

ACTEMRA

- **Products Affected**
 - Actemra 162 Mg/0.9 Ml Syringe
- Actemra Actpen

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started in tocilizumab (IV/SC) for a Covered Use.
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	The diagnosis is moderate to severe rheumatoid arthritis and the disease must be active. For Juvenile Idiopathic Arthritis, the member must have a confirmed diagnosis of Juvenile Idiopathic Arthritis and the disease must be active.
Age Restriction	N/A
Prescriber Restriction	Prescribed by or in consultation with a Rheumatologist.
Coverage Duration	Lifetime.

Other Criteria

For Rheumatoid Arthritis, approve if the patient has tried TWO of the following: Enbrel, Humira, Orencia (IV/SC), or Xeljanz/XR (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: Cimzia, infliximab, golimumab SC/IV) OR if, according to the prescribing physician, the patient has heart failure or a previously treated lymphoproliferative disorder. For Juvenile Idiopathic Arthritis, must have tried and failed methotrexate for at least two months OR if the member has an absolute contraindication to methotrexate, then Actemra will be approved. For Giant Cell Arteritis, the member must have tried and had an inadequate response to methotrexate or a glucocorticoid OR the member has an absolute contraindication to methotrexate or glucocorticoid therapy, then Actemra will be approved.

ACTHAR

• **Products Affected**

• **Acthar**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	MS exacerbation, history of corticosteroid use.
Age Restriction	Infantile spasms-less than 2yo. Acute MS exac-adult.
Prescriber Restriction	Infantile spasms, prescribed by or in consultation with a neurologist or an epileptologist. MS exacerbation, prescribed by or in consultation with a neurologist or physician that specializes in the treatment of MS.
Coverage Duration	Infantile spasms, 1 month. MS exacerbation, approve 1 month.
Other Criteria	For acute MS exacerbation, approve if the patient cannot use high-dose IV corticosteroids because IV access is not possible or if the patient has tried high-dose corticosteroids administered IV for an acute MS exacerbation and has experienced a severe or limiting adverse effect AND is NOT being used as pulse therapy on a monthly basis. Coverage is not provided for diagnostic procedure.

ADEMPAS

- **Products Affected**

- **Adempas**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	PAH and CTEPH-must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	3 years
Other Criteria	For PAH-must have PAH (WHO Group 1) and had a right heart catheterization to confirm the diagnosis of PAH (WHO Group 1). Right heart catheterization is not required in pts who are currently receiving Adempas or another agent indicated for WHO group 1.

AFINITOR

- **Products Affected**
- Afinitor
- Afinitor Disperz

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already taking Afinitor for a Covered Use. Advanced, unresectable neuroendocrine tumors. Perivascular Epithelioid Cell Tumors (PEComa), Recurrent Angiomyolipoma, Lymphangioleiomyomatosis, relapsed or refractory classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL).
Exclusion Criteria	N/A
Required Medical Information	Breast Cancer-HER2 status, hormone receptor (HR) status.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.

Other Criteria

Advanced HER2-negative breast cancer, approve if the patient is postmenopausal and has HR+ disease and Afinitor will be used in combination with exemestane or tamoxifen and the patient has tried letrozole or anastrozole. Renal cell carcinoma (RCC), approve if patient meets one of the following: 1) patient has advanced RCC with predominant clear cell histology AND the patient has tried Inlyta, Votrient, Sutent, or Nexavar OR 2) patient has relapsed or medically unresectable RCC with non-clear cell histology. Tuberous sclerosis complex (TSC) for the treatment of subependymal giant cell astrocytoma (SEGA), approve if the patient requires therapeutic intervention but cannot be curatively resected. NET-approve. Renal angiomyolipoma with TSC-approve. WM/LPL - approve if 1. patient has progressive or relapsed disease OR 2. patient has not responded to primary therapy (e.g., Velcade+/- Rituxan, Velcade with dexamethasone +/-Rituxan, Kyprolis with Rituxan and dexamethasone, cyclophosp/doxorubicin/vincristine/pred/Rituxan, Imbruvica, Rituxan, Rituxan with cyclophosphamide and dexamethasone, Thalomid+/- Rituxan). Osteosarcoma, approve if the patient has tried standard chemotherapy for osteosarcoma AND the patient has relapsed/refractory or has metastatic disease. Thymomas and Thymic Carcinomas, approve if the patient has tried chemotherapy. Tuberous sclerosis complex (TSC)-associated partial-onset seizures-approve.

- **Products Affected**
- Aimovig Autoinjector
- Aimovig Autoinjector (2 Pack)

PA Criteria	Criteria Details
Covered Uses	All FDA approved indication not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried.
Age Restriction	18 years of age and older
Prescriber Restriction	Prescribed by or in consultation with a neurologist or a headache specialist.
Coverage Duration	Initial: 3 months. Continuation: 12 months.
Other Criteria	For Initial approval: Trial of 2 different drug classes prior to Aimovig approval for minimum of 2 months each. Drug classes include: Beta blockers (ex. Metoprolol, Propranolol, and Timolol), Antidepressants (ex. Amitriptyline, Nortriptyline, and Venlafaxine), Anticonvulsants (ex. Valproate and Topiramate), and Calcium Channel Blockers (ex. Verapamil). Other Criteria for Initial Approval: The member must have a diagnosis of migraine, as indicated by 4 or more attacks per month, for 3 or more months in a row, that include BOTH of the following: Headache Symptoms (as indicated by 2 or more of the following: unilateral location and/or pulsating quality and/or moderate to severe pain intensity and/or aggravation by or causing avoidance of routine physical activity) AND Associated Symptoms (as indicated by 1 or more of the following: Nausea/vomiting and/or photophobia). Criteria for continuation approval: Prescriber confirms that the member demonstrates improvement after a 3 month trial of Aimovig.

ALECENSA

- **Products Affected**

- **Alecensa**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Must have metastatic NSCLC that is anaplastic lymphoma kinase (ALK)-positive.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	N/A

ALUNBRIG

- **Products Affected**

- Alunbrig

PA Criteria	Criteria Details
Covered Uses	An FDA approved indication not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Indefinite
Other Criteria	N/A

AMPYRA

- **Products Affected**
- Dalfampridine Er
- Ampyra

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The member has sustained walking impairment AND the member is able to walk.
Age Restriction	N/A
Prescriber Restriction	Neurologist.
Coverage Duration	Initial: 3 months. Continuation: 3 years
Other Criteria	For continuation, authorization may be granted to members with multiple sclerosis for improvement in walking if the member has experienced an improvement in walking speed OR another objective measure of walking ability since starting Ampyra.

ANABOLIC STEROIDS

- **Products Affected**
- Oxandrolone 10 Mg Tablet
- Anadrol-50
- Oxandrolone 2.5 Mg Tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Members with Turner's Syndrome or Ullrich-Turner Syndrome (oxandrolone only), management of protein catabolism w/burns or burn injury (oxandrolone only), AIDS wasting and cachexia.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	One year.
Other Criteria	N/A

ARANESP

- **Products Affected**
- Aranesp 100 Mcg/0.5 MI Syringe
- Aranesp 150 Mcg/0.3 MI Syringe
- Aranesp 200 Mcg/ml Vial
- Aranesp 25 Mcg/ml Vial
- Aranesp 300 Mcg/ml Vial
- Aranesp 40 Mcg/ml Vial
- Aranesp 60 Mcg/0.3 MI Syringe
- Aranesp 10 Mcg/0.4 MI Syringe
- Aranesp 100 Mcg/ml Vial
- Aranesp 200 Mcg/0.4 MI Syringe
- Aranesp 25 Mcg/0.42 MI Syringe
- Aranesp 300 Mcg/0.6 MI Syringe
- Aranesp 40 Mcg/0.4 MI Syringe
- Aranesp 500 Mcg/1 MI Syringe
- Aranesp 60 Mcg/ml Vial

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D worded as Anemia associated with Chronic Renal Failure, including patients on dialysis and not on dialysis. Anemia due to the effects of chemotherapy in Nonmyeloid Malignancy. Anemia related to Multiple Myeloma. Refractory Anemia related to Myelodysplastic Syndrome.
Exclusion Criteria	Refractory anemia related to Myelodysplastic Syndrome must be an EPO insufficiency that cannot be assigned to a specific vitamin or mineral deficiency. Uncontrolled hypertension. Anemic patients willing to donate autologous blood. Anemia due to factors other than diagnoses noted (iron or folate deficiency, hemolysis, GI bleeding). Patients receiving hormonal agents, therapeutic biological products, or radiotherapy UNLESS also receiving concomitant myelosuppressive chemotherapy. For immediate anemia correction or as a substitute for emergency transfusion. Prophylactic use to prevent chemotherapy included anemia.

Required Medical Information	Chronic renal failure patients not on dialysis must have symptomatic anemia with a HGB of 10g/dl or less. Non myeloid malignancy chemotherapy induced anemia must have HCT of 30% or less or HGB of 10g/dl or less in past 30 days. Multiple myeloma anemia must have HCT of 30% or less or HGB of 10g/dl or less in past 30 days. For Myelodysplastic Syndrome refractory anemia diagnosis must include excess blasts, or excess blasts in transformation to leukemia when, for medical reasons, the patient is not a candidate for active treatment of active leukemia. For Myelodysplastic Syndrome the patient must have a HCT of less than 30% or HGB of less than 10g/dl, and endogenous EPO serum level less than 500mu/ml.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	For non myeloid malignancy anemia related to chemotherapy, the member must have received chemotherapy in past 8 weeks and will be receiving chemo for a minimum of 2 months. Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition.

ARCALYST

- **Products Affected**

- Arcalyst

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	12 years or greater.
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	Must be up to date and have received all recommended vaccines, or must receive all recommended vaccinations prior to initiation of therapy.

AUBAGIO

- **Products Affected**

- Aubagio

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	MS, patient must have a relapsing form of MS (RRMS, SPMS with relapses, or PRMS).
Age Restriction	N/A
Prescriber Restriction	Prescribed by or in consultation with a neurologist or MS specialist.
Coverage Duration	Lifetime.
Other Criteria	N/A

AUSTEDO

• **Products Affected**

• **Austedo**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Impaired hepatic function, Concomitant use of monoamine oxidase inhibitors (minimum of 14 days should elapse after stopping MAOI and before starting Austedo), Concomitant use of reserpine (minimum of 20 days should elapse after stopping reserpine and before starting Austedo), Concomitant use of tetrabenazine, Current suicidality, Untreated or inadequately-treated depression, Non-Huntington's Disease related Chorea
Required Medical Information	Patient has a diagnosis of tardive dyskinesia or chorea (involuntary movements) associated with Huntington's Disease.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

BALVERSA

- **Products Affected**

- **Balversa**

PA Criteria	Criteria Details
Covered Uses	Any FDA-approved indications not otherwise excluded from Part D. Plus patients currently receiving Balversa for a covered use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies, test results.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	3 years
Other Criteria	Urothelial carcinoma, locally advanced or metastatic: Approve if the patient has susceptible fibroblast growth factor receptor 3 or fibroblast growth factor receptor 2 genetic alterations AND the patient has progressed during or following prior platinum-containing chemotherapy.

BOSULIF

• **Products Affected**

• **Bosulif**

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Bosulif for a Covered Use. Plus patients with Philadelphia chromosome positive Chronic Myelogenous Leukemia (CML). Plus patients with Acute Lymphoblastic Leukemia (ALL) that is Philadelphia chromosome positive.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. For CML, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For CML, prior therapies tried.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	For acute lymphoblastic leukemia (ALL) that is Philadelphia chromosome positive, patient has tried ONE other tyrosine kinase inhibitor.

BRAFTOVI

- **Products Affected**

- Braftovi 75 Mg Capsule

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients with colon or rectal cancer. Plus patients already started on Braftovi for a covered use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRAF V600 status, concomitant medications
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	3 years
Other Criteria	Approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation AND will be used in combination with Mektovi. Colon or Rectal cancer-approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer.

CABLIVI

- **Products Affected**

- Cablivi 11 Mg Kit

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, concurrent medications
Age Restriction	18 years and older
Prescriber Restriction	Prescribed by or in consultation with a hematologist
Coverage Duration	3 months
Other Criteria	For acquired thrombotic thrombocytopenic purpura (aTTP): Approve if the patient is currently receiving at least one immunosuppressant therapy.

CABOMETYX

- **Products Affected**

- Cabometyx

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The member must have Renal Cell Carcinoma with predominant clear cell or non-clear cell histology. Hepatocellular Carcinoma-approve if the patient has been previously treated with at least one other systemic therapy (e.g., Nexavar, Lenvima).
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

CALQUENCE

- **Products Affected**

- Calquence

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Previous medications/therapies tried.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	3 years
Other Criteria	Mantle cell lymphoma - approve if the patient has tried one other therapy

CGRP INHIBITORS

- **Products Affected**
 - Emgality Pen
- Ajovy
 - Emgality Syringe

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried.
Age Restriction	18 years of age and older.
Prescriber Restriction	Prescribed by or in consultation with a neurologist or a headache specialist.
Coverage Duration	Migraine prevention: Initial 3 months. Continuation 12 months. Cluster headache (Emgality) 6 months.

Other Criteria

For migraine prevention:

For initiation of therapy:

Adequate trial of 2 different drug classes prior to approval. Drug classes include: Beta blockers (ex. Metoprolol, Propranolol, Timolol), Antidepressants (ex. Amitriptyline, Nortriptyline, and Venlafaxine), Anticonvulsants (ex. Valproate and Topiramate), and Calcium Channel Blockers (ex. Verapamil).

AND

The member must have a diagnosis of migraine, as indicated by 4 or more attacks per month, for 3 or more months in a row, that include BOTH of the following: Headache symptoms (as indicated by 2 or more of the following: unilateral location and/or pulsating quality and/or moderate to severe pain intensity and/or aggravation by or causing avoidance of routine physical activity) AND associated symptoms (as indicated by 1 or more of the following: Nausea/vomiting and/or photophobia and phonophobia).

For continuation of therapy: Prescriber confirms that the member demonstrates improvement after a 3-month trial.

For episodic cluster headache treatment (Emgality only):

Approve if the patient has between one headache every other day and eight headaches per day.

CIALIS

- **Products Affected**
- Cialis 5 Mg Tablet
- Tadalafil 5 Mg Tablet
- Cialis 2.5 Mg Tablet
- Tadalafil 2.5 Mg Tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Erectile Dysfunction. Concomitant use of nitrates.
Required Medical Information	The member must have a diagnosis of benign prostatic hyperplasia.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Initial duration 3 months. If BPH symptoms improve (AUA-SI score decrease), approve for 1 year.
Other Criteria	The daily dose is prescribed as 2.5 mg or 5 mg once daily. The member must have symptoms of at least moderate severity that are bothersome, as defined by the American Urological Association Symptom Index (AUA-SI) greater than or equal to 8. Must have tried and failed or be intolerant of or contraindicated to two other drugs, one each from any two of the following different therapeutic classes: Alpha-1 adrenergic blockers (terazosin, doxazosin, tamsulosin, alfuzosin, silodosin) tried for a minimum of one month at the maximum tolerated dose, 5-alpha reductase inhibitors (finasteride, dutasteride) tried for a minimum of four months at the maximum tolerated dose, combination alpha-1 adrenergic blocker/5-alpha reductase inhibitors (dutasteride/tamsulosin) tried for a minimum of four months at the maximum tolerated dose.

- Products Affected - Cimzia	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. •Plus patients already started on certolizumab pegol for a Covered Use.
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	For Rheumatoid Arthritis, the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis and the disease must be active. For Crohn's Disease, the member must have a confirmed diagnosis of moderate to severe Crohn's Disease. For Anklyosing Spondylitis, the member must have a confirmed diagnosis of Ankylosing Spondylitis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc...) and an expert opinion based on clinical features, acute phase reactants and imaging modalities. For Psoriatic Arthritis, the member must have a confirmed diagnosis of Psoriatic Arthritis. For Plaque Psoriasis (PP), the member has a confirmed diagnosis of moderate to severe plaque psoriasis (defined as a minimum body surface area involvement of greater than or equal to 5% or by involvement of the hands, facial, or genital regions, by which despite involvement of a small BSA, the disease may interfere significantly with activities of daily life).
Age Restriction	N/A
Prescriber Restriction	RA/AS-prescribed by or in consultation with a rheumatologist. CD-prescribed by or in consultation with a gastroenterologist or a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. PP-prescribed by or in consultation with a dermatologist.

Coverage Duration	For AS 12wk initial, w/pos response then 3 years. Other approved indications, 3 years.
Other Criteria	For RA, approve if the patient has tried two of the following: Enbrel, Humira, Orencia, or Xeljanz/XR. For AS, approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx. For PsA, approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx, Stelara, Otezla, Orencia or Xeljanz/XR. For CD, approve if patient has previously tried Humira. For PP, approve if the patient has tried TWO of the following: Enbrel, Humira, Stelara SC, Otezla, or Cosentyx. Must be up to date and received all recommended vaccines, or must receive all recommended vaccines prior to initiation of therapy.

• **Products Affected**

• Cinryze

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Hereditary Angiodema: Abdominal, facial or laryngeal attacks. Hereditary Angiodema Prophylaxis.
Exclusion Criteria	N/A
Required Medical Information	Confirmation of diagnosis of hereditary or acquired angioedema based on laboratory verification of C1 inhibitor deficiency.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Longterm prpylxs 1 yr. Shortterm prpylxs suffcent duraton to cvr event per MD. Trtmt acute attack 1x.
Other Criteria	Long term prophylaxis requires that the member must have previously tried and failed or be intolerant of or contraindicated to one of the following: danazol, oxandrolone, Amicar (aminocaproic acid), or Cyklokapron (tranexamic acid) AND either of the following: The member has 2 or more episodes of angioedema per month OR the member's attack location occurs in body sites associated with a high risk of mortality (e.g. laryngeal). Short term prophylaxis requires one of the following instances occur: prior to minor manipulations (i.e. mild dental procedures) or prior to intubation or major procedures. Acute attacks require that airway involvement is suspected.

COPIKTRA

- **Products Affected**

- Copiktra

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Copiktra for a covered use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	3 years
Other Criteria	Chronic lymphocytic leukemia (CLL)/Follicular Lymphoma/small lymphocytic lymphoma (SLL)- approve if the patient has tried two prior therapies.

COSENTYX

- **Products Affected**
- Cosentyx Pen
- Cosentyx Syringe
- Cosentyx (2 Syringes)
- Cosentyx Pen (2 Pens)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already taking Cosentyx for a Covered Use.
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)
Required Medical Information	For Plaque Psoriasis, the member must have a confirmed diagnosis of moderate to severe Plaque Psoriasis, and defined as a minimum body surface area involvement of greater than or equal to 5%, or by involvement of the hands, feet, facial, or genital regions, by which, despite involvement of a smaller BSA, the disease may interfere significantly with activities of daily life. For Psoriatic Arthritis, the member must have a confirmed diagnosis of active Psoriatic Arthritis. For Ankylosing Spondylitis, the member must have a confirmed diagnosis of Ankylosing Spondylitis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc...) and an expert opinion based on clinical features, acute phase reactants and imaging modalities.
Age Restriction	N/A
Prescriber Restriction	PP-prescribed by or in consultation with a dermatologist. AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist.
Coverage Duration	For AS 12wk initial, w/pos response then 3 years. Other approved indications, 3 years.

Other Criteria

For Plaque Psoriasis, approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to “step back” and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. For axial forms of Psoriatic Arthritis, Cosentyx will be approved. For non axial forms of Ankylosing Spondylitis, the member must first try and fail any two of the following conventional therapies over a three month period: NSAIDs, intraarticular steroids, methotrexate, other DMARD agents.

COTELLIC

• **Products Affected**

• Cotellic

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus, patients with melanoma already started on cobimetinib prior to joining health plan in the absence of confirmed BRAF V600E or V600K mutation status.
Exclusion Criteria	Patients with melanoma with wild-type BRAF (i.e., no detected BRAF V600E or V600K mutation). Patients with melanoma initiating therapy with cobimetinib whose BRAF V600E and V600K status is unknown.
Required Medical Information	For patients new to therapy, BRAF V600E or V600K status required. Members already started on therapy prior to joining health plan with unconfirmed BRAF status must confirm BRAF V600E or V600K status to continue.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	BRAFV600E/V600K confrmd, Lifetime. If cont. use from prior to joining plan and BRAF unknown, 1mo.
Other Criteria	Patients new to therapy must have BRAF V600E or V600K mutation. Patients continuing therapy from prior to joining health plan already started on therapy must confirm BRAF V600E or V600K to continue treatment. Melanoma - being prescribed in combination with Zelboraf.

CRINONE GEL

- **Products Affected**

- **Crinone**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus, secondary amenorrhea, support of an established pregnancy.
Exclusion Criteria	Use in patients to supplement or replace progesterone in the management of infertility.
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Secondary amenorrhea, 12 months. Support of an established pregnancy, 9 months.
Other Criteria	N/A

DAURISMO

- **Products Affected**

- **Daurismo**

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, concomitant therapies, previous therapies
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	3 years
Other Criteria	N/A

DICLOFENAC

- **Products Affected**

- **Diclofenac Sodium 3% Gel**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	1 year
Other Criteria	N/A

DIFICID

- **Products Affected**

- **Dificid**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Ten days.
Other Criteria	Must first try and fail or have recurrence of disease after two courses of either metronidazole or vancomycin in the past 90 days, with at least one course of treatment being vancomycin. If members are allergic to both vancomycin and metronidazole, Dificid will be approved. If members are continuing therapy started during a hospitalization, Dificid will be approved.

DOXEPIN TOPICAL

- **Products Affected**
- Prudoxin
- Doxepin 5% Cream

PA Criteria	Criteria Details
Covered Uses	All FDA approved indication not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of moderate pruritus. Patient has atopic dermatitis or lichen simplex chronicus.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	1 month
Other Criteria	The patient had an inadequate response, contraindication, or intolerance to at least one medium potency topical corticosteroid, or is not a candidate for topical corticosteroids (e.g., treatment is on face, axilla, or groin).

DUPIXENT

• **Products Affected**

• **Dupixent**

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty, other medications tried and length of trials.
Age Restriction	For atopic dermatitis, 12 years of age or older. For asthma, 12 years of age or older. For chronic rhinosinusitis with nasal polyposis, 18 years of age or older.
Prescriber Restriction	For Atopic Dermatitis: The medication must be prescribed by or in consultation with an allergist, immunologist, or dermatologist. For Asthma, the medication is prescribed by or in consultation with an allergist, pulmonologist, or immunologist. For rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist.
Coverage Duration	Asthma/Rhinosinusitis initial-6 months, AD-1 year, Asthma cont-3 years

Other Criteria

For Atopic Dermatitis: The member must meet all of the following indication specific requirements (A, B, and C): A. Patient has chronic atopic dermatitis (AND), B. Patient has atopic dermatitis involvement estimated to be greater than or equal to 10% of the body surface area (BSA) according to the prescribing physician. If the patient's atopic dermatitis involvement is estimated to be greater than 20%, topical treatment is not required as prerequisite (AND), C. Patient meets all of the following (1 and 2): 1. Patient has tried tacrolimus ointment (0.03% or 0.1%) within 6 months of the initial trial of dupilumab, 2. Patient meets both the following (a and b): a. The patient has tried at least one of the following systemic agents: oral corticosteroid, intramuscular corticosteroid, oral cyclosporine, oral azathioprine, oral methotrexate, or oral mycophenolate mofetil (AND) b. Inadequate efficacy was demonstrated with systemic therapy, according to the prescribing physician. For asthma: the patient must meet the following indication specific requirements (A, B, C, and D): A. Patient has moderate to severe asthma, eosinophilic phenotype or oral corticosteroid-dependent AND B. For eosinophilic phenotype, the member must have a peripheral blood eosinophil count greater than or equal to 150 cells per microliter, within the previous 6 weeks (prior to treatment with Dupixent) AND C. For Initial therapy (a. and b.): a. The member must have received at least 3 consecutive months of combination therapy with an oral corticosteroid or inhaled corticosteroid AND one of the following: inhaled long acting beta agonist, inhaled long acting muscarinic antagonist, leukotriene receptor antagonist, or theophylline. AND b. The patient's asthma continues to be uncontrolled as defined by one of the following: Experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, Experienced one or more asthma exacerbations requiring hospitalization or treatment in an emergency department in the previous year, Patient has a FEV1 less than 80 percent predicted, Patient has FEV1/FVC less than 0.80, or Patient's asthma worsens upon tapering of oral corticosteroid therapy. AND D. For Continuation therapy: The member meets the following criteria, then therapy will be continued indefinitely: The patient has responded to Dupixent therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations,

decreased asthma symptoms, decreased hospitalizations/emergency department/urgent care/physician visits due to the asthma, decreased requirement for oral corticosteroid therapy), AND The patient continues to receive therapy with an oral or inhaled corticosteroid. Chronic rhinosinusitis with Nasal Polyposis-Initial-patient is currently receiving therapy with an intranasal corticosteroid AND is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell

EGRIFTA

• **Products Affected**

• **Egrifta**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis is HIV-associated lipodystrophy. Egrifta is prescribed for the reduction of excess abdominal fat. Patient is HIV-infected.
Age Restriction	Adults, 18 years of age and older.
Prescriber Restriction	Prescribed by or in consultation with an endocrinologist or a physician specializing in the treatment of HIV (eg, infectious disease, oncology).
Coverage Duration	Authorization will be for 12 months.
Other Criteria	N/A

EMFLAZA

• **Products Affected**

• **Emflaza**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	The patient meets ONE of the following conditions ([i] or [ii]): i. The patient has tried a corticosteroid (parenteral or oral) for greater than or equal to 3 months AND according to the prescribing physician, the patient has had at least one significant intolerable adverse effect(AE). ii. According to the prescribing physician, the patient has experienced a severe behavioral AE while on corticosteroid (parenteral/oral) therapy that has or would require a corticosteroid (parenteral/oral) dose reduction.
Age Restriction	Patient is greater than or equal to 5 years of age.
Prescriber Restriction	Prescribed by or in consultation with physician who specializes in the treatment of Duchenne muscular dystrophy (DMD) and/or neuromuscular disorders.
Coverage Duration	1 year
Other Criteria	N/A

ENBREL

- **Products Affected**
- Enbrel
- Enbrel Mini
- Enbrel Sureclick

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patient already on etanercept for a Covered Use. Plus Graft versus host disease, Behcet's disease, and Uveitis.
Exclusion Criteria	Concurrent use with biologic therapy or targeted synthetic DMARD.
Required Medical Information	For Rheumatoid Arthritis the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis and the disease must be active. For Ankylosing Spondylitis, the member must have a confirmed diagnosis of Ankylosing Spondylitis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc...) and an expert opinion based on clinical features, acute phase reactants and imaging modalities. For Psoriatic Arthritis, the member must have a confirmed diagnosis of Psoriatic Arthritis. For Plaque Psoriasis, the member must have a confirmed diagnosis of chronic and moderate to severe Plaque Psoriasis, and defined as a minimum body surface area involvement of greater than or equal to 5%, or by involvement of the hands, feet, facial, or genital regions, by which, despite involvement of a smaller BSA, the disease may interfere significantly with activities of daily life.
Age Restriction	N/A

Prescriber Restriction	RA/AS/JIA/JRA prescribed by or in consult w/ a rheumatologist. PsA, prescribed by or in consult w/ a rheumatologist or a dermatologist. PP, prescribed by or in consult w/ a dermatologist or rheumatologist. GVHD, prescribed by on in consult w/ an oncologist, hematologist, or a transplant center physician. Behcet's disease, prescribed by or in consult w/ a rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist. Uveitis, ophthalmologist or rheumatologist.
Coverage Duration	For AS 12wk initial, w/pos response then 3 years. Other approved indications, 3 years.

Other Criteria

For Rheumatoid Arthritis, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to “step back” and try a conventional synthetic DMARD). For Juvenile Idiopathic Arthritis or Juvenile Rheumatoid Arthritis, approve if the pt has aggressive disease, as determined by the prescriber, or the pt has tried one other agent for this condition (eg, MTX, sulfasalazine, leflunomide, NSAID, biologic DMARD or the pt will be started on Enbrel concurrently with MTX, sulfasalazine, or leflunomide or the pt has an absolute contraindication to MTX (eg, pregnancy, breast feeding, alcoholic liver disease, immunodeficiency syndrome, blood dyscrasias), sulfasalazine, or leflunomide and non axial forms of Psoriatic Arthritis, must first try and fail methotrexate for at least two months, OR if the member has an absolute contraindication to methotrexate, then Enbrel will be approved. For axial forms of Psoriatic Arthritis, Enbrel will be approved. For non axial forms of Ankylosing Spondylitis, the member must first try and fail any two of the following conventional therapies over a three month period: NSAIDs, intraarticular steroids, methotrexate, other DMARD agents. For Plaque Psoriasis, approve if the patient meets one of the following conditions: 1) patient has tried at least one traditional systemic agent for at least 3 months for plaque psoriasis, unless intolerant (eg, MTX, cyclosporine, Soriatane, oral methoxsalen plus PUVA, (note: pts who have already tried a biologic for psoriasis are not required to “step back” and try a traditional agent first) OR 2) the patient has a contraindication to one oral agent for psoriasis such as MTX. For GVHD, Tried or currently is receiving with etanercept one conventional GVHD txment (high-dosesystemic corticosteroid, CSA, tacrolimus, etc.). Behcet's, tried at least one conventional therapy (eg, systemic corticosteroids, immunosuppressives, interferon alpha, etc) or adalimumab or infliximab. Uveitis, tried 1 of the following periocular, intraocular, or systemic CS, immunosuppressives, Humira or an infliximab product.

Clinical criteria incorporated into the Enbrel 25 mg quantity limit edit: approve additional quantity (to allow for 50 mg twice weekly dosing) if one of the following is met: Patient has plaque psoriasis, OR Patient has RA/JIA/PsA/AS and is started and

stabilized on 50 mg twice weekly dosing, OR Patient has RA and the dose is being increased to 50 mg twice weekly and patient has taken MTX in combination with Enbrel 50 mg once weekly for at least 2 months, unless MTX is contraindicated or intolerant, OR Patient has JIA/PsA/AS and the dose is being increased to 50 mg twice weekly after taking 50 mg once weekly for at least 2 months.

ENDARI

- **Products Affected**

- Endari

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from part D.
Exclusion Criteria	N/A
Required Medical Information	Endari will be used to reduce the acute complications of sickle cell disease.
Age Restriction	The patient is greater than or equal to 5 years of age.
Prescriber Restriction	Prescribed by or in consultation with a hematologist or oncologist.
Coverage Duration	1 year
Other Criteria	The patient is currently taking Hydroxyurea or has an intolerance or contraindication to Hydroxyurea therapy.

EPCLUSA

- **Products Affected**
- Sofosbuvir-velpatasvir
- Epclusa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin
Required Medical Information	N/A
Age Restriction	18 years or older
Prescriber Restriction	Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician.
Coverage Duration	12wks as specified in Other Criteria
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.

EPIDIOLEX

- **Products Affected**

- Epidiolex

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patient already started on Epidiolex for a covered use.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	The member is 2 years of age or older.
Prescriber Restriction	Prescribed by or in consultation with a neurologist.
Coverage Duration	Lifetime.
Other Criteria	For seizures associated with Lennox-Gastaut Syndrome, the patient must have a previous trial of ONE of the following: lamotrigine, topiramate, rufinamide, clobazam, valproate, felbamate or clonazepam. For seizures associated with Dravet Syndrome, the patient must have a previous trial of ONE of the following: valproate, clobazam or topiramate.

EPOGEN/PROCRIT

- **Products Affected**
- Epogen 20,000 Units/2 Ml Vial
- Epogen 3,000 Units/ml Vial
- Procrit
- Epogen 2,000 Units/ml Vial
- Epogen 20,000 Units/ml Vial
- Epogen 4,000 Units/ml Vial
- Retacrit

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D worded as Anemia associated with Chronic Renal Failure, including patients on dialysis and not on dialysis. Anemia due to the effects of chemotherapy in Nonmyeloid Malignancy. Anemia in HIV infected patients associated with Zidovudine therapy. Anemic patients at high risk for perioperative transfusions (secondary to significant, anticipated blood loss and are scheduled to undergo elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusions). Anemia related to Multiple Myeloma. Refractory Anemia related to Myelodysplastic Syndrome. Anemia in patients with Hepatitis C who are being treated with the combination ribavirin and interferon alfa or ribavirin and peginterferon alfa.
Exclusion Criteria	Refractory anemia related to Myelodysplastic Syndrome must be an EPO insufficiency that cannot be assigned to a specific vitamin or mineral deficiency. Uncontrolled hypertension. Anemic patients willing to donate autologous blood. Anemia due to factors other than diagnoses noted (iron or folate deficiency, hemolysis, GI bleeding). Patients receiving hormonal agents, therapeutic biological products, or radiotherapy UNLESS also receiving concomitant myelosuppressive chemotherapy. For immediate anemia correction or as a substitute for emergency transfusion. Prophylactic use to prevent chemotherapy included anemia.

Required Medical Information	Chronic renal failure patients not on dialysis must have symptomatic anemia with a HGB of 10g/dl or less. HIV-infected Zidovudine use requires a Zidovudine dose of 4200mg/week or less and an endogenous serum EPO level less than or equal to 500mUnits/ml. Non myeloid malignancy chemotherapy induced anemia must have HCT of 30% or less or HGB of 10g/dl or less in past 30 days. Multiple myeloma anemia must have HCT of 30% or less or HGB of 10g/dl or less in past 30 days. For Myelodysplastic Syndrome refractory anemia diagnosis must include excess blasts, or excess blasts in transformation to leukemia when, for medical reasons, the patient is not a candidate for active treatment of active leukemia. For Myelodysplastic Syndrome the patient must have a HCT of less than 30% or HGB of less than 10g/dl, and endogenous EPO serum level less than 500mu/ml. Anemia patients scheduled to undergo elective surgery require hemoglobin greater than 10 but 13 or less. Anemia related to ribavirin therapy in Hepatitis C treatment requires a pretreatment hemoglobin 10g/dl or less.
Age Restriction	For Hep C treatment related anemia, 18 or older.
Prescriber Restriction	For Hep C treatment related anemia, hematologist, gastroenterologist, or infectious disease physician who specializes in the management of Hep C.
Coverage Duration	Lifetime.
Other Criteria	For non myeloid malignancy anemia related to chemotherapy, the member must have received chemotherapy in past 8 weeks and will be receiving chemo for a minimum of 2 months. In anemic patients scheduled to undergo surgery, the surgery must be elective, noncardiac and nonvascular, or in patients at high risk for perioperative transfusion with significant anticipated blood loss who are receiving anticoagulant prophylaxis. Part B versus Part D determination will be made at time of prior authorization review per CMS guidance to establish if the drug prescribed is to be used for an end-stage renal disease (ESRD)-related condition.

ERLEADA

- **Products Affected**

- Erleada

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Nonmetastatic, Castration-Resistant Prostate Cancer.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

EVEKEO

- **Products Affected**
- Evekeo
- Amphetamine Sulfate
- Evekeo Odt

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Weight loss.
Required Medical Information	Diagnosis
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	12 months
Other Criteria	N/A

FAMILIAL HYPERCHOLESTEROLEMIA

- **Products Affected**
- Juxtapid
- Kynamro

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	For Juxtapid, cannot be used in combination with Kynamro, Praluent, or Repatha. For Kynamro, cannot be used in combination with Juxtapid, Praluent, or Repatha.
Required Medical Information	The member must have a confirmed diagnosis of homozygous familial hypercholesterolemia.
Age Restriction	18 years of age and older
Prescriber Restriction	Prescribed by or in consultation with a cardiologist, an endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders
Coverage Duration	Initial 6 mo. With positive response, then lifetime.
Other Criteria	The member must first try and fail alternative treatment approaches, including drug therapies (for example, maximum doses of statin therapy, bile acid sequestrants, niacin, ezetimibe), unless contraindicated. For coverage duration extension after the initial 6 months, a positive response is evidenced by a significant LDL-C level reduction.

FASENRA

• **Products Affected**

• Fasenra

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	Member will not be using in combination with Xolair, Nucala, or Cinqair.
Required Medical Information	Diagnosis. Previous therapy. Peripheral blood eosinophil count.
Age Restriction	12 years or older
Prescriber Restriction	The drug is being prescribed by or in consultation with an allergist, immunologist or pulmonologist.
Coverage Duration	Initial 6 months. Continuation, indefinitely.

Other Criteria

The patient has a diagnosis of severe asthma, with an eosinophilic phenotype. The member must have peripheral blood eosinophil count greater than or equal to 150 cells per microliter, within the previous 6 weeks (prior to treatment of Fasenra). The member must have received at least 3 consecutive months of combination therapy with an inhaled corticosteroid AND one of the following: inhaled long acting beta agonist, inhaled long acting muscarinic antagonist, leukotriene receptor antagonist, theophylline. The patient's asthma continues to be uncontrolled as defined by one of the following: Experienced one or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, Experienced one or more asthma exacerbations requiring hospitalization or treatment in an emergency department in the previous year, Patient has a FEV1 less than 80 percent predicted, Patient has FEV1/FVC less than 0.80, Patient's asthma worsens upon tapering of oral corticosteroid therapy. For continuation of therapy, if the member meets the following criteria, then therapy will be continued indefinitely: The patient has responded to Fasenra therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations/emergency department/urgent care/physician visits due to the asthma, decreased requirement for oral corticosteroid therapy), AND The patient continues to receive therapy with an inhaled corticosteroid.

FIRAZYR

- **Products Affected**
- Icatibant
- Firazyr

PA Criteria	Criteria Details
Covered Uses	All FDA approved indication not otherwise excluded from Part D.
Exclusion Criteria	Firazyr (icatibant) will not be used in combination with other approved treatments for acute hereditary angioedema (HAE) attacks.
Required Medical Information	Diagnosis of HAE and Firazyr (icatibant) is being used for the treatment of acute HAE attacks.
Age Restriction	18 years or older
Prescriber Restriction	Prescribed by an immunologist, allergist, otolaryngologist or rheumatologist
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A

FIRDAPSE

• **Products Affected**

• **Firdapse**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	History of seizures (initial therapy).
Required Medical Information	Diagnosis, seizure history, lab and test results.
Age Restriction	18 years and older.
Prescriber Restriction	Prescribed by or in consultation with a neurologist or a neuromuscular specialist.
Coverage Duration	For initiation of therapy: 3 months For continuation of therapy: 1 year
Other Criteria	Initial therapy: Diagnosis confirmed by at least one electrodiagnostic study (e.g., repetitive stimulation) OR anti-P/Q-type voltage-gated calcium channels (VGCC) antibody testing according to the prescribing physician. Continuation therapy: Patient continues to derive benefit (e.g., improved muscle strength, improvement in mobility) from Firdapse, according to the prescribing physician.

FLECTOR

- **Products Affected**
- Flector
- Diclofenac Epolamine

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Authorization will be for 12 mos.
Other Criteria	Patients must try and fail a generic oral NSAID or diclofenac gel first.

GALAFOLD

- **Products Affected**

- Galafold

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concomitant use of enzyme replacement therapy (ERT)
Required Medical Information	Diagnosis
Age Restriction	16 years and older
Prescriber Restriction	Prescribed by or in consultation with a geneticist, nephrologist, or a physician who specializes in the treatment of Fabry disease.
Coverage Duration	3 years
Other Criteria	Approve if the patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.

• **Products Affected**

• Gattex

PA Criteria	Criteria Details
Covered Uses	All FDA approved indication not otherwise excluded from Part D.
Exclusion Criteria	Members with biliary and/or pancreatic disease. Members with active gastrointestinal malignancy.
Required Medical Information	Parenteral nutrition (PN) and/or intravenous (IV) fluid dependency.
Age Restriction	Member is 18 years of age or older.
Prescriber Restriction	Prescribed by or in consultation with a gastroenterologist
Coverage Duration	6 months initial, 12 months continuation.
Other Criteria	For initial authorization, chart notes supporting the use of parenteral nutrition/IV fluids for 12 months and current volume of parenteral support in liters per week. For continuation, the provider must provide medical records documenting tolerance and effectiveness of therapy. Effectiveness of therapy is defined as a decrease in parenteral nutrition/IV volume from baseline weekly requirement at start of Gattex treatment.

GILOTRIF

• **Products Affected**

• Gilotrif

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	For NSCLC - non-resistant EGFR mutations. Prior therapies.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	For the treatment of metastatic non small cell lung cancer (NSCLC) must be used in tumors with non-resistant epidermal growth factor receptor (EGFR) mutation positive OR the patient must have metastatic squamous NSCLC progressing after platinum-based therapy.

GLEEVEC

• **Products Affected**

• **Imatinib Mesylate**

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus AIDS Related Kaposi's Sarcoma, chordoma, advanced or unresectable fibromatosis (desmoid tumors), cKit positive advanced/recurrent or metastatic melanoma, and pigmented Villonodular Synovitis/Tenosynovial Giant Cell Tumor. Plus patients already started on Gleevec for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	For ALL/CML, new patient must have Ph-positive for approval of imatinib. For AIDS related Kaposi's Sarcoma-approve if the patient has tried one prior regimen AND has relapsed or refractory disease.

GROWTH HORMONE

- **Products Affected**
- Humatrope
- Nutropin Aq Nuspin
- Saizen
- Serostim
- Zorbtive
- Genotropin
- Norditropin Flexpro
- Omnitrope
- Saizen-saizenprep
- Zomacton

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A

Required Medical Information	HIV initial-1.wasting/cachexia due to malabsorption, poor diet, opportunistic infx, depression and other causes which have been addressed prior to starting tx, 2.on antiretroviral or HAART or more than 30 days and will cont throughout Serostim tx, 3.not being used for alternations in body fat distribution (abdom girth, liopdystrophy, buffalo hump, excess abdm fat), AND 4. unintentional wt loss greater than 10 percent from baseline, wt less than 90 percent of lower limit of IBW, or BMI less than or equal to 20 kg/m2.HIV Cont tx -meets intial tx criteria.GHD in children/adoles initial must meet ONE of the following-1.had hypophysectomy,2.has congenital hypopit AND GH response to one preferred GH test of less than 10 ng/mL (preferred tests levodopa, insulin-induced hypoglycemia, arginine, clonidine, glucagon),3.panhypopit AND had GH response to one preferred GH test of less than 10 ng/mL, has 3 or more pit hormone def(ACTH, TSH, LH/FSH, or prolactin), or pit stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior bright spot on MRI or CT, 4. brain rad, had GH response to one preferred GH test of less than 10 ng/mL, AND meets one of these a. pretxgrowth rate (GR) is less than 7 cm/yr in children younger than 3 or b. or if 18 y/o or younger with growth velocity that is less than 10th percentile for age/gender on last 6 months of data, OR 5. had GH response to one preferred GH test of less than 10 ng/mL, ht less than the 10th percentile for age/gender, AND meets one of these a. pretx growth rate (GR) is less than 7 cm/yr in children younger than 3 or b. GR is less than 4 cm/yr in 3 y/o or older, c. or if 18 y/o or younger with growth velocity that is less than 10th percentile for age/gender on last 6 months of data. Additionally, pts older than 12 must also have open epiphyses and pts older than 18 must also not attained midparental ht.
Age Restriction	ISS 5 y/o or older, SGA 2 y/o or older, SBS and HIV wasting/cachexia 18 y/o or older
Prescriber Restriction	GHD (Initial tx children or adolescents w/o hypophysectomy), GHD adults or transitional adolescents, Noonan (initial), Prader Willi (initial for child/adult and cont tx in adults), SHOX (initial), SGA (initial) - prescribed by or in consultation with an endocrinologist. CKD (initial) endocrinologist or nephrologist.
Coverage Duration	ISS - 6 mos intial, 12 months cont tx, SBS 4 weeks, HIV 24 weeks, others 12 mos

Other Criteria

GHD initial in adults and adoles 1. endocrin must certify not being prescribed for anti-aging or to enhance athletic performance, 2. has either childhood onset or adult onset resulting from GHD alone, multiple hormone deficiency from pituitary dx, hypothalamic dz, pituitary surgery, cranial radiation tx, tumor treatment, TBI or subarachnoid hemorrhage, AND 3. meets one of the following - A. childhood onset has known mutations, embryonic lesions, congenital defects or irreversible structural hypothalamic pituitary lesion/damage, B. 3 or more pituitary hormone def (ACTH, TSH, LH/FSH, or prolactin, IGF1 less than 84 mcg/L (Esoterix RIA), AND other causes of low serum IGF-1 have been excluded, C. Neg response to ONE preferred GH stim test (insulin peak response less than or equal to 5 mcg/L, Glucagon peak less than or equal to 3 mcg/L, if insulin and glucagon contraindicated then Arginine alone test with peak of less than or equal to 0.4 mcg/L, GHRH plus arginine peak of less than or equal to 11 mcg/L if BMI is less than 25, peak less than 8 mcg/L if BMI is more than 25 but less than 30, or peak less than 4 mcg/L if BMI if more than 30) AND if a transitional adoles must be off tx for at least one month before retesting. Cont tx - endocrin must certify not being prescribed for anti-aging or to enhance athletic performance. ISS initial - baseline ht less than the 1.2 percentile or a standard deviation score (SDS) less than -2.25 for age and gender, open epiphyses, does not have CDGP and height velocity is either growth rate (GR) is a. less than 4 cm/yr for pts older than 5 or b. growth velocity is less than 10th percentile for age/gender. Cont tx - prescriber confirms response to therapy. Additionally, pts older than 12 must also have open epiphyses and pts older than 18 must also have not attained midparental height. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline height less than 5th percentile. PW cont tx in adults or adolescents who don't meet child requir - physician certifies not being used for anti-aging or to enhance athletic performance. SHOX initial - SHOX def by chromo analysis, open epiphyses, height less than 3rd percentile for age/gender. SGA initial -baseline ht less than 5th percentile for age/gender and born SGA (birth weight/length that is more than 2 SD below mean for gestational age/gender and didn't have sufficient catch up growth by 2-4 y/o). Cont tx - prescriber confirms response to therapy. Additionally, pts older

than 12 must also have open epiphyseal plates and pts older than 18 must also have not attained midparental height. Cont Tx for CKD, Noonan, PW in child/adoles, SHOX, and TS in members-prescriber confirms response to therapy. SBS initial pt receiving specialized nutritional support. Cont tx - 2nd course if pt responded to tx with a decrease in the requirement for specialized nutritional support.

HAEGARDA

• **Products Affected**

• Haegarda

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Confirmation of diagnosis of hereditary or acquired angioedema based on laboratory verification of C1 inhibitor deficiency.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Longterm prpylxs 1 yr. Shortterm prpylxs suffcent duraton to cvr event per MD.
Other Criteria	Long term prophylaxis requires that the member must have previously tried and failed or be intolerant of or contraindicated to one of the following: danazol, oxandrolone, methyltestosterone, Amicar (aminocaproic acid), or Cyklokapron (tranexamic acid) AND either of the following: The member has 2 or more episodes of angioedema per month OR the member's attack location occurs in body sites associated with a high risk of mortality (e.g. laryngeal). Short term prophylaxis requires one of the following instances occur: prior to minor manipulations (i.e. mild dental procedures) or prior to intubation or major procedures.

HARVONI

- **Products Affected**
- Harvoni 90-400 Mg Tablet
- Ledipasvir-sofosbuvir

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients with recurrent HCV post-liver transplant. Plus patients already started on Harvoni for a covered use.
Exclusion Criteria	Combination use with other direct acting antivirals, excluding ribavirin.
Required Medical Information	Hep C genotype, concurrent medications, medication history, cirrhosis status.
Age Restriction	12 years or older
Prescriber Restriction	Prescribed by or in consultation with GI, hepatologist, ID, or liver transplant MD.
Coverage Duration	12 weeks or 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.

HEMATOPOIETIC GROWTH FACTOR

• **Products Affected**

• **Promacta**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Chronic ITP is defined as greater than 6 months. For ITP, baseline platelet count must be less than 30,000/mm³, OR baseline platelet count must be 30,000-50,000/mm³ AND in the presence of a clinically significant previous bleeding episode OR at high risk of experiencing a clinically significant bleeding episode (for example, upcoming surgery, if the member is at high risk of falls, etc...). For continuation of therapy, a clinically positive response is either a platelet count with a positive increase to greater than 50,000/mm³ OR a clinically significant improvement in bleeding status if platelet count remains less than 50,000/mm³. If the platelet count does not increase after 4 weeks at maximum dose, then therapy will not be reauthorized. Diagnosis of Severe Aplastic Anemia, as defined based on the criteria of the International Aplastic Anemia Study Group (IAASG), requires that the member meet BOTH of the following criteria (1 and 2): (1.) Any two or three of the following peripheral blood criteria (Neutrophils less than 0.5 x 10 to the 9th/L AND/OR Platelets less than 20 x 10 to the 9th/L AND/OR Reticulocytes less than 1% corrected (percentage of actual hematocrit to normal hematocrit)) AND (2.) Any one of the following marrow criteria (Severe hypocellularity OR Moderate hypocellularity with hematopoietic cells representing less than 30% of residual cells)
Age Restriction	N/A
Prescriber Restriction	For Hepatitis C related thrombocytopenia, must be prescribed by or in consultation with a gastroenterologist, hematologist, or infectious disease physician.

Coverage Duration	ITP 90 day initial trial, w/pos clinical resp then 1 yr. Hep C thrombocytopenia and Aplastic Anemia 12mo.
Other Criteria	For chronic ITP must try and have insufficient response to (defined as the inability to achieve a platelet count of greater than 50,000/mm ³) or be intolerant to both of the following: Corticosteroids AND one of either splenectomy, IVIG, or anti-D immunoglobulins. For Hepatitis C related thrombocytopenia, if currently on interferon based therapy, the member must have attempted and failed to improve platelet levels through interferon dose reduction.

• **Products Affected**

• **Hetlitz**

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Patient is totally blind with no perception of light
Age Restriction	18 years or older
Prescriber Restriction	Prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders
Coverage Duration	6 months initial, 12 months cont.
Other Criteria	Initial - dx of Non-24 is confirmed by either assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels, dim light melatonin onset, assessment of core body temperature), or if assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for at least 1 week plus evaluation of sleep logs recorded for at least 1 month. Cont - Approve if pt has received at least 6 months of continuous therapy (i.e., 6 consecutive months of daily treatment) with Hetlitz under the guidance of a physician who specializes in the treatment of sleep disorders AND has achieved adequate results with Hetlitz therapy according to the prescribing physician (e.g., entrainment, clinically meaningful or significant increases in nighttime sleep, clinically meaningful or significant decreases in daytime sleep).

HIGH RISK MEDICATION - FIRST GENERATION

ANTI-HISTAMINES

- **Products Affected**
- Hydroxyzine Hcl 25 Mg Tablet
- Promethazine 12.5 Mg Tablet
- Promethazine 50 Mg Tablet
- Promethazine 6.25 Mg/5 Ml Syrp
- Hydroxyzine Hcl 10 Mg Tablet
- Hydroxyzine Hcl 50 Mg Tablet
- Promethazine 25 Mg Tablet
- Promethazine 6.25 Mg/5 Ml Soln

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restriction	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	Unless specifically referenced, all other FDA approved indications not excluded from Part D will be covered as first line therapy without other previous drug trial criteria requirements. For anti-emetic use, approve promethazine tablets or syrup if the patient has either tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant) for the current condition OR approve if the member requires promethazine use secondary to cancer/chemotherapy related emesis. For the management of anxiety, approve hydroxyzine tablets if the patient has tried at least two other FDA-approved products for the management of anxiety. Prior to approval of any drug, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that the physician would still like to initiate/continue therapy.

HIGH RISK MEDICATION - NSAIDS

- **Products Affected**
- Indocin 25 Mg/5 Ml Suspension
- Tivorbex

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restriction	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For gout, approve indomethacin as first line therapy without other previous drug trial criteria requirements. For other indications for indomethacin, the patient must try and fail at least two other FDA-approved products for the indication being treated. Prior to approval, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that the physician would still like to initiate/continue therapy.

HIGH RISK MEDICATION - SKELETAL MUSCLE RELAXANTS

- **Products Affected**
- Chlorzoxazone 500 Mg Tablet
- Cyclobenzaprine 10 Mg Tablet
- Cyclobenzaprine 7.5 Mg Tablet
- Chlorzoxazone 375 Mg Tablet
- Chlorzoxazone 750 Mg Tablet
- Cyclobenzaprine 5 Mg Tablet
- Orphenadrine Citrate Er

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restriction	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	The physician has assessed risk versus benefit in using this High Risk Medication (HRM) in this patient and has confirmed that the physician would still like to initiate/continue therapy.

HIGH RISK MEDICATION - TERTIARY TRICYCLIC ANTIDEPRESSANTS

- **Products Affected**
- Amitriptyline Hcl 100 Mg Tab
- Amitriptyline Hcl 25 Mg Tab
- Amitriptyline Hcl 75 Mg Tab
- Clomipramine 50 Mg Capsule
- Doxepin 10 Mg Capsule
- Doxepin 100 Mg Capsule
- Doxepin 25 Mg Capsule
- Doxepin 75 Mg Capsule
- Imipramine Hcl 25 Mg Tablet
- Imipramine Pamoate
- Amitriptyline Hcl 10 Mg Tab
- Amitriptyline Hcl 150 Mg Tab
- Amitriptyline Hcl 50 Mg Tab
- Clomipramine 25 Mg Capsule
- Clomipramine 75 Mg Capsule
- Doxepin 10 Mg/ml Oral Conc
- Doxepin 150 Mg Capsule
- Doxepin 50 Mg Capsule
- Imipramine Hcl 10 Mg Tablet
- Imipramine Hcl 50 Mg Tablet
- Trimipramine Maleate

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.
Prescriber Restriction	N/A
Coverage Duration	Authorization will be for 12 months.

Other Criteria

For the treatment of depression, approve if the patient has tried at least two of the following agents (brand or generic): citalopram, escitalopram, fluoxetine, paroxetine, sertraline, venlafaxine, desvenlafaxine, duloxetine, bupropion, mirtazapine, nortriptyline, desipramine, or trazodone. For the treatment of pain, may approve amitriptyline (single-entity only, not amitriptyline combination products) or imipramine if the patient has tried at least two of the following agents: duloxetine, pregabalin, gabapentin, venlafaxine, venlafaxine Er, desipramine, or nortriptyline. For the treatment of obsessive compulsive disorder (OCD), may approve clomipramine (brand or generic) if the patient has tried at least two of the following medications: fluoxetine, fluvoxamine, paroxetine, sertraline, citalopram, escitalopram, or venlafaxine. Prior to approval of any drug, the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that the physician would still like to initiate/continue therapy.

HUMIRA

- **Products Affected**
- Humira Pediatric Crohn's
- Humira Pen Crohn's-uc-hs
- Humira(cf)
- Humira(cf) Pen 40 Mg/0.4 Ml
- Humira(cf) Pen Psor-uv-adol Hs
- Humira
- Humira Pen
- Humira Pen Psor-uveits-adol Hs
- Humira(cf) Pediatric Crohn's
- Humira(cf) Pen Crohn's-uc-hs

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on adalimumab for a Covered Use.
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD.

Required Medical Information	For Rheumatoid Arthritis the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis and the disease must be active. For Juvenile Idiopathic Arthritis, the member must have a confirmed diagnosis of Juvenile Idiopathic Arthritis and the disease must be active. For Anklyosing Spondylitis, the member must have a confirmed diagnosis of Ankylosing Spondylitis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc...) and an expert opinion based on clinical features, acute phase reactants and imaging modalities. For Psoriatic Arthritis, the member must have a confirmed diagnosis of Psoriatic Arthritis. For Plaque Psoriasis, the member must have a confirmed diagnosis of chronic and moderate to severe Plaque Psoriasis, and defined as a minimum body surface area involvement of greater than or equal to 5%, or by involvement of the hands, feet, facial, or genital regions, by which, despite involvement of a smaller BSA, the disease may interfere significantly with activities of daily life. For Pediatric and Adult Crohn's Disease, the member must have a confirmed diagnosis of moderate to severe Crohn's Disease. For Ulcerative Colitis, the member must have a confirmed diagnosis of moderate to severe ulcerative colitis. For Hidradenitis Suppurativa, the member must have a confirmed diagnosis of moderate to severe Hidradenitis Suppurativa, defined as Hurley Stage II or III.
Age Restriction	CD-6 years or older UC-18 years or older
Prescriber Restriction	RA/JIA/JRA/AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. PP-prescribed by or in consultation with a dermatologist or rheumatologist. UC/CD-prescribed by or in consultation with a gastroenterologist or a rheumatologist. HS-Dermatologist. UV-ophthalmologist or rheumatologist.
Coverage Duration	AS 12wk initl,w/pos resp, 3 year. UC 8wk initl,w/remssn evidnce, 3 year. Othr aprvd indictn, 3 year.

Other Criteria

For RA, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to “step back” and try a conventional synthetic DMARD). For JIA and JRA, patient has tried another agent (e.g MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on adalimumab concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX, sulfasalazine, or leflunomide or if pt has aggressive disease. For non axial forms of PsA, must first try and fail methotrexate for at least three months, OR if the member has an absolute contraindication to methotrexate, then Humira will be approved. For axial forms of PsA, Humira will be approved. For non axial forms of AS, the member must first try and fail any two of the following conventional therapies over a three month period: NSAIDs, intraarticular steroids, methotrexate, other DMARD agents. For PP, approve if the patient meets one of the following criteria: 1) pt has tried at least one traditional systemic agent (eg, MTX, cyclosporine, acitretin, PUVA) for at least 3 months, unless intolerant (note: pts who have already tried a biologic for psoriasis are not required to “step back” and try a traditional agent first) OR 2) pt has a contraindication to MTX as determined by the prescribing physician. For CD, tried corticosteroids (CSs) or if CSs are contraindicated or if pt currently on CSs or patient has tried one other agent for CD (eg, azathioprine, 6-mercaptopurine, MTX, certolizumab, infliximab, ustekinumab, or vedolizumab) OR pt had ilecolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. For Crohn's Disease diagnosis, first line coverage will be provided if the patient had an ilecolnic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. For UC, Pt has tried a systemic therapy (eg, 6-mercaptopurine, azathioprine, CSA, tacrolimus, infliximab, golimumab SC, or a corticosteroid such as prednisone or methylprednisolone) for 2 months or was intolerant to one of these agents, or the pt has pouchitis and has tried therapy with an antibiotic, probiotic, corticosteroid enema, or mesalamine (Rowasa) enema. For HS, the member must have tried and failed or had an inadequate response to one other therapy (e.g.,

intralesional or oral corticosteroids, systemic antibiotics, isotretinoin, cyclosporine).

Clinical criteria incorporated into the Humira 40 mg quantity limit edit: Allow for approval of additional quantities to accommodate induction dosing. The allowable quantity is dependent upon the induction dosing regimen for the applicable FDA-labeled indications as outlined in product labeling.

ICLUSIG

- **Products Affected**

- Iclusig

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Iclusig for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status
Age Restriction	CML/ALL - Adults
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	CML Ph+, T315I-positive or has tried TWO other TKIs indicated for use in Philadelphia chromosome positive CML (e.g., Gleevec, Sprycel, Tasigna). ALL Ph+, T315I-positive or has tried TWO other TKIs indicated for use in Ph+ ALL (e.g. Gleevec, Sprycel.)

IDHIFA

- **Products Affected**

- Idhifa

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Isocitrate dehydrogenase (DH2) mutation status detected by an FDA-approved test.
Age Restriction	The member is 18 years of age or older.
Prescriber Restriction	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

IDIOPATHIC PULMONARY FIBROSIS

- **Products Affected**
- Ofev
- Esbriet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	N/A

• **Products Affected**

• Ilumya

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Ilumya for a covered use.
Exclusion Criteria	Concurrent use with other biologics or targeted synthetic disease-modifying antirheumatic drugs (DMARDs).
Required Medical Information	Diagnosis. Previous therapies.
Age Restriction	18 years and older
Prescriber Restriction	Prescribed by or in consultation with a dermatologist
Coverage Duration	Initial: 4 months Continuation: 3 years
Other Criteria	For initiation of therapy, the patient meets all of the following indication specific requirements (A and B): A. The patient meets either of the following criteria: 1) At least 5 percent body surface area was affected by plaque psoriasis at the time of diagnosis, or 2) Crucial body areas (e.g. feet, hands, face, neck, groin, intertriginous areas) were affected by plaque psoriasis at the time of diagnosis. B. The patient meets the following criteria: Patient has tried TWO of the following: Enbrel, Humira, Stelara SC, Otezla, or Cosentyx. For continuation of therapy: Patient had demonstrated a positive response to the medication.

INSULIN THERAPY

- **Products Affected**
- Admelog Solostar
- Apidra Solostar
- Humalog 100 Units/ml Cartridge
- Humalog Kwikpen U-100
- Humalog Mix 50-50
- Humalog Mix 75-25
- Humulin 70-30
- Humulin N
- Humulin R
- Humulin R U-500 Kwikpen
- Admelog
- Apidra 100 Units/ml Vial
- Humalog 100 Unit/ml Vial
- Humalog Junior Kwikpen
- Humalog Kwikpen U-200
- Humalog Mix 50-50 Kwikpen
- Humalog Mix 75-25 Kwikpen
- Humulin 70/30 Kwikpen
- Humulin N Kwikpen
- Humulin R U-500

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experienced with the preferred product, or the clinical condition for which an exception to the preferred product is requested).
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.

Other Criteria

NovoNordisk products are considered preferred. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to the preferred formulary/preferred drug list alternative for the given diagnosis, OR the member has a documented contraindication to the preferred formulary alternative, or the member had an adverse reaction or would be reasonably expected to have an adverse reaction to the preferred formulary alternative, OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature. Part B versus D determination per CMS guidance to establish if drug used in an insulin pump.

INTERMEZZO

- **Products Affected**
- Zolpidem Tart 1.75 Mg Tab Sl
- Zolpidem Tart 3.5 Mg Tablet Sl

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	Diagnosis is for as needed use for the treatment of insomnia when a middle of the night awakening is followed by difficulty returning to sleep (the insomnia must be characterized by difficulty returning to sleep after middle of the night awakening).
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	One year.
Other Criteria	N/A

INTRAROSA/OSPHENA

- **Products Affected**
- Intrarosa
- Osphena

PA Criteria	Criteria Details
Covered Uses	All FDA approved indication not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	1 year.
Other Criteria	N/A

IRESSA

- **Products Affected**

- Iressa

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	Metastatic NSCLC - The patient has epidermal growth factor receptor (EGFR) exon 19 deletions OR has exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

IVIG

- **Products Affected**
- Gammagard Liquid
- Gammagard S-d 5 G (iga<1) Soln
- Gammaplex 10 Gram/100 Ml Vial
- Gammaplex 20 Gram/200 Ml Vial
- Gammaplex 5 Gram/100 Ml Vial
- Gamunex-c 1 Gram/10 Ml Vial
- Panzyga
- Flebogamma Dif 10% Vial
- Gammagard S-d 10 G (iga<1) Sol
- Gammaked 1 Gram/10 Ml Vial
- Gammaplex 10 Gram/200 Ml Vial
- Gammaplex 20 Gram/400 Ml Vial
- Gammaplex 5 Gram/50 Ml Vial
- Octagam
- Privigen

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	One year.
Other Criteria	Part B versus D determination per CMS guidance to establish if drug used for Primary Immune Deficiency in patients home.

KALYDECO

• **Products Affected**

• Kalydeco

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Patients who are homozygous for the F508del mutation.
Required Medical Information	For patients new to therapy, CFTR gene mutation status required. Members already started on therapy prior to joining health plan with unconfirmed mutation status must confirm CFTR mutation status to continue.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	CFTR gene mutation confirmed, lifetime. If continue use from prior to joining plan and mutation unknown, 3mo
Other Criteria	Patients new to therapy must have appropriate CFTR gene mutation. Patients continuing therapy from prior to joining health plan already started on therapy must confirm CFTR gene mutation to continue treatment.

KEVZARA

- **Products Affected**
 - Kevzara 150 Mg/1.14 Ml Syringe
 - Kevzara 200 Mg/1.14 Ml Syringe

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prescriber specialty, other medications tried.
Age Restriction	N/A
Prescriber Restriction	Rheumatologist
Coverage Duration	Lifetime
Other Criteria	The patient had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).

KINERET

• **Products Affected**

• **Kineret**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patient already started on anakinra for a Covered Use. Still's disease. Juvenile Rheumatoid Arthritis.
Exclusion Criteria	Concurrent use with another biologic DMARD or targeted synthetic DMARD.
Required Medical Information	For Rheumatoid Arthritis, the member must have a confirmed diagnosis of Rheumatoid Arthritis and the disease must be active. For Cryopyrin Associated Periodic Syndrome, the member must have a confirmed diagnosis of CAPS with subtype Neonatal-Onset Multisystem Inflammatory Disease (NOMID).
Age Restriction	N/A
Prescriber Restriction	RA and Still's disease-prescribed by or in consultation with a rheumatologist. CAPS-prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, pediatrician.
Coverage Duration	Lifetime.
Other Criteria	For Rheumatoid Arthritis, approve if the patient has tried TWO of the following: Enbrel, Humira, Orencia (IV/SC), or Xeljanz/XR. (Note: if the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the 'try TWO' requirement: Actemra, Cimzia, infliximab, golimumab IV/SC). For Still's disease, Approve if the patient has tried a corticosteroid and has had an inadequate response to one conventional synthetic disease-modifying antirheumatic drug (DMARD) or was intolerant to this therapy.

KORLYM

• **Products Affected**

• **Korlym**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Pregnancy.
Required Medical Information	The member must have a confirmed diagnosis of endogenous Cushing's syndrome, requiring control of hyperglycemia secondary to hypercortisolism, with Type 2 Diabetes Mellitus or glucose intolerance. Members must not be pregnant, as evidenced by a documented negative pregnancy test prior to the initiation of treatment. For continuation of therapy, the member must achieve 25% or greater improvement in glucose tolerance, as measured by a standard two-hour glucose tolerance test after 12 weeks of treatment, OR must achieve improved glycemic control as evidenced by the member's HbA1C value.
Age Restriction	Aged 18 years or older.
Prescriber Restriction	Endocrinologist or specialist in treating Cushing's syndrome.
Coverage Duration	Initial authorization 3 months. If improvement met, then lifetime.
Other Criteria	The member must have failed surgery, or is not a candidate for surgery. Members must utilize adequate measures such as non-hormonal contraceptive methods to prevent pregnancy.

• **Products Affected**

• **Kuvan**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Initial 2 months, if positive response, then lifetime. In pregnancy, through term.
Other Criteria	For continuation of therapy, a positive response is defined as showing a 30% or greater reduction in blood phenylalanine level after initial 2 months of therapy.

LIDODERM

- **Products Affected**
- Ztlido
- Lidocaine 5% Patch

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus diabetic neuropathic pain. Plus chronic back pain.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Authorization will be for 12 months
Other Criteria	Chronic back pain - approve if the patient has tried two pharmacologic therapies with each one from a different class of medication used to treat low back pain (e.g. nonsteroidal anti-inflammatory drugs [NSAIDs], muscle relaxants, celecoxib, duloxetine, gabapentin).

LONSURF

• **Products Affected**

• Lonsurf

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	Metastatic CRC - As per labeling, the patient has been previously treated with a fluoropyrimidine (e.g., capecitabine, 5-FU) AND oxaliplatin AND irinotecan AND if the tumor or metastases are wild-type KRAS and/or NRAS (that is, the tumors or metastases are KRAS and/or NRAS mutation negative) Erbitux or Vectibix has been tried.

LORBRENA

• **Products Affected**

• **Lorbrena**

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Lorbrena for a covered use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, ALK status, previous therapies.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	3 years
Other Criteria	For NSCLC – Approve if the patient has ALK-positive metastatic NSCLC and meets one of the following: a. patient has disease progression on Xalkori (crizotinib capsules) and at least one other ALK inhibitor (e.g., Zykadia [ceritinib capsules], Alecensa [alectinib capsules], Alunbrig [brigatinib tablets]), or b. patient has disease progression on Alecensa (alectinib capsules) as the first ALK inhibitor therapy, or c. patient has disease progression on Zykadia (ceritinib capsules) as the first ALK inhibitor therapy.

LUCEMYRA

- **Products Affected**

- Lucemyra

PA Criteria	Criteria Details
Covered Uses	All FDA approved indication not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried.
Age Restriction	18 years of age and older.
Prescriber Restriction	N/A
Coverage Duration	1 month
Other Criteria	The prescriber indicates that there was a documented trial and failure with clonidine (oral or topical patch) prior to Lucemyra approval.

LYNPARZA

- **Products Affected**
 - Lynparza 100 Mg Tablet
 - Lynparza 150 Mg Tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Lynparza.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	N/A

LYRICA CR

• **Products Affected**

• **Lyrice Cr**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Previous Therapy
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	lifetime
Other Criteria	For diabetic peripheral neuropathy, the member tried and failed therapy, has a contraindication to, or clinical inappropriateness of treatment to pregabalin immediate release. For postherpetic neuralgia, the member tried and failed therapy with, has a contraindication to, or clinical inappropriateness of treatment to all of the following (A and B): A. Pregabalin immediate release B. Gabapentin.

MAVENCLAD

• **Products Affected**

• **Mavenclad**

PA Criteria	Criteria Details
Covered Uses	Any FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis.
Required Medical Information	Diagnosis, other medications that will be used in combination.
Age Restriction	N/A
Prescriber Restriction	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.
Coverage Duration	1 year
Other Criteria	Approve if the patient has tried at least one other disease-modifying therapy for multiple sclerosis.

MAVYRET

- **Products Affected**

- Mavyret

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Member has been tested for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with Mavyret.
Age Restriction	Member is 18 years of age or older.
Prescriber Restriction	The medication must be prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician.
Coverage Duration	8, 12, or 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.

MAYZENT

- **Products Affected**
- Mayzent 0.25 Mg Tablet
- Mayzent 2 Mg Tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use with other disease-modifying agents used for multiple sclerosis.
Required Medical Information	Diagnosis
Age Restriction	N/A
Prescriber Restriction	Prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of multiple sclerosis.
Coverage Duration	1 year
Other Criteria	N/A

MEKINIST

• **Products Affected**

• **Mekinist**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus colon or rectal cancer. Plus, patients with melanoma already started on trametinib prior to joining health plan in the absence of confirmed BRAF V600E or V600K mutation status.
Exclusion Criteria	Patients with melanoma with wild-type BRAF (i.e., no detected BRAF V600E or V600K mutation). Patients with melanoma initiating therapy with trametinib whose BRAF V600E and V600K status is unknown.
Required Medical Information	For patients new to therapy, BRAF V600E or V600K status required. Members already started on therapy prior to joining health plan with unconfirmed BRAF status must confirm BRAF V600E or V600K status to continue.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	BRAFV600E/V600K confrmd, lifetime. If cont. use from prior to joining plan and BRAF unknown, 1mo.
Other Criteria	Patients new to therapy must have BRAF V600E or V600K mutation. Patients continuing therapy from prior to joining health plan already started on therapy must confirm BRAF V600E or V600K to continue treatment. Must either be used 1. as single agent monotherapy or 2. in combination with Tafenlar per product labeling. Colon or Rectal cancer-approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer.

MEKTOVI

• **Products Affected**

• **Mektovi**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients with colon or rectal cancer. Plus patients already started on Mektovi for a covered use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, BRAF V600 status, concomitant medications.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	3 years
Other Criteria	Approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation AND Mektovi will be used in combination with Braftovi. Colon or Rectal cancer-approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer.

METHAMPHETAMINE

- **Products Affected**

- **Methamphetamine Hcl**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Use in patients for weight loss.
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	12 months
Other Criteria	N/A

MYALEPT

- **Products Affected**

- Myalept

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Authorization will be for 3 years.
Other Criteria	N/A

NAMENDA

- **Products Affected**
- Memantine Hcl 10 Mg Tablet
- Memantine Hcl 5 Mg Tablet
- Namenda Xr Titration Pack
- Memantine 5-10 Mg Titration Pk
- Memantine Hcl 2 Mg/ml Solution
- Memantine Hcl Er
- Namzaric

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	Members requesting Namzaric must try and fail one generic drug (Donepezil, Galantamine, or Rivastigmine) first. Memantine will be allowed for mild to moderate vascular dementia.

NATPARA

- **Products Affected**

- Natpara

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Increased baseline risk for osteosarcoma. Post-surgical hypoparathyroidism or for hypoparathyroidism secondary to calcium sensing receptor mutations.
Required Medical Information	Baseline stores of 25-hydroxy vitamin D and serum calcium levels. Previous treatment.
Age Restriction	N/A
Prescriber Restriction	Prescribed by or in consultation with an endocrinologist.
Coverage Duration	Lifetime.
Other Criteria	Hypocalcemia secondary to hypoparathyroidism - Before starting Natpara, serum calcium concentration is greater than 7.5 mg/dL and 25-hydroxyvitamin D stores are sufficient per the prescribing physician.

• **Products Affected**

• Nerlynx

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Previous therapy and HER2-positive status
Age Restriction	Member is 18 years of age or older.
Prescriber Restriction	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

• **Products Affected**

• Nexavar

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus , patients already started on Nexavar for a covered use, osteosarcoma, angiosarcoma, advanced or unresectable desmoids tumors, gastrointestinal stromal tumors (GIST), medullary thyroid carcinoma, Acute Myeloid Leukemia, Chordoma with recurrent disease, solitary fibrous tumor and hemangiopericytoma, ovarian, fallopian tube, primary peritoneal cancer.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	Osteosarcoma, approve if the patient has tried standard chemotherapy and have relapsed/refractory or metastatic disease. GIST, approve if the patient has tried TWO of the following: imatinib mesylate (Gleevec), sunitinib (Sutent), or regorafenib (Stivarga). Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma (DTC), approve if the patient is refractory to radioactive iodine treatment. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). AML - Approve. Ovarian, fallopian tube, primary peritoneal cancer - approve if the patient has platinum resistant disease and Nexavar is used in combination with topotecan.

NUBEQA

- **Products Affected**

- Nubeqa

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	3 years.
Other Criteria	N/A

NUCALA

- **Products Affected**

- Nucala

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use with Xolair
Required Medical Information	N/A
Age Restriction	12 years of age and older
Prescriber Restriction	Prescribed by or in consultation with an allergist, immunologist, or pulmonologist
Coverage Duration	Initial 6 months. If criteria met for continuation, then therapy will be approved lifetime.

Other Criteria

Initial for severe asthma with an eosinophilic phenotype - must have peripheral blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks (prior to treatment with Nucala) AND Patient has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid AND one of the following A. inhaled LABA, B. inhaled long-acting muscarinic antagonist, C. Leukotriene receptor antagonist, or D. Theophylline. Patients asthma continues to be uncontrolled as defined by ONE of the following - patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year, patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year, patient has a FEV1 less than 80 percent predicted, Patient has an FEV1/FVC less than 0.80, or Patients asthma worsens upon tapering of oral corticosteroid therapy. For continuation therapy for severe asthma with an eosinophilic phenotype - The patient has responded to Nucala therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations, decreased asthma symptoms, decreased hospitalizations, emergency department (ED)/urgent care, or physician visits due to asthma, decreased requirement for oral corticosteroid therapy) AND Patient continues to receive therapy with an inhaled corticosteroid. For initial therapy for eosinophilic granulomatosis with polyangiitis (EGPA) - The patient has a history or the presence of an eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin (IL)-5 therapy (e.g., Nucala, Cinquair, Fasenra). For continuation of therapy for EGPA - The patient has responded to Nucala therapy as determined by the prescribing physician (e.g., reduced rate of relapse, corticosteroid dose reduction, reduced eosinophil levels).

NUEDEXTA

- **Products Affected**

- Nuedexta

PA Criteria	Criteria Details
Covered Uses	All FDA approved indication not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of pseudobulbar affect.
Age Restriction	N/A
Prescriber Restriction	Prescribed by a neurologist or a psychiatrist.
Coverage Duration	Initial: 3 months, Continuation: 1 year.
Other Criteria	For continuation, the member experienced a positive response (decrease in number of episodes of laughing or crying compared to baseline before starting Nuedexta) to Nuedexta Therapy.

NUPLAZID

- **Products Affected**
- Nuplazid 10 Mg Tablet
- Nuplazid 34 Mg Capsule

PA Criteria	Criteria Details
Covered Uses	All FDA approved indication not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis of Parkinson's disease psychosis. Patient has at least one of the following: hallucinations or delusions.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Initial: 3 months. Continuation: 1 year
Other Criteria	For continuation, the member experienced a positive response to Nuplazid Therapy.

OCALIVA

• **Products Affected**

• **Ocaliva**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	New to therapy: 6 months. Continuing patients 3 years.
Other Criteria	Currently receiving therapy prior to joining health plan or started therapy in past 6 months. or Diagnosis of primary biliary cholangitis (cirrhosis)(PBC). and one the following 1. Have not achieved an adequate response to an appropriate dosage of UDCA(Ursodeoxycholic acid) for at least one year or are intolerant to UDCA. or 2. Used in combination therapy with Ursodeoxycholic acid (UDCA) after an inadequate response to UDCA

OLUMIANT

- Products Affected

- Olumiant

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous medication use, concurrent medication
Age Restriction	18 years of age and older
Prescriber Restriction	Prescribed by or in consultation with a rheumatologist
Coverage Duration	Initial: 3 months Continuation of therapy: 3 years
Other Criteria	For initiation of therapy: For Rheumatoid Arthritis, approve if the patient has tried TWO of the following: Enbrel, Humira, Orencia (IV/SC), or Xeljanz/XR. (NOTE: If the patient has not tried TWO of these drugs listed, previous trial(s) with the following drugs can count towards meeting the "try TWO" requirement: Actemra, Cimzia, infliximab, golimumab IV/SC). For continuation of therapy: Approve if the patient has had a positive response, as determined by the prescriber.

• **Products Affected**

• **Opsumit**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	PAH WHO group, right heart catheterization
Age Restriction	N/A
Prescriber Restriction	PAH-must be prescribed by or in consultation with a cardiologist or a pulmonologist.
Coverage Duration	3 years
Other Criteria	Pulmonary arterial hypertension (PAH) WHO Group 1 patients not currently on Opsumit or another agent indicated for WHO Group 1 PAH are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment. PAH WHO Group 1 patients currently on Opsumit or another agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization.

ORENCIA

- **Products Affected**
- Orencia 50 Mg/0.4 Ml Syringe
- Orencia Clickject
- Orencia 125 Mg/ml Syringe
- Orencia 87.5 Mg/0.7 Ml Syringe

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients who have already been started on abatacept (IV or SC) for a covered use.
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried.
Age Restriction	N/A
Prescriber Restriction	RA and JIA/JRA-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist.
Coverage Duration	Lifetime.
Other Criteria	For Rheumatoid Arthritis, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to “step back” and try a conventional synthetic DMARD). For Juvenile Idiopathic Arthritis or Juvenile Rheumatoid Arthritis, must first try and fail methotrexate for at least 3 months, OR if the member has an absolute contraindication to methotrexate, then Orencia will be approved.

• **Products Affected**

• **Orkambi**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	For patients new to therapy, homozygous F508del mutation status in the CFTR gene required. Members already started on therapy prior to joining health plan with unconfirmed mutation status must confirm CFTR mutation status to continue.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	CFTR gene mutation confirmed, lifetime. If continue use from prior to joining plan and mutation unknown, 1mo
Other Criteria	Patients new to therapy must have appropriate CFTR gene mutation. Patients continuing therapy from prior to joining health plan already started on therapy must confirm CFTR gene mutation to continue treatment.

OTEZLA

- **Products Affected**
- Otezla 28 Day Starter Pack
- Otezla 30 Mg Tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	For Psoriatic Arthritis, the member must have a confirmed diagnosis of active Psoriatic Arthritis. For Plaque Psoriasis, the member must have a confirmed diagnosis of moderate to severe Plaque Psoriasis, and defined as a minimum body surface area involvement of greater than or equal to 5%, or by involvement of the hands, feet, facial, or genital regions, by which, despite involvement of a smaller BSA, the disease may interfere significantly with activities of daily life.
Age Restriction	N/A
Prescriber Restriction	Rheumatologist, Dermatologist.
Coverage Duration	Lifetime.
Other Criteria	For non axial forms of Psoriatic Arthritis, must first try and fail methotrexate for at least two months, OR if the member has an absolute contraindication to methotrexate, then Otezla will be approved. For axial forms of Psoriatic Arthritis, Otezla will be approved. For Plaque Psoriasis, the member must first try and fail over a three month period to one of the following: Methotrexate, Oral retinoids, cyclosporine, phototherapy.

• **Products Affected**

• Palynziq

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, phenylalanine concentrations
Age Restriction	18 years of age and older
Prescriber Restriction	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases
Coverage Duration	Initial: 1 year Continuation: 3 years
Other Criteria	For initiation of therapy: Approve if the patient has uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on at least one existing treatment modality (e.g., restriction of dietary phenylalanine and protein intake, prior treatment with Kuvan). For continuation of therapy: Approve if the patient's blood phenylalanine concentration is less than or equal to 600 micromol/L OR the patient has achieved at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline.

PANRETIN

- **Products Affected**

- **Panretin**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	N/A

PART D VS PART B

- **Products Affected**
- Acetylcysteine 10% Vial
- Actimmune
- Acyclovir 500 Mg/10 Ml Vial
- Albuterol 2.5 Mg/0.5 Ml Sol
- Albuterol 5 Mg/ml Solution
- Albuterol Sul 1.25 Mg/3 Ml Sol
- Ambisome
- Aminosyn Ii 15% Iv Solution
- Amphotericin B 50 Mg Vial
- Astagraf Xl
- Azathioprine 50 Mg Tablet
- Brovana
- Budesonide 0.5 Mg/2 Ml Susp
- Cancidas
- Cesamet
- Clinimix 4.25%-10% Solution
- Clinimix 4.25%-5% Solution
- Clinimix 5%-20% Solution
- Clinimix E 2.75%-5% Solution
- Clinimix E 4.25%-5% Solution
- Clinimix E 5%-20% Solution
- Cyclophosphamide 25 Mg Capsule
- Cyclosporine 100 Mg Capsule
- Cyclosporine Modified
- Duopa
- Engerix-b 20 Mcg/ml Syrn
- Envarsus Xr
- Freamine Hbc
- Gengraf 100 Mg/ml Solution
- Granisetron Hcl 1 Mg Tablet
- Abelcet
- Acetylcysteine 20% Vial
- Acyclovir 1,000 Mg/20 Ml Vial
- Albuterol 15 Mg/3 Ml Solution
- Albuterol 20 Mg/4 Ml Solution
- Albuterol Sul 0.63 Mg/3 Ml Sol
- Albuterol Sul 2.5 Mg/3 Ml Soln
- Aminosyn Ii 10% Iv Solution
- Aminosyn-pf
- Aprepitant
- Azasan
- Bethkis
- Budesonide 0.25 Mg/2 Ml Susp
- Budesonide 1 Mg/2 Ml Inh Susp
- Caspofungin Acetate
- Cinacalcet Hcl
- Clinimix 4.25%-25% Solution
- Clinimix 5%-15% Solution
- Clinimix 5%-25% Solution
- Clinimix E 4.25%-10% Solution
- Clinimix E 5%-15% Solution
- Cromolyn 20 Mg/2 Ml Neb Soln
- Cyclophosphamide 50 Mg Capsule
- Cyclosporine 25 Mg Capsule
- Dronabinol
- Emend 125 Mg Powder Packet
- Engerix-b Pedi 10 Mcg/0.5 Syrn
- Firmagon
- Gengraf 100 Mg Capsule
- Gengraf 25 Mg Capsule
- Hepatamine

- | | |
|----------------------------------|----------------------------------|
| • Intralipid | • Intron A |
| • Ipratropium Br 0.02% Soln | • Ipratropium-albuterol |
| • Levalbuterol Concentrate | • Levalbuterol Hcl |
| • Methotrexate 2.5 Mg Tablet | • Methotrexate 250 Mg/10 Ml Vial |
| • Methotrexate 50 Mg/2 Ml Vial | • Methotrexate Sodium |
| • Mycophenolate 200 Mg/ml Susp | • Mycophenolate 250 Mg Capsule |
| • Mycophenolate 500 Mg Tablet | • Mycophenolic Acid |
| • Nebupent | • Nephramine |
| • Ondansetron 4 Mg/5 Ml Solution | • Ondansetron Hcl 24 Mg Tablet |
| • Ondansetron Hcl 4 Mg Tablet | • Ondansetron Hcl 8 Mg Tablet |
| • Ondansetron Odt | • Perforomist |
| • Plenamine | • Premasol |
| • Procalamine | • Prograf 0.2 Mg Granule Packet |
| • Prograf 1 Mg Granule Packet | • Prosol |
| • Pulmozyme | • Rapamune 1 Mg/ml Oral Soln |
| • Recombivax Hb 10 Mcg/ml Syr | • Recombivax Hb 10 Mcg/ml Vial |
| • Recombivax Hb 40 Mcg/ml Vial | • Recombivax Hb 5 Mcg/0.5 Ml Syr |
| • Sandimmune 100 Mg/ml Soln | • Sensipar |
| • Sirolimus 0.5 Mg Tablet | • Sirolimus 1 Mg Tablet |
| • Sirolimus 1 Mg/ml Solution | • Sirolimus 2 Mg Tablet |
| • Syndros | • Synribo |
| • Tacrolimus 0.5 Mg Capsule | • Tacrolimus 1 Mg Capsule |
| • Tacrolimus 5 Mg Capsule | • Tobramycin 300 Mg/5 Ml Ampule |
| • Travasol | • Trelstar 11.25 Mg Vial |
| • Trelstar 22.5 Mg Vial | • Trelstar 3.75 Mg Vial |
| • Trexall | • Trophamine |
| • Varubi 90 Mg Tablet | • Ventavis |
| • Xatmep | • Xgeva |
| • Yupelri | • Zortress |

Details

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

PCSK9 INHIBITORS (PENDING CMS APPROVAL)

- **Products Affected**
- Repatha Pushtronex
- Repatha Syringe
- Praluent Pen
- Repatha Sureclick

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use of Juxtapid or Kynamro
Required Medical Information	Prior therapies tried, medication adverse event history, medical history.
Age Restriction	N/A
Prescriber Restriction	Prescribed by or in consultation with a Cardiologist/lipid/cardiometabolic specialist/endocrinologist.
Coverage Duration	3 years

Other Criteria

For Heterozygous Familial Hypercholesterolemia and Clinical Atherosclerotic Cardiovascular Disease, the member must have tried and failed ONE high intensity statin (for example, atorvastatin greater than or equal to 40mg daily or rosuvastatin greater or equal to 20mg daily), unless a physician has diagnosed rhabdomyolysis or the member is determined to be statin intolerant. Statin intolerance is defined by experiencing statin related skeletal-related muscle symptoms while receiving two separate trials of statins and during both trials the skeletal-related symptoms resolved during drug discontinuation. The statin trials may be either a trial of two different statins or a rechallenge of the same statin at a lower dose. The member need not exceed two trials total to confirm intolerance. Additionally, for Clinical Atherosclerotic Cardiovascular Disease, the treatment must be for secondary prevention, which requires a history of one of the following conditions: prior MI, history of acute coronary syndrome, diagnosis of angina, history of stroke or transient ischemic attack, peripheral arterial disease, undergone a coronary or other arterial revascularization procedure. For Repatha only, Homozygous Familial Hypercholesterolemia will be approved. For Repatha only, allow approval for primary hyperlipidemia in an adult to reduce the risk of myocardial infarction, stroke, or coronary revascularization in patient with established cardiovascular disease. For Praluent-primary hyperlipidemia (not associated with ASCVD or HoFH)-approve if the member tried one high-intensity statin therapy (defined above) and ezetimibe for 8 weeks or longer and LDL remains 100 mg/dL or higher unless statin intolerant (defined above).

• **Products Affected**

• **Piqray**

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapies
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	3 years
Other Criteria	Approve if the patient meets the following criteria (A, B, C, D and E): A) The patient is a postmenopausal female or a male [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] AND B) The patient has advanced or metastatic hormone receptor (HR)-positive disease AND C) The patient has human epidermal growth factor receptor 2 (HER2)-negative disease AND D) The patient has PIK3CA-mutated breast cancer as detected by an approved test AND E) The patient has progressed on or after at least one prior endocrine-based regimen (e.g., anastrozole, letrozole, exemestane, Faslodex, tamoxifen, toremifene).

PPIS

- **Products Affected**
- Prilosec Dr 2.5 Mg Suspension
- Prilosec Dr 10 Mg Suspension
- Protonix 40 Mg Suspension

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	Must try and fail any TWO of the following generic products first, taken for a minimum of two weeks each: esomeprazole magnesium, lansoprazole, omeprazole, pantoprazole, rabeprazole.

PROVIGIL/NUVIGIL

- **Products Affected**
- Armodafinil
- Modafinil

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Confirmed diagnosis for a covered use. For Sleep Work Shift Disorder, other sleep disorders or contributing factors to sleep disorder have been ruled out, such as sleep apnea, restless leg syndrome/periodic limb movements, insomnia, or other causes for circadian rhythm misalignment (depression, gastrointestinal problems).
Age Restriction	N/A
Prescriber Restriction	For narcolepsy, the prescriber is a neurologist or sleep specialist
Coverage Duration	For Sleep Work Disorder, 12 months. All others, Lifetime.
Other Criteria	For narcolepsy, therapy will be allowed if one of the following is met: The member tried and failed or has a contraindication to TWO first line products: Amphetamine/dextroamphetamine (amphetamine salt combinations), Dexmethylphenidate, Dextroamphetamine, Methamphetamine, Methylphenidate, OR the member has a history of substance abuse. For Sleep Work Shift Disorder, the member must have a documented shift work schedule (night shifts, rotating shifts). Modafinil will be allowed for patients with Multiple Sclerosis-related fatigue.

REVATIO

- **Products Affected**
- Alyq
- Sildenafil 10 Mg/ml Oral Susp
- Tadalafil 20 Mg Tablet
- Adcirca
- Revatio 10 Mg/ml Oral Susp
- Sildenafil 20 Mg Tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Erectile dysfunction. Benign Prostatic hyperplasia.
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	Members requesting tadalafil (Adcirca) must try and fail sildenafil first.

- **Products Affected**
- Tiglutik
- Riluzole

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	Neurologist.
Coverage Duration	Lifetime.
Other Criteria	Requires documentation of exclusion of other diagnoses by neurologist.

• **Products Affected**

• Rinvok Er

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent use with a biologic or with a targeted synthetic DMARD. Concurrent use with other potent immunosuppressants.
Required Medical Information	Diagnosis, concurrent medications, previous drugs tried
Age Restriction	18 years and older
Prescriber Restriction	For rheumatoid arthritis: Prescribed by or in consultation with a rheumatologist.
Coverage Duration	3 years
Other Criteria	For rheumatoid arthritis (RA): Approve if the patient tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to step back and try a conventional synthetic DMARD).

RUBRACA

• **Products Affected**

• **Rubraca**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	For ovarian cancer, Fallopian tube, or primary peritoneal cancer - Deleterious BRCA mutation (germline and/or somatic) after 2 or more previous chemotherapies. For ovarian cancer, Fallopian tube, or primary peritoneal cancer recurrent disease - maintenance therapy after complete or partial response to platinum-based chemotherapy.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	Patient has been treated with two or more previous chemotherapies. Rubraca will be used as monotherapy.

RUZURGI

• **Products Affected**

• **Ruzurgi**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	History of seizures (initial therapy)
Required Medical Information	Diagnosis, seizure history, lab and test results
Age Restriction	6 to less than 17 years of age
Prescriber Restriction	Prescribed by or in consultation with a neurologist or a neuromuscular specialist.
Coverage Duration	Initial therapy: 3 months Continuation of therapy: 1 year
Other Criteria	For initial therapy: Diagnosis confirmed by at least one electrodiagnostic study (e.g., repetitive stimulation) OR anti-P/Q-type voltage-gated calcium channels (VGCC) antibody testing according to the prescribing physician. For continuation of therapy: Patient continues to derive benefit (e.g., improved muscle strength, improvement in mobility) from Ruzurgi, according to the prescribing physician.

RYDAPT

• **Products Affected**

• Rydapt

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	For acute myeloid leukemia, FLT3-positive, midostaurin is not indicated for single-agent induction therapy.
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Indefinite.
Other Criteria	N/A

• **Products Affected**

• Samsca

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Patients requiring urgent intervention to raise serum sodium acutely. Patients unable to sense or appropriately respond to thirst. Patients with hypovolemic hyponatremia. Concomitant use of strong CYP 3A inhibitors. Patients who are anuric. Liver disease.
Required Medical Information	The diagnosis must be clinically significant hyponatremia, hypervolemic or euvolemic, defined as serum sodium less than 125meq/l or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, and the patient must be symptomatic (symptoms may include nausea/vomiting, headache, confusion, lethargy, fatigue, loss of appetite, restlessness and irritability, muscle weakness, spasm, cramps, seizures, decreased consciousness, or coma), including patients with heart failure, cirrhosis, and SIADH.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	30 days.
Other Criteria	Therapy must be initiated or re-initiated in a hospital setting. The patient must have failed or resisted correction with both fluid restriction and one other means of treatment, such as loop diuretics, hypertonic saline, or salt tablets. The patient has been discontinued from any other possible causes of drug-induced hyponatremia or SIADH (such as carbamazepine, oxcarbazepine, chlorpropamide, fluoxetine, sertraline, vincristine, vinblastine, cisplatin, cyclophosphamide, thiothixene, thioridazine, haloperidol, amitriptyline, MAO inhibitors, methotrexate, NSAIDs, interferon alpha and gamma, amiodarone, ciprofloxacin, and opiates).

SGLT-2

- **Products Affected**
- Segluromet
- Steglatro
- Steglujan

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	When the non-preferred product is requested, documentation must be provided including the preferred medication tried, dates of preferred drug trial, and/or the specific reason for requesting the exception (for example, the reason for failure on the preferred product, the contraindication to the preferred product, the adverse reaction experienced with the preferred product, or the clinical condition for which an exception to the preferred product is requested).
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	One year.
Other Criteria	Invokana, Invokamet, Jardiance, Farxiga and Xigduo are the preferred products. The drug must be prescribed within the manufacturers published dosing guidelines or the dose falls within dosing guidelines found in accepted compendia or current literature AND one of the following: The member has demonstrated a failure of or intolerance to one preferred formulary/preferred drug list alternatives for the given diagnosis, OR the member has a documented contraindication to one preferred formulary alternative, or the member had an adverse reaction or would be reasonably expected to have an adverse reaction to one preferred formulary alternative, OR the member has a clinical condition for which there is no listed preferred formulary alternative to treat the condition based on published guidelines or clinical literature.

• **Products Affected**

• Siliq

PA Criteria	Criteria Details
Covered Uses	All FDA approved indication not otherwise excluded from Part D. Plus patients already started on Siliq for a covered use
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).
Required Medical Information	Diagnosis, prescriber specialty, other medications tried and length of trials.
Age Restriction	18 years of age or older
Prescriber Restriction	Prescribed by or in consultation with a dermatologist.
Coverage Duration	Initial-4 months, Positive Response-Indefinite.
Other Criteria	The member meets all of the following indication specific requirements (A and B): A. The patient meets either of the following criteria: 1) At least 5 percent of the body surface area was affected by plaque psoriasis at the time of diagnosis, or 2) Crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) were affected by plaque psoriasis at the time of diagnosis. B. The patient meets the following criteria: 1) Patient has the patient has tried TWO of the following: Enbrel, Humira, Stelara SC, Otezla, or Cosentyx.

• **Products Affected**

• **Simponi**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on golimumab (IV or SC) for a covered use.
Exclusion Criteria	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
Required Medical Information	For Rheumatoid Arthritis, the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis and the disease must be active. For Ankylosing Spondylitis, the member must have a confirmed diagnosis of Ankylosing Spondylitis as defined by presence of active disease for at least 4 weeks defined by any disease specific functional scoring tool (i.e. a BASDAI Index of at least 4, Health Assessment Questionnaire (HAQ), Modified Health Assessment Questionnaire (MHAQ), etc...) and an expert opinion based on clinical features, acute phase reactants and imaging modalities. For Psoriatic Arthritis, the member must have a confirmed diagnosis of Psoriatic Arthritis. For Ulcerative Colitis, the member must have a confirmed diagnosis of moderate to severe ulcerative colitis.
Age Restriction	N/A
Prescriber Restriction	RA/AS-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. UC-prescribed by or in consultation with a gastroenterologist or a rheumatologist.
Coverage Duration	AS 12wk initl,w/pos resp, 3 year. UC 8wk initl,w/remssn evidnce, 3 year. Othr aprvd indictn, 3 year.

Other Criteria

For AS, approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx. For PsA, approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx, Stelara, Otezla, Orencia, Xeljanz/XR. For RA, approve if the patient has tried two of the following: Enbrel, Humira, Orencia, or Xeljanz/XR. For UC, approve if the patient has had a trial with Humira.

• **Products Affected**

• Skyrizi (2 Syringes) Kit

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients currently receiving Skyrizi for a Covered Use.
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).
Required Medical Information	Diagnosis, prescriber specialty, other medications tried and length of trials.
Age Restriction	18 years of age and older.
Prescriber Restriction	Prescribed by or in consultation with a dermatologist.
Coverage Duration	Initial: 4 months. Continued use and if member is receiving positive response: 3 years
Other Criteria	Initial Therapy-The patient meets ONE of the following conditions (a or b): a) The patient has tried at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant. NOTE: An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (e.g., an adalimumab product [Humira], a certolizumab pegol product [Cimzia], an etanercept product [Enbrel, Erelzi], an infliximab product [e.g., Remicade, Inflectra, Renflexis], Cosentyx [secukinumab SC injection], Ilumya [tildrakizumab SC injection], Siliq [brodalumab SC injection], Stelara [ustekinumab SC injection], Taltz [ixekizumab SC injection], or Tremfya [guselkumab SC injection]). These patients who have already tried a biologic for psoriasis are not required to 'step back' and try a traditional systemic agent for psoriasis) b) The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician. Continuation Therapy - Patient must have responded, as determined by the prescriber.

SOVALDI

- **Products Affected**

- Sovaldi 400 Mg Tablet

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Sovaldi for a covered use. Plus Recurrent HCV Post-Liver Transplantation genotypes 1, 2, 3, and 4 and CHC Genotype 5 or 6.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	18 years or older. 12 and older in Genotype 2 and 3
Prescriber Restriction	Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD
Coverage Duration	12 wk, 16 wk, 24 wk, or 48 wk. Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.

SPORANOX

- **Products Affected**
- Itraconazole 100 Mg Capsule
- Tolsura
- Itraconazole 10 Mg/ml Solution
- Sporanox 10 Mg/ml Solution

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Also Tinea type infections including Versicolor, Capitis, Barbae, Crurus, Faciei, Manuum, Imbricata, Pedis (non moccasin or non chronic type), Corporis. Plantar type or Moccasin type dry chronic Tinea Pedis. Vaginal Candidiases. Prevention of recurrent vulvovaginal or vaginal candidiasis. Pityriasis versicolor. Other superficial and systemic mycosis. Oral candidiasis. Febrile neutropenia.
Exclusion Criteria	Vaginal candidiasis hypersensitivity syndrome.
Required Medical Information	Onychomycosis must be due to dermatophytes, and treatment must not be solely for cosmetic purposes as cosmetic use is excluded under Medicare Part D.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Twelve weeks.

Other Criteria

Tinea or Pityriasis Versicolor requires one trial and failure of ketoconazole or a topical antifungal agent first. Tinea Capitis and Barbae require failure of one trial of griseofulvin or ketoconazole first. Tinea Cruris, Faciei, Manuum, Imbricata and Pedis (non moccasin or chronic type) require failure of one topical antifungal agent. Tinea Corporis requires failure of one topical antifungal agent first, except when condition is considered extensive. Vaginal Candidiasis requires failure of both one topical antifungal regimen and one trial of oral fluconazole (patients of age less than 16 years are excluded from a trial of a topical vaginal antifungal preparation). For oral and esophageal candidiasis, must try and fail ketoconazole or fluconazole first. Itraconazole may be covered for other systemic infection if used for continuation of itraconazole therapy that has already been started and stabilized. Itraconazole may be used first line when the prescriber is a Pulmonologist or an Infectious Disease physician. For Torsura, may be used first line for Blastomycosis(pulmonary and extrapulmonary), Histoplasmosis(including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis), and Aspergillosis (pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy).

SPRYCEL

• **Products Affected**

• **Sprycel**

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus GIST, chondrosarcoma or chordoma and patients already started on Sprycel for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Sprycel is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	For CML, new patient must have Ph-positive CML for approval of Sprycel. For ALL, new patient must have Ph-positive ALL for approval of Sprycel. GIST - has D842V mutation AND previously tried Sutent and Gleevec.

STELARA

- **Products Affected**
- Stelara 45 Mg/0.5 MI Vial
- Stelara 45 Mg/0.5 MI Syringe
- Stelara 90 Mg/ml Syringe

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus approve Stelara SC in patients already started on Stelara (IV/SC) for a Covered Use.
Exclusion Criteria	Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthesis DMARD.
Required Medical Information	The member must have a confirmed diagnosis of moderate to severe Plaque Psoriasis, defined as a minimum body surface area involvement of greater than or equal to 5%, or by involvement of the hands, feet, facial, or genital regions, by which, despite involvement of a smaller BSA, the disease may interfere significantly with activities of daily life. For Psoriatic Arthritis, the member must have a confirmed diagnosis of Psoriatic Arthritis.
Age Restriction	Adults-PsA and CD PP-12 years and older
Prescriber Restriction	PP-prescribed by or in consultation with a dermatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist. CD-prescribed by or in consultation with a gastroenterologist or a rheumatologist.
Coverage Duration	Lifetime.

Other Criteria

For Plaque Psoriasis, patient must have tried and failed over a three month period a trial of one of the following: methotrexate, oral retinoids, cyclosporine, or phototherapy. For non axial forms of Psoriatic Arthritis, must first try and fail methotrexate for at least two months, OR if the member has an absolute contraindication to methotrexate, then Stelara will be approved. For axial forms of Psoriatic Arthritis, Stelara will be approved. For Crohn's Disease-induction therapy, approve single dose of IV formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD (eg, azathioprine, 6-MP, MTX, certolizumab, vedolizumab, adalimumab, infliximab). For Crohn's Disease-non-induction therapy, approve the SC formulation if the patient meets ONE of the following criteria: 1) patient has tried or is currently taking corticosteroids, or corticosteroids are contraindicated, OR 2) patient has tried one other agent for CD.

STIVARGA

• **Products Affected**

• **Stivarga**

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus Soft Tissue Sarcoma. Plus patients already started on Stivarga for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Stivarga is being used. For metastatic colorectal cancer (CRC) and gastrointestinal stromal tumors (GIST), prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	Metastatic CRC, patient must have previously been treated with each of the following for approval: a fluoropyrimidine (eg, Xeloda, 5-FU), oxaliplatin, and irinotecan. If patients tumor or metastases are wild-type KRAS and/or NRAS (that is, the tumors or metastases are KRAS and/or NRAS mutation negative), approve if fluoropyrimidine, oxaliplatin, irinotecan, AND either Erbitux or Vectibix. For GIST, patient must have previously been treated with imatinib (Gleevec) and sunitinib (Sutent). Hepatocellular carcinoma (HCC), patient must have previously been treated with at least one tyrosine kinase inhibitor (e.g., Nexavar (sorafenib), Lenvima).

SUNOSI (PENDING CMS APPROVAL)

• **Products Affected**

• Sunosi

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Concurrent treatment with monoamine oxidase inhibitor (MAOI) or use of an MAOI with the preceding 14 days.
Required Medical Information	Diagnosis, medications that will be used in combination, prior therapies
Age Restriction	18 years and older
Prescriber Restriction	Prescribed by or in consultation with a neurologist or a sleep specialist
Coverage Duration	1 year
Other Criteria	For Narcolepsy - One of the following (1 or 2): 1. The member tried and failed or has a contraindication to two first line products: Amphetamine/dextroamphetamine (amphetamine salt combinations), Dexmethylphenidate, Dextroamphetamine, Methamphetamine, Methylphenidate (or their branded products: Adderall, Adderall XR, Focalin, Focalin XR, Dexedrine Spansules, Procentra, Zenzedi, Desoxyn, Methylin, Concerta, Daytrana, Metadate CD, Metadate ER, Quillivant, Ritalin, Ritalin LA, Ritalin SR) OR 2. The member has a history of substance abuse.

SYMDEKO

- **Products Affected**

- Symdeko

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Cystic fibrosis diagnosis. Homozygous for F508 del mutation or Tezacaftor/Ivacaftor-responsive mutation in CFTR gene.
Age Restriction	6 years of age or older.
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	N/A

TAFAMIDIS

• **Products Affected**

• **Vyndaqel**

PA Criteria	Criteria Details
Covered Uses	All FDA indications not otherwise excluded from Part D.
Exclusion Criteria	Concomitant use with Onpattro or Tegsedi. Concurrent use of Vyndaqel and Vyndamax.
Required Medical Information	Diagnosis, genetic tests and lab results.
Age Restriction	18 years and older.
Prescriber Restriction	Prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis.
Coverage Duration	1 year.
Other Criteria	For cardiomyopathy of Wild-Type or Hereditary Transthyretin Amyloidosis: approve if the patient meets all of the following: A. The patient has genetic testing to identify a transthyretin (TTR) mutation (e.g., Val122Ile mutation, Thr60Ala mutation) or wild-type amyloidosis AND B. The diagnosis was confirmed by one of the following (i or ii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy) OR ii. Amyloid deposits are identified on cardiac biopsy AND C. Diagnostic cardiac imaging (e.g., echocardiogram, cardiac magnetic imaging) has demonstrated cardiac involvement (e.g., increased thickness of the ventricular wall or interventricular septum)

TAFINLAR

• **Products Affected**

• Tafinlar

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients with Colon or Rectal Cancer. Plus, patients with melanoma already started on dabrafenib prior to joining health plan in the absence of confirmed BRAF mutation status (unknown BRAF V600E for single agent treatment, unknown BRAF V600E and V600K for combination treatment with trametinib).
Exclusion Criteria	Patients with melanoma with wild-type BRAF (i.e., no detected BRAF V600E mutation for single treatment, no detected BRAF V600E or V600K for combination treatment). Patients with melanoma initiating single agent therapy with dabrafenib whose BRAF V600E status is unknown. Patients initiating combination therapy with trametinib whose BRAF V600E and V600K is unknown.
Required Medical Information	For patients new to therapy, BRAF V600E status required for single agent therapy. For patients new to therapy in combination with trametinib, BRAF V600E and/or V600K status required. Members already started on therapy prior to joining health plan with unconfirmed BRAF status must confirm BRAF V600E for single agent treatment and/or V600K status for combination treatment with trametinib to continue.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	BRAFV600E and/or V600K confrmd, lifetime. If cont from prior to joining plan and BRAF unknwn, 1mo.

Other Criteria

Patients new to single agent therapy must have BRAF V600E mutation. Patients continuing single agent therapy from prior to joining health plan already started on therapy must confirm BRAF V600E to continue treatment. Patients new to combination therapy with trametinib must have BRAF V600E or V600K mutation. Patients continuing combination treatment with trametinib from prior to joining health plan already started on therapy must confirm BRAF V600E or V600K to continue treatment. Colon or Rectal cancer-approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer.

TAGRISSE

• **Products Affected**

• Tagrisso

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	NSCLC - prior therapies and EGFR T790M mutation or EGFR exon 19 deletion or exon 21 (L858R) substitution.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	NSCLC - Must have metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive NSCLC as detected by an approved test AND has progressed on or after one of Vizimpro, Tarceva, Iressa, or Gilotrif therapy. Tagrisso will be approved for use in first-line setting in patients with exon 19 deletion or exon 21 substitution mutation.

TAKHZYRO

- **Products Affected**

- Takhzyro

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis. Lab values. Previous medication trials.
Age Restriction	12 years of age and older.
Prescriber Restriction	Prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of hereditary angioedema (HAE) or related disorders (initial and continuation).
Coverage Duration	3 years

Other Criteria

For initiation of prophylactic therapy (must meet 1 AND 2):

1. Approve if the patient meets all of the following criteria: a)

Patient has HAE due to C1 inhibitor (C1-INH) deficiency (Type I or II), AND b) patient has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values, AND c) patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values

AND

2. The patient must have previously tried and failed or be intolerant of or have a contraindication to one of the following: danazol, oxandrolone, methyltestosterone, Amicar

(aminocaproic acid), or Cyklokapron (tranexamic acid) AND either of the following: The patient has 2 or more episodes of angioedema per month OR the patient's attack location occurs in body sites associated with a high risk of morbidity or mortality (e.g. laryngeal).

For continuation of prophylactic therapy: Approve if the patient meets all of the following criteria:

1. Patient is currently receiving Takhzyro for HAE type I or II,

AND

2. According to the prescribing physician, the patient has had a favorable clinical response to therapy (e.g. decrease in number of HAE acute attack frequency, decrease in HAE attack severity, decrease in duration of HAE attacks.)

- **Products Affected**
- Taltz Autoinjector (2 Pack)
- Taltz Syringe
- Taltz Syringe (3 Pack)
- Taltz Autoinjector
- Taltz Autoinjector (3 Pack)
- Taltz Syringe (2 Pack)

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients currently receiving Taltz for a Covered Use.
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).
Required Medical Information	The member must have a confirmed diagnosis of moderate to severe Plaque Psoriasis, defined as a minimum body surface area involvement of greater than or equal to 5%, or by involvement of the hands, feet, facial, or genital regions, by which, despite involvement of a smaller BSA, the disease may interfere significantly with activities of daily life. The member must have a confirmed diagnosis of active Psoriatic Arthritis.
Age Restriction	18 years of age and older.
Prescriber Restriction	PP-prescribed by or in consultation with a dermatologist. PsA-Prescribed by or in consultation with a rheumatologist or a dermatologist.
Coverage Duration	Lifetime.
Other Criteria	For Plaque Psoriasis, approve if the patient has tried TWO of the following: Enbrel, Humira, Stelara (SC), Otezla, of Cosentyx. For Psoriatic Arthritis, approve if the patient has tried TWO of the following: Enbrel, Humira, Stelara SC, Otezla, Orencia, Xeljanz/XR or Cosentyx.

TALZENNA

- **Products Affected**

- Talzenna

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Talzenna for a covered use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restriction	18 years and older
Prescriber Restriction	Prescribed by or in consultation with an oncologist
Coverage Duration	Lifetime
Other Criteria	N/A

TARCEVA (PENDING CMS APPROVAL)

- **Products Affected**
- Erlotinib Hcl
- Tarceva

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on erlotinib for a Covered Use, renal cell carcinoma (RCC).
Exclusion Criteria	N/A
Required Medical Information	Advanced, recurrent, or metastatic non small cell lung cancer (NSCLC), EGFR mutation or gene amplification status.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	Metastatic NSCLC, approve if the patient has EGFR exon 19 deletions or exon 21 (L858R) substitution mutations. Locally advanced or metastatic NSCLC, approve if the patient has failed at least one prior chemotherapy regimen or the patient's disease has not progressed after four cycles of platinum-based first-line chemotherapy (switch-maintenance therapy). Pancreatic locally advanced, unresectable, or metastatic cancer, approve if erlotinib is being prescribed in combination with gemcitabine. Advanced RCC, approve if the patient has non-clear cell histology.

TASIGNA

• **Products Affected**

• **Tasigna**

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tasigna for a Covered Use. Plus Philadelphia positive Acute Lymphoblastic Leukemia (ALL) and Gastrointestinal Stromal Tumor (GIST).
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Tasigna is being used. For indication of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For indication of gastrointestinal stromal tumor (GIST) and ALL, prior therapies tried.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	For CML, new patient must have Ph-positive CML for approval of Tasigna. For GIST, patient must have tried TWO of the following - sunitinib (Sutent), imatinib (Gleevec), or regorafenib (Strivarga). For ALL, approve if the patient has tried ONE other tyrosine kinase inhibitor that is used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc).

TAVALISSE

• **Products Affected**

• **Tavalisse**

PA Criteria	Criteria Details
Covered Uses	All FDA approved indication not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried. Pre-treatment platelet count of less than 50,000/microL.
Age Restriction	18 years of age and older
Prescriber Restriction	Prescribed by or in consultation with a hematologist.
Coverage Duration	Initial - 4 months. Continuation - 3 years.
Other Criteria	For initiation of therapy: Member must have an FDA-approved indication for Tavalisse with pre-treatment platelet count of less than 50,000/microL. Allow initial approval if the patient has tried two other therapies or the patient has undergone splenectomy. For continuation of therapy: Platelet count must increase to a level sufficient to avoid clinically important bleeding after 12 weeks of Tavalisse therapy.

TAZAROTENE

- **Products Affected**
- Fabior
- Tazorac 0.05% Cream
- Tazorac 0.1% Gel
- Duobrii
- Tazarotene 0.1% Cream
- Tazorac 0.05% Gel

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Pregnancy. Fine wrinkle disorder/fine wrinkles on face.
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	Diagnosis of acne vulgaris requires failure on at least two other formulary anti-acne preparations. Members must utilize adequate measures to prevent pregnancy.

TEGSEDI

• **Products Affected**

• Tegsedi

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restriction	18 years and older
Prescriber Restriction	Prescribed by or in consultation with a neurologist, geneticist, or a physician who specializes in the treatment of amyloidosis.
Coverage Duration	1 year
Other Criteria	Approve if the patient has a documented transthyretin (TTR) mutation verified by genetic testing AND the patient has symptomatic peripheral neuropathy (e.g., reduced motor strength/coordination, impaired sensation [e.g., pain, temperate, vibration, touch]).

TESTOSTERONE

- **Products Affected**
- Androgel 1.62% Gel Pump
- Androgel 1.62%(2.5g) Gel Pckt
- Striant
- Testosterone 1.62% (2.5 G) Pkt
- Testosterone 1.62%(1.25 G) Pkt
- Testosterone 12.5 Mg/1.25 Gram
- Testosterone 30 Mg/1.5 Ml Pump
- Testosterone 50 Mg/5 Gram Pkt
- Androderm
- Androgel 1.62%(1.25g) Gel Pckt
- Fortesta
- Testim
- Testosterone 1.62% Gel Pump
- Testosterone 10 Mg Gel Pump
- Testosterone 25 Mg/2.5 Gm Pkt
- Testosterone 50 Mg/5 Gram Gel
- Vogelxo

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	Erectile dysfunction. Decreased Libido.
Required Medical Information	Patient must be symptomatic with a total testosterone level of less than 300ng/dl.
Age Restriction	Aged 18 years or older.
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	

TIBSOVO

- **Products Affected**

- Tibsovo

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Isocitrate dehydrogenase (IDH1) mutation status detected by an FDA-approved test.
Age Restriction	The member is 18 years of age or older.
Prescriber Restriction	N/A
Coverage Duration	Lifetime
Other Criteria	N/A

TOPAMAX/ZONEGRAN

- **Products Affected**
- Topiramate 100 Mg Tablet
- Topiramate 200 Mg Tablet
- Topiramate 25 Mg Tablet
- Topiramate Er
- Zonisamide 100 Mg Capsule
- Zonisamide 50 Mg Capsule
- Qudexy Xr
- Topiramate 15 Mg Sprinkle Cap
- Topiramate 25 Mg Sprinkle Cap
- Topiramate 50 Mg Tablet
- Trokendi Xr
- Zonisamide 25 Mg Capsule

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Coverage is not provided for weight loss or smoking cessation.
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	One year.
Other Criteria	Members requesting a brand product must try one generic drug first. Generic options are Carbamazepine, Carbamazepine XR, Divalproex, Epitol, Felbamate, Gabapentin, Lamotrigine, Lamotrigine ER, Levetiracetam, Oxcarbazepine, Phenytoin, Tiagabine, Topiramate, Valproic Acid, Zonisamide.

TOPICAL ALPHA-ADRENERGIC AGENTS FOR ROSACEA

- **Products Affected**
- Rhofade
- Mirvaso

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	18 years of age or older
Prescriber Restriction	N/A
Coverage Duration	12 months
Other Criteria	N/A

TOPICAL RETINOID PRODUCTS

- **Products Affected**
- Adapalene 0.1% Gel
- Adapalene 0.1% Swab
- Adapalene 0.3% Gel Pump
- Altreno
- Clindamycin Phos-tretinoin
- Epiduo Forte
- Retin-a Micro Pump 0.08% Gel
- Tretinoin 0.025% Cream
- Tretinoin 0.05% Cream
- Tretinoin 0.1% Cream
- Adapalene 0.1% Cream
- Adapalene 0.1% Solution
- Adapalene 0.3% Gel
- Adapalene-benzoyl Peroxide
- Avita
- Differin 0.1% Lotion
- Retin-a Micro Pump 0.06% Gel
- Tretinoin 0.01% Gel
- Tretinoin 0.025% Gel
- Tretinoin 0.05% Gel
- Tretinoin Microsphere

PA Criteria	Criteria Details
Covered Uses	All medically accepted indications not otherwise excluded from Part D.
Exclusion Criteria	Coverage is not provided for cosmetic use.
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	N/A

TRANSMUCOSAL IR FENTANYL DRUGS

- **Products Affected**
- Fentanyl Cit 100 Mcg Buccal Tb
- Fentanyl Cit 400 Mcg Buccal Tb
- Fentanyl Cit 800 Mcg Buccal Tb
- Fentanyl Cit Otfc 1,600 Mcg
- Fentanyl Citrate Otfc 400 Mcg
- Fentanyl Citrate Otfc 800 Mcg
- Lazanda
- Subsys 200 Mcg Spray
- Subsys 600 Mcg Spray
- Abstral
- Fentanyl Cit 200 Mcg Buccal Tb
- Fentanyl Cit 600 Mcg Buccal Tb
- Fentanyl Cit Otfc 1,200 Mcg
- Fentanyl Citrate Otfc 200 Mcg
- Fentanyl Citrate Otfc 600 Mcg
- Fentora
- Subsys 100 Mcg Spray
- Subsys 400 Mcg Spray
- Subsys 800 Mcg Spray

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	For breakthrough pain in patients with cancer if patient is unable to swallow, has dysphagia, esophagitis, mucositis, or uncontrollable nausea/vomiting OR patient is unable to take 2 other short-acting narcotics (eg, oxycodone, morphine sulfate, hydromorphone, etc) secondary to allergy or severe adverse events AND patient is on or will be on a long-acting narcotic (eg, Duragesic), or the patient is on intravenous, subcutaneous, or spinal (intrathecal, epidural) narcotics (eg, morphine sulfate, hydromorphone, fentanyl citrate).

TREMFYA

• **Products Affected**

• Tremfya

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Tremfya for a covered use.
Exclusion Criteria	Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).
Required Medical Information	Diagnosis, prescriber specialty, other medications tried and length of trials.
Age Restriction	18 years of age or older.
Prescriber Restriction	The medication must be prescribed or in consultation with a dermatologist.
Coverage Duration	Initial-4 months, Positive Response-3 years
Other Criteria	The member meets all of the following indication specific requirements (A and B): A. The patient meets either of the following criteria: 1) At least 5 percent of the body surface area was affected by plaque psoriasis at the time of diagnosis, or 2) Crucial body areas (e.g., feet, hands, face, neck, groin, intertriginous areas) were affected by plaque psoriasis at the time of diagnosis. B.The patient meets the following criteria: 1) patient has tried TWO of the following: Enbrel, Humira, Stelara SC, Otezla or Cosentyx.

TURALIO

- **Products Affected**

- Turalio

PA Criteria	Criteria Details
Covered Uses	Any FDA approved indication not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies tried, liver function tests prior to beginning treatment and at specified intervals during treatment.
Age Restriction	18 years of age or older
Prescriber Restriction	N/A
Coverage Duration	3 years
Other Criteria	N/A

TYKERB

• **Products Affected**

• **Tykerb**

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus bone cancer-chordoma, EGFR positive recurrent disease. Plus patients already started on Tykerb for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis for which Tykerb is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	HER2-positive advanced or metastatic breast cancer, approve if Tykerb will be used in combination with Xeloda or Herceptin and the patient has received prior therapy with Herceptin. HER2-positive HR positive metastatic breast cancer, approve if the patient is postmenopausal and Tykerb will be used in combination with an aromatase inhibitor, that is letrozole (Femara), anastrozole, or exemestane. HER-2 positive early breast cancer, approve if Tykerb will be used in combination with Herceptin.

VENCLEXTA

- **Products Affected**
- Venclexta
- Venclexta Starting Pack

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients currently taking Venclexta for a Covered Use.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, prior therapy, 17p deletion status
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	CLL with or without 17p deletion- approve.

VIEKIRA

• Products Affected • Viekira Pak	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Viekira for a covered use.
Exclusion Criteria	Combination with other direct acting antivirals, excluding Ribavirin.
Required Medical Information	Genotype 1, Cirrhosis status and genotype 1 subtype
Age Restriction	18 years or older
Prescriber Restriction	Prescribed by or in consultation with GI, hepatologist, ID, or liver transplant MD.
Coverage Duration	12 weeks or 24 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. Viekira must be prescribed in combination with Ribavirin for Genotype 1a, and Recurrent HCV post liver transplant. Gilead products and Mavyret are the preferred products. Authorization for Viekira requires that the member must have confirmation of one of the following: A documented failure to one of the preferred products, OR A documented intolerance to one the preferred products, OR A documented contraindication to the preferred products, OR A documented adverse reaction to one of the preferred products or would be reasonably expected to have an adverse reaction to the preferred products, OR A clinical condition/diagnosis for which there is no preferred product to treat the condition based on published guidelines or clinical literature.

VITRAKVI

• Products Affected • Vitrakvi	
PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	3 years
Other Criteria	N/A

VIZIMPRO

- **Products Affected**

- Vizimpro

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Vizimpro for a covered use.
Exclusion Criteria	N/A
Required Medical Information	NSCLC-EGFR mutation
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime
Other Criteria	Non small cell lung cancer (NSCLC): must have metastatic epidermal growth factor receptor (EGFR) exon 19 or exon 21 L858R substitution mutation as detected by an approved test.

VOSEVI

• **Products Affected**

• Vosevi

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Previous therapy. Member has been tested for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment of Vosevi.
Age Restriction	18 years of age or older
Prescriber Restriction	The medication must be prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease physician, or a liver transplant physician.
Coverage Duration	12 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance.

• **Products Affected**

• **Xalkori**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus, patients with non-small cell lung cancer (NSCLC) already started on crizotinib prior to joining health plan in the absence of confirmed ALK or ROS-1 status. Plus, patients with Peripheral T-Cell Lymphoma-Anaplastic Large Cell Lymphoma (ALCL). Plus soft tissue sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation, Plus NSCLC with high level MET amplification or MET Exon 14 skipping mutation.
Exclusion Criteria	Patients with anaplastic lymphoma kinase (ALK)-negative or reactive oxygen species (ROS)-1 negative NSCLC. Patients with NSCLC initiating therapy whose ALK and ROS-1 status are unknown.
Required Medical Information	For NSCLC patients new to therapy, ALK status, high level MET amplification status, MET Exon 14 skipping mutation, and ROS1 arrangement. Members already started on therapy prior to joining health plan with unconfirmed ALK or ROS-1 status must confirm ALK positive or ROS-1 positive status to continue. For soft tissue sarcoma IMT, ALK translocation.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	ALK/ROS-1 pos confrmd, lifetime. If cont use from prior to joining plan and ALK/ROS-1 unknown, 1mo.
Other Criteria	For NSCLC, patient new to therapy must have ALK positive, have high level MET amplification, have MET Exon 14 skipping mutation, or have ROS-1 rearrangement for approval. Patients continuing therapy from prior to joining health plan already started on therapy must confirm ALK positive or ROS-1 positive status to continue treatment. For IMT, patient new to therapy must have ALK translocation for approval.

- **Products Affected**
- Xeljanz
- Xeljanz Jr

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Xeljanz/XR for a Covered Use.
Exclusion Criteria	Concurrent use with a biologic for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil] that are not methotrexate (MTX).
Required Medical Information	For Rheumatoid Arthritis, the member must have a confirmed diagnosis of moderate to severe Rheumatoid Arthritis and the disease must be active. For Psoriatic Arthritis, the member must have a confirmed diagnosis of active Psoriatic Arthritis. For Ulcerative Colitis, the member must have a confirmed diagnosis of moderate to severe ulcerative colitis and the disease must be active.
Age Restriction	N/A
Prescriber Restriction	RA-prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist. UC-prescribed by or in consultation with a gastroenterologist.
Coverage Duration	Lifetime.
Other Criteria	For RA/PsA/UC, patient has tried one conventional synthetic DMARD for at least 3 months (note: patients who have already had a 3-month trial of a biologic for RA are not required to “step back” and try a conventional synthetic DMARD).

XENAZINE

- **Products Affected**

- Tetrabenazine

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	Impaired hepatic function, Concomitant use of MAOIs or Reserpine, Non-Huntington's related chorea.
Required Medical Information	Diagnosis must be chorea associated with Huntington's Disease.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	N/A

XOLAIR

• **Products Affected**

• **Xolair**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D
Exclusion Criteria	N/A
Required Medical Information	For asthma, diagnosis must be moderate to severe persistent asthma, and member must have a positive skin test or in vitro testing (blood test for allergen-specific IgE antibodies such as RAST) for one or more perennial aeroallergens or for one or more seasonal aeroallergens. For urticaria, diagnosis must be Chronic Idiopathic Urticaria.
Age Restriction	6 years or greater.
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	Asthma requires trial and failure to control symptoms by inhaled moderate to high dose corticosteroids after at least 2 months of therapy or an intolerance or contraindication to corticosteroids. Failure is demonstrated by hospitalization for asthma, requirement for systemic (oral or parenteral) corticosteroids to control exacerbations of asthma, increasing need (usually greater than once per day) for short-acting inhaled beta2 agonist for symptom control (excluding preventive use of exercise induced asthma). Chronic Idiopathic Urticaria requires the that member remains symptomatic despite H1 antihistamine treatment or an intolerance or contraindication to H1 antihistamine treatment.

XOSPATA

- **Products Affected**

- Xospata

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Diagnosis, previous therapies, FLT3 mutation
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	3 years
Other Criteria	N/A

XYREM

- **Products Affected**

- **Xyrem**

PA Criteria	Criteria Details
Covered Uses	All FDA approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Previous therapies
Age Restriction	N/A
Prescriber Restriction	Prescribed by a sleep specialist physician or a Neurologist
Coverage Duration	12 months
Other Criteria	For Excessive Daytime Sleepiness (EDS) in patients with narcolepsy-approve if the patient has tried one CNS stimulant (e.g., methylphenidate, dexamethylphenidate, dextroamphetamine), modafinil, or armodafinil. For narcolepsy with cataplexy-approve if the patient has tried one REM sleep-suppressing medication (eg, venlafaxine, fluoxetine, atomoxetine).

ZEJULA

- **Products Affected**

- Zejula

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D.
Exclusion Criteria	N/A
Required Medical Information	Prior therapies
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime
Other Criteria	Approve if the patient has had a complete or partial response after platinum-based chemotherapy regimen AND Zejula is requested for maintenance treatment.

ZELBORAF

• **Products Affected**

• **Zelboraf**

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients with colon or rectal cancer. Plus, patients with melanoma already started on vemurafenib prior to joining health plan in the absence of confirmed BRAF V600E mutation status.
Exclusion Criteria	Patients with melanoma with wild-type BRAF (i.e., no detected BRAFV600E mutation). Patients with melanoma initiating therapy with vemurafenib whose BRAFV600E status is unknown.
Required Medical Information	For patients new to therapy, BRAFV600 mutation status required. Members already started on therapy prior to joining health plan with unconfirmed BRAF status must confirm BRAFV600 mutation status to continue.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	BRAFV600 mutation confirmed, lifetime. Continuing prior to joining plan and BRAF unknown, 1mo.
Other Criteria	Malignant Melanoma - Patients new to therapy must have BRAFV600E mutation. Erdheim-Chester Disease - Patients new to therapy must have BRAF V600 mutation. Patients continuing therapy from prior to joining health plan already started on therapy must confirm BRAFV600 mutation to continue treatment. Colon or Rectal cancer-approve if the patient meets the following (A, B, and C): A) The patient has BRAF V600E mutation-positive disease AND B) The patient has previously received a chemotherapy regimen for colon or rectal cancer AND C) The agent is prescribed as part of a combination regimen for colon or rectal cancer.

ZEPATIER

• Products Affected • Zepatier	
PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Zepatier for a Covered Use.
Exclusion Criteria	Combination use with other direct acting antivirals, excluding Sovaldi and ribavirin.
Required Medical Information	Hep C genotype, concurrent medications, medication history, NS5A polymorphism
Age Restriction	18 years or older
Prescriber Restriction	Prescribed by or in consultation w/ GI, hepatologist, ID, or liver transplant MD.
Coverage Duration	12 weeks or 16 weeks. Criteria will be applied consistent with current AASLD/IDSA guidance.
Other Criteria	Criteria will be applied consistent with current AASLD/IDSA guidance. Harvoni, Epclusa, Sovaldi, Vosevi and Mavyret are the preferred products. Authorization for Zepatier requires that the member must have confirmation of one of the following: A documented failure to one of the preferred products, OR A documented intolerance to one the preferred products, OR A documented contraindication to one of the preferred products, OR A documented adverse reaction to one of the preferred products.

ZYKADIA

- **Products Affected**

- Zykadia

PA Criteria	Criteria Details
Covered Uses	All FDA-approved indications not otherwise excluded from Part D. Plus Soft Tissue Sarcoma Inflammatory Myofibroblastic (IMT) with ALK Translocation. Allow approval as first line therapy for NSCLC that is ALK positive.
Exclusion Criteria	N/A
Required Medical Information	Must have metastatic NSCLC that is anaplastic lymphoma kinase (ALK)-positive. IMT - ALK Translocation status.
Age Restriction	N/A
Prescriber Restriction	N/A
Coverage Duration	Lifetime.
Other Criteria	N/A

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