

# ACTEMRA SQ

## Products Affected

- ACTEMRA SUBCUTANEOUS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started in tocilizumab (IV/SC) for a Covered Use.  |
| <b>Exclusion Criteria</b>           | Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.   |
| <b>Required Medical Information</b> | Diagnosis, concurrent medications, previous drugs tried.  |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | RA/GCA/PJIA - Prescribed by or in consultation with a rheumatologist.   |
| <b>Coverage Duration</b>            | GCA-6 mo initial, 3 yr cont.PJIA-4 mo initial, 3 yr cont.All other dx-3 mo initial, 3 yr cont.  |
| <b>Other Criteria</b>               | RA initial - approve if the patient has tried TWO of the following: Enbrel, Humira, Oencia (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. PJIA, approve if the patient has tried etanercept, Oencia or adalimumb. (Note: the patient does not have to have a trial with etanercept, Oencia or adalimumb if they have had a trial with infliximab in the past.) Cont tx - pt must have had a response as determined by the prescriber. |

# ACTHAR

## Products Affected

- ACTHAR H.P.

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | Coverage is not provided for diagnostic procedure.   |
| <b>Required Medical Information</b> | Diagnosis, prescriber or consulting physician specialty, previous medications tried and response   |
| <b>Age Restrictions</b>             | Infantile spasms- less than 2yo. Acute MS exac-adult   |
| <b>Prescriber Restrictions</b>      | Infantile spasms, prescr/consult w/neurolo/epileptologist.MS exacerbation, prescr/consult w/neuro/phys specializes MS.RA, JIA/JRA, AS, PsA, SLE, Systemic Dermatomyositis, prescr/consult w/rheum.Severe Erythema Multiforme, prescr/consult w/derm.Serum Sickness,prescr/consult w/allergist.Severe acute/chronic allergic/inflamm processes of eye and its adnexa, prescr/consult w/ ophthalmologist.Symptomatic Sarcoidosis, prescr/consult w/pulm/cardio.Nephrotic Syndrome, prescr/consult w/nephrologist.  |
| <b>Coverage Duration</b>            | All diagnoses-1 month  |
| <b>Other Criteria</b>               | 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 adverse effect or treatment failure AND is NOT being used as pulse therapy on a monthly basis. For all other FDA approved diagnoses (other than Infantile spasms or MS exacerbation), approve if the patient has tried a systemic corticosteroid (oral or IV) for the current condition and patient has experienced a severe adverse effect or treatment failure with the corticosteroid (e.g., a psychotic reaction). |

# ADEMPAS

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## Products Affected

- ADEMPAS

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | PAH and CTEPH- must be prescribed by or in consultation with a cardiologist or a pulmonologist.   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | 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  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already taking Afinitor for a Covered Use. Advanced, unresectable or metastatic neuroendocrine tumors. Perivascular Epitheloid Cell Tumors (PEComa), Recurrent Angiomyolipoma, Lymphangiomyomatosis, relapsed or refractory classical Hodgkin lymphoma, Waldenstrom's Macroglobulinemia/Lymphoplasmacytic Lymphoma (WM/LPL), Osteosarcoma, Thymomas and Thymic carcinomas, Differentiated (i.e. papillary, follicular, and Hurthle cell) Thyroid Carcinoma, Endometrial Carcinoma, Gastrointestinal Stromal Tumors (GIST) and Recurrent or progressive Meningioma. |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Breast Cancer-HER2 status, hormone receptor (HR) status.  |
| <b>Age Restrictions</b>             | Relapsed or refractory classical Hodgkin lymphoma-18 years and older  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | Under CMS Review  |

# ALECENSA

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## Products Affected

- ALECENSA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.                                 |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | Metastatic NSCLC - is anaplastic lymphoma kinase (ALK)-positive as detected by an approved test. |

## ALPHA 1 PROTEINASE INHIBITORS

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### Products Affected

- ARALAST NP INTRAVENOUS RECON SOLN 1,000 MG
- GLASSIA
- PROLASTIN-C INTRAVENOUS RECON SOLN
- ZEMAIRA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | PiMZ or PiMS phenotypes of AAT, IgA antibody deficient with antibodies against IgA   |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | 18 years and older (initial and continuation therapy)  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a pulmonologist  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | For AAT deficiency with panacinar emphysema, approve when all of the following criteria are met: 1) alpha1-antitrypsin (AAT) concentration less than 80mg/dl or less than 11 micromolar and 2) confirmation of PiZZ, PiZ(null) or Pi(null, null) phenotype (homozygous) AAT deficiency and 3) obstructive lung disease as defined by a forced expiratory volume in one second (FEV1) of 35 to 65% of predicted or a rapid decline in lung function defined as a change in FEV1 of greater than 120ml per year. |

# ALUNBRIG

## Products Affected

- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLETS,DOSE PACK

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on brigatinib for a Covered Use.                 |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | ALK status, treatment history and results   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 3 years   |
| <b>Other Criteria</b>               | Metastatic NSCLC, patient new to therapy must be ALK-positive AND experienced progression or intolerance while on Xalkori, Zykadia or Alecensa. |

# AMPYRA

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## Products Affected

- AMPYRA
- dalfampridine

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.               |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | MS. If prescribed by, or in consultation with, a neurologist or MS specialist. |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | N/A  |



# ANABOLIC STEROIDS

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## Products Affected

- ANADROL-50
- oxandrolone

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Patients w/Turner's Syndrome or Ullrich-Turner Syndrome (oxandrolone only), management of protein catabolism w/burns or burn injury (oxandrolone only), AIDS wasting and cachexia. |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.  |
| <b>Other Criteria</b>               | N/A   |

# ARANESP

## Products Affected

- ARANESP (IN POLYSORBATE) INJECTION SOLUTION 100 MCG/ML, 200 MCG/ML, 25 MCG/ML, 300 MCG/ML, 40 MCG/ML, 60 MCG/ML
- ARANESP (IN POLYSORBATE) INJECTION SYRINGE

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. All FDA-approved indications not otherwise excluded from Part D worded as anemia associated with chronic renal failure (CRF), including patients on dialysis and not on dialysis, and worded as anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia. Anemia due to myelodysplastic syndrome (MDS).   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Anemia w/CRF on and not on dialysis. A hemoglobin (Hb) of less than 10.0 g/dL for adults and less than or equal to 11 g/dL for children required for start, Hb has to be less than or equal 11.5 g/dL adults or less than or equal to 12 g/dL in children if previously receiving epoetin alfa (EA) or Aranesp or less than or equal to 11.5 g/dL in adults currently receiving Mircera. Anemia due to myelosuppressive chemotx, Hb is 10.0 g/dL or less to start or less than or equal to 12.0 g/dL if previously on EA or Aranesp AND currently receiving myelosuppressive chemo. MDS, approve tx if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start. If the pt has previously been receiving Aranesp or EA, approve only if Hb is 12.0 g/dL or less. All conds, deny if Hb exceeds 12.0 g/dL. |
| <b>Age Restrictions</b>             | MDS anemia = 18 years of age and older.  |
| <b>Prescriber Restrictions</b>      | MDS anemia, prescribed by or in consultation with, a hematologist or oncologist.   |
| <b>Coverage Duration</b>            | Anemia w/myelosuppressive = 4 mos, Other=6 mos.  |
| <b>Other Criteria</b>               | For all covered uses, the patient is required to try Procrit first line.   |

# ARCALYST

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## Products Affected

- ARCALYST

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | Concurrent biologic therapy   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | Initial tx CAPS-Greater than or equal to 12 years of age.   |
| <b>Prescriber Restrictions</b>      | Initial tx CAPS-prescribed by, or in consultation with, a rheumatologist, geneticist, allergist/immunologist, or dermatologist. |
| <b>Coverage Duration</b>            | 3 mos initial, 3 years continue.  |
| <b>Other Criteria</b>               | CAPS renewal - approve if the patient has had a response as determined by the prescriber.                                       |

# ARIKAYCE

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## Products Affected

- ARIKAYCE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis, previous medication history  |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      | Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections  |
| <b>Coverage Duration</b>            | 1 year  |
| <b>Other Criteria</b>               | MAC Lung disease-approve if the patient has NOT achieved negative sputum cultures for Mycobacterium avium complex after greater than or equal to 6 consecutive months of a background multidrug regimen AND Arikayce will be used in conjunction to a background multidrug regimen. Note-a multidrug regimen typically includes a macrolide (azithromycin or clarithromycin), ethambutol and a rifamycin (rifampin or rifabutin). |

# AUBAGIO

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## Products Affected

- AUBAGIO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. All FDA approved indications not otherwise excluded from Part D. |
| <b>Exclusion Criteria</b>           | Concurrent use of Aubagio with other disease-modifying agents used for multiple sclerosis (MS)                                    |
| <b>Required Medical Information</b> | MS, patient must have a relapsing form of MS (RRMS, SPMS with relapses, or PRMS). MS, previous MS therapies tried.                |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a neurologist or MS specialist.   |
| <b>Coverage Duration</b>            | Authorization will be for 1 year.   |
| <b>Other Criteria</b>               | For patients already taking Aubagio, approve.   |

# AURYXIA

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## Products Affected

- AURYXIA

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

# AVONEX

## Products Affected

- AVONEX (WITH ALBUMIN)
- AVONEX INTRAMUSCULAR PEN INJECTOR KIT
- AVONEX INTRAMUSCULAR SYRINGE KIT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | Concurrent use of other disease-modifying agent used for multiple sclerosis (ie, interferon beta-1a, interferon beta-1b, glatiramer, natalizumab, fingolimod, teriflunomide, dimethyl fumarate DR) |
| <b>Required Medical Information</b> | Multiple Sclerosis (MS) diagnosis worded or described as patients with a diagnosis of MS or have experienced an attack and who are at risk of MS.  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or after consultation with a neurologist or an MS specialist.  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | N/A  |

## BENLYSTA SC

### Products Affected

- BENLYSTA SUBCUTANEOUS

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | Concurrent use with other biologics or with cyclophosphamide intravenous (IV)   |
| <b>Required Medical Information</b> | Diagnosis, medications that will be used in combination, autoantibody status  |
| <b>Age Restrictions</b>             | 18 years and older (initial and continuation)   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a rheumatologist, clinical immunologist, nephrologist, neurologist or dermatologist (initial and continuation)  |
| <b>Coverage Duration</b>            | Initial-4 months, cont-3 years  |
| <b>Other Criteria</b>               | Initial-The patient has autoantibody-positive SLE (i.e., positive for antinuclear antibodies [ANA] and/or anti-double-stranded DNA antibody [anti-dsDNA]) AND Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician.<br>Continuation-Benlysta is being used concurrently with at least one other standard therapy (i.e., antimalarials [e.g., hydroxychloroquine], a systemic corticosteroid [e.g., prednisone], and/or other immunosuppressants [e.g., azathioprine, mycophenolate mofetil, methotrexate]) unless the patient is determined to be intolerant due to a significant toxicity, as determined by the prescribing physician AND The patient has responded to Benlysta as determined by the prescriber. |



## BETASERON/EXTAVIA

### Products Affected

- BETASERON SUBCUTANEOUS KIT
- EXTAVIA SUBCUTANEOUS KIT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | Concurrent use with other disease-modifying agent used for multiple sclerosis   |
| <b>Required Medical Information</b> | Multiple Sclerosis (MS) diagnosis worded or described as patients with a diagnosis of MS or have experienced an attack and who are at risk of MS.   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or after consultation with a neurologist or an MS specialist.   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | For patients requesting Extavia, approve if the patient has tried two of the following: interferon beta-1a intramuscular (Avonex), interferon beta-1a subcutaneous (Rebif), interferon beta-1b (Betaseron), pegylated interferon beta-1a (Plegridy) or glatiramer acetate (Copaxone). |

# BOSULIF

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## Products Affected

- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus patients with Philadelphia chromosome positive Acute Lymphoblastic Leukemia. Plus patients already started on Bosulif for a Covered Use.                 |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis. For CML/ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported. For ALL, prior therapies tried   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.   |
| <b>Other Criteria</b>               | For CML, patient must have Ph-positive CML For ALL, patient must have Ph-positive ALL and has tried ONE other tyrosine kinase inhibitors that are used for Philadelphia chromosome positive ALL (e.g., Gleevec, Sprycel, etc). |

# BRAFTOVI

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## Products Affected

- BRAFTOVI ORAL CAPSULE 50 MG,  
75 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Braftovi for a covered use. |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis, BRAF V600 status   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 3 years   |
| <b>Other Criteria</b>               | Melanoma - approve if the patient has unresectable, advanced or metastatic melanoma AND has a BRAF V600 mutation.             |

## C1 ESTERASE INHIBITORS

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### Products Affected

- RUCONEST

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on the prescribed drug for a covered use.     |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders |
| <b>Coverage Duration</b>            | Authorization will be for 3 Years.   |
| <b>Other Criteria</b>               | N/A  |

# CABOMETYX

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## Products Affected

- CABOMETYX

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients with Non-Small Cell Lung Cancer with RET Gene Rearrangements. Plus patients already taking Cabometyx for a Covered Use. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, histology, RET gene rearrangement status  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | Advance Renal Cell Carcinoma (Predominant Clear Cell or Non-Clear Cell Histology)-Approve.   |

# CALQUENCE

## Products Affected

- CALQUENCE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus Chronic Lymphocytic Leukemia (CLL). Plus Small Lymphocytic Lymphoma (SLL). |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Previous medications/therapies tried   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | CLL and SLL-approve if the patient has tried one prior therapy.  |

# CAPRELSA

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## Products Affected

- CAPRELSA ORAL TABLET 100 MG,  
300 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma. Plus Non-Small Cell Lung Cancer with RET Gene Rearrangements |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 3 YEARS   |
| <b>Other Criteria</b>               | MTC - approve. DTC - approve if refractory to radioactive iodine therapy.disease AND has nonradioiodine-responsive tumors at sites other than central nervous system.   |

# CHENODAL

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## Products Affected

- CHENODAL

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | For the treatment of gallstones, approve if the patient has tried or is currently using an ursodiol product. |



# CHOLBAM

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## Products Affected

- CHOLBAM

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | Combination Therapy with Chenodal  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with hepatologist, metabolic specialist, GI or geneticist   |
| <b>Coverage Duration</b>            | 3 mos initial, 12 mos cont   |
| <b>Other Criteria</b>               | Bile acid synthesis d/o due to SEDs initial - Diagnosis based on an abnormal urinary bile acid as confirmed by Fast Atom Bombardment ionization - Mass Spectrometry (FAB-MS) analysis. Cont - responded to initial Cholbam tx with an improvement in LFTs AND does not have complete biliary obstruction. Bile-Acid Synthesis Disorders Due to Peroxisomal Disorders (PDs), Including Zellweger Spectrum Disorders initial - PD with an abnormal urinary bile acid analysis by FAB-MS AND has liver disease, steatorrhea, or complications from decreased fat soluble vitamin absorption (e.g., rickets). Cont - responded to initial Cholbam therapy as per the prescribing physician (e.g., improvements in liver enzymes, improvement in steatorrhea) AND does not have complete biliary obstruction. |

# CIALIS

## Products Affected

- CIALIS ORAL TABLET 2.5 MG, 5 MG
- tadalafil oral tablet 2.5 mg, 5 mg

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Indication for which tadalafil is being prescribed.  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 12 mos.  |
| <b>Other Criteria</b>               | Benign prostatic hyperplasia (BPH), after confirmation that tadalafil is being prescribed as once daily dosing, to treat the signs and symptoms of BPH and not for the treatment of erectile dysfunction (ED). |

# CIMZIA

## Products Affected

- CIMZIA
- CIMZIA POWDER FOR RECONST

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D plus patients already started on certolizumab pegol for Covered use.   |
| <b>Exclusion Criteria</b>           | Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD   |
| <b>Required Medical Information</b> | Diagnosis, concurrent medications, previous therapies tried  |
| <b>Age Restrictions</b>             | Adults for CD.   |
| <b>Prescriber Restrictions</b>      | RA/AS, prescribed by or in consultation with a rheumatologist. Crohn's disease, prescribed by or in consultation with a gastroenterologist. PsA prescribed by or in consultation with a rheumatologist or dermatologist  |
| <b>Coverage Duration</b>            | 3 months initial, 3 years cont.  |
| <b>Other Criteria</b>               | AS, approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx. PsA, approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx, Stelara, Otezla, Orencia or Xeljanz/XR. RA, approve if the patient has tried two of the following: Enbrel, Humira, Orencia, or Xeljanz/XR. CD, approve if patient has previously tried Humira. Plaque Psoriasis-approve if the patient has tried TWO of the following: Enbrel, Humira, Stelara SC, Otezla, or Cosentyx. Cont tx - approve if the patient has had a response to therapy, as according to the prescribing physician |

# COMETRIQ

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## Products Affected

- COMETRIQ

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus Non-Small Cell Lung Cancer with RET Gene Rearrangements, Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma and patients already started on Cometriq for a Covered Use. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | MTC - approve. Non-Small Cell Lung Cancer with RET Gene Rearrangements - approve. Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma-approve if the patient's carcinoma is refractory to radioactive iodine therapy.                          |

# COPAXONE

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## Products Affected

- COPAXONE SUBCUTANEOUS SYRINGE 20 MG/ML, 40 MG/ML
- glatiramer subcutaneous syringe 20 mg/ml, 40 mg/ml
- glatopa subcutaneous syringe 20 mg/ml, 40 mg/ml

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | Concurrent use with other disease-modifying agent used for multiple sclerosis   |
| <b>Required Medical Information</b> | Multiple Sclerosis (MS) diagnosis worded or described as patients with a diagnosis of MS or have experienced an attack and who are at risk of MS. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or after consultation with a neurologist or an MS specialist.   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | N/A   |

# COPIKTRA

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## Products Affected

- COPIKTRA

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

# CORLANOR

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## Products Affected

- CORLANOR

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Previous use of a Beta-blocker, LVEF, sinus rhythm, and resting HR   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | HF in pts not currently receiving Corlanor - must all of the following 1. have LVEF of less than or equal 35 percent, 2. have sinus rhythm and a resting HR of greater than or equal to 70 BPM, AND 3. tried or is currently receiving a Beta-blocker for HF (e.g., metoprolol succinate sustained-release, carvedilol, bisoprolol, carvedilol ER) unless the patient has a contraindication to the use of beta blocker therapy (e.g., bronchospastic disease such as COPD and asthma, severe hypotension or bradycardia). HF in pts currently receiving Corlanor - had a LVEF of less than or equal to 35 percent prior to initiation of Corlanor therapy AND has tried or is currently receiving a Beta-blocker for HF unless the patient has a contraindication to the use of beta blocker therapy. |

# COSENTYX

## Products Affected

- COSENTYX (2 SYRINGES)
- COSENTYX PEN (2 PENS)

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already taking Cosentyx for a Covered Use.  |
| <b>Exclusion Criteria</b>           | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)   |
| <b>Required Medical Information</b> | Diagnosis and previous medications use   |
| <b>Age Restrictions</b>             | PP/AS/PSA initial - 18 years of age and older  |
| <b>Prescriber Restrictions</b>      | PP initial - prescribed by or in consultation with a dermatologist or rheumatologist. AS initial- by or in consultation with rheumatologist, PsA initial- by or in consultation with rheumatologist or dermatologist.  |
| <b>Coverage Duration</b>            | PP/AS/PsA -initial tx 3 mos, cont tx 3 years   |
| <b>Other Criteria</b>               | PP initial-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. PP/AS/PsA cont - patient must have responded, as determined by the prescriber. |



# COTELLIC

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## Products Affected

- COTELLIC

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.                                 |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Melanoma initial - must have BRAF V600 mutation.   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | Melanoma (unresectable, advanced or metastatic) - being prescribed in combination with Zelboraf. |

# CRINONE GEL

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## Products Affected

- CRINONE VAGINAL GEL 8 %

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

# DALIRESP

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## Products Affected

- DALIRESP

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Chronic Obstructive Pulmonary Disease (COPD), medications tried.   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | COPD, approve in patients who meet all of the following conditions: Patients has severe COPD or very severe COPD, AND Patient has a history of exacerbations, AND Patient has tried a medication from two of the three following drug categories: long-acting beta2-agonist (LABA) [eg, salmeterol, indacaterol], long-acting muscarinic antagonist (LAMA) [eg, tiotropium], inhaled corticosteroid (eg, fluticasone). |

# DARAPRIM

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## Products Affected

- DARAPRIM

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Patient's immune status  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Toxoplasma gondii Encephalitis, Chronic Maintenance and Prophylaxis (Primary)-prescribed by or in consultation with an infectious diseases specialist. Toxoplasmosis Treatment-prescribed by or in consultation with an infectious diseases specialist, a maternal-fetal medicine specialist, or an ophthalmologist. |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Toxoplasma gondii Encephalitis, Chronic Maintenance, approve if the patient is immunosuppressed. Toxoplasma gondii Encephalitis Prophylaxis (Primary), approve if the patient is immunosuppressed.   |

# DESOXYN

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## Products Affected

- methamphetamine

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

## DIABETIC SUPPLIES

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### Products Affected

- alcohol pads
- GAUZE PADS 2 X 2
- INSULIN PEN NEEDLE 29 GAUGE X 1/2"
- INSULIN SYRINGE (DISP) U-100 0.3 ML, 1 ML, 1/2 ML
- NEEDLES, INSULIN DISP.,SAFETY

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.                            |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Confirmation that medical supply is directly associated with delivering insulin to the body |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 12 mos.   |
| <b>Other Criteria</b>               | N/A   |

# DOPTELET

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## Products Affected

- DOPTELET

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis, platelet count, date of procedure  |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 5 days  |
| <b>Other Criteria</b>               | Approve if the patient has a current platelet count less than 50 x 10 <sup>9</sup> /L AND the patient is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy. |

# DUPIXENT

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## Products Affected

- DUPIXENT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.                    |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis, prescriber specialty, other medications tried and length of trials       |
| <b>Age Restrictions</b>             | Under CMS Review  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a an allergist, immunologist or dermatologist |
| <b>Coverage Duration</b>            | Initial-16 weeks, Continuation-1 year   |
| <b>Other Criteria</b>               | Under CMS Review  |



# ENBREL

## Products Affected

- ENBREL
- ENBREL SURECLICK

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D plus patient already on etanercept for a Covered Use. Graft versus host disease (GVHD). Behcet's disease. Uveitis  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, concurrent medications, previous therapies tried.   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | RA/Ankylosing spondylitis/JIA/JRA,prescribed by or in consult w/ rheumatologist. Psoriatic arthritis, prescribed by or in consultation w/ rheumatologist or dermatologist.Plaque psoriasis (PP), prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center. Behcet's disease,prescribed by or in consult w/ rheumatologist,dermatologist,ophthalmologist,gastroenterologist,or neurologist.  |
| <b>Coverage Duration</b>            | FDA approved indications - 3 months initial, 3 years cont, others 12 months.   |
| <b>Other Criteria</b>               | RA initial, 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). JIA/JRA, 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.Plaque psoriasis (PP) initial 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, |

| PA Criteria | Criteria Details   |
|-------------|--|
|             | <p>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. GVHD. Tried or currently is receiving with etanercept 1 conventional GVHD tx (high-dose systemic corticosteroid, CSA, tacrolimus, MM, thalidomide, antithymocyte globulin, etc.). Behcet's. Has tried at least 1 conventional tx (eg, systemic corticosteroid, immunosuppressant, interferon alfa, MM, etc) or adalimumab or infliximab. Uveitis-tried one of the following: periocular, intraocular, or systemic coricosteroid, immunosuppressives, Humira or an infliximab product.RA/AS/JIA/PP/PsA Cont - must have a response to tx according to the prescriber. 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: 1) Patient has plaque psoriasis, OR 2) Patient has RA/JIA/PsA/AS and is started and stabilized on 50 mg twice weekly dosing, OR 3) 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 4) 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.</p> |

# EPCLUSA

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## Products Affected

- EPCLUSA
- sofosbuvir-velpatasvir

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients started on Eplusa for a Covered Use.                      |
| <b>Exclusion Criteria</b>           | Combination use with other direct acting antivirals, excluding ribavirin.  |
| <b>Required Medical Information</b> | Genotype, prescriber specialty, other medications tried or used in combination with requested medication                                 |
| <b>Age Restrictions</b>             | 18 years or older  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician |
| <b>Coverage Duration</b>            | Criteria will be applied consistent with current AASLD/IDSA guidance.  |
| <b>Other Criteria</b>               | Criteria will be applied consistent with current AASLD/IDSA guidance.  |

# EPIDIOLEX

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## Products Affected

- EPIDIOLEX

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Epidiolex for a covered use. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, previous therapies  |
| <b>Age Restrictions</b>             | Patients 2 years and older   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a neurologist  |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | N/A  |

# EPOETIN/PROCRIT

## Products Affected

- EPOGEN INJECTION SOLUTION 2,000 UNIT/ML, 20,000 UNIT/2 ML, 20,000 UNIT/ML, 3,000 UNIT/ML, 4,000 UNIT/ML
- PROCRIT INJECTION SOLUTION 10,000 UNIT/ML, 2,000 UNIT/ML, 20,000 UNIT/ML, 3,000 UNIT/ML, 4,000 UNIT/ML, 40,000 UNIT/ML

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus anemia in patients with HIV who are receiving zidovudine. Anemic patients (Hb of 13.0 g/dL or less) 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). Plus anemia due to myelodysplastic syndrome (MDS).   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | CRF anemia in patients on and not on dialysis. Hemoglobin (Hb) of less than 10.0 g/dL for adults or less than or equal to 11 g/dL for children to start. Hb less than or equal to 11.5 g/dL for adults or 12 g/dL or less for children if previously on epoetin alfa or Aranesp or less than or equal to 11.5 g/dL if currently receiving Mircer. Anemia w/myelosuppressive chemotx. pt must be currently receiving myelosuppressive chemo and Hb 10.0 g/dL or less to start. Hb less than or equal to 12.0 g/dL if previously on epoetin alfa or Aranesp. MDS, approve if Hb is 10 g/dL or less or serum erythropoietin level is 500 mU/mL or less to start. Previously receiving Aranesp or EA, approve if Hb is 12.0 g/dL or less. Anemia in HIV with zidovudine, Hb is 10.0 g/dL or less or endogenous erythropoietin levels are 500 mU/mL or less at tx start. Previously on EA approve if Hb is 12.0 g/dL or less. Surgical pts to reduce RBC transfusions - pt is unwilling or unable to donate autologous blood prior to surgery |
| <b>Age Restrictions</b>             | MDS anemia/HepC anemia = 18 years of age and older   |
| <b>Prescriber Restrictions</b>      | MDS anemia, prescribed by or in consultation with a hematologist or oncologist.  |
| <b>Coverage Duration</b>            | Anemia w/myelosuppressive = 4 mos. Transfus=1 mo. Other=6mo. HIV + zidovudine = 4 mo   |

| <b>PA Criteria</b>    | <b>Criteria Details</b>   |
|-----------------------|---|
| <b>Other Criteria</b> | For all covered uses, if the request is for Epogen, then the patient is required to try Procrit first line. |

# ERIVEDGE

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## Products Affected

- ERIVEDGE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus, patient already started on Erivedge for a covered use.   |
| <b>Exclusion Criteria</b>           | BCC (La or Met) - must not have had disease progression while on Odomzo.  |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 12 months   |
| <b>Other Criteria</b>               | Locally advanced basal cell carcinoma (LABCC), approve if 1. the patient's BCC has recurred following surgery or radiation, OR 2. the patient is not a candidate for surgery and radiation therapy. |

# ERLEADA

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## Products Affected

- ERLEADA

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



# ESBRIET

## Products Affected

- ESBRIET ORAL CAPSULE
- ESBRIET ORAL TABLET 267 MG, 801 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | Combination use with nintedanib   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | 18 years of age and older   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a pulmonologist   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | IPF baseline - must have FVC greater than or equal to 50 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP. |

# FARYDAK

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## Products Affected

- FARYDAK ORAL CAPSULE 10 MG, 15 MG, 20 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 12 month.                              |
| <b>Other Criteria</b>               | N/A  |

# FIRAZYR

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## Products Affected

- FIRAZYR

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by, or in consultation with, an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | N/A  |

# FORTEO

## Products Affected

- FORTEO

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, raloxifene, calcitonin nasal spray [Fortical], abaloparatide), except calcium and Vitamin D.  |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 2 years of therapy over a patient's lifetime  |
| <b>Other Criteria</b>               | Treatment of PMO, approve if pt has tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the pt cannot swallow or has difficulty swallowing or the pt cannot remain in an upright position post oral bisphosphonate administration or pt has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR pt has severe renal impairment (creatinine clearance less than 35 mL/min) or CKD or pt has had an osteoporotic fracture or fragility fracture. Increase bone mass in men (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) with primary or hypogondal osteoporosis/Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), |

| <b>PA Criteria</b> | <b>Criteria Details</b>  |
|--------------------|--|
|                    | OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture. |

## GABAPENTIN/LYRICA

### Products Affected

- gabapentin oral capsule
- gabapentin oral solution 250 mg/5 ml
- gabapentin oral tablet 600 mg, 800 mg
- LYRICA ORAL CAPSULE 100 MG, 150 MG, 200 MG, 225 MG, 25 MG, 300 MG, 50 MG, 75 MG
- LYRICA ORAL SOLUTION

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All medically accepted indications not otherwise excluded from Part D. Plus, patients already started on Lyrica for a Covered Use. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.   |
| <b>Other Criteria</b>               | N/A  |

# GALAFOLD

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## Products Affected

- GALAFOLD

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a geneticist, nephrologist, or a physician who specializes in the treatment of Fabry disease |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | Approve if the patient has an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.                        |

# GATTEX

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## Products Affected

- GATTEX 30-VIAL

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | N/A  |



# GILENYA

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## Products Affected

- GILENYA ORAL CAPSULE 0.5 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.                                |
| <b>Exclusion Criteria</b>           | Concurrent use of Gilenya with other disease-modifying agents used for multiple sclerosis (MS). |
| <b>Required Medical Information</b> | For use in MS, patient has a relapsing form of MS.  |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by, or in consultation with, a neurologist or an MS specialist.                      |
| <b>Coverage Duration</b>            | Authorization will be for 1 year.   |
| <b>Other Criteria</b>               | N/A   |

# GILOTRIF

## Products Affected

- GILOTRIF

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For NSCLC - EGFR exon deletions or mutations, or if NSCLC is squamous cell type  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | NSCLC EGFR pos - For the treatment of metastatic non small cell lung cancer (NSCLC) must be used in tumors with non-resistant EGFR mutation positive NSCLC as detected by an approved test. NSCLC metastatic squamous cell must have disease progression with first line treatment with platinum based chemotherapy. |

## GLUCAGON-LIKE PEPTIDE-1 AGONISTS

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### Products Affected

- BYDUREON MCG/ML) 2.4 ML, 5 MCG/DOSE (250
- BYDUREON BCISE MCG/ML) 1.2 ML
- BYETTA SUBCUTANEOUS PEN INJECTOR 10 MCG/DOSE(250
- TRULICITY

| 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 Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Authorization will be for 3 years.                               |
| Other Criteria               | N/A  |

## GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

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**Products Affected**

- LUPRON DEPOT
- LUPRON DEPOT (3 MONTH)
- LUPRON DEPOT (4 MONTH)
- LUPRON DEPOT (6 MONTH)

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.                              |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | For abnormal uterine bleeding/endomet/uterine leiomyomata approve 6 months/all other dx 12 mo |
| <b>Other Criteria</b>               | N/A   |

# GROWTH HORMONES

## Products Affected

- HUMATROPE
- NORDITROPIN FLEXPPO

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Covered Uses                 | All FDA-approved indications not otherwise excluded from Part D.  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | <p>GHD in children/adolescents initial must meet ONE of the following - 1. had hypophysectomy, 2. has congenital hypopituitarism AND had growth hormone response to one preferred GH test of less than 10 ng/mL (preferred tests are levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon), 3. has panhypopituitarism AND had growth hormone response to one preferred GH test of less than 10 ng/mL, has 3 or more pituitary hormone deficiencies (ACTH, TSH, LH/FSH, or prolactin), or pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior "bright spot" on MRI or CT, 4. pt had brain radiation, had growth hormone response to one preferred GH test of less than 10 ng/mL, AND meets one of these a. pretreatment 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, OR 5. had growth hormone 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. pretreatment 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. Continuation of tx-approve if the patient has experienced improvement, according to the prescribing physician.</p> |
| Age Restrictions             | ISS-5y/o or older,SGA 2y/o or older,SBS/HIVwasting/cachexia 18y/o or older  |
| Prescriber Restrictions      | 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.   |

| PA Criteria              | Criteria Details   |
|--------------------------|--|
| <b>Coverage Duration</b> | ISS - 6 mos initial, 12 months cont tx, SBS 4 weeks, others 12 mos   |
| <b>Other Criteria</b>    | <p>GHD initial in adults and adolescents 1. endocrine 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 adolescent must be off tx for at least one month before retesting. Cont tx - endocrine 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. 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. Cont Tx for CKD, Noonan, PW in child/adolescents, SHOX, and TS - 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.</p> |

# HAEGARDA

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## Products Affected

- HAEGARDA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders |
| <b>Coverage Duration</b>            | Authorization will be for 3 Years.   |
| <b>Other Criteria</b>               | N/A  |

# HARVONI

## Products Affected

- HARVONI
- ledipasvir-sofosbuvir

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients with recurrent HCV post-liver transplant. Plus patients started on Harvoni for a covered use. |
| <b>Exclusion Criteria</b>           | Combination use with other direct acting antivirals, excluding ribavirin.  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | 12 years or older  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation w/ GI, hepatologist, ID, or a liver transplant MD   |
| <b>Coverage Duration</b>            | Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug  |
| <b>Other Criteria</b>               | Criteria will be applied consistent with current AASLD/IDSA guidance.  |



# HETLIOZ

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## Products Affected

- HETLIOZ

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Confirmation the patient is totally blind with no perception of light.   |
| <b>Age Restrictions</b>             | 18 years or older  |
| <b>Prescriber Restrictions</b>      | Prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of sleep disorders   |
| <b>Coverage Duration</b>            | 6 mos initial, 12 mos cont   |
| <b>Other Criteria</b>               | 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. Approve if pt has received at least 6 months of continuous therapy (i.e., 6 consecutive months of daily treatment) with HetlioZ under the guidance of a physician who specializes in the treatment of sleep disorders AND has achieved adequate results with HetlioZ 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- ANTIEMETICS

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### Products Affected

- promethazine oral

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Previous medication use  |
| <b>Age Restrictions</b>             | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | End of the Contract Year   |
| <b>Other Criteria</b>               | PA does NOT apply to patients less than 65 yrs of age. These medications will be approved if ALL of the following are met: a. Patient has an FDA-approved diagnosis or CMS-approved compendia accepted indication for the requested high risk medication. For the treatment of emesis, approve if the patient has had a trial of one of the following non high risk medication alternative (brand or generic): prochlorperazine, ondansetron or granisetron b. Prescriber has completed a risk assessment of the high risk medication for the patient and has indicated that the benefits of the requested high risk medication outweigh the risks for the patient AND c. Prescriber has documented that s/he discussed risks and potential side effects of the medication with the patient. |

## HIGH RISK MEDICATION- ESTROGENS

### Products Affected

- estradiol oral
- estradiol transdermal patch semiweekly
- estradiol transdermal patch weekly
- estradiol-norethindrone acet
- MENEST ORAL TABLET 0.3 MG, 0.625 MG, 1.25 MG
- PREMARIN ORAL

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All medically accepted indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Previous medication use   |
| <b>Age Restrictions</b>             | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | End of the Contract Year  |
| <b>Other Criteria</b>               | <p>PA does NOT apply to patients less than 65 yrs of age. These medications will be approved if ALL of the following are met: a. Patient has an FDA-approved diagnosis or CMS-approved compendia accepted indication for the requested high risk medication. For the treatment of Vulvar Vaginal Atrophy, approve if the patient has had a trial of one of the following : Estradiol Vaginal Cream, or Estring. For the prophylaxis of Postmenopausal Osteoporosis, approve if the patient has had a trial of one of the following (brand or generic): alendronate, ibandronate, risidronate, Raloxifene, or Prolia. For the treatment of vasomotor symptoms of menopause, approve if the patient has had a trial of one of the following : Citalopram, Fluoxetine, Paroxetine, Venlafaxine or Gabapentin</p> <p>b. Prescriber has completed a risk assessment of the high risk medication for the patient and has indicated that the benefits of the requested high risk medication outweigh the risks for the patient AND c. Prescriber has documented that s/he discussed risks and potential side effects of the medication with the patient.</p> |

# HIGH RISK MEDICATION PRIOR AUTHORIZATION

## Products Affected

- benzotropine oral
- dicyclomine oral capsule
- dicyclomine oral solution
- dicyclomine oral tablet
- digitek oral tablet 250 mcg
- digox oral tablet 250 mcg
- digoxin oral solution 50 mcg/ml
- digoxin oral tablet 250 mcg
- ergoloid
- meclizine oral tablet 12.5 mg, 25 mg
- megestrol oral suspension 400 mg/10 ml (40 mg/ml), 625 mg/5 ml
- megestrol oral tablet
- phenobarbital
- scopolamine base
- thioridazine

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | End of the Contract Year  |
| <b>Other Criteria</b>               | PA does NOT apply to patients less than 65 yrs of age. High Risk Medications will be approved if ALL of the following is met: a.Patient has an FDA-approved diagnosis or CMS-approved compendia accepted indication for the requested high risk medication AND b.Prescriber has completed a risk assessment of the high risk medication for the patient and has indicated that the benefits of the requested high risk medication outweigh the risks for the patient AND c.Prescriber has documented that s/he discussed risks and potential side effects of the medication with the patient. |

## HIGH RISK MEDICATION- SEDATIVE HYPNOTICS

### Products Affected

- zaleplon oral capsule 10 mg, 5 mg
- zolpidem oral tablet

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Covered Uses                 | All medically accepted indications not otherwise excluded from Part D.  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Previous medication use   |
| Age Restrictions             | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.  |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | End of the Contract Year  |
| Other Criteria               | PA does NOT apply to patients less than 65 yrs of age. These medications will be approved if ALL of the following are met: a. Patient has an FDA-approved diagnosis or CMS-approved compendia accepted indication for the requested high risk medication. For the treatment of Insomnia, approve if the patient has had a trial of one of the following (brand or generic): Rozerem or Trazodone b. Prescriber has completed a risk assessment of the high risk medication for the patient and has indicated that the benefits of the requested high risk medication outweigh the risks for the patient AND c. Prescriber has documented that s/he discussed risks and potential side effects of the medication with the patient. |

# HIGH RISK MEDICATION- URINARY ANTI INFECTIVES

## Products Affected

- nitrofurantoin
- nitrofurantoin monohyd/m-cryst
- nitrofurantoin macrocrystal

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Covered Uses                 | All medically accepted indications not otherwise excluded from Part D.  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Previous medication use   |
| Age Restrictions             | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.  |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | End of the Contract Year  |
| Other Criteria               | <p>PA does NOT apply to patients less than 65 yrs of age. These medications will be approved if ALL of the following are met: a. Patient has an FDA-approved diagnosis or CMS-approved compendia accepted indication for the requested high risk medication. For the treatment of urinary track infections and acute cystitis the patient must have tried and failed one formulary non high risk medication alternative (brand or generic): ciprofloxacin, levofloxacin, ampicillin, amoxiciliin/clavulanate, amoxicillin, cephalexin or SMZ/TMP b. Prescriber has completed a risk assessment of the high risk medication for the patient and has indicated that the benefits of the requested high risk medication outweigh the risks for the patient AND c. Prescriber has documented that s/he discussed risks and potential side effects of the medication with the patient.</p> |

## HIGH RISK MEDICATION-ANTIPLATELETS

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### Products Affected

- dipyridamole oral

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All medically accepted indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Previous medication use  |
| <b>Age Restrictions</b>             | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | End of the Contract Year   |
| <b>Other Criteria</b>               | PA does NOT apply to patients less than 65 yrs of age. These medications will be approved if ALL of the following are met: a. Patient has an FDA-approved diagnosis or CMS-approved compendia accepted indication for the requested high risk medication. For the treatment of thromboembolic complications, approve if the patient has had a trial of one of the following (brand or generic) : clopidogrel, Brilinta or Effient b. Prescriber has completed a risk assessment of the high risk medication for the patient and has indicated that the benefits of the requested high risk medication outweigh the risks for the patient AND c. Prescriber has documented that s/he discussed risks and potential side effects of the medication with the patient. |

## HIGH RISK MEDICATIONS - BENZODIAZEPINES

### Products Affected

- alprazolam oral tablet 0.25 mg, 0.5 mg, 1 mg, 2 mg
- clobazam
- clonazepam
- clorazepate dipotassium oral tablet 15 mg, 3.75 mg, 7.5 mg
- diazepam intensol
- diazepam oral solution 5 mg/5 ml (1 mg/ml)
- diazepam oral tablet
- lorazepam oral concentrate
- lorazepam oral tablet 0.5 mg, 1 mg, 2 mg
- ONFI ORAL SUSPENSION
- ONFI ORAL TABLET 10 MG, 20 MG
- oxazepam
- temazepam

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All medically accepted indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Procedure-related sedation = 1mo. All other conditions = End of the Contract Year  |
| <b>Other Criteria</b>               | PA does NOT apply to patients less than 65 yrs of age. These medications will be approved if ALL of the following are met: a. Patient has an FDA-approved diagnosis or CMS-approved compendia accepted indication for the requested high risk medication. For Insomnia, approve lorazepam, oxazepam, or temazepam if the patient has had a trial with two of the following: ramelteon, trazodone, or zaleplon AND b. Prescriber has completed a risk assessment of the high risk medication for the patient and has indicated that the benefits of the requested high risk medication outweigh the risks for the patient AND c. Prescriber has documented that s/he discussed risks and potential side effects of the medication with the patient AND d. if patient is taking concomitantly a benzodiazepine with an opioid, the prescriber indicated that the benefits of the requested combination therapy outweigh the risks for the patient. |



**Updated 02/2019**

## HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

### Products Affected

- hydroxyzine hcl oral tablet

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All medically accepted indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | End of the Contract Year  |
| <b>Other Criteria</b>               | PA does NOT apply to patients less than 65 yrs of age. Hydroxyzine hydrochloride will be approved if ALL of the following are met: a. Patient has an FDA-approved diagnosis. For the management of anxiety, approve hydroxyzine hydrochloride if the patient has tried at least two of the following formulary medications: buspirone, escitalopram, paroxetine, sertraline, venlafaxine, alprazolam, clonazepam, clorazepate, diazepam, lorazepam, oxazepam AND b.Prescriber has completed a risk assessment of the high risk medication for the patient and has indicated that the benefits of the requested high risk medication outweigh the risks for the patient AND c.Prescriber has documented that s/he discussed risks and potential side effects of the medication with the patient. |

## HIGH RISK MEDICATIONS - SKELETAL MUSCLE RELAXANTS

### Products Affected

- cyclobenzaprine oral tablet

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All medically accepted indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | Patients aged less than 65 years, approve. Patients aged 65 years and older, other   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | End of the Contract Year   |
| <b>Other Criteria</b>               | PA does NOT apply to patients less than 65 yrs of age. High Risk Medications will be approved if ALL of the following are met: a. Patient has an FDA-approved diagnosis or CMS-approved compendia accepted indication for the requested high risk medication. Musculoskeletal conditions/disorders, approve if the patient has had a trial with Chlorzoxazone, AND b.Prescriber has completed a risk assessment of the high risk medication for the patient and has indicated that the benefits of the requested high risk medication outweigh the risks for the patient AND c.Prescriber has documented that s/he discussed risks and potential side effects of the medication with the patient AND d. if patient is taking concomitantly a muscle relaxant with an opioid, the prescriber indicated that the benefits of the requested combination therapy outweigh the risks for the patient. |

## HIGH RISK MEDICATIONS - TERTIARY TRICYCLIC ANTIDEPRESSANTS

### Products Affected

- amitriptyline
- clomipramine
- desipramine
- doxepin oral
- imipramine hcl
- nortriptyline
- trimipramine

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All medically accepted indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | Patients aged less than 65 years, approve. Patients aged 65 years and older, other criteria apply.  |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | End of the Contract Year  |
| <b>Other Criteria</b>               | PA does NOT apply to patients less than 65 yrs of age. High Risk Medications will be approved if ALL of the following are met: a. Patient has an FDA-approved diagnosis or CMS-approved compendia accepted indication for the requested high risk medication. 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 (brand or generic) 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 AND b.Prescriber has completed a risk |

| <b>PA Criteria</b> | <b>Criteria Details</b>   |
|--------------------|---|
|                    | assessment of the high risk medication for the patient AND c.Prescriber has indicated that the benefits of the requested high risk medication outweigh the risks for the patient AND d.Prescriber has documented that s/he discussed risks and potential side effects of the medication with the patient. |

# HUMIRA

## Products Affected

- HUMIRA PEDIATRIC CROHNS START SUBCUTANEOUS SYRINGE KIT 40 MG/0.8 ML, 40 MG/0.8 ML (6 PACK)
- HUMIRA PEN
- HUMIRA PEN CROHNS-UC-HS START
- HUMIRA PEN PSOR-UVEITS-ADOL HS
- HUMIRA SUBCUTANEOUS SYRINGE KIT 10 MG/0.2 ML, 20 MG/0.4 ML, 40 MG/0.8 ML
- HUMIRA(CF) PEDI CROHNS STARTER SUBCUTANEOUS SYRINGE KIT 80 MG/0.8 ML, 80 MG/0.8 ML-40 MG/0.4 ML
- HUMIRA(CF) PEN
- HUMIRA(CF) PEN CROHNS-UC-HS
- HUMIRA(CF) PEN PSOR-UV-ADOL HS
- HUMIRA(CF) SUBCUTANEOUS SYRINGE KIT 10 MG/0.1 ML, 20 MG/0.2 ML, 40 MG/0.4 ML

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on adalimumab for a Covered Use. Hidradenitis Suppurativa.  |
| <b>Exclusion Criteria</b>           | Concurrent use with another biologic DMARD or targeted synthetic DMARD.  |
| <b>Required Medical Information</b> | Diagnosis, concurrent medications, previous therapies tried  |
| <b>Age Restrictions</b>             | Crohn's disease (CD), 6 or older. Ulcerative colitis (UC), adults.   |
| <b>Prescriber Restrictions</b>      | RA/JIA/JRA/Ankylosing spondylitis, prescribed by or in consultation with rheumatologist. Psoriatic arthritis (PsA), prescribed by or in consultation with a rheumatologist or dermatologist. Plaque psoriasis (PP), prescribed by or in consultation with a dermatologist. UC/ CD, prescribed by or in consultation with a gastroenterologist. HS - dermatologist.UV-ophthalmologist |
| <b>Coverage Duration</b>            | Initial 3 mo, cont tx 3 years.   |
| <b>Other Criteria</b>               | RA initial, 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). JIA/JRA initial. Tried another agent (e.g MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD (eg, etanercept,                         |

| PA Criteria | Criteria Details   |
|-------------|--|
|             | <p>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. PP initial-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. CD initial. 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 ileocolonic resection OR enterocutaneous (perianal or abdominal) or rectovaginal fistulas. UC initial. 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. FDA approve indications cont tx - must respond to tx as determined by prescriber. HS - tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). 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.</p> |

# IBRANCE

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## Products Affected

- IBRANCE

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus liposarcoma.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | Breast cancer - approve advanced (metastatic) hormone receptor positive (HR+) [i.e., estrogen receptor positive- (ER+) and/or progesterone receptor positive (PR+)] disease, and HER2-negative breast cancer for patients who have not had disease progression while on Ibrance, Kisqali or Verzenio when the pt meets ONE of the following 1. Pt is postmenopausal and Ibrance will be used as first line therapy in combination with anastrozole, exemestane, or letrozole 2, pt is premonopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonists, or has had surgical bilateral oophorectomy, or ovarian irradiation AND it will be used as first line endocrine therapy in combination with anastrozole, exemestane, or letrozole, 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH agonist AND Ibrance with be used as first line endocrine therapy in combination with anastrozole, exemestane, tamoxifen or letrozole, 4. Pt is postmenopausal and has relapsed or progressed during endocrine therapy with at least one of the following: anastrozole, exemestane, letrozole, tamoxifen Fareston, exemestane plus Afinitor, Faslodex, Afinitor plus Faslodex or tamoxifen, megestrol acetate, fluoxymesterone or ethinyl estradiol AND will be used in combination with Faslodex, 5. Pt is premenopausal or perimenopausal |



| <b>PA Criteria</b> | <b>Criteria Details</b>  |
|--------------------|--|
|                    | and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation, relapsed or progressed on prior endocrine therapy with at least one of the following: anastrozole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus Afinitor, Faslodex, Afinitor plus Faslodex or tamoxifen, megestrol acetate, fluoxymesterone, or ethinyl estradiol AND will be used in combination with Faslodex. |

# ICLUSIG

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## Products Affected

- ICLUSIG ORAL TABLET 15 MG, 45 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Iclusig for a Covered Use.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis the Philadelphia chromosome (Ph) status of the leukemia must be reported. T315I status   |
| <b>Age Restrictions</b>             | CML/ALL - Adults   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | 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

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## Products Affected

- IDHIFA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus, patients already started on Idhifa for a Covered Use. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | IDH2-mutation status   |
| <b>Age Restrictions</b>             | Adults   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | AML - approve if relapsed or refractory-AND the patient is IDH2-mutation status positive as detected by an approved test     |

## IMATINIB

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### Products Affected

- imatinib oral tablet 100 mg, 400 mg

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus 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 imatinib for a covered use. |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis for indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | For ALL/CML, new patient must have Ph-positive CML for approval of Imatinib.  |

# IMBRUVICA

## Products Affected

- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL TABLET 140 MG, 280 MG, 420 MG, 560 MG

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus relapsed or refractory Central Nervous System Lymphoma (Primary). Plus relapsed or refractory Hairy Cell Leukemia. Plus Diffuse Large B-Cell Lymphoma (e.g., follicular lymphoma, gastric MALT lymphoma, nongastric MALT lymphoma, primary DLBCL of the central nervous system). Plus patients already taking Imbruvica for a Covered Use.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | GVHD-1 year, all others-3 years  |
| <b>Other Criteria</b>               | Marginal Zone Lymphoma - Approve if the patient has tried Rituxan (rituximab for intravenous infusion) or according to the prescribing physician, Rituxan is contraindicated for use in this patient. GVHD- Approve if the patient has tried one conventional systemic treatment for graft versus host disease (e.g., corticosteroids [methylprednisolone, prednisone], cyclosporine, tacrolimus, mycophenolate mofetil, imatinib). Diffuse large B-cell lymphoma-approve if the patient is using Imbruvica as second-line or subsequent therapy according to the prescribing physician. |

# INLYTA

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## Products Affected

- INLYTA ORAL TABLET 1 MG, 5 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus, Differentiated (i.e., papillary, follicular, and Hurthle) Thyroid Carcinoma. Plus, patients already started on Inlyta for a Covered Use. |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years   |
| <b>Other Criteria</b>               | Advanced renal cell carcinoma, approve. Differentiated thyroid cancer, approve if patient is refractory to radioactive iodine therapy.  |

# IRESSA

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## Products Affected

- IRESSA

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

- BIVIGAM
- CARIMUNE NF NANOFILTERED INTRAVENOUS RECON SOLN 6 GRAM
- FLEBOGAMMA DIF INTRAVENOUS SOLUTION 10 %
- GAMMAGARD LIQUID
- GAMMAGARD S-D (IGA < 1 MCG/ML)
- GAMMAKED INJECTION SOLUTION 1 GRAM/10 ML (10 %)
- GAMMAPLEX
- GAMMAPLEX (WITH SORBITOL)
- GAMUNEX-C INJECTION SOLUTION 1 GRAM/10 ML (10 %)
- OCTAGAM
- PANZYGA
- PRIVIGEN

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All medically accepted indications not otherwise excluded from Part D.                         |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.   |
| <b>Other Criteria</b>               | Part B versus D determination per CMS guidance to establish if drug used for PID in pt's home. |



# JAKAFI

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## Products Affected

- JAKAFI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus, patients already started on Jakafi for a Covered Use. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | For polycythemia vera patients must have tried hydroxyurea.  |

# JUXTAPID

## Products Affected

- JUXTAPID

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D  |
| <b>Exclusion Criteria</b>           | Combination use with Kynamro, Praluent, or Repatha.  |
| <b>Required Medical Information</b> | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history.  |
| <b>Age Restrictions</b>             | 18 years of age and older  |
| <b>Prescriber Restrictions</b>      | 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.  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | Patient must meet ALL of the following criteria: 1) Patient has had genetic confirmation of two mutant alleles at the LDL receptor, apolipoprotein B APOB, PCSK9, or LDLRAP1 gene locus OR the patient has an untreated LDL-C level greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents) OR the patient has a treated LDL-C level greater than or equal to 300 mg/dL (after treatment with antihyperlipidemic agents but prior to agents such as Repatha or Kynamro) OR the patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) Patient has tried Repatha and had an inadequate response according to the prescribing physician OR the patient is known to have two LDL-receptor negative alleles, AND 3) Patient has tried one high-intensity statin therapy (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than 20 mg daily [as a single-entity or as a combination product]) for greater than or equal to 8 continuous weeks and the LDL-C level remains greater than or equal to 70 mg/dL OR the patient has been determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or patient experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation. |

**Updated 02/2019**

# JYNARQUE

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## Products Affected

- JYNARQUE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | Patient is currently receiving Samsca (tolvaptan tablets) . Patients with Stage 5 CKD  |
| <b>Required Medical Information</b> | Diagnosis, renal function  |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a nephrologist   |
| <b>Coverage Duration</b>            | 1 year (initial and continuation)  |
| <b>Other Criteria</b>               | Approve if the patient has rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD) (e.g., reduced or declining renal function, high or increasing total kidney volume [height adjusted]),according to the prescriber. |

# KALYDECO

## Products Affected

- KALYDECO ORAL GRANULES IN PACKET
- KALYDECO ORAL TABLET

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | Combination use with Orkambi or Symdeko   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | two years of age and older  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF  |
| <b>Coverage Duration</b>            | 3 years   |
| <b>Other Criteria</b>               | CF - must have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, S945L, S977F, F1052V, K1060T, A1067T, G1069R, R1070Q, R1070W, F1074L, D1152H, D1270N, G551D, G178R, S549N, S549R, G551S, G1244E, S1251N, S1255P, G1349D, 2789+5G A, 3272-26A G, 3849+10kbC T, 711+3A G, E831X OR R117H AND must NOT be Homozygous for the F508del Mutation in the CFTR Gene or have unknown CFTR gene mutations. |

# KISQALI

## Products Affected

- KISQALI
- KISQALI FEMARA CO-PACK

| 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 Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | 3 years   |
| Other Criteria               | Breast cancer - approve advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer in patients who have not had disease progression while on Kisqali, Ibrance or Verzenio when the pt meets ONE of the following 1. Pt is postmenopausal and Kisqali will be used as first line endocrine therapy in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Kisqali will be used as first line endocrine therapy in combination with anastrozole, exemestane, or letrozole 3. pt is a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) who is receiving GnRH agonist AND Kisqali with be used as first line endocrine therapy in combination with anastrozole, exemestane, tamoxifen or letrozole. If the request is for Kisqali Femara, patients do not need to use in combination with anastrozole, exemestane, letrozole or tamoxifen. |

# KORLYM

## Products Affected

- KORLYM

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus patients with Endogenous Cushing's Syndrome, awaiting surgery  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, prior surgeries   |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of Cushing's syndrome   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years  |
| <b>Other Criteria</b>               | Approve if, according to the prescribing physician, the patient is not a candidate for surgery or surgery has not been curative AND if Korlym is being used to control hyperglycemia secondary to hypercortisolism in patients who have type 2 diabetes mellitus or glucose intolerance. |

# KYNAMRO

## Products Affected

- KYNAMRO

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D  |
| <b>Exclusion Criteria</b>           | Combination use with Juxtapid, Praluent, or Repatha.   |
| <b>Required Medical Information</b> | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history.  |
| <b>Age Restrictions</b>             | 18 years of age and older  |
| <b>Prescriber Restrictions</b>      | 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.  |
| <b>Coverage Duration</b>            | 12 months  |
| <b>Other Criteria</b>               | <p>Patient must meet ALL of the following criteria: 1) Patient has had genetic confirmation of two mutant alleles at the LDL receptor, apolipoprotein B APOB, PCSK9, or LDLRAP1 gene locus OR the patient has an untreated LDL-C level greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents) OR the patient has a treated LDL-C level greater than or equal to 300 mg/dL (after treatment with antihyperlipidemic agents but prior to agents such as Repatha or Juxtapid) OR the patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) Patient has tried Repatha and had an inadequate response according to the prescribing physician OR the patient is known to have two LDL-receptor negative alleles, AND 3) Patient has tried one high-intensity statin therapy (i.e., atorvastatin greater than or equal to 40 mg daily, rosuvastatin greater than 20 mg daily [as a single-entity or as a combination product]) for greater than or equal to 8 continuous weeks and the LDL-C level remains greater than or equal to 70 mg/dL OR the patient has been determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or patient experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and rosuvastatin and during both trials the skeletal-related symptoms resolved during discontinuation.</p> |



**Updated 02/2019**

# LENVIMA

## Products Affected

- LENVIMA ORAL CAPSULE 10 MG/DAY (10 MG X 1), 12 MG/DAY (4 MG X 3), 14 MG/DAY(10 MG X 1-4 MG X 1), 18 MG/DAY (10 MG X 1-4 MG X2), 20 MG/DAY (10 MG X 2), 24 MG/DAY(10 MG X 2-4 MG X 1), 4 MG, 8 MG/DAY (4 MG X 2)

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients with Medullary Thyroid Carcinoma (MTC).  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 3 Years   |
| <b>Other Criteria</b>               | DTC - must be refractory to radioactive iodine treatment for approval. RCC - approve if the pt meets ONE of the following criteria: 1) pt has RCC with predominant clear-cell histology AND the pt has tried one antiangiogenic therapy (eg, Inlyta, Votrient, Sutent, Cabometyx) AND Lenvima will be used in combination with everolimus (Afinitor), OR 2) pt has RCC with non-clear cell histology AND Lenvima will be used in combination with everolimus (Afinitor). MTC-approve if the patient has tried Caprelsa or Cometriq. |

## LETAIRIS/TRACLEER

### Products Affected

- LETAIRIS
- TRACLEER

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Chronic thromboembolic pulmonary hypertension (CTEPH) (Tracleer).   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Pulmonary arterial hypertension (PAH) WHO Group 1 patients not currently on Letairis or Tracleer 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 Letairis or Tracleer or another agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | For treatment of pulmonary arterial hypertension, Letairis or Tracleer must be prescribed by or in consultation with a cardiologist or a pulmonologist. CTEPH-prescribed by or in consultation with a cardiologist or pulmonologist  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | CTEPH - pt must have tried Adempas, has a contraindication to Adempas, or is currently receiving Tracleer for CTEPH. PAH-pt must have tried Opsumit or Letairis prior to approval of Tracleer.   |

# LIDODERM

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## Products Affected

- lidocaine topical adhesive patch,medicated

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus diabetic neuropathic pain. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 12 months  |
| <b>Other Criteria</b>               | N/A  |

## LONG ACTING OPIOIDS

### Products Affected

- fentanyl transdermal patch 72 hour 100 mcg/hr, 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr
- methadone oral solution 10 mg/5 ml, 5 mg/5 ml
- methadone oral tablet 10 mg, 5 mg
- morphine oral capsule, er multiphase 24 hr 120 mg, 30 mg, 45 mg, 60 mg, 75 mg, 90 mg
- morphine oral capsule, extend. release pellets
- morphine oral tablet extended release 100 mg, 15 mg, 200 mg, 30 mg, 60 mg
- tramadol oral tablet extended release 24 hr
- tramadol oral tablet, er multiphase 24 hr
- XTAMPZA ER

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All medically accepted indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | Concurrent use of Medicated Assisted Treatment (MAT) therapy  |
| <b>Required Medical Information</b> | Nature and intensity of pain, past and current treatments of pain, underlying or co-occurring disorders and conditions.   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a pain specialist or oncologist   |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.  |
| <b>Other Criteria</b>               | Long acting opioids will be approved if ALL of the following is met: a. Patient has an FDA-approved diagnosis or CMS-approved compendia accepted indication AND b. Documentation that shows the patient's diagnosis, evaluation and medical assessment for the requested medication which clearly indicates ALL of the following: diagnosis, evaluation and medical assessment for the requested medication including the nature and intensity of pain, past and current treatments of pain (e.g., receiving opioids previously in treatment of acute pain), underlying or concomitant disorders and conditions, effect of the pain on physical and psychological functioning, review of history, physical examination and laboratory findings AND c. Attestation from the provider that a pain management agreement is signed by the patient and the provider in the past six months AND d. Attestation from the provider that he/she has completed a risk assessment for aberrant behavior associated with opioid misuse AND e. |

| <b>PA Criteria</b> | <b>Criteria Details</b>  |
|--------------------|--|
|                    | Attestation that Prescriber has checked the state controlled substance database in the past 90 days AND f. Attestation from the provider that a treatment plan that has been signed by the patient and the provider that includes goals and monitoring AND g. Attestation from the provider that the patient experienced previous treatment with short-acting opioids at the lowest dose possible as calculated using morphine milligram equivalent (MME). |

# LONSURF

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## Products Affected

- LONSURF

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

# LORBRENA

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## Products Affected

- LORBRENA ORAL TABLET 100 MG,  
25 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Lorbrena for a covered use.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, ALK status, previous therapies  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | 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. |



# LYNPARZA

## Products Affected

- LYNPARZA ORAL CAPSULE
- LYNPARZA ORAL 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 Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | 3 years  |
| Other Criteria               | <p>Ovarian cancer approve if the patient has a germline BRCA mutation confirmed by an approved test AND as per product labeling, has progressed on three or more prior lines of chemotherapy. Breast Cancer- Approve if the patient meets the following criteria (A, B, C, and D)-A. The patient has metastatic, germline BRCA mutation-positive breast cancer AND B. The patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND C. The patient meets ONE of the following criteria (i or ii)- i. The patient meets BOTH of the following criteria (a and b)-a) The patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive ER+ and/or progesterone receptor positive PR+] disease AND b) The patient meets ONE of the following criteria (1 or 2)-1- The patient has been treated with prior endocrine therapy OR-2 The patient is considered inappropriate for endocrine therapy OR ii. Patient has triple negative disease (i.e., ER-negative, PR-negative, and HER2-negative) AND D. The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting.</p> |

# LYRICA CR

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## Products Affected

- LYRICA CR ORAL TABLET  
EXTENDED RELEASE 24 HR 165 MG,  
330 MG, 82.5 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All medically accepted indications not otherwise excluded from Part D. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.                                   |
| <b>Other Criteria</b>               | N/A  |

# MAVYRET

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## Products Affected

- MAVYRET

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients started on Mavyret for a Covered Use.                     |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Genotype, prescriber specialty, other medications tried or used in combination with requested medication                                 |
| <b>Age Restrictions</b>             | 18 years or older  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician |
| <b>Coverage Duration</b>            | Criteria will be applied consistent with current AASLD/IDSA guidance.  |
| <b>Other Criteria</b>               | Criteria will be applied consistent with current AASLD/IDSA guidance.  |

# MEKINIST

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## Products Affected

- MEKINIST ORAL TABLET 0.5 MG, 2 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Mekinist for a Covered Use.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis for which Mekinist is being used. For melanoma, thyroid cancer and NSCLC must have documentation of BRAF V600 mutations  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | Melanoma must be used in patients with BRAF V600 mutation, and patient has unresectable, advanced (including Stage III or Stage IV disease), or metastatic melanoma. Note-This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC requires BRAF V600E Mutation and use in combination with Tafenlar. Thyroid cancer, anaplastic-patient has locally advanced or metastatic anaplastic disease AND Mekinist will be taken in combination with Tafenlar, unless intolerant AND the patient has BRAF V600-positive disease. |

# MEKTOVI

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## Products Affected

- MEKTOVI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Mektovi for a covered use.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis, BRAF V600 status, concomitant medications  |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 3 years   |
| <b>Other Criteria</b>               | Melanoma - 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. |

# MULPLETA

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## Products Affected

- MULPLETA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, platelet count, date of procedure   |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 7 days   |
| <b>Other Criteria</b>               | Approve if the patient has a current platelet count less than 50 x 10 <sup>9</sup> /L AND the patient is scheduled to undergo a procedure within 8 to 14 days after starting Mulpleta therapy. |

# NAMENDA

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## Products Affected

- memantine
- NAMZARIC

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus patients with mild to moderate vascular dementia who are receiving memantine. |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Indication for which memantine is being prescribed.   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.  |
| <b>Other Criteria</b>               | N/A   |

# NATPARA

## Products Affected

- NATPARA

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an endocrinologist.   |
| <b>Coverage Duration</b>            | 3 years   |
| <b>Other Criteria</b>               | Chronic hypoparathyroidism, initial therapy - approve if before starting Natpara, serum calcium concentration is greater than 7.5 mg/dL and 25-hydroxyvitamin D stores are sufficient per the prescribing physician.<br>Chronic hypoparathyroidism, continuing therapy - approve if during Natpara therapy, the patient's 25-hydroxyvitamin D stores are sufficient per the prescribing physician, AND the patient is responding to Natpara therapy, as determined by the prescriber. |



# NERLYNX

## Products Affected

- NERLYNX

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Stage of cancer, HER2 status, previous or current medications tried   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Approve for 12 months   |
| <b>Other Criteria</b>               | Breast cancer - approve if the patient meets all of the following criteria: 1. Patient has early stage disease, AND 2. Patient has HER2-positive breast cancer, AND 3. Patient has completed one year of adjuvant therapy with trastuzumab OR could not tolerate one year of therapy. |

# NEULASTA

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## Products Affected

- NEULASTA SUBCUTANEOUS SYRINGE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients undergoing PBPC collection and therapy   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Cancer patients receiving chemotherapy, if prescribed by or in consultation with an oncologist or hematologist. PBPC - prescribed by or in consultation with an oncologist, hematologist, or physician that specializes in transplantation. Radiation syndrome-prescribed by or in consultation with physician with expertise in treating acute radiation syndrome.   |
| <b>Coverage Duration</b>            | Cancer pts receiving chemo-6 mo. PBPC/Radiation Syndrome-1 mo   |
| <b>Other Criteria</b>               | Cancer patients receiving chemotherapy, approve if the patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), OR the patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years, prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status or HIV infection, OR the patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor and a reduced dose or frequency of chemotherapy may compromise treatment. |

# NEUPOGEN

## Products Affected

- NEUPOGEN

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D worded more broadly as cancer patients receiving myelosuppressive chemotherapy, patients with acute myeloid leukemia (AML) receiving chemotherapy, cancer patients receiving bone marrow transplantation (BMT), patients undergoing peripheral blood progenitor cell (PBPC) collection and therapy, and patients with severe chronic neutropenia [SCN] (e.g., congenital neutropenia, cyclic neutropenia, idiopathic neutropenia). Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL). |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | AML, HIV/AIDS, MDS - adults. Other uses - no age requirements.   |
| <b>Prescriber Restrictions</b>      | Cancer/AML, MDS, ALL, oncologist or a hematologist. Cancer patients receiving BMT and PBPC, prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. SCN, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.  |
| <b>Coverage Duration</b>            | chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,AA,ALL,BMT-3 mo.All other=12mo.   |
| <b>Other Criteria</b>               | Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years,   |

| <b>PA Criteria</b> | <b>Criteria Details</b>  |
|--------------------|--|
|                    | <p>prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver or renal dysfunction, poor performance status, HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, Neulasta, Neupogen Granix, or Zarxio) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil account less than 100 cells/mm<sup>3</sup>], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).</p> |

# NEXAVAR

## Products Affected

- NEXAVAR

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | 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   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | 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 |

# NINLARO

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## Products Affected

- NINLARO ORAL CAPSULE 2.3 MG, 3 MG, 4 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus , patients already started on Ninlaro.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | MM - be used in combination with Revlimid and dexamethasone AND pt had received at least ONE previous therapy for multiple myeloma (e.g., Thalomid, Revlimid, Pomalyst, Alkeran, dexamethasone, prednisone). |

# NIVESTYM

## Products Affected

- NIVESTYM

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D worded more broadly as cancer patients receiving myelosuppressive chemotherapy, patients with acute myeloid leukemia (AML) receiving chemotherapy, cancer patients receiving bone marrow transplantation (BMT), patients undergoing peripheral blood progenitor cell (PBPC) collection and therapy, and patients with severe chronic neutropenia [SCN] (e.g., congenital neutropenia, cyclic neutropenia, idiopathic neutropenia). Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL). |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | AML, HIV/AIDS, MDS - adults  |
| <b>Prescriber Restrictions</b>      | Cancer/AML, MDS, ALL, oncologist or a hematologist. Cancer patients receiving BMT and PBPC, prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. SCN, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.  |
| <b>Coverage Duration</b>            | Under CMS Review   |
| <b>Other Criteria</b>               | Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years,   |

| <b>PA Criteria</b> | <b>Criteria Details</b>  |
|--------------------|--|
|                    | prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, or HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, Neulasta, Neupogen) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil count less than 100 cells/mm <sup>3</sup> ], neutropenia expected to be greater than 10 days in duration, invasive fungal infection). |



# NORTHERA

## Products Affected

- NORTHERA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Medication history  |
| <b>Age Restrictions</b>             | 18 years of age and older   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a cardiologist or a neurologist   |
| <b>Coverage Duration</b>            | 12 months   |
| <b>Other Criteria</b>               | NOH, approve if the patient meets ALL of the following criteria: a) Patient has been diagnosed with symptomatic NOH due to primary autonomic failure (Parkinson's disease, multiple system atrophy, pure autonomic failure), dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy, AND b) Patient has tried midodrine |

# NUCALA

## Products Affected

- NUCALA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | Concurrent use with Xolair   |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | 12 years of age and older  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an allergist, immunologist, or pulmonologist   |
| <b>Coverage Duration</b>            | Authorization will be for 6 months initial, 12 months continuation.  |
| <b>Other Criteria</b>               | <p>Asthma Initial - 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 an IL-5 antagonist monoclonal antibody) 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. Patient's 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 Patient's asthma worsens upon tapering of oral corticosteroid therapy. Continuation - 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. EGPA initial-patient has/had a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6</p> |

| <b>PA Criteria</b> | <b>Criteria Details</b>  |
|--------------------|--|
|                    | weeks or within 6 weeks prior to treatment with any anti-interleukin (IL)-5 therapy (e.g., Nucala, Cinqair, Fasenra). Continuation-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

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## Products Affected

- NUEDEXTA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a neurologist              |
| <b>Coverage Duration</b>            | 1 year   |
| <b>Other Criteria</b>               | N/A  |

# NUPLAZID

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## Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG, 17 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 12 months                              |
| <b>Other Criteria</b>               | N/A  |

# NUVIGIL/PROVIGIL

## Products Affected

- modafinil

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Excessive daytime sleepiness (EDS) due to myotonic dystrophy - modafinil only. Adjunctive/augmentation for treatment of depression in adults - modafinil only.                |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | Patients must be greater than or equal to 17 years of age.   |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.   |
| <b>Other Criteria</b>               | Excessive sleepiness due to SWSD if the patient is working at least 5 overnight shifts per month. Adjunctive/augmentation treatment for depression in adults if the patient is concurrently receiving other medication therapy for depression. |

# ODOMZO

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## Products Affected

- ODOMZO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus metastatic BCC.   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | BCC - Must not have had disease progression while on Erivedge (vismodegib).   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 3 years   |
| <b>Other Criteria</b>               | Locally advanced BCC approve if the BCC has recurred following surgery/radiation therapy or if the patient is not a candidate for surgery AND the patient is not a candidate for radiation therapy, according to the prescribing physician. Metastatic BCC - approve. |

## OFEV

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### Products Affected

- OFEV

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | Combination use with pirfenidone.   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | 18 years of age and older.  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a pulmonologist.  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | IPF baseline - must have FVC greater than or equal to 50 percent of the predicted value AND IPF must be diagnosed with either findings on high-resolution computed tomography (HRCT) indicating usual interstitial pneumonia (UIP) or surgical lung biopsy demonstrating UIP. |



# OPSUMIT

## Products Affected

- OPSUMIT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | PAH WHO group, right heart catheterization results, WHO functional status, previous drugs tried  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | PAH - must be prescribed by or in consultation with a cardiologist or a pulmonologist.   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | 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
- ORENCIA CLICKJECT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | 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.  |
| <b>Exclusion Criteria</b>           | Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.  |
| <b>Required Medical Information</b> | Diagnosis, concurrent medications, previous drugs tried.   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | RA and JIA/JRA prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or dermatologist.  |
| <b>Coverage Duration</b>            | 3 mos initial, 3 years cont  |
| <b>Other Criteria</b>               | RA initial, 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). Juvenile idiopathic arthritis (JIA) [or Juvenile Rheumatoid Arthritis (JRA)], approve. Cont tx - responded to therapy as per the prescriber. |

# ORILISSA

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## Products Affected

- ORILISSA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Previous medication use  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an obstetrician-gynecologist or a health care practitioner who specializes in the treatment of womens health.  |
| <b>Coverage Duration</b>            | Initial- 6 months. Cont- up to a total duration of therapy of 24 months  |
| <b>Other Criteria</b>               | Initial tx Endometriosis- Approve if ALL of the following are met: a) The patient has tried a prescription strength non-steroidal anti-inflammatory medication (NSAID), or has a contraindication to NSAID use AND b) The patient has tried one of the following: a contraceptive (e.g., combination oral contraceptives, levonorgestrel-releasing intrauterine systems [e.g., Mirena, Liletta]) or a progesterone product (e.g., norethindrone tablets, depo-medroxyprogesterone injection), unless contraindicated (NOTE: An exception to the requirement for trials of both of the above therapies can be made if the patient had previously used a gonadotropin-releasing hormone [GnRH] agonist (e.g., Lupron Depot)). AND c) The patient has continued to experience moderate to severe pain associated with endometriosis after treatment with 1) a NSAID and a contraceptive or a progesterone product unless contraindicated or 2) a gonadotropin-releasing hormone [GnRH] agonist . Cont tx - pt must have had a response as determined by the prescriber. |

# ORKAMBI

## Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | Combination use with Kalydeco  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | 2 years of age and older   |
| <b>Prescriber Restrictions</b>      | prescribed by or in consultation with a pulmonologist or a physician who specializes in CF   |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | CF - homozygous for the Phe508del (F508del) mutation in the CFTR gene (meaning the patient has two copies of the Phe508del mutation) |

# OTEZLA

## Products Affected

- OTEZLA
- OTEZLA STARTER ORAL TABLETS,DOSE PACK 10 MG (4)-20 MG (4)-30 MG (47)

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Covered Uses                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients currently taking Otezla for a Covered Use.   |
| Exclusion Criteria           | N/A   |
| Required Medical Information | Diagnosis, previous drugs tried   |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | PsA - Prescribed by or in consultation with a dermatologist or rheumatologist. PP - prescribed by or in consultation with a dermatologist.  |
| Coverage Duration            | 4 months initial, 3 years cont  |
| Other Criteria               | PP initial-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. PsA initial-approve if the patient has tried at least one conventional synthetic DMARD (eg, MTX, leflunomide, sulfasalazine) for at least 3 months, unless intolerant (note: pts who have already tried a biologic DMARD are not required to step back and try a conventional DMARD first). PsA/PP cont - pt has received 4 months of therapy and had a response, as determined by the prescribing physician. |

# PALYNZIQ

## Products Affected

- PALYNZIQ

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis, phenylalanine concentrations   |
| <b>Age Restrictions</b>             | 18 years and older  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases   |
| <b>Coverage Duration</b>            | 1 year (initial and continuation)   |
| <b>Other Criteria</b>               | Initial 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). Maintenance 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. |

# PHEOCHROMOCYTOMA

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## Products Affected

- DEMSER
- phenoxybenzamine

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, prior medication trials   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an endocrinologist or a physician who specializes in the management of pheochromocytoma (initial therapy for phenoxybenzamine, initial and continuation therapy for Demser)  |
| <b>Coverage Duration</b>            | Authorization will be for 1 year   |
| <b>Other Criteria</b>               | If brand Dibenzylamine is being requested, approve if the patient has tried and cannot take generic phenoxybenzamine due to a formulation difference in the inactive ingredients between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or a serious adverse reaction. If the requested drug is Demser for initial therapy, approve if the patient has tried a selective alpha blocker (e.g., doxazosin, terazosin or prazosin) AND the patient has tried phenoxybenzamine (brand or generic). If the requested drug is Demser for continuation therapy, approve if the patient is currently receiving Demser or has received Demser in the past. |

## PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

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### Products Affected

- ADCIRCA
- sildenafil (pulmonary arterial hypertension) oral

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Pulmonary arterial hypertension (PAH) WHO Group 1, patients not currently taking an agent indication for WHO Group 1 PAH are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. PAH WHO Group 1 patients currently receiving an agent indicated for WHO Group 1 PAH may continue therapy without confirmation of a right-heart catheterization. |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | For PAH, if prescribed by, or in consultation with, a cardiologist or a pulmonologist.  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets and suspension (Revatio, generics) require confirmation that the indication is PAH (ie, FDA labeled use) prior to reviewing for quantity exception.   |



# PLEGRIDY

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## Products Affected

- PLEGRIDY SUBCUTANEOUS PEN INJECTOR 125 MCG/0.5 ML, 63 MCG/0.5 ML- 94 MCG/0.5 ML
- PLEGRIDY SUBCUTANEOUS SYRINGE 125 MCG/0.5 ML, 63 MCG/0.5 ML- 94 MCG/0.5 ML

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Covered Uses                 | All FDA-approved indications not otherwise excluded from Part D.                        |
| Exclusion Criteria           | Concurrent use of with other disease-modifying agents used for multiple sclerosis (MS). |
| Required Medical Information | For use in MS, patient has a relapsing form of MS.                                      |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | Prescribed by, or in consultation with, a neurologist or an MS specialist.              |
| Coverage Duration            | Authorization will be for 3 years.  |
| Other Criteria               | N/A   |

# POMALYST

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## Products Affected

- POMALYST

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus Myelofibrosis and Systemic Light Chain Amyloidosis |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, prior therapies   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years  |
| <b>Other Criteria</b>               | N/A  |

# PRALUENT

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## Products Affected

- PRALUENT PEN SUBCUTANEOUS  
PEN INJECTOR 150 MG/ML, 75  
MG/ML

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | Concurrent use of Juxtapid or Kynamro.   |
| <b>Required Medical Information</b> | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history   |
| <b>Age Restrictions</b>             | 18 years of age and older.   |
| <b>Prescriber Restrictions</b>      | Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | Hyperlipidemia in patients with HeFH-approve if meets all of the following<br>1. Pt has been diagnosed with HeFH AND 2. tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or Crestor greater than or equal to 20 mg daily) AND 3. LDL-C remains greater than or equal to 70 mg/dL unless is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c.<br>Hyperlipidemia Pt with Clinical ASCVD -approve if meets all of the following: has one of the following conditions prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND tried ONE high intensity statin (as defined above) AND LDL-C remains greater than or equal to 70 mg/dL unless the pt is determined to be statin intolerant defined by experiencing statin related rhabdomyolysis or pt experienced skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the skeletal-related symptoms resolved during d/c. |

# PROLIA

## Products Affected

- PROLIA

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, raloxifene, calcitonin nasal spray [ Fortical], abaloparatide), except calcium and Vitamin D.   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | Treatment of postmenopausal osteoporosis/Treatment of osteoporosis in men (to increase bone mass) [a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression], approve if the patient meets one of the following: 1. has had inadequate response after 12 months of therapy with an oral bisphosphonate, had osteoporotic fracture or fragility fracture while receiving an oral bisphosphonate, or intolerability to an oral bisphosphonate, OR 2. the patient cannot take an oral bisphosphonate because they cannot swallow or have difficulty swallowing, they cannot remain in an upright position, or they have a pre-existing GI medical condition, OR 3. pt has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR 4. the patient has severe renal impairment (eg, creatinine clearance less than 35 mL/min) or chronic kidney disease, or if the patient has an osteoporotic fracture or fragility fracture . Treatment of bone loss in patient at high risk for fracture receiving ADT for nonmetastatic prostate cancer, approve if the patient has prostate cancer that is not metastatic to the bone and the patient is receiving ADT (eg, leuprolide, triptorelin, goserelin) or the patient has undergone a bilateral orchiectomy. Treatment of bone loss (to increase bone mass) in patients at high risk for fracture receiving adjuvant AI therapy for breast cancer, |

| <b>PA Criteria</b> | <b>Criteria Details</b>  |
|--------------------|--|
|                    | <p>approve if the patient has breast cancer that is not metastatic to the bone and in receiving concurrent AI therapy (eg, anastrozole, letrozole, exemestane). Treatment of GIO, approve if pt tried one oral bisphosphonate OR pt cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or the patient cannot remain in an upright position post oral bisphosphonate administration or has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR pt has tried zoledronic acid (Reclast), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture.</p> |

# PROMACTA

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## Products Affected

- PROMACTA

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | Use in the management of thrombocytopenia in myelodysplastic syndrome (MDS).   |
| <b>Required Medical Information</b> | Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy.  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Thrombocytopenia due to chronic ITP or Aplastic Anemia, approve if prescribed by, or after consultation with, a hematologist.<br>Thrombocytopenia due to HCV-related cirrhosis, approve if prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease.  |
| <b>Coverage Duration</b>            | Chronic ITP - 3 years, others 12 months.   |
| <b>Other Criteria</b>               | Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura, approve if the patient has tried corticosteroids or IVIG or has undergone a splenectomy. Treatment of thrombocytopenia due to HCV-related cirrhosis, approve to allow for initiation of antiviral therapy if the patient has low platelet counts (eg, less than 75,000 mm <sup>3</sup> ) and the patient has chronic HCV infection and is a candidate for hepatitis C therapy. Aplastic anemia - has low platelet counts at baseline/pretreatment (e.g., less than 30,000 mm <sup>3</sup> ) AND tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate mofetil, sirolimus) |

## REBIF

### Products Affected

- REBIF (WITH ALBUMIN) MCG/0.5 ML, 8.8MCG/0.2ML-22
- REBIF REBIDOSE SUBCUTANEOUS MCG/0.5ML (6)
- PEN INJECTOR 22 MCG/0.5 ML, 44
- REBIF TITRATION PACK

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients who experienced an attack and are at risk for multiple sclerosis.  |
| <b>Exclusion Criteria</b>           | Concurrent use with other disease-modifying agent used for multiple sclerosis (ie, interferon beta-1a, interferon beta-1b, glatiramer, natalizumab, fingolimod, terflunomide, dimethyl fumarate). |
| <b>Required Medical Information</b> | Diagnosis of MS includes the following patient types: patients with actual diagnosis of MS, patients who have experienced an MS attack, and patients who are at risk for developing MS.           |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or after consultation with a neurologist or an MS specialist.   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | N/A   |

# REPATHA

## Products Affected

- REPATHA
- REPATHA SURECLICK
- REPATHA PUSHTRONEX

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | LDL-C and response to other agents, prior therapies tried, medication adverse event history, medical history   |
| <b>Age Restrictions</b>             | ASCVD/HeFH/Primary Hyperlipidemia - 18 yo and older, HoFH 13 yo and older.   |
| <b>Prescriber Restrictions</b>      | Prescribed by, or in consultation with, a cardiologist, endocrinologist, or a physician who focuses in the treatment of CV risk management and/or lipid disorders  |
| <b>Coverage Duration</b>            | ASCVD/HeFH/HoFH - 3 years. Primary hyperlipidemia- 1 year.   |
| <b>Other Criteria</b>               | Hyperlipidemia with HeFH - approve if: 1) diagnosis of HeFH AND 2) tried ONE high intensity statin (i.e. atorvastatin greater than or equal to 40 mg daily or Crestor greater than or equal to 20 mg daily) and LDL remains 70 mg/dL or higher unless pt is statin intolerant defined by experiencing statin related rhabdomyolysis or skeletal-related muscle symptoms while receiving separate trials of atorvastatin and Crestor and during both trials the symptoms resolved upon discontinuation. Hyperlipidemia with ASCVD -approve if: 1) has one of the following conditions: prior MI, h/o ACS, diagnosis of angina, h/o CVA or TIA, PAD, undergone a coronary or other arterial revascularization procedure, AND 2) tried ONE high intensity statin (defined above) and LDL remains 70 mg/dL or higher unless pt is statin intolerant (defined above). HoFH - approve if: 1) has one of the following: a) genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus, OR b) untreated LDL greater than 500 mg/dL (prior to treatment), OR c) treated LDL greater than or equal to 300 mg/dL (after treatment but prior to agents such as Repatha, Kynamro or Juxtapid), OR d) has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma), AND 2) tried ONE high intensity statin |



| <b>PA Criteria</b> | <b>Criteria Details</b>   |
|--------------------|---|
|                    | <p>(defined above) for 8 weeks or longer and LDL remains 70 mg/dL or higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if all of the following are met: 1) coronary artery calcium or calcification (CAC) score 300 Agatston units or higher, AND 2) 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).</p> |

# REVLIMID

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## Products Affected

- REVLIMID

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Revlimid for a Covered Use. Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Follicular Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis and previous therapies or drug regimens tried.  |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.  |
| <b>Other Criteria</b>               | MCL-approve if the patient meets one of the following 1) Pt has tried two prior therapies or therapeutic regimens OR 2) Pt has tried one prior therapy or therapeutic regimen and cannot take Velcade according to the prescribing physician. MDS-approve if the patient meets one of the following: 1) Pt has symptomatic anemia, OR 2) Pt has transfusion-dependent anemia, OR 3) Pt has anemia that is not controlled with an erythroid stimulating agent (eg, Epogen, Procrit [epoetin alfa injection], Aranesp [darbepoetin alfa injection]). Diffuse, Large B Cell Lymphoma (Non-Hodgkin's Lymphoma)-approve if the pt has tried one other medication treatment regimen. Myelofibrosis-approve if the pt has tried one other therapy. |

# RUBRACA

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## Products Affected

- RUBRACA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Rubraca for a Covered Use.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis for which Rubraca is being used. BRCA-mutation (germline or somatic) status. Other medications tried for the diagnosis provided   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 3years  |
| <b>Other Criteria</b>               | Initial Therapy-treatment. Approve for 3 years if the patient meets the following criteria (i and ii): i.The patient has a BRCA-mutation (germline or somatic) as confirmed by an approved test, AND ii.The patient has progressed on two or more prior lines of chemotherapy. Recurrence, Maintenance Therapy of Ovarian, Fallopian tube or Primary peritoneal cancer-i. The patient is in a complete response or a partial response to platinum-based chemotherapy. |

# RYDAPT

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## Products Affected

- RYDAPT

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on midostaurin for a Covered Use. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | For AML, FLT3 status   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | AML-approve if the patient is FLT3-mutation positive as detected by an approved test.  |

# SAMSCA

## Products Affected

- SAMSCA ORAL TABLET 15 MG, 30 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Serum sodium less than 125 mEq/L at baseline or less marked hyponatremia, defined as serum sodium less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion).  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 30 days  |
| <b>Other Criteria</b>               | Hyponatremia - Pt must meet ONE of the following: 1. serum sodium less than 125 mEq/L at baseline, OR 2. marked hyponatremia, defined as less than 135 mEq/L at baseline, that is symptomatic (eg, nausea, vomiting, headache, lethargy, confusion), OR 3. patient has already been started on Samsca and has received less than 30 days of therapy. |

# SIMPONI

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## Products Affected

- SIMPONI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus patients already started on golimumab (IV or SC) for a covered use.   |
| <b>Exclusion Criteria</b>           | Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD  |
| <b>Required Medical Information</b> | Diagnosis, concurrent medications, previous therapies tried.  |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | RA/Ankylosing spondylitis, prescribed by or in consultation with a rheumatologist. Psoriatic arthritis, prescribed by or in consultation with a rheumatologist or dermatologist. UC-prescribed by or in consultation with a gastroenterologist  |
| <b>Coverage Duration</b>            | 3 mos initial, 3 years cont   |
| <b>Other Criteria</b>               | AS approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx. PsA-approve if the patient has tried TWO of the following: Enbrel, Humira, Cosentyx, Stelara, Otezla, Orencia, Xeljanz/XR. RA, approve if the patient has tried two of the following: Enbrel, Humira, Orencia, or Xeljanz/XR. Ulcerative colitis - approve if the patient has had a trial with Humira. Cont tx - must have a response to therapy as according to prescriber |

# SOLARAZE

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## Products Affected

- diclofenac sodium topical gel 3 %

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 6 months.                              |
| <b>Other Criteria</b>               | N/A  |

# SPRYCEL

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## Products Affected

- SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus GIST and patients already started on Sprycel for a Covered Use.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis for which Sprycel is being used. For indications of CML and ALL, the Philadelphia chromosome (Ph) status of the leukemia must be reported.   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.   |
| <b>Other Criteria</b>               | 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 SUBCUTANEOUS

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | 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.   |
| <b>Exclusion Criteria</b>           | Ustekinumab should not be given in combination with a Biologic DMARD or Targeted Synthetic DMARD   |
| <b>Required Medical Information</b> | Diagnosis, concurrent medications, previous drugs tried.   |
| <b>Age Restrictions</b>             | Adults-PsA and CD. PP-12 years and older.  |
| <b>Prescriber Restrictions</b>      | Plaque psoriasis.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.  |
| <b>Coverage Duration</b>            | PP/PsA Init-3mo,CD load-approve 1 dose IV,CD post IV load-approve SC 3 mo,cont tx-approve SC 3 yr  |
| <b>Other Criteria</b>               | PP initial - approve Stelara SC. CD, 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, adalimumb, infliximab). CD, initial therapy (only after receiving single IV loading dose) - approve 3 months of 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. PP/PsA/CD cont - approve Stelara SC if according to the prescribing physician, the patient has responded to therapy. |

# STIVARGA

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## Products Affected

- STIVARGA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Stivarga for a Covered Use.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis for which Stivarga is being used. Prior therapies tried. For metastatic CRC, KRAS/NRAS mutation status.  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | For GIST, patient must have previously been treated with imatinib (Gleevec) and sunitinib (Sutent). For HCC, patient must have previously been treated with Nexavar (sorafenib). |

# SUTENT

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## Products Affected

- SUTENT

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Sutent for a Covered Use. Advanced, unresectable neuroendocrine tumors, chordoma, angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma (ASPS), differentiated (ie, papillary, follicular, and Hurthle) thyroid carcinoma, medullary thyroid carcinoma, meningioma, thymic carcinoma.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | Gastrointestinal stromal tumors (GIST), approve if Sutent will be used as a single agent and the patient has previously tried imatinib (Gleevec) OR Sutent will be used in combination with Afinitor AND the patient has tried TWO of the following: imatinib, Sutent, or Stivarga. Chordoma, approve if the patient has recurrent disease. Differentiated thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Medullary thyroid carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). Meningioma, approve if the patient has recurrent or progressive disease. Thymic carcinoma - has tried chemotherapy or radiation therapy. |

## SYMDEKO

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### Products Affected

- SYMDEKO

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D   |
| <b>Exclusion Criteria</b>           | Patients with unknown CFTR gene mutations   |
| <b>Required Medical Information</b> | Diagnosis, specific CFTR gene mutations   |
| <b>Age Restrictions</b>             | Twelve years of age and older   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a pulmonologist or a physician who specializes in CF  |
| <b>Coverage Duration</b>            | 3 years   |
| <b>Other Criteria</b>               | CF - must have at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: E56K, P67L, R74W, D110E, D110H, R117C, E193K, L206W, R347H, R352Q, A455E, D579G, 711+3A G, S945L, S977F, F1052V, E831X, K1060T, A1067T, R1070W, F1074L, D1152H, D1270N, 2789+5G A, 3272-26A G, or 3849 + 10kbC T OR the patient has two copies of the F508del mutation |

# SYMLIN

## Products Affected

- SYMLINPEN 120
- SYMLINPEN 60

| PA Criteria                  | Criteria Details   |
|------------------------------|--|
| Covered Uses                 | All FDA-approved indications not otherwise excluded from Part D worded as patient has type 1 or 2 diabetes mellitus. |
| Exclusion Criteria           | N/A  |
| Required Medical Information | N/A  |
| Age Restrictions             | N/A  |
| Prescriber Restrictions      | N/A  |
| Coverage Duration            | Authorization will be for 3 years.   |
| Other Criteria               | N/A  |

# SYPRINE

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## Products Affected

- trientine

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Trientine for a Covered Use.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis, medication history, pregnancy status, disease manifestations   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician.  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | For Wilson's Disease, approve if the patient meets ONE of the following:<br>1) Patient has tried a penicillamine product and per the prescribing physician the patient is intolerant to penicillamine therapy, OR 2) Per the prescribing physician, the patient has clinical features indicating the potential for intolerance to penicillamine therapy (ie, history of any renal disease, congestive splenomegaly causing severe thrombocytopenia, autoimmune tendency), OR 3) Per the prescribing physician, the patient has a contraindication to penicillamine therapy, OR 4) The patient has neurologic manifestations of Wilson's disease, OR 5) The patient is pregnant. |

# TAFINLAR

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## Products Affected

- TAFINLAR

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients with Differentiated Thyroid Cancer. Plus patients already started on Tafinlar for a Covered Use.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis for which Tafinlar is being used. BRAF V600 mutations  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | Melanoma with BRAF V600 mutation AND patient has unresectable, advanced (including Stage III or Stage IV disease) or metastatic melanoma. Note - This includes adjuvant treatment in patients with Stage III disease with no evidence of disease post-surgery. For NSCLC, must have BRAF V600E mutation. Thyroid Cancer, anaplastic-must have BRAF V600-positive disease AND Tafinlar will be taken in combination with Mekinist, unless intolerant AND the patient has locally advanced or metastatic anaplastic disease. Thyroid Cancer, differentiated (i.e., papillary, follicular, or Hurthle cell) AND the patient has disease that is refractory to radioactive iodine therapy AND the patient has BRAF-positive disease. |

# TAGRISO

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## Products Affected

- TAGRISO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | NSCLC - prior therapies and EGFR T790M mutation or EGFR exon 19 deletion or exon 21 (L858R) substitution   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | 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 Tarceva, Iressa, or Gilotrif therapy OR Advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) who have EGFR exon 19 deletion or exon 21 (L858R) substitution as detected by an approved test. |



# TAKHZYRO

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## Products Affected

- TAKHZYRO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, lab values  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders (initial and continuation). |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | Under CMS Review   |

# TALZENNA

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## Products Affected

- TALZENNA ORAL CAPSULE 0.25 MG,  
1 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Talzenna for a covered use.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, BRCA mutation status, HER2 status   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | Locally-advanced or metastatic breast cancer-approve if the patient has germline BRCA mutation-positive AND human epidermal growth factor receptor 2 (HER2) negative disease |

# TARCEVA

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## Products Affected

- TARCEVA ORAL TABLET 100 MG, 150 MG, 25 MG

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus Renal Cell Carcinoma and Bone Cancer-Chordoma. Plus patients already started on Tarceva for a Covered Use.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Advanced, recurrent, or metastatic non small cell lung cancer (NSCLC), EGFR mutation or gene amplification status.  |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | Metastatic NSCLC, approve if the patient meets both of the following: 1. patient is EGFR mutation positive, AND 2. patient has EGFR exon 19 deletions OR exon 21 (L858R) substitution mutations as detected by an FDA-approved test. Advanced RCC, approve if the patient has non-clear cell histology. |

# TASIGNA

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## Products Affected

- TASIGNA ORAL CAPSULE 150 MG, 200 MG, 50 MG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | 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).  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | 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.  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.   |
| <b>Other Criteria</b>               | 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 (Stivarga). 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

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## Products Affected

- TAVALISSE

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.                             |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, prior therapies or surgeries  |
| <b>Age Restrictions</b>             | 18 years and older   |
| <b>Prescriber Restrictions</b>      | Prescribed by, or in consultation with a hematologist  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | Approve if the patient has tried one other therapy or the patient has undergone splenectomy. |

# TAZORAC

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## Products Affected

- tazarotene
- TAZORAC TOPICAL GEL
- TAZORAC TOPICAL CREAM 0.05 %

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All medically accepted indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | Cosmetic uses  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | PP/acne vulgaris - 3 years, other - 12 months  |
| <b>Other Criteria</b>               | Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene). |

# TECFIDERA

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## Products Affected

- TECFIDERA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | Concurrent use with other disease-modifying agents used for multiple sclerosis (MS).                               |
| <b>Required Medical Information</b> | MS, patient must have a relapsing form of MS (RRMS, SPMS with relapses, or PRMS). MS, previous MS therapies tried. |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a neurologist or MS specialist.  |
| <b>Coverage Duration</b>            | Authorization will be for 1 year.  |
| <b>Other Criteria</b>               | N/A  |

# THALOMID

## Products Affected

- THALOMID

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Thalomid for a Covered Use, Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, Waldenstrom's macroglobulinemia/lymphoplasmacytic lymphoma.   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.  |
| <b>Other Criteria</b>               | Discoid lupus erythematosus or cutaneous lupus erythematosus, approve if the patient has tried two other therapies (eg, corticosteroids [oral, topical, intralesional], hydroxychloroquine, tacrolimus [Protopic], methotrexate, dapsone, acitretin [Soriatane]). Myelofibrosis, approve if the patient has tried one other therapy (eg, ruxolitinib [Jakafi], danazol, epoetin alfa [Epogen/Procrit], prednisone, lenalidomide [Revlimid], hydroxyurea). Prurigo nodularis, approve if the patient has tried two other therapies (eg, azathioprine, capsaicin, psoralen plus ultraviolet A [PUVA] therapy, ultraviolet B [UVB] therapy). Recurrent aphthous ulcers or aphthous stomatitis, approve if the patient has tried two other therapies (eg, topical or intralesional corticosteroids, systemic corticosteroids, topical anesthetics/analgesics [eg, benzocaine lozenges], antimicrobial mouthwashes [eg, tetracycline], acyclovir, colchicine). |



# TIBSOVO

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## Products Affected

- TIBSOVO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Tibsovo for a covered use.           |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, IDH1 Status   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | AML- approve if the patient has relapsed or refractory disease AND the disease is isocitrate dehydrogenase-1 (IDH1) mutation positive. |

## TOPICAL AGENTS FOR ATOPIC DERMATITIS

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### Products Affected

- tacrolimus topical

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All medically accepted indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.  |
| <b>Other Criteria</b>               | Authorize use in patients who have tried a prescription strength topical corticosteroid (brand or generic) for the current condition. Dermatologic condition on or around the eyes, eyelids, axilla, or genitalia, authorize use without a trial of a prescription strength topical corticosteroid. |

## TOPICAL RETINOID PRODUCTS

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### Products Affected

- adapalene topical cream
- adapalene topical gel
- avita topical cream
- tretinoin topical

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

## TOPICAL TESTOSTERONE PRODUCTS

### Products Affected

- ANDRODERM
- ANDROGEL TRANSDERMAL GEL IN METERED-DOSE PUMP 20.25 MG/1.25 GRAM (1.62 %)
- ANDROGEL TRANSDERMAL GEL IN PACKET 1.62 % (20.25 MG/1.25 GRAM), 1.62 % (40.5 MG/2.5 GRAM)
- testosterone transdermal gel in metered-dose pump 20.25 mg/1.25 gram (1.62 %)
- testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1.62 % (20.25 mg/1.25 gram), 1.62 % (40.5 mg/2.5 gram)

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis of primary hypogonadism (congenital or acquired) in males. Diagnosis of secondary (hypogonadotropic) hypogonadism (congenital or acquired) in males. Hypogonadism (primary or secondary) in males, serum testosterone level. [Man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 12 months  |
| <b>Other Criteria</b>               | Hypogonadism (primary or secondary) in males - initial therapy, approve if all of the following criteria are met: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) [eg, depressed mood, decreased energy, progressive decrease in muscle mass, osteoporosis, loss of libido, AND 2) patient has had two pre-treatment serum testosterone (total or available) measurements, each taken in the morning on two separate days, AND 3) the two serum testosterone levels are both low, as defined by the normal laboratory reference values. hypogonadism has been confirmed by a low for age serum testosterone (total or free) level defined by the normal laboratory reference values. Hypogonadism (primary or secondary) in males - continuing therapy, approve if the patient meets all of the following criteria: 1) patient has persistent signs and symptoms of androgen deficiency (pre-treatment) AND 2) patient had at least one pre- |

| <b>PA Criteria</b> | <b>Criteria Details</b>  |
|--------------------|--|
|                    | treatment serum testosterone level that was low. For patients requesting Androderm, approve if the patient has previously tried Androgel 1.62% or testosterone 1% gel.[Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.] |

## TRANSMUCOSAL FENTANYL DRUGS

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### Products Affected

- fentanyl citrate buccal lozenge on a handle  
1,200 mcg, 1,600 mcg, 200 mcg, 400 mcg,  
600 mcg, 800 mcg

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.  |
| <b>Other Criteria</b>               | 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). Clinical criteria incorporated into the quantity limit edits for all transmucosal fentanyl drugs require confirmation that the indication is breakthrough cancer pain (ie, FDA labeled use) prior to reviewing for quantity exception. |

# TREMFYA

## Products Affected

- TREMFYA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tremfya for a covered use.  |
| <b>Exclusion Criteria</b>           | Concurrent Use with other Biologics or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs)  |
| <b>Required Medical Information</b> | Previous medication use   |
| <b>Age Restrictions</b>             | 18 years of age and older   |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a dermatologist   |
| <b>Coverage Duration</b>            | Initial therapy - 3 months, Continuation therapy - 3 years  |
| <b>Other Criteria</b>               | Plaque Psoriasis initial therapy-approve if the patient has tried TWO of the following: Enbrel, Humira, Stelara SC, Otezla, or Cosentyx. Cont tx - approve if the patient has had a response to therapy, as according to the prescribing physician. |

# TYKERB

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## Products Affected

- TYKERB

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA approved indications not otherwise excluded from Part D. Plus patients already started on Tykerb for a Covered Use.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis for which Tykerb is being used. Metastatic breast cancer, HER2 status or hormone receptor (HR) status.   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | 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 a man receiving a LHRH agonist, a premenopausal or perimenopausal woman receiving ovarian suppression/ablation with a LHRH agonist, or a postmenopausal woman and Tykerb will be used in combination with an aromatase inhibitor, that is letrozole (Femara), anastrozole, or exemestane. In this criteria, man/woman is defined as an individual with the biological traits of a man/woman, regardless of the individual's gender identity or expression. |



# TYMLOS

## Products Affected

- TYMLOS

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.   |
| <b>Exclusion Criteria</b>           | Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, calcitonin nasal spray [Fortical], Forteo), except calcium and Vitamin D. Previous use of Tymlos and/or Forteo for a combined total no greater than 2 years duration during a patient's lifetime.  |
| <b>Required Medical Information</b> | Previous medications tried, renal function   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 2 years of therapy over a patient's lifetime   |
| <b>Other Criteria</b>               | Treatment of PMO, approve if the patient meets ONE of the following criteria: patient has tried one oral bisphosphonate or cannot take an oral bisphosphonate because the patient cannot swallow or has difficulty swallowing or patient cannot remain in an upright position post oral bisphosphonate administration or patient has a pre-existing GI medical condition (eg, patient with esophageal lesions, esophageal ulcers, or abnormalities of the esophagus that delay esophageal emptying [stricture, achalasia]), OR patient has tried an IV bisphosphonate (ibandronate or zoledronic acid), OR patient has severe renal impairment or CKD, OR patient has had an osteoporotic fracture or fragility fracture |

# UPTRAVI

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## Products Affected

- UPTRAVI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients currently taking Uptravi.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Confirmation of right heart catheterization (select populations), medication history.   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | PAH must be prescribed by, or in consultation with, a cardiologist or a pulmonologist.  |
| <b>Coverage Duration</b>            | 3 years   |
| <b>Other Criteria</b>               | 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 Uptravi or another agent indicated for PAH (WHO group 1). Patient must meet a) OR b): a) tried TWO or is currently taking TWO oral therapies for PAH (either alone or in combination) each for 30 days, unless patient has experienced treatment failure, intolerance, or oral therapy is contraindicated: PDE5 inhibitor (eg, sildenafil, Revatio), endothelin receptor antagonist (ERA) [eg, Tracleer, Letairis or Opsumit], or Adempas, OR b) receiving or has received in the past one prostacyclin therapy for PAH (eg, Orenitram, Ventavis, or epoprostenol injection). |

# VENCLEXTA

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## Products Affected

- VENCLEXTA
- VENCLEXTA STARTING PACK

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus Small Lymphocytic Lymphoma (SLL). Plus Mantle Cell Lymphoma. Plus patients currently taking Venclexta for a Covered Use.                          |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis, prior therapy  |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 3 years   |
| <b>Other Criteria</b>               | CLL with or without 17p deletion - approve if the patient has tried one prior therapy. SLL-approve if the patient has tried one prior therapy. Mantle Cell Lymphoma-approve if the patient has tried one prior therapy. |

# VERZENIO

## Products Affected

- VERZENIO

| PA Criteria                  | Criteria Details  |
|------------------------------|---|
| Covered Uses                 | All FDA approved indications not otherwise excluded from Part D.  |
| Exclusion Criteria           | N/A   |
| Required Medical Information | HR status, HER2 status, previous medications/therapies tried, concomitant therapy, menopausal status  |
| Age Restrictions             | N/A   |
| Prescriber Restrictions      | N/A   |
| Coverage Duration            | 3 years   |
| Other Criteria               | Breast cancer - approve advanced or metastatic hormone receptor positive (HR+) [i.e., estrogen receptor positive (ER+) and/or progesterone receptor positive (PR+)]disease, and HER2-negative breast cancer in patients who have not had disease progression while on Kisqali, Ibrance or Verzenio when the pt meets ONE of the following 1. Pt is postmenopausal and Verzenio will be used as first line endocrine therapy in combination with anastrozole, exemestane, or letrozole 2. pt is premenopausal or perimenopausal and is receiving ovarian suppression/ablation with GnRH agonist, or has had surgical bilateral oophorectomy, or ovarian irradiation AND Verzenio will be used as first line endocrine therapy in combination with anastrozole, exemestane, or letrozole 3. Patient is postmenopausal and meets the following conditions: The patient has relapsed or progressed during prior endocrine therapy with at least one of the following: anastrozole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus Afinitor, Faslodex, Afinitor plus Faslodex or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol AND Verzenio will be used in combination with Faslodex. 4. patient is premenopausal or perimenopausal and meets the following conditions: The patient is receiving ovarian suppression/ablation with a gonadotropin-releasing hormone (GnRH) agonist, or has had surgical bilateral oophorectomy or ovarian irradiation AND patient has relapsed or progressed during prior endocrine therapy |

| PA Criteria | Criteria Details  |
|-------------|---|
|             | <p>with at least one of the following: anastrozole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus Afinitor, Faslodex, Afinitor plus Faslodex or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol AND Verzenio will be used in combination with Faslodex 5. patient is postmenopausal, premenopausal, perimenopausal or a man (a man is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression) and meets the following conditions: Verzenio will be used as monotherapy AND patient's breast cancer has relapsed or progressed during prior endocrine therapy with at least one of the following: anastrozole, exemestane, letrozole, tamoxifen, Fareston, exemestane plus Afinitor, Faslodex, Afinitor plus Faslodex or tamoxifen, megestrol acetate, fluoxymesterone, ethinyl estradiol AND patient has tried chemotherapy for metastatic breast cancer. 6. pt is a man who is receiving GnRH agonist AND Verzenio with be used as first line endocrine therapy in combination with anastrozole, exemestane, tamoxifen or letrozole.</p> |

# VIZIMPRO

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## Products Affected

- VIZIMPRO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.Plus patients already started on Vizimpro for a covered use.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, EGFR status, exon deletions or substitutions  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | Metastatic-NSCLC-Epidermal Growth Factor Receptor (EGFR) mutation positive AND has epidermal growth factor receptor (EGFR) exon 19 deletion as detected by an approved test OR exon 21 (L858R) substitution mutations as detected by an approved test. |

# VOLTAREN GEL

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## Products Affected

- diclofenac sodium topical gel 1 %

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 12 months.                             |
| <b>Other Criteria</b>               | N/A  |

# VOSEVI

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## Products Affected

- VOSEVI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients started on Vosevi for a Covered Use.                      |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Genotype, prescriber specialty, other medications tried or used in combination with requested medication                                 |
| <b>Age Restrictions</b>             | 18 years or older  |
| <b>Prescriber Restrictions</b>      | Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician |
| <b>Coverage Duration</b>            | Will be c/w AASLD guidance and inclusive of treatment already received for the requested drug  |
| <b>Other Criteria</b>               | Criteria will be applied consistent with current AASLD/IDSA guidance.  |



# VOTRIENT

## Products Affected

- VOTRIENT

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus, patients already taking Votrient for a Covered Use. Differentiated (ie, papillary, follicular, Hurthle cell) thyroid carcinoma. Uterine sarcoma, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gastrointestinal Stromal Tumor (GIST).  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | Soft tissue sarcoma other than GIST [angiosarcoma, Pleomorphic rhabdomyosarcoma, retroperitoneal/intra-abdominal soft tissue sarcoma that is unresectable or progressive, soft tissue sarcoma of the extremity/superficial trunk or head/neck, including synovial sarcoma, or other non-lipogenic (non-adipocytic) soft tissue sarcoma], approve. Differentiated (ie, papillary, follicular, Hurthle) thyroid carcinoma, approve if the patient is refractory to radioactive iodine therapy. Uterine sarcoma, approve if the patient has recurrent, advanced or metastatic disease. Advanced RCC - approve. Ovarian Cancer (ie, Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer) - approve if the patient has persistent or recurrent disease OR the patient has complete clinical remission after receiving primary treatment with chemotherapy and/or surgery. GIST - approve if the patient has tried TWO of the following: Gleevec, Sutent, or Stivarga. Medullary Thyroid Carcinoma, approve if the patient has tried vandetanib (Caprelsa) or cabozantinib (Cometriq). |

# XALKORI

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## Products Affected

- XALKORI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus soft tissue sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK translocation, Plus peripheral T-Cell Lymphoma - Anaplastic Large Cell Lymphoma (ALCL), Plus NSCLC with high level MET amplification or MET Exon 14 skipping mutation. Plus patients already started on crizotinib for a Covered Use. |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | For the FDA-approved indication of NSCLC for patients new to therapy, ALK status and ROS1 rearrangement required. For soft tissue sarcoma IMT, ALK translocation.   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years   |
| <b>Other Criteria</b>               | NSCLC, patient new to therapy must be ALK-positive, have high level MET amplification, have MET Exon 14 skipping mutation, or have ROS1 rearrangement for approval. For IMT, patient new to therapy must have ALK translocation for approval.   |

# XELJANZ

## Products Affected

- XELJANZ
- XELJANZ XR

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Xeljanz/XR for a Covered Use.   |
| <b>Exclusion Criteria</b>           | Concurrent use with a biologic for an inflammatory condition (eg, tocilizumab, anakinra, abatacept, rituximab) or a TNF inhibitor (eg, certolizumab pegol, etanercept, adalimumab, infliximab, golimumab). Concurrent use with potent immunosuppressants that are not methotrexate (MTX) [eg, azathioprine, tacrolimus, cyclosporine, mycophenolate mofetil]. |
| <b>Required Medical Information</b> | Diagnosis, concurrent medications, previous drugs tried.  |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | RA, prescribed by or in consultation with a rheumatologist. PsA-prescribed by or in consultation with a rheumatologist or a dermatologist.  |
| <b>Coverage Duration</b>            | Authorization will be for 3months initial, 3 years cont.  |
| <b>Other Criteria</b>               | RA/PsA initial, 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). Continuation Therapy - Patient must have responded, as determined by the prescriber                                 |

# XENAZINE

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## Products Affected

- tetrabenazine oral tablet 12.5 mg, 25 mg
- XENAZINE ORAL TABLET 12.5 MG, 25 MG

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | For treatment of chorea associated with Huntington's disease, Tourette syndrome or related tic disorders, hyperkinetic dystonia, or hemiballism, must be prescribed by or after consultation with a neurologist. For TD, must be prescribed by or after consultation with a neurologist or psychiatrist. |
| <b>Coverage Duration</b>            | Authorization will be for 12 months  |
| <b>Other Criteria</b>               | N/A  |

# XERMELO

## Products Affected

- XERMELO

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis, previous therapy, concomitant therapy  |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | 3 years   |
| <b>Other Criteria</b>               | Initial therapy - approve if the patient meets ALL of the following criteria: 1) patient has been on long-acting somatostatin analog (SSA) therapy (eg, Somatuline Depot [lanreotide for injection]) for at least 3 consecutive months, AND 2) while on long-acting SSA therapy (prior to starting Xermelo), the patient continues to have at least four bowel movements per day, AND 3) Xermelo will be used concomitantly with a long-acting SSA therapy. Continuation therapy - approve if the patient is continuing to take Xermelo concomitantly with a long-acting SSA therapy for carcinoid syndrome diarrhea. |

# XOLAIR

## Products Affected

- XOLAIR SUBCUTANEOUS RECON SOLN
- XOLAIR SUBCUTANEOUS SYRINGE 150 MG/ML, 75 MG/0.5 ML

| PA Criteria                         | Criteria Details  |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Seasonal or perennial allergic rhinitis (SAR or PAR).  |
| <b>Exclusion Criteria</b>           | Concurrent use with an Interleukin (IL) Antagonist Monoclonal Antibody  |
| <b>Required Medical Information</b> | Moderate to severe persistent asthma and SAR/PAR, baseline IgE level of at least 30 IU/mL. For asthma, patient has a positive skin test or in vitro testing (ie, a blood test for allergen-specific IgE antibodies such as an enzyme-linked immunoabsorbant assay (eg, immunoCAP, ELISA) or the RAST) for 1 or more perennial aeroallergens (eg, house dust mite, animal dander [dog, cat], cockroach, feathers, mold spores) and/or for 1 or more seasonal aeroallergens (grass, pollen, weeds). For SAR/PAR, patient has positive skin testing (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach) and/or positive in vitro testing (ie, a blood test for allergen-specific IgE antibodies) for one or more relevant allergens (eg, grass, tree, or weed pollen, mold spores, house dust mite, animal dander, cockroach). CIU - must have urticaria for more than 6 weeks, with symptoms present more than 3 days/wk despite daily non-sedating H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) AND must have tried therapy with a leukotriene modifier (e.g., montelukast) with a daily non-sedating H1 antihistamine |
| <b>Age Restrictions</b>             | Moderate to severe persistent asthma-6 years and older. All other diagnoses-12 years and older  |
| <b>Prescriber Restrictions</b>      | Moderate to severe persistent asthma/SAR/PAR if prescribed by, or in consultation with an allergist, immunologist, or pulmonologist. CIU if prescribed by or in consultation with an allergist, immunologist, or dermatologist.   |
| <b>Coverage Duration</b>            | Initial tx 4 months, continued tx 12 months.  |
| <b>Other Criteria</b>               | Moderate to severe persistent asthma approve if pt meets criteria 1 and 2: 1)pt has received at least 3 months of combination therapy with an inhaled   |

| PA Criteria | Criteria Details   |
|-------------|--|
|             | <p>corticosteroid and at least one the following: long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, and 2) inadequate control demonstrated by hospitalization for asthma or requirement for systemic corticosteroids to control asthma exacerbation(s). For continued Tx for asthma - must meet specialist criteria and patient has responded to therapy as determined by the prescribing physician. SAR/PAR - approve if pt meets all of the following criteria: 1) pt has tried concurrent therapy with at least one drug from 2 of the following classes: an oral non-sedating or low-sedating antihistamine, a nasal antihistamine, a nasal corticosteroid, or montelukast, AND 2) pt has had immunotherapy, is receiving immunotherapy, or will be receiving immunotherapy or has contraindications to immunotherapy. For continued tx SAR/PAR - must meet specialist criteria and pt must have responded to therapy as determined by the prescribing physician. For CIU cont tx - must meet specialist criteria and have responded to therapy as determined by the prescribing physician.</p> |

# XTANDI

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## Products Affected

- XTANDI

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Xtandi for a Covered Use. |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Diagnosis for which Xtandi is being used.   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years   |
| <b>Other Criteria</b>               | N/A   |



# XYREM

## Products Affected

- XYREM

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D.  |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Medication history  |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | Prescribed by a sleep specialist physician or a Neurologist   |
| <b>Coverage Duration</b>            | 12 months.  |
| <b>Other Criteria</b>               | 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 Nuvigil. |

# YONSA

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## Products Affected

- YONSA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Yonsa for a covered use.                   |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | Diagnosis, concomitant medications   |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | Metastatic castration-resistant prostate cancer (mCRPC) - approve if the patient will be using Yonsa in combination with methylprednisolone. |

# ZARXIO

## Products Affected

- ZARXIO

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D worded more broadly as cancer patients receiving myelosuppressive chemotherapy, patients with acute myeloid leukemia (AML) receiving chemotherapy, cancer patients receiving bone marrow transplantation (BMT), patients undergoing peripheral blood progenitor cell (PBPC) collection and therapy, and patients with severe chronic neutropenia [SCN] (e.g., congenital neutropenia, cyclic neutropenia, idiopathic neutropenia). Neutropenia associated with human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS). Treatment of myelodysplastic syndromes (MDS). Drug induced agranulocytosis or neutropenia. Aplastic anemia (AA). Acute lymphocytic leukemia (ALL). |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | AML, HIV/AIDS, MDS - adults  |
| <b>Prescriber Restrictions</b>      | Cancer/AML, MDS, ALL, oncologist or a hematologist. Cancer patients receiving BMT and PBPC, prescribed by or in consultation with an oncologist, hematologist, or a physician who specializes in transplantation. SCN, AA - hematologist. HIV/AIDS neutropenia, infectious disease (ID) physician (MD), hematologist, or MD specializing in HIV/AIDS.  |
| <b>Coverage Duration</b>            | chemo/SCN/AML-6 mo.HIV/AIDS-4 mo.MDS-3 mo.PBPC,Drug induce A/N,AA,ALL,BMT-3 mo.All other=12mo.   |
| <b>Other Criteria</b>               | Cancer patients receiving chemotherapy, approve if the patient meets one of the following conditions: patient is receiving myelosuppressive anti-cancer medications that are associated with a high risk of febrile neutropenia (the risk is at least 20% based on the chemotherapy regimen), patient is receiving myelosuppressive anti-cancer medications that are associated with a risk of febrile neutropenia but the risk is less than 20% based on the chemotherapy regimen and the patient has one or more risk factors for febrile neutropenia (eg, aged greater than or equal to 65 years,   |

| <b>PA Criteria</b> | <b>Criteria Details</b>   |
|--------------------|---|
|                    | <p>prior chemotherapy or radiation therapy, persistent neutropenia, bone marrow involvement by tumor, recent surgery and/or open wounds, liver and/or renal dysfunction, poor performance status, or HIV infection), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, Neulasta, Neupogen) and a reduced dose or frequency of chemotherapy may compromise treatment, patient has received chemotherapy has febrile neutropenia and has at least one risk factor (eg, sepsis syndrome, aged greater than 65 years, severe neutropenia [absolute neutrophil count less than 100 cells/mm<sup>3</sup>], neutropenia expected to be greater than 10 days in duration, invasive fungal infection).</p> |

# ZEJULA

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## Products Affected

- ZEJULA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus patients already started on Zejula for a Covered Use.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | 3 years  |
| <b>Other Criteria</b>               | Recurrent ovarian, fallopian tube, or primary peritoneal cancer - 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

| <b>PA Criteria</b>                  | <b>Criteria Details</b>  |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus, patients with Hairy Cell Leukemia, Non-Small Cell Lung Cancer (NSCLC) with BRAF V600E Mutation, Differentiated thyroid carcinoma (i.e., papillary, follicular, or Hurthle cell) with BRAF-positive disease and patients already started on vemurafenib for a Covered Use. |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | BRAFFV600 mutation status required.  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | Melanoma, patient new to therapy must have BRAFFV600 mutation for approval AND have unresectable, advanced or metastatic melanoma. HCL - must have relapsed or refractory disease AND tried at least two therapies for hairy cell leukemia. Thyroid Cancer-patient has disease that is refractory to radioactive iodine therapy.                 |

# ZYDELIG

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## Products Affected

- ZYDELIG

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus Marginal Zone Lymphoma.   |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | N/A   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | CLL-approve if the patient has tried one prior therapy. Marginal Zone Lymphoma/Follicular B-Cell Non-Hodgkin Lymphoma/SLL - approve if the patient has tried two prior therapies. |

# ZYKADIA

## Products Affected

- ZYKADIA

| <b>PA Criteria</b>                  | <b>Criteria Details</b>   |
|-------------------------------------|---|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus Soft Tissue Sarcoma Inflammatory Myofibroblastic Tumor (IMT) with ALK Translocation. Plus patients with NSCLC with ROS1 Rearrangement-First-line therapy. |
| <b>Exclusion Criteria</b>           | N/A   |
| <b>Required Medical Information</b> | Must have metastatic NSCLC that is anaplastic lymphoma kinase (ALK)-positive as detected by an approved test or ROS1 Rearrangement. IMT - ALK Translocation status.   |
| <b>Age Restrictions</b>             | N/A   |
| <b>Prescriber Restrictions</b>      | N/A   |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.  |
| <b>Other Criteria</b>               | N/A   |



# ZYTIGA

## Products Affected

- abiraterone
- ZYTIGA ORAL TABLET 250 MG, 500 MG

| PA Criteria                         | Criteria Details   |
|-------------------------------------|--|
| <b>Covered Uses</b>                 | All FDA-approved indications not otherwise excluded from Part D. Plus Prostate Cancer-Regional Risk Group or Locally Advanced. Plus Prostate Cancer - Metastatic (Castration-Resistant or Castration-Sensitive), Post-External Beam Radiation Therapy (EBRT). Plus, patients already started on Zytiga for a Covered Use.  |
| <b>Exclusion Criteria</b>           | N/A  |
| <b>Required Medical Information</b> | N/A  |
| <b>Age Restrictions</b>             | N/A  |
| <b>Prescriber Restrictions</b>      | N/A  |
| <b>Coverage Duration</b>            | Authorization will be for 3 years.   |
| <b>Other Criteria</b>               | Prostate Cancer-Metastatic, Castration-Resistant (mCRPC) and Metastatic, Castration-Sensitive (mCSPC), high risk-Approve if Zytiga is being used in combination with prednisone. Prostate Cancer - Regional Risk Group or Locally Advanced. Approve if the patient meets all of the following criteria (A, B, and C): A) Zytiga is used in combination with prednisone AND B) Patient has regional lymph node metastases and no distant metastases AND C) Patient meets one of the following criteria (i or ii): i. Zytiga with prednisone is used in combination with gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide acetate for injection], Lupron Depot [leuprolide acetate for depot suspension], Trelstar [triptorelin pamoate for injectable suspension], Zoladex [goserelin acetate implant], Vantas [histrelin acetate subcutaneous implant]) OR ii. Patient has had an orchiectomy. Prostate Cancer - Metastatic (Castration-Resistant or Castration-Sensitive), Post-External Beam Radiation Therapy (EBRT)-Approve if the patient meets all of the following criteria (A, B, C, D, and E): A) Zytiga is used in combination with prednisone AND B) Patient |

| PA Criteria | Criteria Details  |
|-------------|---|
|             | <p>meets one of the following criteria (i, ii, or iii): i. Zytiga with prednisone is used in combination with gonadotropin-releasing hormone (GnRH) agonist (e.g., Lupron [leuprolide acetate for injection], Lupron Depot [leuprolide acetate for depot suspension], Trelstar [triptorelin pamoate for injectable suspension], Zoladex [goserelin acetate implant], Vantas [histrelin acetate subcutaneous implant]) OR ii. Zytiga with prednisone is used in combination with GnRH antagonist (e.g., Firmagon [degarelix for injection]) OR iii. Patient has had an orchiectomy. C) Patient meets one of the following criteria (i or ii): i. There is an increase in prostate specific antigen (PSA) after EBRT OR ii Patient has had a positive digital rectal exam (DRE) after EBRT AND D) Patient is not a candidate for local therapy AND E) Patient has had a positive bone scan.</p> |

## PART B VERSUS PART D

### Products Affected

- ABELCET
- acetylcysteine
- acyclovir sodium intravenous solution
- albuterol sulfate inhalation solution for nebulization 0.63 mg/3 ml, 1.25 mg/3 ml, 2.5 mg /3 ml (0.083 %), 5 mg/ml
- AMBISOME
- AMINOSYN 7 % WITH ELECTROLYTES
- AMINOSYN II 10 %
- AMINOSYN II 15 %
- AMINOSYN II 8.5 %
- AMINOSYN II 8.5 %-ELECTROLYTES
- AMINOSYN-HBC 7%
- AMINOSYN-PF 10 %
- AMINOSYN-PF 7 % (SULFITE-FREE)
- AMINOSYN-RF 5.2 %
- amphotericin b
- aprepitant
- azathioprine
- BETHKIS
- budesonide inhalation
- caspofungin
- CLINIMIX 5%/D15W SULFITE FREE
- CLINIMIX 5%/D25W SULFITE-FREE
- CLINIMIX 4.25%/D10W SULF FREE
- CLINIMIX 4.25%/D5W SULFIT FREE
- CLINIMIX 4.25%-D25W SULF-FREE
- CLINIMIX 5%-D20W(SULFITE-FREE)
- CLINIMIX E 4.25%/D10W SUL FREE
- CLINIMIX E 5%/D15W SULFIT FREE
- cromolyn inhalation
- cyclophosphamide oral capsule
- cyclosporine modified
- cyclosporine oral capsule
- dronabinol
- ENGERIX-B (PF) INTRAMUSCULAR SYRINGE
- ENGERIX-B PEDIATRIC (PF) INTRAMUSCULAR SYRINGE
- FIRMAGON KIT W DILUENT SYRINGE
- gengraf oral capsule 100 mg, 25 mg
- gengraf oral solution
- granisetron hcl oral
- HEPATAMINE 8%
- intralipid intravenous emulsion 20 %
- INTRALIPID INTRAVENOUS EMULSION 30 %
- ipratropium bromide inhalation
- ipratropium-albuterol
- levalbuterol hcl
- methotrexate sodium (pf) injection solution
- methotrexate sodium injection
- mycophenolate mofetil
- mycophenolate sodium
- NEBUPENT
- NEPHRAMINE 5.4 %
- ondansetron
- ondansetron hcl oral
- PERFOROMIST
- plenamine
- premasol 10 %
- PREMASOL 6 %
- PULMOZYME
- RAPAMUNE ORAL SOLUTION
- RECOMBIVAX HB (PF) INTRAMUSCULAR SUSPENSION 10 MCG/ML, 40 MCG/ML
- RECOMBIVAX HB (PF) INTRAMUSCULAR SYRINGE
- sirolimus
- SYNRIPO
- tacrolimus oral
- tobramycin in 0.225 % nacl
- travasol 10 %
- TRELSTAR INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION
- TROPHAMINE 10 %
- TROPHAMINE 6%
- XGEVA
- ZORTRESS

**Updated 02/2019**

**Details**

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.

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