

### **Products Affected**

• Uptravi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (initial): Diagnosis of PAH AND Patient is symptomatic AND One of the following: a) Diagnosis of PAH was confirmed by right heart catheterization OR b) patient is currently on any therapy for the diagnosis of PAH. One of the following: a) History of trial and failure, contraindication, or intolerance to a PDE5 inhibitor (ie, Adcirca, Revatio) or Adempas (riociguat), and History of trial and failure, contraindication, or intolerance to an endothelin receptor antagonist [e.g. Letairis (ambrisentan), Opsumit (macitentan), or Tracleer (bosentan)] OR b) For continuation of prior Uptravi therapy. Not taken in combination with a prostanoid/prostacyclin analogue (eg, epoprostenol, iloprost, treprostinil).
Age Restrictions	N/A
Prescriber Restrictions	PAH (initial): Prescribed by or in consultation with a pulmonologist or cardiologist
Coverage Duration	Initial: 6 months Reauth: 12 months
Other Criteria	PAH (Reauth): Documentation of positive clinical response to Uptravi therapy. Not taken in combination with a prostanoid/prostacyclin analogue (eg, epoprostenol, iloprost, treprostinil)

Members Health Insurance Company Date Effective: November 1, 2018

# VALCHLOR (S)

### **Products Affected**

• Valchlor

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL) (initial): All of the following: 1) diagnosis of Stage IA MF-CTCL, OR diagnosis of Stage IB MF-CTCL, AND 2) patient has received at least one prior skin-directed therapy [e.g., topical corticosteroids, bexarotene topical gel (Targretin topical gel), topical nitrogen mustard, etc.].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or dermatologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# VARIZIG (S)

#### **Products Affected**

• Varizig INJ 125UNIT/1.2ML

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Presence of contraindications to immune globulin therapy (i.e., IgA deficiency with antibodies to IgA and a history of hypersensitivity or product specific contraindication).
Required Medical Information	Immune globulin is being used intramuscularly. The immune globulin is being used for passive immunization or post exposure-prophylaxis of varicella. Patient is considered a high risk individual (i.e., immune compromised, pregnant woman, newborn of mother with varicella, premature infant, and infant less than 1 year old).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months (approve one dose only)
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# VELCADE (S)

### **Products Affected**

• Velcade

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple myeloma (MM): Diagnosis of MM. Mantle cell lymphoma (MCL): Diagnosis of MCL.
Age Restrictions	N/A
Prescriber Restrictions	MM, MCL: Prescribed by or in consultation with an oncologist/hematologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# VENCLEXTA (S)

- Venclexta
- Venclexta Starting Pack

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL): Diagnosis of CLL or SLL. Patient has received at least one prior therapy for CLL/SLL [e.g., Cytoxan (cyclophosphamide), Fludara (fludarabine), Rituxan (rituximab), etc.].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist or oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# **VENTAVIS (S)**

### **Products Affected**

• Ventavis

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Pulmonary arterial hypertension (PAH) (Initial): Diagnosis of PAH. PAH is symptomatic. One of the following: A) Diagnosis of PAH was confirmed by right heart catheterization or B) Patient is currently on any therapy for the diagnosis of PAH.
Age Restrictions	N/A
Prescriber Restrictions	PAH (Initial): Prescribed by or in consultation with a pulmonologist or cardiologist.
Coverage Duration	PAH (Initial): 6 months. (Reauth): 12 months
Other Criteria	Subject to Part B vs D review. PAH (Reauth): Documentation of positive clinical response to therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# VERZENIO (S)

### **Products Affected**

• Verzenio

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer: Diagnosis of advanced or metastatic breast cancer. Disease is hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative. One of the following: a) used in combination with an aromatase inhibitor (e.g., Arimidex [anastrozole], Aromasin [exemestane], Femara [letrozole]) and patient is a postmenopausal woman, OR b) used in combination with Faslodex (fulvestrant) and disease has progressed following endocrine therapy, OR c) used as monotherapy and disease has progressed following endocrine therapy and patient has already received at least one prior chemotherapy regimen.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# VIEKIRA (S)

- Viekira Pak
- Viekira Xr

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	All of the following: A) Criteria will be applied consistent with current AASLD/IDSA guideline AND B) ONE of the following: 1) Patient has a trial and failure, contraindication, or intolerance to a) Harvoni OR Epclusa and b) Mavyret, OR 2) For continuation of prior Viekira therapy AND C) Patient is not receiving Viekira in combination with another HCV direct acting antiviral agent [e.g., Harvoni (ledipasvir-sofosbuvir), Sovaldi (sofosbuvir), Olysio (simeprevir)], AND D) Patient is without decompensated liver disease (e.g., Child-Pugh Class B or C), AND E) ONE of the following: 1) Patient has not experienced prior failure with an NS5A inhibitor or NS3/4A protease inhibitor-containing regimen OR 2) patient has failed prior therapy with an NS5A inhibitor or NS3/4A protease inhibitor AND submission of medical records documenting that the patient does not have NS3 protease inhibitor or NS5A inhibitor resistance-associated variants detected using commercially available assays.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
Coverage Duration	12 to 24 wks. Criteria will be applied consistent with current AASLD/IDSA guideline
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# VIMIZIM (S)

### **Products Affected**

• Vimizim

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Mucopolysaccharidosis (initial): Diagnosis of Mucopolysaccharidosis type IVA (MPS IVA, Morquio A syndrome) confirmed by both of the following: a) documented clinical signs and symptoms of the disease (e.g., kyphoscoliosis, genu valgum, pectus carinatum, gait disturbance, growth deficiency, etc.) and b) documented reduced fibroblast or leukocyte GALNS enzyme activity or molecular genetic testing of GALNS.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Reauthorization: Documentation of positive clinical response to Vimizim therapy

Members Health Insurance Company Date Effective: November 1, 2018

# Vosevi (s)

### **Products Affected**

• Vosevi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Criteria will be applied consistent with current AASLD/IDSA guideline. All patients: Submission of medical records (e.g., chart notes, laboratory values) documenting diagnosis of chronic hepatitis C, patient is without decompensated liver disease (defined as Child-Pugh Class B or C), and patient is not receiving Vosevi in combination with another HCV direct acting antiviral agent [e.g., Harvoni, Zepatier].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine
Coverage Duration	12 wks. Criteria will be applied consistent with current AASLD/IDSA guideline
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# VOTRIENT (S)

## **Products Affected**

• Votrient

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Renal cell carcinoma (RCC): Diagnosis of advanced/metastatic RCC. Soft tissue sarcoma: Diagnosis of advanced soft tissue sarcoma and patient received at least one prior chemotherapy (e.g., ifosfamide, doxorubicin, cisplatin, dacarbazine, docetaxel, oxaliplatin, etc.)
Age Restrictions	N/A
Prescriber Restrictions	All Uses: Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# VPRIV (S)

### **Products Affected**

• Vpriv

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Gaucher disease: Diagnosis of type 1 Gaucher disease. Patient has evidence of symptomatic disease (e.g., moderate to severe anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Gaucher disease: 12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# VYTORIN (S)

#### **Products Affected**

• Ezetimibe/simvastatin TABS 10MG; 80MG

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient has been taking simvastatin 80 mg per day chronically (12 months or more) and no evidence of muscle toxicity/myopathy (eg, muscle pain, muscle tenderness, muscle weakness) on simvastatin 80 mg per day.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# VYXEOS (S)

### **Products Affected**

• Vyxeos

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Newly diagnosed therapy related acute myeloid leukemia (t-AML): Diagnosis of t-AML. Acute myeloid leukemia myelodysplasia-related changes (AML-MRC): Diagnosis of AML-MRC.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

Members Health Insurance Company Date Effective: November 1, 2018

# XALKORI (S)

### **Products Affected**

• Xalkori

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of locally advanced or metastatic (stage IIIB or IV) NSCLC AND One of the following: A) Patient has an anaplastic lymphoma kinase (ALK)-positive tumor as detected with an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility or B) Patient has MET amplification- or ROS1 rearrangements-positive tumor as detected with an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility.
Age Restrictions	N/A
Prescriber Restrictions	NSCLC: Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

Members Health Insurance Company

Date Effective: November 1, 2018

# XELJANZ (S)

- Xeljanz
- Xeljanz Xr

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Xeljanz/Xeljanz XR: Rheumatoid arthritis (RA) (Initial): Diagnosis of moderately to severely active RA. Psoriatic arthritis (PsA) (Initial): Diagnosis of active PsA. RA/PsA (initial): One of the following: Failure, contraindication, or intolerance to both Enbrel (etanercept) and Humira (adalimumab), or attestation demonstrating a trial may be inappropriate, OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-IV-TR 300.29 for specific phobia diagnostic criteria), OR for continuation of prior tofacitinib therapy. Xeljanz only: Ulcerative colitis (UC) (Initial): Diagnosis of moderately to severely active UC. Trial and failure, contraindication, or intolerance to one of the following conventional therapies: 6-mercaptopurine (Purinethol), aminosalicylate [e.g., mesalamine (Asacol, Pentasa, Rowasa), olsalazine (Dipentum), sulfasalazine (Azulfidine, Sulfazine)], azathioprine (Imuran), or corticosteroids (e.g., prednisone, methylprednisolone). Trial and failure, contraindication, or intolerance to Humira (adalimumab), OR patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR F40.2 for specific phobia diagnostic criteria), OR for continuation of prior Xeljanz therapy. All indications (initial): Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).
Age Restrictions	N/A
Prescriber Restrictions	RA (initial): Prescribed by or in consultation with a rheumatologist. PsA (initial): Prescribed by or in consultation with a dermatologist or rheumatologist. UC (initial): Prescribed by or in consultation with a gastroenterologist.
Coverage Duration	RA/PsA (initial, reauth): 12 months. UC (init): 4 mo. UC (reauth): 12 mo.
Other Criteria	All Indications (Reauth): Documentation of positive clinical response to tofacitinib therapy. Patient is not receiving tofacitinib in combination with a potent immunosuppressant (eg, azathioprine, cyclosporine).

Members Health Insurance Company Date Effective: November 1, 2018

# XENAZINE (S)

### **Products Affected**

• Tetrabenazine

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chorea associated with Huntington's Disease (HD) (Initial): Diagnosis of chorea in patients with Huntington's disease. Tardive dyskinesia (Initial): Patient has stereotypies associated with tardive dyskinesia. Tourette's syndrome (Initial): Patient has tics associated with Tourette's syndrome. Failure, contraindication, or intolerance to Haldol (haloperidol).
Age Restrictions	Tardive dyskinesia (Initial): Age greater than or equal to 18 years.
Prescriber Restrictions	HD (Initial): Prescribed by or in consultation with a neurologist. Tardive dyskinesia, Tourette's syndrome (Initial): Prescribed by or in consultation with neurologist or psychiatrist.
Coverage Duration	All indications: (Initial) 3 months, (Reauth) 12 months.
Other Criteria	All indications (Reauth): Documentation of clinical response and benefit from therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# XEOMIN (S)

### **Products Affected**

• Xeomin INJ 200UNIT

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Cervical Dystonia (CD) (init): Diagnosis of CD (also known as spasmodic torticollis). Blepharospasm (initial): Diagnosis of blepharospasm. History of previous use of Botox (onabotulinumtoxinA) for the treatment of blepharospasm. Upper limb spasticity (ULS) (init): Diagnosis of upper limb spasticity.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All indications (init, reauth): 3 months (for 1 dose)
Other Criteria	All indications (reauth): Confirmed improvement in symptoms with initial Xeomin treatment. At least 3 months have elapsed since the last treatment with Xeomin

Members Health Insurance Company Date Effective: November 1, 2018

# XERMELO (S)

### **Products Affected**

• Xermelo

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Carcinoid syndrome diarrhea (Initial): Diagnosis of carcinoid syndrome diarrhea AND diarrhea is inadequately controlled by a stable dose of somatostatin analog (SSA) therapy (e.g., octreotide [Sandostatin, Sandostatin LAR], lanreotide [Somatuline Depot]) for at least 3 months AND used in combination with SSA therapy.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist
Coverage Duration	Initial: 6 months, Reauth: 12 months
Other Criteria	Carcinoid syndrome diarrhea (Reauthorization): Documentation of a positive clinical response to Xermelo therapy AND Xermelo will continue to be used in combination with SSA therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# XGEVA (S)

## **Products Affected**

• Xgeva

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Multiple Myeloma (MM)/Bone metastasis from solid tumors (BMST): One of the following: 1) Diagnosis of multiple myeloma OR 2) diagnosis of solid tumors (eg, breast cancer, kidney cancer, lung cancer, prostate cancer, thyroid cancer), AND documented evidence of one or more metastatic bone lesions. Giant cell tumor of bone (GCTB): Both of the following: 1) diagnosis of giant cell tumor of bone AND 2) One of the following: a) tumor is unresectable, OR b) surgical resection is likely to result in severe morbidity. Hypercalcemia of malignancy (HCM): Both of the following: 1) diagnosis of hypercalcemia of malignancy, AND 2) Trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (eg, Aredia (pamidronate), Zometa (zoledronic acid).
Age Restrictions	N/A
Prescriber Restrictions	GCTB, HCM: Prescribed by or in consultation with an oncologist
Coverage Duration	MM/BMST, GCTB: 12 mo. HCM: 2 mo.
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# XIAFLEX (S)

## **Products Affected**

• Xiaflex

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Dupuytren's contracture (DC) (initial, reauth): Diagnosis of Dupuytren's contracture with a palpable cord AND Prescriber is enrolled in the Xiaflex REMS program for Dupuytren's contracture AND Patient has a positive "table top test" (defined as the inability to simultaneously place the affected finger and palm flat against a table top) AND Patient has a documented contracture of at least 20 degrees flexion for a metacarpophalangeal joint or a proximal interphalangeal joint AND Patient has a flexion deformity that results in functional limitations. Peyronie's disease (PD) (initial, reauth): Diagnosis of Peyronie's disease AND Prescriber is enrolled in the Xiaflex REMS program for Peyronie's disease AND Patient has a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy AND The plaques do not involve the penile urethra AND Patient has a curvature deformity that results in pain (e.g., pain upon erection or intercourse)
Age Restrictions	Initial (DC, PD): 18 years of age or older
Prescriber Restrictions	N/A
Coverage Duration	DC, PD (Initial and reauth): 12 months
Other Criteria	Peyronie's disease (reauth): patient has a new plaque that results in a curvature deformity.

Members Health Insurance Company Date Effective: November 1, 2018

# XIFAXAN (S)

## **Products Affected**

• Xifaxan

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Travelers' diarrhea (TD) (200 mg strength only): Diagnosis of travelers' diarrhea, AND one of the following: a) Trial and failure, contraindication, or intolerance to one of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin) OR b) resistance to all of the following: Cipro (ciprofloxacin), Levaquin (levofloxacin), ofloxacin, Zithromax (azithromycin). Prophylaxis of hepatic encephalopathy (HE) recurrence (550mg strength only): Used for the prophylaxis of hepatic encephalopathy recurrence, AND trial and failure, contraindication or intolerance to lactulose. Treatment of HE: Used for the treatment of HE. Trial and failure, contraindication, or intolerance to lactulose. Irritable bowel syndrome with diarrhea (IBS-D) (550mg strength only) (initial): Diagnosis of IBS-D, AND trial and failure, contraindication or intolerance to an antidiarrheal agent [eg, loperamide].
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	TD: One time only. HE (prophylaxis, treatment): 12 months. IBS-D (initial, reauth): 2 weeks.
Other Criteria	IBS-D (reauth): Patient experiences IBS-D symptom recurrence.

Members Health Insurance Company

Date Effective: November 1, 2018

# XOLAIR (S)

## **Products Affected**

• Xolair

Date Effective: November 1, 2018

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Asthma (init): Diagnosis of moderate to severe persistent allergic asthma. Positive skin test or in vitro reactivity to a perennial aeroallergen. Pretreatment serum immune globulin (Ig)E level between 30 to 700 IU/mL. Symptoms are not adequately controlled on a high-dose inhaled corticosteroid and a long-acting beta2-agonist combination for at least 3 months, unless there is a contraindication or intolerance to these therapies. Chronic Idiopathic Urticaria (CIU): Diagnosis of CIU. Persistent symptoms (itching and hives) for at least 4 consecutive weeks despite titrating to an optimal dose with a second generation H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines. Patient has tried and had an inadequate response or intolerance or contraindication to at least one of the following additional therapies: H2 antagonist, leukotriene receptor antagonist, H1 antihistamine, hydroxyzine, doxepin. Used concurrently with an H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamine,
Age Restrictions	N/A
Prescriber Restrictions	Asthma (init): Prescribed by or in consultation with an allergist, immunologist, or pulmonologist. CIU (init): Prescribed by or in consultation with an allergist, immunologist, or dermatologist
Coverage Duration	Asthma (init, reauth): 6 months CIU (init): 3 months (reauth) 6 months
Other Criteria	Asthma (reauth): Patient has experienced one or more of the following: Reduction in number of asthma exacerbations from baseline (eg, asthma exacerbation requiring treatment with systemic corticosteroids or doubling of inhaled corticosteroid [ICS] dose from baseline) or Improvement in forced expiratory volume in 1 second (FEV1) from baseline or Decreased use of rescue medications from baseline. CIU (reauth): Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment. Patient has experienced one or both of the following: Reduction in itching severity from baseline or Reduction in the number of hives from baseline.

Members Health Insurance Company Date Effective: November 1, 2018

# XTANDI (S)

## **Products Affected**

• Xtandi

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Castration-resistant prostate cancer (CRPC): Diagnosis of CRPC.
Age Restrictions	N/A
Prescriber Restrictions	Prescribed or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# **XURIDEN (S)**

## **Products Affected**

• Xuriden

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Hereditary orotic aciduria (Initial): Diagnosis of hereditary orotic aciduria.
Age Restrictions	N/A
Prescriber Restrictions	Initial: Prescribed by or in consultation with a medical geneticist or other specialist that treats inborn errors of metabolism
Coverage Duration	Initial, reauth: 12 months
Other Criteria	Hereditary orotic aciduria (reauth): Documentation of positive clinical response to Xuriden therapy

Members Health Insurance Company Date Effective: November 1, 2018

# XYREM (S)

## **Products Affected**

• Xyrem

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Narcolepsy with cataplexy (Narcolepsy Type 1)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are present, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present. Narcolepsy without cataplexy (Narcolepsy Type 2)(initial): Diagnosis of narcolepsy as confirmed by sleep study (unless the prescriber provides justification confirming that a sleep study would not be feasible), AND symptoms of cataplexy are absent, AND symptoms of excessive daytime sleepiness (eg, irrepressible need to sleep or daytime lapses into sleep) are present, AND trial and failure, contraindication, or intolerance to one of the following: 1) amphetamine-based stimulant (eg, amphetamine, dextroamphetamine), OR 2) methylphenidate-based stimulant.
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	All uses (initial, reauth): 12 months
Other Criteria	Narcolepsy Type 1 (reauth): Documentation demonstrating a reduction in the frequency of cataplexy attacks associated with Xyrem therapy, OR documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy. Narcolepsy Type 2 (reauth): Documentation demonstrating a reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# YERVOY (S)

## **Products Affected**

• Yervoy

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Unresectable or metastatic melanoma: Diagnosis of unresectable, metastatic melanoma. Cutaneous melanoma: Diagnosis of cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm. Patient has undergone resection, including total lymphadenectomy. Renal Cell Carcinoma (RCC): Diagnosis of renal cell carcinoma. Disease is advanced, relapsed, or stage IV disease that is surgically unresectable. Intermediate- or poor-prognosis risk. Previously untreated disease. Used in combination with Opdivo (nivolumab). Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer (CRC): Diagnosis of MSI-H or dMMR metastatic colorectal cancer. Disease has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. Used in combination with Opdivo (nivolumab).
Age Restrictions	MSI-H/dMMR CRC: Patient is 12 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

# YONSA (S)

## **Products Affected**

• Yonsa

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Prostate Cancer: Diagnosis of metastatic castration-resistant (chemical or surgical) or recurrent prostate cancer. Used in combination with methylprednisolone. One of the following: 1) Used in combination with a gonadotropin-releasing hormone (GnRH) analog or 2) Patient received a bilateral orchiectomy. Trial and failure or intolerance to Xtandi (enzalutamide).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist or urologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

Members Health Insurance Company Date Effective: November 1, 2018

# ZALTRAP (S)

## **Products Affected**

• Zaltrap

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Colon and/or rectal cancer: Diagnosis of metastatic colon and/or rectal cancer. Ziv-aflibercept is being used in combination with 5-fluorouracil, leucovorin, and irinotecan (FOLFIRI) regimen. Patient has disease that is resistant to or has progressed following an oxaliplatin-containing regimen [e.g., 5-fluorouracil, leucovorin, and oxaliplatin (FOLFOX)].
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy.

Members Health Insurance Company Date Effective: November 1, 2018

## ZAVESCA (S)

## **Products Affected**

- Miglustat
- Zavesca

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Gaucher disease: Diagnosis of mild to moderate type 1 Gaucher disease. Patient is unable to receive enzyme replacement therapy due to one of the following conditions: allergy or hypersensitivity to enzyme replacement therapy, poor venous access, unavailability of enzyme replacement therapy (e.g., Cerezyme, VPRIV).
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Gaucher disease: 12 months
Other Criteria	N/A

Members Health Insurance Company Date Effective: November 1, 2018

# ZEJULA (S)

## **Products Affected**

• Zejula

PA Criteria	Criteria Details
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of recurrent epithelial ovarian cancer, recurrent fallopian tube cancer, or recurrent primary peritoneal cancer. Used for maintenance treatment in patients who are in a complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin).
Age Restrictions	N/A
Prescriber Restrictions	Prescribed by or in consultation with an oncologist
Coverage Duration	12 months
Other Criteria	Approve for continuation of prior therapy

Members Health Insurance Company Date Effective: November 1, 2018

# **ZELBORAF** (S)

## **Products Affected**

• Zelboraf

PA Criteria	Criteria Details	
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.	
Exclusion Criteria	N/A	
Required Medical Information	Melanoma: Diagnosis of unresectable melanoma or metastatic melanoma. Cancer is BRAFV600 mutant type (MT) as detected by an FDA-approved test (eg, cobas 4600 BRAFV600 Mutation Test) or performed at a facility approved by Clinical Laboratory Improvement Amendments (CLIA). Erdheim-Chester Disease: Diagnosis of Erdheim-Chester disease AND Disease is BRAFV600 mutant type (MT).	
Age Restrictions	N/A	
Prescriber Restrictions	Melanoma: Prescribed by or in consultation with an oncologist. Erdheim-Chester Disease: Prescribed by or in consultation with a hematologist/oncologist.	
Coverage Duration	12 months	
Other Criteria	All indications: Approve for continuation of therapy.	

Members Health Insurance Company Date Effective: November 1, 2018

# **ZEPATIER (S)**

## **Products Affected**

• Zepatier

PA Criteria	Criteria Details			
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.			
Exclusion Criteria	N/A			
Required Medical Information	All of the following: A) Criteria will be applied consistent with current AASLD/IDSA guideline AND B) ONE of the following: 1) Patient has a trial and failure, contraindication or intolerance to a) Harvoni OR Epclusa AND b) Mavyret, OR 2) For continuation of prior Zepatier therapy AND C) Patient is not receiving Zepatier in combination with another HCV direct acting antiviral agent, AND D) patient does not have moderate to severe hepatic impairment (eg, Child-Pugh Class B or C), AND E) For genotype 1a, patient has been tested for the presence of NS5A resistance-associated polymorphisms (ie, polymorphisms at amino acid positions 28, 30, 31, or 93).			
Age Restrictions	N/A			
Prescriber Restrictions	Prescribed by or in consultation with one of the following: Hepatologist, Gastroenterologist, Infectious disease specialist, HIV specialist certified through the American Academy of HIV Medicine			
Coverage Duration	12 to 16 wks. Criteria will be applied consistent with current AASLD/IDSA guideline			
Other Criteria	N/A			

Members Health Insurance Company Date Effective: November 1, 2018

# ZOLINZA (S)

## **Products Affected**

• Zolinza

PA Criteria	Criteria Details			
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.			
Exclusion Criteria	N/A			
Required Medical Information	Cutaneous T-cell lymphoma (CTCL): Diagnosis of CTCL. Progressive, persistent or recurrent disease on or contraindication or intolerance to two systemic therapies (e.g., bexarotene, romidepsin, etc.).			
Age Restrictions	N/A			
Prescriber Restrictions	Prescribed by or in consultation with a hematologist/oncologist.			
Coverage Duration	12 months			
Other Criteria	Approve for continuation of prior therapy.			

Members Health Insurance Company Date Effective: November 1, 2018

# **ZORBTIVE (S)**

## **Products Affected**

• Zorbtive

PA Criteria	Criteria Details			
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.			
Exclusion Criteria	N/A			
Required Medical Information	Short Bowel Syndrome (SBS): Diagnosis of SBS. Patient is currently receiving specialized nutritional support (eg, intravenous parenteral nutrition, fluid, and micronutrient supplements). Patient has not previously received 4 weeks of treatment with Zorbtive.			
Age Restrictions	N/A			
Prescriber Restrictions	Prescribed by or in consultation with a gastroenterologist.			
Coverage Duration	SBS: 4 weeks.			
Other Criteria	N/A			

Members Health Insurance Company Date Effective: November 1, 2018

# **ZORTRESS (S)**

## **Products Affected**

• Zortress

PA Criteria	Criteria Details			
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.			
Exclusion Criteria	N/A			
Required Medical Information	Prevention of kidney transplant organ rejection: The medication is being used for prevention of kidney transplant organ rejection. Patient is at low-to-moderate immunologic risk. Patient is prescribed concurrent therapy with reduced doses of cyclosporine AND corticosteroids. Prevention of liver transplant organ rejection: The medication is being used for prevention of liver transplant organ rejection. Thirty (30) or more days have passed since the transplant procedure. Patient is prescribed concurrent therapy with reduced doses of tacrolimus and corticosteroids.			
Age Restrictions	All indications: 18 years of age or older			
Prescriber Restrictions	All indications: Prescriber is experienced in immunosuppressive therapy and management of transplant patients.			
Coverage Duration	12 months			
Other Criteria	Subject to Part B vs. Part D review. Approve for continuation of prior therapy.			

Members Health Insurance Company Date Effective: November 1, 2018

# ZYDELIG (S)

## **Products Affected**

• Zydelig

PA Criteria	Criteria Details			
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.			
Exclusion Criteria	N/A			
Required Medical Information	Chronic lymphocytic leukemia (CLL): Diagnosis of CLL. Used in combination with Rituxan (rituximab). The patient has relapsed on at least one prior therapy (eg, purine analogues [fludarabine, pentostatin, cladribine], alkylating agents [chlorambucil, cyclophosphamide], or monoclonal antibodies [rituximab]). Patient is a candidate for Rituxan (rituximab) monotherapy due to presence of other comorbidities (eg, coronary artery disease, peripheral vascular disease, diabetes mellitus, pulmonary disease [COPD]). Follicular Lymphoma (FL): Diagnosis of FL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]). Small lymphocytic lymphoma (SLL): Diagnosis of SLL. The patient has relapsed on at least two prior systemic therapies (eg, rituximab, alkylating agents [cyclophosphamide, chlorambucil], anthracyclines [doxorubicin, daunorubicine], purine analogs [fludarabine]).			
Age Restrictions	N/A			
Prescriber Restrictions	All uses: Prescribed by or in consultation with an oncologist/hematologist.			
Coverage Duration	12 months			
Other Criteria	Approve for continuation of prior therapy.			

Members Health Insurance Company Date Effective: November 1, 2018

# ZYKADIA (S)

## **Products Affected**

• Zykadia

PA Criteria	Criteria Details			
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.			
Exclusion Criteria	N/A			
Required Medical Information	Non-small cell lung cancer (NSCLC): Diagnosis of NSCLC that is metastatic or recurrent. Tumor is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test or Clinical Laboratory Improvement Amendments-approved facility.			
Age Restrictions	N/A			
Prescriber Restrictions	Prescribed by or in consultation with an oncologist			
Coverage Duration	12 months			
Other Criteria	Approve for continuation of prior therapy.			

Members Health Insurance Company Date Effective: November 1, 2018

# ZYTIGA (S)

## **Products Affected**

• Zytiga

PA Criteria	Criteria Details			
<b>Covered Uses</b>	All medically accepted indications not otherwise excluded from Part D.			
Exclusion Criteria	N/A			
Required Medical Information	Prostate Cancer: One of the following: 1) Diagnosis of metastatic castration-resistant (chemical or surgical) or recurrent prostate cancer or 2) Diagnosis of metastatic high-risk castration-sensitive prostate cancer. Used in combination with prednisone.			
Age Restrictions	N/A			
Prescriber Restrictions	Prostate Cancer: Prescribed by or in consultation with an oncologist or urologist			
Coverage Duration	Prostate Cancer: 12 months			
Other Criteria	Approve for continuation of prior therapy			

# PART B VERSUS PART D

#### **Products Affected**

- Abelcet
- Acetylcysteine SOLN
- Acyclovir Sodium INJ 1000MG, 500MG, 50MG/ML
- Adriamycin INJ 10MG, 2MG/ML, 50MG
- Adrucil INJ 2.5GM/50ML, 500MG/10ML, 5GM/100ML
- Akynzeo CAPS
- Albuterol Sulfate NEBU
- Ambisome
- Amino Acid
- Aminosyn INJ 148MEQ/L; 1280MG/100ML; 980MG/100ML; 1280MG/100ML; 300MG/100ML; 720MG/100ML; 940MG/100ML; 720MG/100ML; 400MG/100ML; 440MG/100ML; 5.4MEQ/L; 860MG/100ML; 420MG/100ML; 520MG/100ML; 160MG/100ML; 44MG/100ML; 800MG/100ML
- Aminosyn 7%/electrolytes
- Aminosyn 8.5%/electrolytes
- Aminosyn II INJ 50.3MEQ/L; 695MG/100ML; 713MG/100ML; 490MG/100ML; 517MG/100ML; 350MG/100ML; 210MG/100ML; 462MG/100ML; 700MG/100ML; 735MG/100ML; 120MG/100ML; 209MG/100ML; 505MG/100ML; 371MG/100ML; 31.3MEQ/L; 280MG/100ML; 140MG/100ML; 189MG/100ML; 350MG/100ML, 71.8MEQ/L; 993MG/100ML; 1018MG/100ML; 700MG/100ML; 738MG/100ML; 500MG/100ML; 300MG/100ML; 660MG/100ML; 1000MG/100ML; 1050MG/100ML; 172MG/100ML; 298MG/100ML; 722MG/100ML; 530MG/100ML; 38MEQ/L; 400MG/100ML; 200MG/100ML; 270MG/100ML; 500MG/100ML

Members Health Insurance Company

Date Effective: November 1, 2018

- Aminosyn II 8.5%/electrolytes
- Aminosyn M INJ 65MEQ/L;
  - 448MG/100ML; 343MG/100ML;
  - 40MEO/L; 448MG/100ML;
  - 105MG/100ML; 252MG/100ML;
  - 329MG/100ML; 252MG/100ML;
  - 3MEQ/L; 140MG/100ML;
  - 154MG/100ML; 3.5MMOLE/L;
  - 13MEQ/L; 300MG/100ML;
  - 147MG/100ML; 40MEQ/L;
  - 182MG/100ML; 56MG/100ML;
  - 31MG/100ML; 280MG/100ML
- Aminosyn-hbc
- Aminosyn-pf INJ 46MEQ/L;
  - 698MG/100ML; 1227MG/100ML;
  - 527MG/100ML; 820MG/100ML;
  - 385MG/100ML; 312MG/100ML;
  - 760MG/100ML; 1200MG/100ML;
  - 677MG/100ML; 180MG/100ML;
  - 427MG/100ML; 812MG/100ML;
  - 495MG/100ML; 3.4MEQ/L;
  - 70MG/100ML; 512MG/100ML;
  - 180MG/100ML; 44MG/100ML;
  - 673MG/100ML
- Aminosyn-pf 7%
- Aminosyn-rf
- Amphotericin B INJ
- Anzemet TABS
- Aprepitant
- Azasan
- Azathioprine INJ
- Azathioprine TABS
- Bethkis
- Bleomycin INJ 15UNIT
- Bleomycin Sulfate INJ
- Brovana
- Budesonide SUSP
- Cladribine
- Clinimix 2.75%/dextrose 5%
- Clinimix 4.25%/dextrose 10%
- Clinimix 4.25%/dextrose 20%
- Clinimix 4.25%/dextrose 25%
- Clinimix 4.25%/dextrose 5%
- Clinimix 5%/dextrose 15%

Members Health Insurance Company

Date Effective: November 1, 2018

- Clinimix 5%/dextrose 20%
- Clinimix 5%/dextrose 25%
- Clinimix E 2.75%/dextrose 10%
- Clinimix E 2.75%/dextrose 5%
- Clinimix E 4.25%/dextrose 10%
- Clinimix E 4.25%/dextrose 25%
- Clinimix E 4.25%/dextrose 5%
- Clinimix E 5%/dextrose 15%
- Clinimix E 5%/dextrose 20%
- Clinimix E 5%/dextrose 25%
- Clinimix N14g30e
- Clinimix N9g15e
- Clonidine Hcl INJ
- Cromolyn Sodium NEBU
- Cyclophosphamide CAPS
- Cyclosporine CAPS
- Cyclosporine Modified
- Cytarabine Aqueous
- Deferoxamine Mesylate
- Dobutamine Hcl INJ 250MG/20ML, 500MG/40ML
- Dobutamine Hcl/d5w INJ 5%; 1MG/ML
- Dobutamine Hydrochloride/dextrose
- Dobutamine/dextrose 5% INJ 5%;
   2MG/ML, 5%; 4MG/ML
- Dopamine Hcl
- Dopamine Hydrochloride/dextrose
- Dopamine/d5w INJ 5%; 3.2MG/ML
- Doxorubicin Hcl INJ 10MG, 2MG/ML, 50MG
- Emend SUSR
- Engerix-b
- Fentanyl Citrate INJ 1000MCG/20ML, 100MCG/2ML, 2500MCG/50ML, 250MCG/5ML, 500MCG/10ML
- Floxuridine INJ
- Fluorouracil INJ 1GM/20ML, 2.5GM/50ML, 500MG/10ML, 5GM/100ML
- Freamine Hbc 6.9%

Members Health Insurance Company

Date Effective: November 1, 2018

• Freamine III INJ 89MEQ/L;

710MG/100ML; 950MG/100ML;

3MEQ/L; 24MG/100ML;

1400MG/100ML; 280MG/100ML;

690MG/100ML; 910MG/100ML;

730MG/100ML; 530MG/100ML;

560MG/100ML; 10MMOLE/L;

120MG/100ML; 1120MG/100ML;

590MG/100ML; 10MEQ/L;

400MG/100ML; 150MG/100ML;

660MG/100ML

- Gablofen
- Ganciclovir INJ 500MG, 500MG/10ML
- Gengraf
- Granisetron Hcl TABS
- Hecoria
- Hepagam B
- Hepatamine
- Heplisav-b
- Hyperhep B S/d
- Hyperrab
- Imovax Rabies (h.d.c.v.)
- Intralipid INJ 20GM/100ML
- Ipratropium Bromide INHALATION SOLN 0.02%
- Ipratropium Bromide/albuterol Sulfate
- Levalbuterol NEBU
- Levalbuterol Hcl NEBU
- Lioresal Intrathecal INJ 0.05MG/ML, 2000MCG/ML, 40MG/20ML, 500MCG/ML
- Milrinone In Dextrose INJ 5%; 20MG/100ML, 5%; 40MG/200ML
- Milrinone Lactate INJ 10MG/10ML, 20MG/20ML, 50MG/50ML
- Morphine Sulfate INJ 150MG/30ML, 1MG/ML
- Mycophenolate Mofetil
- Mycophenolic Acid Dr
- Nabi-hb
- Nebupent
- Nephramine

Members Health Insurance Company

Date Effective: November 1, 2018

- Nutrilipid
- Ondansetron Hcl ORAL SOLN
- Ondansetron Hcl TABS
- Ondansetron Odt
- Perforomist
- Premasol
- Procalamine
- Prosol
- Rabavert
- Rapamune SOLN
- Recombivax Hb
- Sandimmune SOLN
- Sirolimus TABS
- Synthamin 17
- Tacrolimus CAPS
- Tobramycin NEBU
- Travasol INJ 52MEQ/L;
- 1760MG/100ML; 880MG/100ML;
  - 34MEO/L; 1760MG/100ML;
  - 372MG/100ML; 406MG/100ML;
  - 526MG/100ML; 492MG/100ML;
  - 492MG/100ML; 526MG/100ML;
  - 356MG/100ML; 356MG/100ML;
  - 390MG/100ML; 34MG/100ML;
  - 152MG/100ML
- Trophamine INJ 97MEQ/L;
  - 0.54GM/100ML; 1.2GM/100ML;
  - 0.32GM/100ML; 0; 0;
  - 0.5GM/100ML; 0.36GM/100ML;
  - 0.48GM/100ML; 0.82GM/100ML;
  - 1.4GM/100ML; 1.2GM/100ML;
  - 0.34GM/100ML; 0.48GM/100ML;
  - 0.68GM/100ML; 0.38GM/100ML;
  - 5MEQ/L; 0.025GM/100ML;
  - 0.42GM/100ML; 0.2GM/100ML;
  - 0.24GM/100ML; 0.78GM/100ML
- Vinblastine Sulfate INJ 1MG/ML
- Vincasar Pfs
- Vincristine Sulfate INJ

#### **Details**

Members Health Insurance Company

Date Effective: November 1, 2018

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

## Prior Authorization Criteria Members Health Insurance Company Date Effective: November 1, 2018

## **INDEX**

$\boldsymbol{A}$	Alunbrig (s)	14
Abelcet	Amabelz	118
Abstral	Ambisome	
Acetylcysteine	Amino Acid	
Actemra 1	Aminosyn	
Actemra IV (s)	Aminosyn 7%/electrolytes	
Actimmune	Aminosyn 8.5%/electrolytes	
Actimmune (s)	Aminosyn II	
Acyclovir Sodium	Aminosyn II 8.5%/electrolytes	358
Adagen	Aminosyn M	
Adagen (s)	Aminosyn-hbc	
Adcirca 4	Aminosyn-pf	
Adcirca (s)	Aminosyn-pf 7%	
Adderall Xr (s)	Aminosyn-rf	359
Adempas 6	Amitriptyline Hcl	
Adempas (s)	Amnesteem	143
Adriamycin	Amoxapine	
Adrucil	Amphetamine/dextroamphetamine	
Afinitor7	Amphotericin B	359
Afinitor (s)	Ampyra	
Afinitor Disperz8	Ampyra (s)	15
Afinitor Disperz (s)	Anadrol-50	
Akynzeo	Anadrol-50 (s)	16
Albuterol Sulfate	Androderm	304
Aldurazyme9	Androgel	304
Aldurazyme (s) 9	Androgel Pump	304
Alecensa	Androxy	17
Alecensa (s)	Androxy (s)	
Aliqopa	Anzemet	359
Aliqopa (s)11	Apokyn	18
Alosetron Hydrochloride	Apokyn (s)	18
Alpha-1 Proteinase Inhibitor, Non-preferred (s). 12	Aprepitant	359
Alpha-1 Proteinase Inhibitor, Prolastin (s) 13	Aralast Np	12
Alprazolam	Aranesp (s)	19
Alprazolam Er	Aranesp Albumin Free	19
Alprazolam Xr	A moolyyat	21
	Arcalyst	
Alunbrig	Arcalyst (s)	

## Members Health Insurance Company

Date l	Effective	November	1 2018

Arzerra	Butalbital/aspirin/caffeine	119
Arzerra (s)	-	
Atropine Sulfate	$\boldsymbol{C}$	
Aubagio	Cabometyx	36
Aubagio (s)23	Cabometyx (s)	36
Auryxia24	Calquence	37
Auryxia (s)	Calquence (s)	37
Austedo	Caprelsa	38
Austedo (s)	Caprelsa (s)	38
Avita309	Carimune Nanofiltered	145
Avonex	Carisoprodol	39
Avonex Pen	Carisoprodol (s)	39
Azasan	Cayston	40
Azathioprine	Cayston (s)	40
•	Cephadyn	119
B	Cerdelga	41
Bavencio	Cerdelga (s)	41
Bavencio (s)	Cerezyme	42
Beleodaq27	Cerezyme (s)	42
Beleodaq (s)27	Chlordiazepoxide Hcl	29
Benlysta28	Chlordiazepoxide/amitriptyline	126
Benlysta (s)	Chlorzoxazone	124
Benzodiazepines (s)	Cholbam	43
Benztropine Mesylate111	Cholbam (s)	43
Berinert	Chorionic Gonadotropin	44
Berinert (s)	Chorionic Gonadotropin (s)	44
Betaseron	Ciclodan	45
Bethkis	Ciclopirox (s)	45
Bexarotene	Ciclopirox Nail Lacquer	45
Bivigam	Cimzia	46
Bleomycin	Cimzia (s)	46
Bleomycin Sulfate	Cimzia Starter Kit	46
Blincyto	Cinryze	48
Blincyto (s)31	Cinryze (s)	48
Bortezomib32	Cladribine	359
Bortezomib (s)	Claravis	143
Bosulif	Climara Pro	118
Bosulif (s)	Clinimix 2.75%/dextrose 5%	359
Botox	Clinimix 4.25%/dextrose 10%	359
Botox (s)	Clinimix 4.25%/dextrose 20%	359
Brovana	Clinimix 4.25%/dextrose 25%	359
Budesonide	Clinimix 4.25%/dextrose 5%	359
Butalbital/acetaminophen119	Clinimix 5%/dextrose 15%	359

## Members Health Insurance Company

Date Effective:	November	1.	2018

Clinimix 5%/dextrose 20%	Dalfampridine Er	15
Clinimix 5%/dextrose 25%	Daliresp	
Clinimix E 2.75%/dextrose 10%	Daliresp (s)	
Clinimix E 2.75%/dextrose 5%	Daraprim	
Clinimix E 4.25%/dextrose 10%	Daraprim (s)	
Clinimix E 4.25%/dextrose 25%	Darzalex	
Clinimix E 4.25%/dextrose 5%	Darzalex (s)	
Clinimix E 5%/dextrose 15%	Decitabine	
Clinimix E 5%/dextrose 20%	Deferasirox (s)	
Clinimix E 5%/dextrose 25%	Deferoxamine Mesylate	
Clinimix N14g30e	Desipramine Hcl	
Clinimix N9g15e	Deschlorpheniramine Maleate	
Clomipramine Hcl	Dexedrine	
Clonidine Hcl	Dexmethylphenidate (s)	
Cometriq	Dexmethylphenidate Hcl	
Cometriq (s)	Dexmethylphenidate Hcl Er	
Copaxone	Dextroamphetamine (s)	
Corlanor	Dextroamphetamine Sulfate	
Corlanor (s)	Dextroamphetamine Sulfate Er	
Cosentyx	Diclofenac Sodium	
Cosentyx (s)		
	Dicyclomine Hel	
Cosentyx Sensoready Pen	Dicyclomine Hydrochloride	
	Digitek Digox	
Cotellic (s)	Digoxin	
	9	
Crinone (s) 53	Diphenatol	
Cromolyn Sodium	Diphenoxylate/atropine	
Cuvitru	Disopyramide Phosphate	
Cyclorhogride 124	Divigel	
Cyclophosphamide	Dobutamine Hcl	
Cyclosporine	Dobutamine Hcl/d5w	
Cyclosporine Modified	Dobutamine Hydrochloride/dextrose	
Cyproheptadine Hcl	Dobutamine/dextrose 5%	
Cyramza	Dopamine Hcl	
Cyramza (s)	Dopamine Hydrochloride/dextrose	
Cystaran	Dopamine/d5w	
Cystaran (s)	Doxepin Hcl	
Cytarabine Aqueous	Doxorubicin Hcl	
D	Dronabinol	
Dacogen (s)	Dupixent	
Daklinza	Dupixent (s)	65
Daklinza (s)		
Dakiniza (s) 3/		

## Prior Authorization Criteria Members Health Insurance Company

Date Effective: November 1, 2018

E	Ezetimibe/simvastatin	329
Elaprase 66	F	
Elaprase (s)	Fabrazyme	82
Elestrin	Fabrazyme (s)	
Emend	Farydak	
Emflaza67	Farydak (s)	
Emflaza (s) 67	Fasenra	
Empliciti	Fasenra (s)	
Empliciti (s)	Fentanyl (s)	
Enbrel	Fentanyl Citrate	
Enbrel (s)	Fentanyl Citrate Oral Transmucosal	
Enbrel Mini69	Fentora	
Enbrel Sureclick	Ferriprox	
Endari	Ferriprox (s)	
Endari (s)	Firazyr	
Engerix-b	Firazyr (s)	
Entyvio71	Firmagon	
Entyvio (s)71	Firmagon (s)	
Epclusa	Flebogamma Dif	
Epclusa (s)	Floxuridine	
Epoetin Alfa (s)73	Fluorouracil	
Epoprostenol (s)		
Epoprostenol Sodium	Folotyn (2)	
Erbitux	Foliation	
Erbitux (s)	Forteo	
Ergoloid Mesylates	Forteo (s)	
Erivedge	Freamine Hbc 6.9%	
Erivedge (s)	Freamine III	
Erleada	Fyavolv	118
Erleada (s)	${\it G}$	
Esbriet	Gablofen	359
Esbriet (s)	Gamastan	
Estazolam	Gamastan S/d	
Estradiol118	Gamastan S/d (s)	
Estradiol/norethindrone Acetate	Gammagard Liquid	
Estropipate118	Gammagard S/d Iga Less Than 1mcg/ml	
Exjade	Gammaked	
Exondys 51 80	Gammaplex	
Exondys 51 (s)	Gamunex-c	
Extavia	Ganciclovir	
Eylea	Gattex	
Eylea (s)	Gattex (s)	
	~~~~~~ \ \ \ / · · · · · · · · · · · · · · · ·	

#### Members Health Insurance Company

Date Effective:	November 1	1 2018

Gazyva	94	Hrm - Antiparkinson Agents	.111
Gazyva (s)	94	Hrm - Antipsychotics	.112
Gengraf	359	Hrm - Antispasmodics	.113
Genotropin	100	Hrm - Cardiovascular, Anti-arrhythmics	.114
Genotropin Miniquick	100	Hrm - Dementia Agents	.115
Gilenya	95	Hrm - Endocrine	.116
Gilenya (s)	95	Hrm - Endocrine, Menest	.117
Gilotrif	96	Hrm - Endocrine, Oral And Transdermal Estro	gens
Gilotrif (s)	96	And Progestins	.118
Glassia	12	Hrm - Pain Medications	.119
Glatiramer Acetate	97	Hrm - Paroxetine	.120
Glatiramer Acetate (s)	97	Hrm - Phenobarbital, Pentobarbital	.121
Glatopa	97	Hrm - Platelet Inhibitors	.122
Gleevec (s)	98	Hrm - Sedative Hypnotic Agents	.123
Glyburide	125	Hrm - Skeletal Muscle Relaxants	.124
Glyburide Micronized	125	Hrm - Sulfonylureas	.125
Glyburide/metformin Hcl	125	Hrm - Tca	.126
Gocovri	99	Humira	.127
Gocovri (s)	99	Humira (s)	.127
Granisetron Hcl	359	Humira Pediatric Crohns Disease Starter Pack.	.127
Growth Hormone (s)	100	Humira Pen	.127
Guanfacine Hcl	110	Humira Pen-cd/uc/hs Starter	.127
H		Humira Pen-ps/uv Starter	.127
		Hydroxyprogesterone (s)	.129
H.p. Acthar		Hydroxyprogesterone Caproate129,	
H.p. Acthar Gel (s)		Hydroxyzine Hcl	
Haegarda		Hydroxyzine Hydrochloride	.109
Haegarda (s)	104	Hydroxyzine Pamoate	
Halaven	105	Hyperhep B S/d	.360
Halaven (s)	105	Hyperrab	.360
Harvoni	106	Hyqvia	.267
Harvoni (s)	106	I	
Hecoria	360	1	
Hepagam B	360	Ibrance	.130
Hepatamine	360	Ibrance (s)	.130
Heplisav-b	360	Iclusig	.131
Herceptin	107	Iclusig (s)	.131
Herceptin (s)	107	Idhifa	.132
Hetlioz	108	Idhifa (s)	.132
Hetlioz (s)	108	Ilaris	.133
Hizentra	267	Ilaris (s)	.133
Hrm - Antihistamines	109	Imatinib Mesylate	98
Hrm - Antihypertensive Agents	110	Imbruvica	.134

#### Prior Authorization Criteria Members Health Insurance Company Date Effective: November 1, 2018 K Kadcyla .......152 Kadcyla (s)......152 Imipramine Hydrochloride......126 Increlex 136 Indomethacin......119 Ketorolac Tromethamine ......119 Keveyis ......156 Keytruda......158 Intralipid......360 Kineret (s) ......160 Intron A W/diluent ...... 141 Kisqali ......161 Kisqali (s)......161 Ipratropium Bromide/albuterol Sulfate ............ 360 Kisqali Femara 200 Dose......162 Kisqali Femara 400 Dose......162 Kisqali Femara 600 Dose......162 Kisqali-femara Pack (s)......162 Korlym ......163 Korlym (s)......163 Istodax (overfill)......144 Krystexxa......164 Krystexxa (s)......164 Kuvan (s)......165 J Kynamro ......166 Kynamro (s) .......166 Jadenu 62 Kyprolis......168 Jadenu Sprinkle ...... 62 Kyprolis (s) ......168 $\boldsymbol{L}$ Jevantique Lo ...... 118

#### Prior Authorization Criteria Members Health Insurance Company Date Effective: November 1, 2018 Lenvima 10 Mg Daily Dose......171 Lenvima 12mg Daily Dose ...... 171 Lenvima 14 Mg Daily Dose ...... 171 Marten-tab......119 Lenvima 18 Mg Daily Dose ...... 171 Lenvima 20 Mg Daily Dose ...... 171 Mavyret (s)......187 Lenvima 24 Mg Daily Dose ...... 171 Megestrol Acetate ......116 Lenvima 4 Mg Daily Dose ...... 171 Lenvima 8 Mg Daily Dose ...... 171 Metadate Er......189 Methotrexate Injection (s)......190 Methyldopa ......110 Methyldopa/hydrochlorothiazide......110 Methylin Chew (s) ......191 Lioresal Intrathecal 360 Methylphenidate (s) .......192 Methylphenidate Er (s) ......193 Methylphenidate Hcl Sr.....189 Methylphenidate Hydrochloride ......191, 192 Methylphenidate Hydrochloride CD......193 Lorazepam......29 Methylphenidate Hydrochloride Er ......189, 193 Methylphenidate Hydrochloride Er (la)......193 Miglustat .......348 Milrinone In Dextrose......360 Lupaneta Pack ...... 179 Milrinone Lactate......360 Mimvey......118 Mimvey Lo......118 Lupron Depot (4-month) ...... 181 Mitoxantrone Hcl......207 Modafinil.....241 Lupron Depot (s) ...... 181 Morphine Sulfate ......360 Mozobil......195 Ms Inteferons (s)......196 Myalept ......197 Myalept (s)......197

## M

Makena
--------

Lynparza Tablet (s) ...... 184

Mycophenolate Mofetil......360

Mycophenolic Acid Dr ......360

Mylotarg (s) .......198

#### Members Health Insurance Company Date Effective: November 1, 2018 0 Myozyme......178 N Ocaliva (s).......213 Ocrevus (s)......214 Naglazyme (s) ...... 199 Octreotide Acetate ......265 Odomzo......216 Odomzo (s)......216 Ofev......217 Nephramine ...... 360 Ofev (s) ......217 Olysio......219 Olysio (s)......219 Ondansetron Hcl ......360 Ondansetron Odt ......360 Onmel (s) .......220 Opdivo......221 Opdivo (s) ......221 Norethindrone Acetate/ethinyl Estradiol........... 118 Norpace Cr ...... 114 Opsumit (s).......223 Orencia Clickject ......225 Nortriptyline Hcl ...... 126 Orencia IV (s) .......224 Orencia Sc (s).......225 Novarel .......44 Orenitram (s).......226 Oxandrolone......229 Nuplazid (s)......212 P Nutropin Aq Nuspin 10...... 100 Nutropin Aq Nuspin 20...... 100 Paroxetine Hcl Er ......120 Part B Versus Part D ......358 Nutropin Aq Pen......100 Pegasys......230

Prior Authorization Criteria

#### Prior Authorization Criteria Members Health Insurance Company Date Effective: November 1, 2018 Pulmozyme ......243 Pulmozyme (s) ......243 $\boldsymbol{\varrho}$ Peg-intron Redipen......231 Qualaquin (s)......244 Peg-intron Redipen Pak 4......231 Quinine Sulfate ......244 R Perjeta......233 Radicava......245 Perphenazine/amitriptyline......126 Rapamune .......360 Phenadoz ...... 109 Phenergan ...... 109 Phenobarbital......121 Ravicti (s)......246 Rebif Rebidose 196 Rebif Titration Pack......196 Recombivax Hb ......360 Relistor (s)......247 Pregnyl W/diluent Benzyl Alcohol/nacl ...... 44 Remicade......249 Premasol 360 Remodulin......251 Premphase ...... 118 Renflexis (s)......252 Repatha ......254 Repatha (s) ......254 Repatha Pushtronex System.....254 Repatha Sureclick ......254 Revlimid......257 Revlimid (s) ......257 Promethazine Hcl Plain......109 Promethazine Hydrochloride......109

Formulary ID 18351, Version 15

#### Prior Authorization Criteria Members Health Insurance Company Date Effective: November 1, 2018 Sprycel (s) .......280 Stelara (iv) (s) .......281 Rubraca 261 Stivarga (s)......282 Supprelin La......284 Supprelin La (s)......284 S Sutent .......285 Sylatron (s)......286 Sylvant ......287 Sylvant (s) .......287 Symdeko (s) .......288 Symlin (s)......289 Symlinpen 120 .......289 Synagis (s)......290 Syndros .......292 Synribo......293 Synribo (s)......293 Synthamin 17 ......360 T Tadalafil ......4 Tafinlar......294 Tagrisso (s)......295 Tarceva......297 Sovaldi......277 Tarceva (s) ......297 Targretin (s) .......298

Tasigna (s)......299

#### Members Health Insurance Company

Date Effective:	November	1	2010
Date Effective:	November		201X

Formulary ID 18351, Version 15

Tavalisse300	Tymlos (s)	313
Tavalisse (s)	Tysabri	314
Tecentriq301	Tysabri (s)	314
Tecentriq (s)	Tyvaso	316
Tecfidera302	Tyvaso (s)	316
Tecfidera (s)	Tyvaso Refill	316
Tecfidera Starter Pack 302	Tyvaso Starter	316
Technivie	$oldsymbol{U}$	
Technivie (s)		
Temazepam29	Uptravi	
Tencon119	Uptravi (s)	317
Testosterone	V	
Testosterone (s)	37 1 1 1	210
Testosterone Cypionate	Valchlor	
Testosterone Enanthate	Valchlor (s)	
Testosterone Enanthate (s)	Vanatol Lq	
Testosterone Pump	Varizig	
Testosterone Topical Solution	Varizig (s)	
Tetrabenazine	Velcade	
Thalomid	Velcade (s)	
Thalomid (s)	Veletri	
Thioridazine Hcl112	Venclexta	
Thyrogen	Venclexta (s)	
Thyrogen (s)	Venclexta Starting Pack	
Ticlopidine Hcl	Ventavis	
Tobramycin	Ventavis (s)	
Topical Retinoid (s)	Verzenio	
Transderm-scop	Verzenio (s)	
Travasol	Viekira (s)	
Trelstar	Viekira Pak	
Trelstar (s)	Viekira Xr	
Trelstar Mixject	Vigabatrin	
Tremfya	Vigadrone	
Tremfya (s)	Vimizim	
Tretinoin	Vimizim (s)	
Tretinoin Microsphere	Vinblastine Sulfate	
Tretinoin Microsphere Pump	Vincasar Pfs	
Trihexyphenidyl Hcl111	Vincristine Sulfate	
Trimipramine Maleate	Vosevi	
Trophamine	Vosevi (s)	
Tykerb	Votrient	
Tykerb (s)	Votrient (s)	
Tymlos	Vpriv	328
· -		

399

#### Prior Authorization Criteria Members Health Insurance Company Date Effective: November 1, 2018 Yervoy (s) ......345 Vpriv (s) ...... 328 $\boldsymbol{Z}$ X Zaltrap......347 Zaltrap (s)......347 Zejula ......349 Zejula (s) .......349 Zelboraf......350 Zenatane......143 Zepatier (s)......351 Zolinza (s)......352 Zolpidem Tartrate ......123 Zolpidem Tartrate Er.....123 Zorbtive......353 Zorbtive (s).......353 Xuriden......343 Zydelig......355 Zydelig (s)......355 Zykadia ......356 Zytiga......357 Y

Zytiga (s)......357