

## ACITRETIN

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### Products Affected

- *acitretin*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of diagnosis.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For initial therapy in the treatment of psoriasis: trial and failure, contraindication, or intolerance to methotrexate or cyclosporine is required. For continuation of therapy, approve if patient has already been started on Acitretin.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ACTIMMUNE

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## Products Affected

- ACTIMMUNE

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ADEMPAS

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## Products Affected

- ADEMPAS

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	1 year
<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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# AIMOVIG

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## Products Affected

- AIMOVIG AUTOINJECTOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination therapy with Ajovy, Vyepti or Emgality
<b>Required Medical Information</b>	Diagnosis, number of migraine headaches per month, prior therapies tried
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient meets the following criteria (A and B): A) Patient has greater than or equal to 4 migraine headache days per month (prior to initiating a migraine-preventative medication), AND B) Patient has tried at least two standard prophylactic pharmacologic therapies, at least one drug each from a different pharmacologic class (e.g., anticonvulsant, beta-blocker), and has had inadequate responses to those therapies or the patient has a contraindication to other prophylactic pharmacologic therapies according to the prescribing physician.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ALDURAZYME

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## Products Affected

- ALDURAZYME

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has a laboratory test demonstrating deficient alpha-L-iduronidase activity in leukocytes, fibroblasts, plasma, or serum OR has a molecular genetic test demonstrating alpha-L-iduronidase gene mutation
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ALOSETRON

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## Products Affected

- *alosetron*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Alosetron will not be approved for use in men, as safety and efficacy in men has not been established.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Alosetron is considered medically necessary for the treatment of severe IBS-D. At least one of the following must be present for diarrhea to be considered severe: frequent and severe abdominal pain or discomfort, frequent bowel urgency or fecal incontinence, and disability or restriction of daily activities due to IBS.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# AMPYRA

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## Products Affected

- *dalfampridine*

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ANABOLIC STEROIDS

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## Products Affected

- ANADROL-50
- *oxandrolone oral tablet 10 mg, 2.5 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<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
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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



# ANTIBIOTICS (INJECTABLE)

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## Products Affected

- *amikacin injection solution 1,000 mg/4 ml, 500 mg/2 ml*
- *ampicillin sodium*
- *ampicillin-sulbactam*
- *azithromycin intravenous*
- *aztreonam*
- BICILLIN L-A
- *cefazolin in dextrose (iso-os) intravenous piggyback 1 gram/50 ml*
- *cefazolin injection recon soln 100 gram, 300 g*
- *cefazolin intravenous*
- CEFEPIME IN DEXTROSE 5 %
- *cefepime in dextrose,iso-osm*
- *cefotaxime injection recon soln 1 gram*
- CEFOTETAN IN DEXTROSE, ISO-OSM
- *cefotetan injection*
- *cefoxitin*
- *cefoxitin in dextrose, iso-osm*
- *ceftazidime*
- CEFTAZIDIME IN D5W
- *ceftriaxone in dextrose,iso-os*
- CEFTRIAZONE INJECTION RECON SOLN 100 GRAM
- *ceftriaxone intravenous*
- *cefuroxime sodium injection recon soln 750 mg*
- *cefuroxime sodium intravenous*
- *ciprofloxacin in 5 % dextrose*
- CLINDAMYCIN IN 0.9 % SOD CHLOR
- *clindamycin in 5 % dextrose*
- *clindamycin phosphate injection*
- *clindamycin phosphate intravenous solution 600 mg/4 ml*
- *colistin (colistimethate na)*
- *doxy-100*
- ERYTHROCIN INTRAVENOUS RECON SOLN 500 MG
- *gentamicin in nacl (iso-osm) intravenous piggyback 100 mg/100 ml, 60 mg/50 ml, 80 mg/100 ml, 80 mg/50 ml*
- GENTAMICIN IN NAACL (ISO-OSM) INTRAVENOUS PIGGYBACK 100 MG/50 ML, 120 MG/100 ML
- *gentamicin injection solution 40 mg/ml*
- *gentamicin sulfate (ped) (pf)*
- *levofloxacin in d5w*
- *levofloxacin intravenous*
- *lincomycin*
- *linezolid in dextrose 5%*
- *linezolid-0.9% sodium chloride metro i.v.*
- *metronidazole in nacl (iso-os)*
- MOXIFLOXACIN-SOD.ACE,SUL-WATER
- *moxifloxacin-sod.chloride(iso)*
- *nafcillin*
- *nafcillin in dextrose iso-osm*
- NUZYRA INTRAVENOUS
- *oxacillin injection*
- *penicillin g potassium*
- *pfizerpen-g*
- PIPERACILLIN-TAZOBACTAM INTRAVENOUS RECON SOLN 13.5 GRAM
- SIVEXTRO INTRAVENOUS
- *streptomycin*
- *sulfamethoxazole-trimethoprim intravenous*
- SYNERCID
- *tazicef*
- TEFLARO
- *tigecycline*
- *tobramycin sulfate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## ANTIFUNGALS (IV)

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### Products Affected

- *caspofungin*
- *fluconazole in nacl (iso-osm) intravenous piggyback 200 mg/100 ml, 400 mg/200 ml*
- *voriconazole intravenous*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	Diagnosis
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	3 months
Other Criteria	N/A
Indications	All FDA-approved Indications.
Off-Label Uses	N/A

# ANTIFUNGALS, POLYENE

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## Products Affected

- ABELCET
- AMBISOME
- *amphotericin b*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	6 months
Other Criteria	B vs D coverage determination
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

# ANTINEOPLASTICS, MONOCLONAL ANTIBODIES

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## Products Affected

- ABRAXANE
- ALIMTA
- ALIQOPA
- BAVENCIO
- BESPONSA
- BORTEZOMIB
- CYRAMZA
- DARZALEX
- ELZONRIS
- EMLICITI
- ENHERTU
- EVOMELA
- GAZYVA
- IMFINZI
- KADCYLA
- KANJINTI
- KEYTRUDA INTRAVENOUS SOLUTION
- LIBTAYO
- LUMOXITI
- MVASI
- MYLOTARG
- OGIVRI
- ONIVYDE
- OPDIVO
- PADCEV
- PERJETA
- POLIVY
- POTELIGEO
- RUXIENCE
- SARCLISA
- TECENTRIQ
- *thiotepa*
- TRAZIMERA
- TRUXIMA
- UNITUXIN
- VECTIBIX
- VELCADE
- YERVOY
- YONDELIS
- ZIRABEV

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	12 months
Other Criteria	B vs D coverage determination

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# APOKYN

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## Products Affected

- APOKYN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with a serotonin 5-HT <sub>3</sub> Antagonist
<b>Required Medical Information</b>	Diagnosis, other therapies
<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>	Parkinson's disease (PD)-approve if the patient has advanced PD, is experiencing off episodes such as muscle stiffness, slow movements, or difficulty starting movements, is currently receiving carbidopa/levodopa and has previously tried two other treatments for off episodes.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ARCALYST

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## Products Affected

- ARCALYST

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 cont
<b>Other Criteria</b>	CAPS renewal - approve if the patient has had a response as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# ARIKAYCE

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## Products Affected

- ARIKAYCE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous medication history
<b>Age Restrictions</b>	MAC-18 years and older
<b>Prescriber Restrictions</b>	MAC-Prescribed by a pulmonologist, infectious disease physician or a physician who specializes in the treatment of MAC lung infections. Cystic fibrosis-prescribed by or in consultation with a pulmonologist or physician who specializes in the treatment of cystic fibrosis
<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 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). Cystic fibrosis-patient has pseudomonas aeruginosa in culture of the airway.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Cystic fibrosis pseudomonas aeruginosa infection

# ATYPICAL ANTIPSYCHOTIC

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## Products Affected

- FANAPT ORAL TABLET
- FANAPT ORAL TABLETS,DOSE PACK
- *paliperidone oral tablet extended release*  
24hr 1.5 mg, 3 mg, 6 mg, 9 mg
- VRAYLAR ORAL CAPSULE
- VRAYLAR ORAL CAPSULE,DOSE PACK

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	1 year
Other Criteria	Approve if the patient has tried two of the following: olanzapine, quetiapine fumarate, risperidone, ziprasidone. Approve requests for paliperidone ER in Schizoaffective Disorder without the trial of other treatment.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

# AURYXIA

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## Products Affected

- AURYXIA

<b>PA Criteria</b>	<b>Criteria Details</b>
<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
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# AUSTEDO

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## Products Affected

- AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist or a psychiatrist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# BANZEL

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## Products Affected

- BANZEL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Patients 1 years of age or older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Initial therapy-approve if the patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs. Continuation-approve if the patient is responding to therapy
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Treatment-Refractory Seizures/Epilepsy

# BENLYSTA

## Products Affected

- BENLYSTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<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).
<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>	<p>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.</p> <p>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.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# BETASERON

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## Products Affected

- BETASERON SUBCUTANEOUS KIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agent used for multiple sclerosis
<b>Required Medical Information</b>	PENDING CMS REVIEW
<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
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# BOTOX

## Products Affected

- BOTOX

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	cosmetic uses (eg, facial rhytides, frown lines, glabellar wrinkling, horizontal neck rhytides, mid and lower face and neck rejuvenation, platysmal bands, rejuvenation of the peri-orbital region)
<b>Required Medical Information</b>	None
<b>Age Restrictions</b>	None
<b>Prescriber Restrictions</b>	Migraine headache prophylaxis in patients with chronic migraine if prescribed by, or after consultation with, a neurologist or HA specialist
<b>Coverage Duration</b>	Authorization will be for 12 months
<b>Other Criteria</b>	<p>Blepharospasm Associated with Dystonia or Strabismus-approve</p> <ul style="list-style-type: none"> <li>•Cervical Dystonia (spasmodic torticollis)-approve</li> <li>•Hyperhidrosis, primary axillary-approve</li> <li>•Chronic low back pain after trial with at least 2 other pharmacologic therapies (eg, NSAID, antispasmodics, muscle relaxants, opioids, antidepressants) and if being used as part of a multimodal therapeutic pain management program.</li> <li>•Essential tremor after a trial with at least 1 other pharmacologic therapy (eg, primidone, propranolol, benzodiazepines, gabapentin, topiramate).</li> <li>•Migraine Headache Prophylaxis in patients with Chronic migraine -must have 15 or more migraine headache days per month with headache lasting 4 hours per day or longer (prior to initiation of Botox therapy) AND have tried at least two other prophylactic pharmacologic therapies, each from a different pharmacologic class (e.g., beta-blocker, anticonvulsant, tricyclic antidepressant).</li> <li>•Urinary incontinence associated with a neurological condition (e.g., spinal cord injury, multiple sclerosis) approve after a trial with at least one other pharmacologic therapy (e.g., anticholinergic medication).</li> </ul>



<b>PA Criteria</b>	<b>Criteria Details</b>
	<ul style="list-style-type: none"> <li>•Overactive Bladder with symptoms of Urge Urinary Incontinence, Urgency and Frequence-approve if the patient has tried at least one other pharmacologic therapy</li> <li>•Spasticity, lower limb-approve</li> <li>•Spasticity, upper limb-approve</li> </ul>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	<p>Achalasia, Anal Fissure (anal sphincter), Chronic facial pain/pain associated with TMJ dysfunction, Chronic low back pain, Hyperhidrosis (Palmar/Plantar, facial), Myofascial pain, Sialorrhea (chronic), Spasticity (other than lower and upper limb (eg, due to cerebral palsy, stroke, brain injury, spinal cord injury, MS, hemifacial spasm)), Essential tremor, Dystonia other than cervical (eg, focal dystonias, tardive dystonia, anismus, laryngeal dystonia/spasmodic dysphonia), Frey's syndrome (gustatory sweating), Ophthalmic disorders (other than blepharospasm or Strabismus (eg, esotropia, exotropia, nystagmus, facial nerve paresis))</p>

# BUPRENORPHINE

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## Products Affected

- *buprenorphine hcl sublingual*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of opioid dependence.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Induction therapy: 1 month. Pregnancy/Hypersensitivity to naloxone: 12 months
<b>Other Criteria</b>	The use of buprenorphine for maintenance therapy should be limited to patients who have experienced a hypersensitivity reaction to naloxone or require buprenorphine during pregnancy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# C1 ESTERASE INHIBITORS

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## Products Affected

- CINRYZE

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CAPLYTA

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## Products Affected

- CAPLYTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	Approve if the patient has tried two of the following: olanzapine, quetiapine fumarate, risperidone, ziprasidone.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# CARBAGLU

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## Products Affected

- CARBAGLU

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a metabolic disease specialist or a specialist who focuses in the treatment of metabolic diseases
<b>Coverage Duration</b>	Pt meets criteria with no genetic test - 3 mo approval. Pt had genetic test - 12 mo approval
<b>Other Criteria</b>	Approve if genetic testing confirmed a mutation leading to N-acetylglutamate synthase deficiency (NAGS) or if the patient has hyperammonemia.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CAYSTON

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## Products Affected

- CAYSTON

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has <i>Pseudomonas aeruginosa</i> in culture of the airway (e.g., sputum culture, oropharyngeal culture, bronchoalveolar lavage culture).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CEREZYME

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## Products Affected

- CEREZYME INTRAVENOUS RECON  
SOLN 400 UNIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorder
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Gaucher Disease, Type 1-approve if there is demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR molecular genetic testing documenting glucocerebrosidase gene mutation
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CHEMET

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## Products Affected

- CHEMET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Blood lead level
<b>Age Restrictions</b>	Approve in patients between the age of 12 months and 18 years
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a professional experienced in the use of chelation therapy (eg, a medical toxicologist or a poison control center specialist)
<b>Coverage Duration</b>	Approve for 2 months
<b>Other Criteria</b>	Approve if Chemet is being used to treat acute lead poisoning (not as prophylaxis) and prior to starting Chemet therapy the patient's blood lead level was greater than 45 mcg/dL.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# CHORIONIC GONADOTROPINS

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## Products Affected

- CHORIONIC GONADOTROPIN,  
HUMAN INTRAMUSCULAR

<b>PA Criteria</b>	<b>Criteria Details</b>
<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
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# CLOBAZAM

## Products Affected

- *clobazam oral suspension*
- *clobazam oral tablet*
- SYMPAZAN

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, other medications tried
<b>Age Restrictions</b>	2 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist (initial therapy)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Lennox-Gastaut Syndrome, initial therapy-patient has tried one of the following: lamotrigine, topiramate, rufinamide, felbamate, or Epidiolex. Treatment refractory seizures/epilepsy, initial therapy-patient has tried and/or is concomitantly receiving at least two other antiepileptic drugs (e.g., valproic acid, lamotrigine, topiramate, clonazepam, levetiracetam, zonisamide, felbamate). Continuation-prescriber confirms patient is responding to therapy.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Dravet Syndrome and treatment-refractory seizures/epilepsy

# COPAXONE

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## Products Affected

- COPAXONE SUBCUTANEOUS  
SYRINGE 20 MG/ML, 40 MG/ML

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agent used for multiple sclerosis
<b>Required Medical Information</b>	PENDING CMS REVIEW
<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 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CORLANOR

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## Products Affected

- CORLANOR ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Previous use of a Beta-blocker, LVEF
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Chronic HF, adults- must have LVEF of less than or equal 35 percent (currently or prior to initiation of Corlanor therapy) AND 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). Heart failure due to dilated cardiomyopathy, children-approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# CYSTARAN

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## Products Affected

- CYSTARAN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an ophthalmologist or a metabolic disease specialist or specialist who focuses in the treatment of metabolic diseases
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has corneal cysteine crystal deposits confirmed by slit-lamp examination
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# DALIRESP

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## Products Affected

- DALIRESP

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 1 year.
<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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# DERMATOLOGICAL WOUND CARE AGENTS

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## Products Affected

- REGRANEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# DIHYDROERGOTAMINE MESYLATE

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## Products Affected

- *dihydroergotamine nasal*

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# DUAVEE

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## Products Affected

- DUAVEE

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	For the prevention of postmenopausal osteoporosis, trial, failure, or intolerance of raloxifene is required prior to the use of Duavee.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# DUPIXENT

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## Products Affected

- DUPIXENT SYRINGE  
SUBCUTANEOUS SYRINGE 200  
MG/1.14 ML, 300 MG/2 ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Xolair or another Anti-interleukin (IL) Monoclonal Antibody.
<b>Required Medical Information</b>	Diagnosis, prescriber specialty, other medications tried and length of trials
<b>Age Restrictions</b>	PENDING CMS REVIEW
<b>Prescriber Restrictions</b>	Atopic Dermatitis-Prescribed by or in consultation with an allergist, immunologist or dermatologist, asthma-prescribed by or in consultation with an allergist, immunologist or pulmonologist. Rhinosinusitis-prescribed by or in consultation with an allergist, immunologist or otolaryngologist.
<b>Coverage Duration</b>	AD-Initial-4 months, Cont-1 year, asthma/Rhinosinusitis-initial-6 months, continuation 1 year
<b>Other Criteria</b>	Atopic Dermatitis-Initial-meets both a and b: a.has used at least one medium, medium-high, high, and/or super-high-potency prescription topical corticosteroid OR has atopic dermatitis affecting ONLY the face, eyes/eyelids, skin folds, and/or genitalia and has tried tacrolimus ointment AND b.Inadequate efficacy was demonstrated with these previously tried topical prescription therapies, according to the prescribing physician.Continuation-Approve if the pt has responded to Dupixent therapy as determined by the prescribing physician. Asthma-Initial-approve if pt meets the following criteria (i, ii, and iii):i.Pt meets ONE of the following criteria (a or b):a)has a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin (IL) therapy or Xolair OR b)has oral corticosteroid-dependent asthma, per the prescriber AND ii.has received combination therapy with BOTH of the following (a and b): a)An inhaled corticosteroid (ICS) AND b)At least one additional asthma controller/maintenance medication (NOTE:An exception to the requirement for a trial of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-5

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>therapy or Xolair used concomitantly with an ICS. Use of a combination inhaler containing both an ICS and a LABA would fulfil the requirement for both criteria a and b) AND iii.asthma is uncontrolled or was uncontrolled prior to starting any anti-IL therapy or Xolair as defined by ONE of the following (a, b, c, d or e): a)experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b)experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department visit in the previous year OR c)has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d)has an FEV1/forced vital capacity (FVC) less than 0.80 OR e)The patient's asthma worsens upon tapering of oral corticosteroid therapy. Continuation-Approve if meets the following criteria (i and ii): i.continues to receive therapy with one inhaled corticosteroid (ICS) or one ICS-containing combination inhaler AND ii.has responded to Dupixent therapy as determined by the prescribing physician. Chronic rhinosinusitis with Nasal Polyposis-Initial-pt is currently receiving therapy with an intranasal corticosteroid AND is experiencing significant rhinosinusitis symptoms such as nasal obstruction, rhinorrhea, or reduction/loss of smell according to the prescriber AND meets ONE of the following (a or b): a)has received treatment with a systemic corticosteroid within the previous 2 years or has a contraindication to systemic corticosteroid therapy OR b)has had prior surgery for nasal polyps. Continuation-approve if the pt continues to receive therapy with an intranasal corticosteroid AND pt has responded to Dupixent therapy as determined by the prescriber.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ELAPRASE

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## Products Affected

- ELAPRASE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has laboratory test demonstrating deficient iduronate-2-sulfatase activity in leukocytes, fibroblasts, or plasma OR a molecular genetic test demonstrating iduronate-2-sulfatase gene mutation
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ENBREL

## Products Affected

- ENBREL MINI
- ENBREL SUBCUTANEOUS RECON SOLN
- ENBREL SUBCUTANEOUS SYRINGE
- ENBREL SURECLICK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with biologic therapy or targeted synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous therapies tried.
<b>Age Restrictions</b>	PP-4 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Initial only-RA/AS/JIA/JRA,prescribed by or in consult w/ rheum. PsA, prescribed by or in consultation w/ rheumatologist or dermatologist.PP, prescribed by or in consult w/ dermatologist.GVHD,prescribed by or in consult w/ oncologist,hematologist,or physician affiliated w/ transplant center. Uveitis, prescribed by or in consultation with an ophthalmologist.
<b>Coverage Duration</b>	PENDING CMS REVIEW
<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). JIA/JRA initial, patient has tried another agent (e.g MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on Enbrel 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. Uveitis initial, tried one of the following: periocular, intraocular, or systemic corticosteroid, immunosuppressives or other biologic therapy. GVHD, tried or currently is receiving with etanercept 1 conventional GVHD tx (high-dose systemic

<b>PA Criteria</b>	<b>Criteria Details</b>
	corticosteroid, CSA, tacrolimus, MM, thalidomide, antithymocyte globulin, etc.). Continuation-approve if the patient has had a response as determined by 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Graft versus host disease (GVHD), Uveitis

# EPCLUSA

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## Products Affected

- EPCLUSA

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	6 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance

# EPIDIOLEX

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## Products Affected

- EPIDIOLEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies
<b>Age Restrictions</b>	PENDING CMS REVIEW
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# EPOETIN ALFA

## Products Affected

- 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
- RETACRIT

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	CRF anemia in patients 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, Mircera or Aranesp. 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 - Hgb is less than or equal to 13, surgery is elective, nonvascular and non-cardiac and pt is unwilling or unable to donate autologous blood prior to surgery
<b>Age Restrictions</b>	MDS anemia = 18 years of age and older.
<b>Prescriber Restrictions</b>	MDS anemia, myelofibrosis-prescribed by or in consultation with, a hematologist or oncologist.
<b>Coverage Duration</b>	Chemo-6m,Transfus-1m, CKD(dialysis)-3yrs, Myelofibrosis-init-3 mo, cont-1 yr, all others-1 yr
<b>Other Criteria</b>	Myelofibrosis-Initial-patient has a Hb less than 10 or serum erythropoietin less than or equal to 500 Mu/mL. Cont-patient has a Hgb less than or equal to 12 and according to the prescriber the patient has had a response defined as Hb greater than or equal to 10 or an increase of greater than or equal to 2 g/dL.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Anemia due to myelodysplastic syndrome (MDS), myelofibrosis

# ERIVEDGE

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## Products Affected

- ERIVEDGE

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 3 years
<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. Central nervous system cancer (this includes brain and spinal cord tumors)-approve if the patient has tried at least one chemotherapy agent and according to the prescriber, the patient has a mutation of the sonic hedgehog pathway.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Central nervous System Cancer

# ERLEADA

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## Products Affected

- ERLEADA

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	Prostate cancer-non-metastatic, castration resistant and prostate cancer-metastatic, castration sensitive-approve if the requested medication will be used in combination with a gonadotropin-releasing hormone (GnRH) analog or if the patient has had a bilateral orchiectomy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ESBRIET

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PENDING CMS REVIEW
<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>	1 year
<b>Other Criteria</b>	IPF - must have FVC greater than or equal to 40 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# EXJADE

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## Products Affected

- DEFERASIROX ORAL TABLET, DISPERSIBLE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Serum ferritin level
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a hematologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Transfusion-related chronic iron overload, initial therapy - approve if the patient is receiving blood transfusions at regular intervals for various conditions (eg, thalassemia syndromes, myelodysplastic syndrome, chronic anemia, sickle cell disease) AND prior to starting therapy, the serum ferritin level is greater than 1,000 mcg/L. Non-transfusion-dependent thalassemia syndromes chronic iron overload, initial therapy - approve if prior to starting therapy the serum ferritin level is greater than 300 mcg/L. Continuation therapy - approve if the patient is benefiting from therapy as confirmed by the prescribing physician.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# EYLEA

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## Products Affected

- EYLEA

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Administered by or under the supervision of an ophthalmologist
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# FIRAZYR

## Products Affected

- *icatibant*

PA Criteria	Criteria Details
<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 1 year.
<b>Other Criteria</b>	Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency [Type I or Type II] - Treatment of Acute Attacks, Initial Therapy-the patient has HAE type I or type II as confirmed by the following diagnostic criteria (i and ii): i. the patient has low levels of functional C1-INH protein (less than 50% of normal) at baseline, as defined by the laboratory reference values AND ii. the patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values. Patients who have treated previous acute HAE attacks with icatibant-the patient has treated previous acute HAE type I or type II attacks with icatibant AND according to the prescribing physician, the patient has had a favorable clinical response (e.g., decrease in the duration of HAE attacks, quick onset of symptom relief, complete resolution of symptoms, decrease in HAE acute attack frequency or severity) with icatibant treatment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# FYCOMPA

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## Products Affected

- FYCOMPA ORAL SUSPENSION
- FYCOMPA ORAL TABLET 10 MG, 12 MG, 2 MG, 4 MG, 6 MG, 8 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Patients 4 years of age or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# GATTEX

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## Products Affected

- GATTEX 30-VIAL
- GATTEX ONE-VIAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	1 year and older
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist (initial and continuation)
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Initial-approve if the patient is currently receiving parenteral nutrition on 3 or more days per week or according to the prescriber, the patient is unable to receive adequate total parenteral nutrition required for caloric needs. Continuation-approve if the patient has experienced at least a 20 percent decrease from baseline in the weekly volume of parenteral nutrition.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# GONADOTROPIN-RELEASING HORMONE AGONISTS - INJECTABLE LONG ACTING

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## Products Affected

- *leuprolide subcutaneous kit*
- LUPRON DEPOT
- LUPRON DEPOT (3 MONTH)
- LUPRON DEPOT (4 MONTH)
- LUPRON DEPOT (6 MONTH)
- LUPRON DEPOT-PED (3 MONTH)
- LUPRON DEPOT-PED INTRAMUSCULAR KIT 11.25 MG, 15 MG, 7.5 MG (PED)
- TRIPTODUR

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For the treatment of cancer diagnosis must be prescribed by or in consultation with an oncologist.
<b>Coverage Duration</b>	For abnormal uterine bleeding, uterine leiomyomata 6 mo. All other=12 mo
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Ovarian cancer, breast cancer, prophylaxis or treatment of uterine bleeding in patients with hematologic malignancy or undergoing cancer treatment or prior to bone marrow/stem cell transplantation, head and neck cancer-salivary gland tumors

# GROWTH HORMONES - GENOTROPIN

## Products Affected

- GENOTROPIN
- GENOTROPIN MINIQUICK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	GHD in Children/Adolescents. Pt meets one of the following-1-had 2 GH stim tests with the following-levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon and both are inadequate as defined by a peak GH response which is below the normal reference range of the testing laboratory OR had at least 1 GH test and results show inadequate response and has at least one risk factor for GHD (e.g., ht for age curve deviated down across 2 major height percentiles [e.g., from above the 25 percentile to below the 10 percentile], growth rate is less than the expected normal growth rate based on age and gender, low IGF-1 and/or IGFBP-3 levels). 2.brain radiation or tumor resection and pt has 1 GH stim test and results is inadequate response or has def in at least 1 other pituitary hormone (that is, ACTH, TSH, gonadotropin deficiency [LH and/or FSH] are counted as 1 def], or prolactin).3. congenital hypopituitarism and has one GH stim test with inadequate response OR def in at least one other pituitary hormone and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk 4.pt has panhypopituitarism and has pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary bright spot on MRI or CT or pt has 3 or more pituitary hormone deficiencies or pt has had one GH test and results were inadequate 5.pt had a hypophysectomy. Cont-pt responding to therapy
<b>Age Restrictions</b>	ISS 5 y/o or older, SGA 2 y/o or older, SBS 18 y/o or older
<b>Prescriber Restrictions</b>	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.
<b>Coverage Duration</b>	ISS - 6 mos intial, 12 months cont tx, SBS-1 month, others 12 mos

PA Criteria	Criteria Details
<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. has known mutations, embryonic lesions, congenital or genetic defects or structural hypothalamic pituitary defects, 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 (BMI is less than or equal to 25), less than or equal to 3 and BMI is greater than or equal to 25 and less than or equal to 30 with a high pretest probability of GH deficiency, less than or equal to 1 and BMI is greater than or equal to 25 and less than or equal to 30 with a low pretest probability of GH deficiency or less than or equal to 1 mcg/L (BMI is greater than 30), if insulin and glucagon contraindicated then Arginine alone test with peak of less than or equal to 0.4 mcg/L, or Macrilen peak less than 2.8 ng/ml AND BMI is less than or equal to 40 AND if a transitional adolescent must be off tx for at least one month before retesting. 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 greater than or equal to 5 or b. growth velocity is less than 10th percentile for age/gender. CKD initial - CKD defined by abnormal CrCl. Noonan initial - baseline height less than 5th percentile. 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). SBS initial pt receiving specialized nutritional support. Continuation of tx-approve if the patient has experienced improvement, according to the prescribing physician.</p>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	SHOX, SBS, CKD

# HALAVEN

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## Products Affected

- HALAVEN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	For metastatic breast cancer, documentation of prior treatment with an anthracycline and a taxane. For unresectable or metastatic liposarcoma, documentation of prior treatment with an anthracycline-containing regimen.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	For metastatic breast cancer, patients must have previously received at least two chemotherapeutic regimens for the treatment of metastatic disease. B vs D coverage determination.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# HARVONI

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## Products Affected

- HARVONI ORAL PELLETS IN PACKET 33.75-150 MG, 45-200 MG
- HARVONI ORAL TABLET 45-200 MG, 90-400 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with other direct acting antivirals, excluding ribavirin
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	3 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance

# HETLIOZ

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## Products Affected

- HETLIOZ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	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 plus evaluation of sleep logs. Cont - Approve if pt 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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# HIGH RISK MEDICATIONS - BENZTROPINE

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## Products Affected

- *benztropine oral*

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	For all medically-accepted indications, approve if the prescriber confirms he/she has assessed risk versus benefit in prescribing benztropine for the patient and he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# HIGH RISK MEDICATIONS - CYCLOBENZAPRINE

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## Products Affected

- *cyclobenzaprine oral tablet 10 mg, 5 mg*

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Patients aged less than 65 years, approve.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	The physician has assessed risk versus benefit in using this High Risk Medication (HRM) in this patient and has confirmed that he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# HIGH RISK MEDICATIONS - FIRST GENERATION ANTIHISTAMINES

## Products Affected

- *hydroxyzine hcl oral tablet*
- *promethazine oral*

PA Criteria	Criteria Details
<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>	Authorization will be for 12 months.
<b>Other Criteria</b>	For promethazine, authorize use without a previous drug trial for all FDA-approved indications other than emesis, including cancer/chemo-related emesis. For hydroxyzine hydrochloride, authorize use without a previous drug trial for all FDA-approved indications other than anxiety. For the treatment of non-cancer/chemo related emesis, approve promethazine hydrochloride if the patient has tried a prescription oral anti-emetic agent (ondansetron, granisetron, dolasetron, aprepitant) for the current condition. Approve hydroxyzine hydrochloride if the patient has tried at least two other FDA-approved products for the management of anxiety. Prior to approval of promethazine and hydroxyzine, approve if the physician must have assessed risk versus benefit in prescribing the requested HRM for the patient and must confirm that he/she would still like to initiate/continue therapy.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# HIGH RISK MEDICATIONS - PHENOBARBITAL

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## Products Affected

- *phenobarbital oral elixir*
- *phenobarbital oral tablet*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coverage is not provided for use in sedation/insomnia.
<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>	12 months
<b>Other Criteria</b>	For the treatment of seizures, approve only if the patient is currently taking phenobarbital.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# HRM - SKELETAL MUSCLE RELAXANTS

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## Products Affected

- *methocarbamol oral*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	The physician has documented the indication for the continued use of the HRM (high risk med) with an explanation of the specific benefit established with the medication and how that benefit outweighs the potential risk, AND the physician will continue to monitor for side effects. For patients concurrently taking multiple anticholinergic medications, the physician has assessed the risk.
<b>Age Restrictions</b>	Automatic approval if member is less than 65 years of age. Prior authorization required for age 65 or older.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# HUMIRA

## Products Affected

- HUMIRA PEN KIT 80 MG/0.8 ML, 80 MG/0.8 ML-40 MG/0.4 ML
- 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
- HUMIRA(CF) PEN CROHNS-UC-HS
- HUMIRA(CF) PEN PSOR-UV-ADOL HS
- HUMIRA(CF) PEN SUBCUTANEOUS INJECTOR KIT 40 MG/0.4 ML
- 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>Exclusion Criteria</b>	Concurrent use with biologic therapy 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 (initial therapy only). Ulcerative colitis (UC), 18 or older (initial therapy only)
<b>Prescriber Restrictions</b>	Initial therapy only all dx-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/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). JIA/JRA initial, patient has tried another agent (e.g MTX, sulfasalazine, leflunomide, NSAID, or biologic DMARD (eg, etanercept, abatacept, infliximab, anakinra, tocilizumab) or will be starting on Humira concurrently with MTX, sulfasalazine, or leflunomide. Approve without trying another agent if pt has absolute contraindication to MTX,

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>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, approve 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. UC initial, approve if the patient has had a trial of one systemic agent for UC. Uveitis initial, tried one of the following: periocular, intraocular, or systemic corticosteroid, immunosuppressives or other biologic therapy. HS initial, tried ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin). Continuation-approve if the patient has had a response as determined by the prescriber. 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>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# IMMUNE SUPPRESSANTS - TRANSPLANT RELATED

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## Products Affected

- *azathioprine*
- *azathioprine sodium*
- *cyclosporine intravenous*
- *cyclosporine modified*
- *cyclosporine oral capsule*
- *everolimus (immunosuppressive) oral tablet 0.25 mg, 0.5 mg, 0.75 mg*
- *engraf oral capsule 100 mg, 25 mg*
- *engraf oral solution*
- *mycophenolate mofetil*
- *mycophenolate mofetil (hcl)*
- *mycophenolate sodium*
- **PROGRAF INTRAVENOUS**
- **PROGRAF ORAL GRANULES IN PACKET**
- **SANDIMMUNE ORAL SOLUTION**
- *sirolimus*
- *tacrolimus oral*

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	B vs D coverage determination
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# INCRELEX

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## Products Affected

- INCRELEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Patients 2 years of age or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# INFLIXIMAB

## Products Affected

- REMICADE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with Biologic DMARD or Targeted Synthetic.
<b>Required Medical Information</b>	Diagnosis, concurrent medication, previous medications tried
<b>Age Restrictions</b>	CD and UC- Pts aged 6 years or more (initial therapy). PP-18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with: RA/Ankylosing spondylitis/Still's disease/JIA/JRA-rheumatologist (initial therapy); Plaque Psoriasis/Pyoderma gangrenosum/Hidradenitis suppurativa-dermatologist (initial therapy), Psoriatic Arthritis-rheumatologist or dermatologist (initial therapy), Crohn's Disease/UC-gastroenterologist (initial therapy), Uveitis ophthalmologist (initial therapy), GVHD-a physician affiliated with a transplant center, oncologist, or hematologist (initial therapy), Behcet's Disease- rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist (initial therapy), Sarcoidosis-pulmonol, ophthalmol, or dermatol (initial therapy).
<b>Coverage Duration</b>	FDA ind initial - 3 mos, cont 1 year, GVHD initial-1 month, cont-3 months, Pyoderma Gangrenosum-initial 4 months, cont 1 year, all others-initial 3 months, cont-12 mo
<b>Other Criteria</b>	<ul style="list-style-type: none"> <li>•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).</li> <li>•CD approve if the pt has tried corticosteroid (CS) or if CSs contraindicated or if currently on CS or if the patient has tried one other conventional systemic therapy for CD OR the patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas OR the patient has had ileocolonic resection. Note-a previous trial of a biologic also counts as a trial of one other agent for Crohn's disease.</li> <li>•Ulcerative colitis (UC).Tried one systemic agent or was intolerant to one of these agents OR the patient has pouchitis AND has tried therapy with an</li> </ul>

PA Criteria	Criteria Details
	<p>antibiotic, probiotic, corticosteroid enema, or mesalamine enema. Note-a previous trial of a biologic also counts as a trial of one systemic agent for UC.</p> <ul style="list-style-type: none"> <li>•Behcet's. Pt has tried at least one conventional tx (eg, systemic CSs, immunosuppressants [e.g., AZA, MTX, MM, CSA, tacrolimus, chlorambucil, cyclophosphamide] or interferon alfa). NOTE: An exception to the requirement for a trial of one conventional therapy can be made if the patient has already had a trial of at least one tumor necrosis factor for Behcet's disease. These patients are not required to "step back" and try a conventional therapy) OR has ophthalmic manifestations.</li> <li>•SD.Tried CS AND 1 conventional synthetic DMARD (eg, MTX) for 2 mos, or was intolerant.</li> <li>•UV.Approve if the patient has tried one of the following therapies- periocular/intraocular CS, systemic CS or immunosuppressant (eg, MTX, MM, CSA, AZA, CPM)An exception can be made if the patient has already had a trial of an etanercept or adalimumab product.</li> <li>•Sarcoidosis.Tried CS and immunosuppressant (eg, MTX, AZA, CSA, chlorambucil), or chloroquine, or thalidomide).</li> <li>•Pyoderma gangrenosum (PG).Tried one systemic CS or immunosuppressant (eg, mycophenolate, CSA) for 2 mos or was intolerant to one of these agents.</li> <li>•Hidradenitis suppurativa (HS).Tried 1 one other therapy(eg, intralesional/oral CS, systemic antibiotic, isotretinoin).</li> <li>•GVHD.Tried 1 at least one conventional systemic treatment (eg, high-dose CS, antithymocyte globulin, CSA, thalidomide, tacrolimus, MM, etc.)</li> <li>•JIA/JRA (regardless of type of onset) Note-this includes patients with juvenile spondyloarthritis/active sacroiliac arthritis-approve if pt has tried 1 other medication for this condition (eg, MTX, sulfasalazine, or leflunomide, an NSAID, or one biologic DMARD or the pt has aggressive disease.</li> <li>•PP- approve if the patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant or the patient has a contraindication to methotrexate (MTX), as determined by the prescriber. Note-A previous trial of a biologic also counts as a trial of a systemic agent.</li> <li>•cont tx - approve if patient has had a response, as determined by the prescriber</li> </ul>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Patients already started on infliximab for a covered use, Behcet's disease, Still's disease, Uveitis, Pyoderma gangrenosum, Hidradenitis suppurativa,, Graft-versus-host disease, Juvenile Idiopathic Arthritis (JIA)/JRA, Sarcoidosis

# KALYDECO

## Products Affected

- KALYDECO ORAL GRANULES IN PACKET
- KALYDECO ORAL TABLET

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Combination use with Orkambi, Trikafta or Symdeko
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	6 months 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>	1 year
<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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# KISQALI

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## Products Affected

- KISQALI FEMARA CO-PACK ORAL TABLET 200 MG/DAY(200 MG X 1)-2.5 MG, 400 MG/DAY(200 MG X 2)-2.5 MG, 600 MG/DAY(200 MG X 3)-2.5 MG
- KISQALI ORAL TABLET 200 MG/DAY (200 MG X 1), 400 MG/DAY (200 MG X 2), 600 MG/DAY (200 MG X 3)

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	For use with an aromatase inhibitor in postmenopausal women or men as initial endocrine-based therapy, approve if the patient has tried Ibrance. For use with fulvestrant in patients with disease progression following endocrine therapy, approve if the patient has tried Ibrance.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# KORLYM

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## Products Affected

- KORLYM

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	Endogenous Cushing's Syndrome-1 year. Pt awaiting surgery or response after radiotherapy-4 months
<b>Other Criteria</b>	Endogenous Cushing's Syndrome-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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Patients with Endogenous Cushing's Syndrome, awaiting surgery, Patients with Endogenous Cushing's syndrome, awaiting a response after radiotherapy

# KUVAN

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## Products Affected

- KUVAN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Palynziq
<b>Required Medical Information</b>	Diagnosis, Phe concentration
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a specialist who focuses in the treatment of metabolic diseases (initial therapy)
<b>Coverage Duration</b>	Initial-12 weeks, Continuation-1 year
<b>Other Criteria</b>	Initial - approve. Continuation - approve if the patient has had a clinical response (e.g., cognitive and/or behavioral improvements) as determined by the prescribing physician OR patient had a 20% or greater reduction in blood Phe concentration from baseline.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# LETAIRIS

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## Products Affected

- AMBRISENTAN

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Pulmonary arterial hypertension (PAH) WHO Group 1-results of right heart cath
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	For treatment of pulmonary arterial hypertension, ambrisentan must be prescribed by or in consultation with a cardiologist or a pulmonologist.
<b>Coverage Duration</b>	Authorization will be for 1 year.
<b>Other Criteria</b>	Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# LIDOCAINE PATCH

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## Products Affected

- *lidocaine topical adhesive patch, medicated 5 %*

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	PENDING CMS REVIEW
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Diabetic neuropathic pain, chronic back pain

# LUMIZYME

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## Products Affected

- LUMIZYME

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, neurologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has a laboratory test demonstrating deficient acid alpha-glucosidase activity in blood, fibroblasts, or muscle tissue OR patient has a molecular genetic test demonstrating acid alpha-glucosidase gene mutation
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# MAVYRET

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## Products Affected

- MAVYRET

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance

# MEGACE

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## Products Affected

- *megestrol oral suspension 400 mg/10 ml (40 mg/ml)*
- *megestrol oral tablet*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coverage is not provided for weight gain for cosmetic reasons.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# MOLECULAR TARGET INHIBITORS

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## Products Affected

- *abiraterone*
- AFINITOR DISPERZ ORAL TABLET FOR SUSPENSION 2 MG, 3 MG, 5 MG
- AFINITOR ORAL TABLET 10 MG
- ALECENSA
- ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG
- ALUNBRIG ORAL TABLETS,DOSE PACK
- AYVAKIT
- BALVERSA
- BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG
- BRAFTOVI ORAL CAPSULE 75 MG
- BRUKINSA
- CABOMETYX ORAL TABLET 20 MG, 40 MG, 60 MG
- CALQUENCE
- CAPRELSA ORAL TABLET 100 MG, 300 MG
- COMETRIQ ORAL CAPSULE 100 MG/DAY(80 MG X1-20 MG X1), 140 MG/DAY(80 MG X1-20 MG X3), 60 MG/DAY (20 MG X 3/DAY)
- COPIKTRA
- COTELLIC
- DAURISMO ORAL TABLET 100 MG, 25 MG
- *erlotinib oral tablet 100 mg, 150 mg, 25 mg*
- *everolimus (antineoplastic)*
- FARYDAK
- GILOTRIF
- IBRANCE
- ICLUSIG ORAL TABLET 15 MG, 45 MG
- IDHIFA
- *imatinib oral tablet 100 mg, 400 mg*
- IMBRUVICA ORAL CAPSULE 140 MG, 70 MG
- IMBRUVICA ORAL TABLET
- INLYTA ORAL TABLET 1 MG, 5 MG
- INREBIC
- IRESSA
- JAKAFI
- 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)
- LONSURF ORAL TABLET 15-6.14 MG, 20-8.19 MG
- LORBRENA ORAL TABLET 100 MG, 25 MG
- LYNPARZA ORAL TABLET
- MEKINIST ORAL TABLET 0.5 MG, 2 MG
- MEKTOVI
- NERLYNX
- NEXAVAR
- NINLARO
- PEMAZYRE
- PIQRAY
- POMALYST
- QINLOCK
- RETEVMO
- RUBRACA
- RYDAPT
- SPRYCEL ORAL TABLET 100 MG, 140 MG, 20 MG, 50 MG, 70 MG, 80 MG
- STIVARGA
- SUTENT
- SYNRIPO
- TABRECTA
- TAFINLAR
- TAGRISSO
- TALZENNA ORAL CAPSULE 0.25 MG, 1 MG
- TASIGNA ORAL CAPSULE 150 MG, 200 MG, 50 MG
- TAZVERIK
- TIBSOVO

- TUKYSA ORAL TABLET 150 MG, 50 MG
- TYKERB
- VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG
- VENCLEXTA STARTING PACK
- VIZIMPRO
- VOTRIENT
- XALKORI
- XOSPATA
- XPOVIO ORAL TABLET 100 MG/WEEK (20 MG X 5), 60 MG/WEEK (20 MG X 3), 80 MG/WEEK (20 MG X 4), 80MG TWICE WEEK (160 MG/WEEK)
- XTANDI
- ZEJULA
- ZELBORAF
- ZYDELIG
- ZYKADIA ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# NAGLAZYME

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## Products Affected

- NAGLAZYME

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, genetic and lab test results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Approve if the patient has a laboratory test demonstrating deficient N-acetylgalactosamine 4-sulfatase (arylsulfatase B) activity in leukocytes or fibroblasts OR has a molecular genetic test demonstrating arylsulfatase B gene mutation.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# NATPARA

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## Products Affected

- NATPARA

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	1 year
<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. Chronic hypoparathyroidism, continuing therapy - approve if during Natpara therapy, the patient's 25-hydroxyvitamin D stores are sufficient per the prescribing physician, AND patient is responding to Natpara therapy, as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# NAYZILAM

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## Products Affected

- NAYZILAM

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, other medications used at the same time
<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>	Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiepileptic medication(s).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# NIVESTYM

## Products Affected

- NIVESTYM

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<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 an intermediate risk of febrile neutropenia (the risk is 10-20% 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), patient has had a neutropenic complication from prior chemotherapy and did not receive prophylaxis with a colony stimulating factor (eg, Leukine, filgrastim products, pegfilgrastim products) 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).

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	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).

# NMDA RECEPTOR ANTAGONIST

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## Products Affected

- *memantine oral capsule, sprinkle, er 24hr*
- *memantine oral solution*
- *memantine oral tablet 10 mg, 5 mg*
- *memantine oral tablets, dose pack*
- NAMZARIC

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Automatic approval if member is greater than 26 years of age. Prior Authorization is required for age 26 or younger.
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# NON-INJECTABLE TESTOSTERONE PRODUCTS

## Products Affected

- *testosterone transdermal gel*
- *testosterone transdermal gel in metered-dose pump 12.5 mg/ 1.25 gram (1 %)*
- *testosterone transdermal gel in packet 1 % (25 mg/2.5gram), 1 % (50 mg/5 gram)*

PA Criteria	Criteria Details
<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 (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-treatment serum testosterone level that was low. [Note: male is defined as an individual with the biological traits of a man, regardless of the individual's gender identity or gender expression.]
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# NORTHERA

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## Products Affected

- NORTHERA ORAL CAPSULE 100 MG, 200 MG, 300 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# NUBEQA

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## Products Affected

- NUBEQA

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	Prostate cancer - non-metastatic, castration resistant-approve if the requested medication will be used concurrently with a gonadotropin-releasing hormone (GnRH) agonist or if the patient has had a bilateral orchiectomy.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# NUEDEXTA

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## Products Affected

- NUEDEXTA

<b>PA Criteria</b>	<b>Criteria Details</b>
<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
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# NULOJIX

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## Products Affected

- NULOJIX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Documentation of Epstein-Barr virus serology and current medication regimen.
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	12 months
<b>Other Criteria</b>	Documentation of use in combination with basiliximab induction, mycophenolate mofetil, and corticosteroids. B vs D coverage determination.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# NUPLAZID

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## Products Affected

- NUPLAZID ORAL CAPSULE
- NUPLAZID ORAL TABLET 10 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<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
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# NUVIGIL/PROVIGIL

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## Products Affected

- *modafinil oral tablet 100 mg, 200 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	Authorization will be for 12 months.
<b>Other Criteria</b>	Excessive sleepiness associated with Shift Work Sleep Disorder (SWSD) - approve if the patient is working at least 5 overnight shifts per month. Adjunctive/augmentation treatment for depression in adults (modafinil only) if the patient is concurrently receiving other medication therapy for depression. Excessive daytime sleepiness associated with obstructive sleep apnea/hypoapnea syndrome-approve. Excessive daytime sleepiness associated with Narcolepsy-approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Excessive daytime sleepiness (EDS) associated with myotonic dystrophy - modafinil only. Adjunctive/augmentation for treatment of depression in adults - modafinil only.

# OCALIVA

## Products Affected

- OCALIVA

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Prescriber specialty, lab values, prior medications used for diagnosis and length of trials
<b>Age Restrictions</b>	18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a gastroenterologist, hepatologist, or liver transplant physician (initial therapy)
<b>Coverage Duration</b>	6 months initial, 1 year continuation
<b>Other Criteria</b>	Initial treatment of PBC-Patient must meet both 1 and 2-1. Patient has a diagnosis of PBC as defined by TWO of the following:a)Alkaline phosphatase (ALP) elevated above the upper limit of normal as defined by normal laboratory reference values b)Positive anti-mitochondrial antibodies (AMAs) or other PBC-specific auto-antibodies, including sp100 or gp210, if AMA is negative c)Histologic evidence of primary biliary cholangitis (PBC) from a liver biopsy 2. Patient meets ONE of the following: a) Patient has been receiving ursodiol therapy for greater than or equal to 1 year and has had an inadequate response. b) Patient is unable to tolerate ursodiol therapy. Cont tx - approve if the patient has responded to Ocaliva therapy as determined by the prescribing physician (e.g., improved biochemical markers of PBC (e.g., alkaline phosphatase [ALP], bilirubin, gamma-glutamyl transpeptidase [GGT], aspartate aminotransferase [AST], alanine aminotransferase [ALT] levels)).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# OCREVUS

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## Products Affected

- OCREVUS

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other Disease-Modifying Agents used for MS
<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 physician who specializes in the treatment of MS and/or a neurologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# OCTREOTIDE

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## Products Affected

- *octreotide acetate injection solution*

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# ODOMZO

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## Products Affected

- ODOMZO

<b>PA Criteria</b>	<b>Criteria Details</b>
<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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Metastatic BCC

# OFEV

## Products Affected

- OFEV

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PENDING CMS REVIEW
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years of age and older
<b>Prescriber Restrictions</b>	IPF-Prescribed by or in consultation with a pulmonologist. Interstitial lung disease associated with systemic sclerosis-prescribed by or in consultation with a pulmonologist or rheumatologist.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	IPF - must have FVC greater than or equal to 40 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. Interstitial lung disease associated with systemic sclerosis-approve if the FVC is greater than or equal to 40 percent of the predicted value and the diagnosis is confirmed by high-resolution computed tomography. Chronic fibrosing interstitial lung disease-approve if the forced vital capacity is greater than or equal to 45% of the predicted value AND according to the prescriber the patient has fibrosing lung disease impacting more than 10% of lung volume on high-resolution computed tomography AND according to the prescriber the patient has clinical signs of progression.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# OPSUMIT

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## Products Affected

- OPSUMIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	PAH WHO group, right heart catheterization
<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 are required to have had a right-heart catheterization to confirm the diagnosis of PAH to ensure appropriate medical assessment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ORENCIA

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## Products Affected

- ORENCIA CLICKJECT
- ORENCIA SUBCUTANEOUS SYRINGE 125 MG/ML, 50 MG/0.4 ML, 87.5 MG/0.7 ML

PA Criteria	Criteria Details
<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>	Initial therapy only-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 months initial, 3 years cont.
<b>Other Criteria</b>	RA, approve if the patient has tried one of the following: Enbrel, Humira, Rinvoq. PsA, approve if the patient has tried one of the following: Enbrel, Humira, Stelara. JIA/JRA, approve if the patient has tried one of the following: Enbrel, Humira. Continuation-approve if the patient has had a response as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ORKAMBI

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## Products Affected

- ORKAMBI ORAL GRANULES IN PACKET
- ORKAMBI ORAL TABLET

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Combination use with Kalydeco, Trikafta or Symdeko.
<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)
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# PHENYL BUTYRATE

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## Products Affected

- *sodium phenylbutyrate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concomitant use of Ravicti and Buphenyl
<b>Required Medical Information</b>	Diagnosis, genetic tests and lab results
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with a metabolic disease specialist (or specialist who focuses in the treatment of metabolic diseases)
<b>Coverage Duration</b>	Pt meets criteria with no genetic test - 3 mo approval. Pt had genetic test - 12 mo approval
<b>Other Criteria</b>	Urea cycle disorders-approve if genetic testing confirmed a mutation resulting in a urea cycle disorder or if the patient has hyperammonemia.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# PHEOCHROMOCYTOMA

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## Products Affected

- DEMSER

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# PHOSPHODIESTERASE-5 INHIBITORS FOR PAH

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## Products Affected

- ALYQ
- *sildenafil (pulmonary arterial hypertension) oral tablet*
- TADALAFIL (PULMONARY ARTERIAL HYPERTENSION) ORAL TABLET 20 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, right heart cath results
<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 1 year.
<b>Other Criteria</b>	Pulmonary arterial hypertension (PAH) WHO Group 1, are required to have had a right-heart catheterization to confirm diagnosis of PAH to ensure appropriate medical assessment. Clinical criteria incorporated into the quantity limit edits for sildenafil 20 mg tablets and suspension require confirmation that the indication is PAH (ie, FDA labeled use) prior to reviewing for quantity exception.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# PROLASTIN-C

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## Products Affected

- PROLASTIN-C

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, pretreatment AAT serum concentration
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Alpha1-Antitrypsin (AAT) Deficiency with Emphysema (or COPD) - approve in patients with baseline (pretreatment) AAT serum concentration of less than 80 mg/dL (11 micromol/L).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# PROMACTA

## Products Affected

- PROMACTA ORAL POWDER IN PACKET 12.5 MG, 25 MG
- PROMACTA ORAL TABLET 12.5 MG, 25 MG, 50 MG, 75 MG

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Cause of thrombocytopenia. Thrombocytopenia due to HCV-related cirrhosis, platelet counts. Severe aplastic anemia, platelet counts and prior therapy. MDS-platelet counts.
<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 (initial therapy). Thrombocytopenia in pt with chronic Hep C, approve if prescribed by, or after consultation with, a gastroenterologist, hematologist, hepatologist, or a physician who specializes in infectious disease (initial therapy). MDS-presc or after consult with heme/onc (initial therapy).
<b>Coverage Duration</b>	Chronic ITP/MDS initial-3 mo, cont 1yr, AA-initial-4 mo, cont-1 yr, Thrombo/Hep C-1 yr.
<b>Other Criteria</b>	Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenia purpura, initial-approve if the patient has a platelet count less than 30, 000 microliters or less than 50, 000 microliters and the patient is at an increased risk for bleeding AND the patient has tried ONE other therapy or has undergone a splenectomy. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications. Treatment of thrombocytopenia in patients with Chronic Hepatitis C initial-approve if the patient will be receiving interferon-based therapy for chronic hepatitis C AND to allow for initiation of antiviral therapy if the patient has low platelet counts at baseline (eg, less than 75,000 microliters). Aplastic anemia initial - approve if the patient has low platelet counts at baseline/pretreatment (e.g., less than 30,000 microliters) AND tried one immunosuppressant therapy (e.g., cyclosporine, mycophenolate moefetil, sirolimus) OR patient will be using Promacta in combination with standard immunosuppressive therapy. Cont-approve if the patient demonstrates a beneficial clinical response. MDS initial-approve if patient has low- to intermediate-risk MDS AND the patient has



<b>PA Criteria</b>	<b>Criteria Details</b>
	a platelet count less than 30, 000 microliters or less than 50, 000 microliters and is at an increased risk for bleeding. Cont-approve if the patient demonstrates a beneficial clinical response and remains at risk for bleeding complications.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Thrombocytopenia in Myelodysplastic Syndrome (MDS)

# PYRIMETHAMINE

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## Products Affected

- *pyrimethamine*

PA Criteria	Criteria Details
<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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Chronic maintenance and prophylaxis of Toxoplasma Gondii encephalitis

# QUININE SULFATE

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## Products Affected

- *quinine sulfate*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Excluded if used for treatment or prevention of nocturnal leg cramps.
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 month
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Babesiosis, uncomplicated Plasmodium vivax malaria.

# RELISTOR INJECTION

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## Products Affected

- RELISTOR SUBCUTANEOUS SOLUTION
- RELISTOR SUBCUTANEOUS SYRINGE

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Patients 18 years of age or older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# REPATHA

## Products Affected

- REPATHA
- REPATHA PUSHTRONEX
- REPATHA SURECLICK

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use of Juxtapid or Praluent.
<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>	Approve for 3 years for ASCVD/HeFH/HoFH. Approve for 1 year for primary hyperlipidemia.
<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 (defined above) for 8 weeks or longer and LDL remains 70 mg/dL or

<b>PA Criteria</b>	<b>Criteria Details</b>
	higher unless statin intolerant (defined above). Primary hyperlipidemia (not associated with ASCVD, HeFH, or HoFH)-approve if the patient has 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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# REVLIMID

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## Products Affected

- REVLIMID

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 3 years.
<b>Other Criteria</b>	PENDING CMS REVIEW
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Systemic Amyloidosis Light Chain, Diffuse Large B Cell Lymphoma (Non-Hodgkin's Lymphoma), Myelofibrosis. Castleman's Disease, Hodgkin lymphoma (Classical), Peripheral T-Cell Lymphoma, T-Cell Leukemia/Lymphoma, Central nervous system cancer (primary), Acquired immune deficiency syndrome (AIDS)-related Kaposi's sarcoma.

# RINVOQ

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## Products Affected

- RINVOQ

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with biologic therapy or targeted synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	RA, prescribed by or in consultation with a rheumatologist.
<b>Coverage Duration</b>	Authorization will be for 3 months 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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# ROZLYTREK

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## Products Affected

- ROZLYTREK ORAL CAPSULE 100 MG, 200 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	Solid Tumors-12 years and older
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Solid Tumors-Approve if the patient meets the following criteria (A, B, and C): A) The patient has locally advanced or metastatic solid tumor AND B) The patient's tumor has neurotrophic receptor tyrosine kinase (NTRK) gene fusion AND C) The patient meets one of the following criteria (i or ii): i. The patient has progressed on prior therapies OR ii. There are no acceptable standard therapies and the medication is used as initial therapy. Non-Small Cell Lung Cancer-Approve if the patient has ROS1-positive metastatic disease.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SABRIL

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## Products Affected

- *vigabatrin*
- *vigadrone*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, medication history (complex partial seizures)
<b>Age Restrictions</b>	PENDING CMS REVIEW
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SAMSCA

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## Products Affected

- SAMSCA ORAL TABLET 15 MG, 30 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with Jynarque.
<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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SIGNIFOR

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## Products Affected

- SIGNIFOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	18 years and older (initial therapy)
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an endocrinologist or a physician or specializes in the treatment of Cushing's syndrome (initial therapy)
<b>Coverage Duration</b>	Cushing's-Initial-4 mo, Cont therapy - 1 yr. Pt awaiting surgery/response after radiotherapy-4 mo
<b>Other Criteria</b>	Cushing's disease, initial therapy - approve if, according to the prescribing physician, the patient is not a candidate for surgery, or surgery has not been curative. Cushing's disease, continuation therapy - approve if the patient has already been started on Signifor/Signifor LAR and, according to the prescribing physician, the patient has had a response and continuation of therapy is needed to maintain response.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SIRTURO

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## Products Affected

- SIRTURO ORAL TABLET 100 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	PENDING CMS REVIEW
<b>Required Medical Information</b>	Diagnosis, concomitant therapy
<b>Age Restrictions</b>	PENDING CMS REVIEW
<b>Prescriber Restrictions</b>	Prescribed by, or in consultation with an infectious diseases specialist
<b>Coverage Duration</b>	9 months
<b>Other Criteria</b>	Tuberculosis, Pulmonary Multidrug-resistant or extensively drug resistant-prescribed as part of a combination regimen with other anti-tuberculosis agents
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SKYRIZI

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## Products Affected

- SKYRIZI SUBCUTANEOUS SYRINGE KIT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with biologic therapy or targeted synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, Previous medication use
<b>Age Restrictions</b>	18 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	PP-Prescribed by or in consultation with a dermatologist (initial therapy)
<b>Coverage Duration</b>	3 mos initial, 3 years cont
<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. Continuation-approve if the patient has had a response as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SOMATULINE

## Products Affected

- SOMATULINE DEPOT

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous treatments/therapies
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Acromegaly-prescribed by or in consultation with an endocrinologist. Carcinoid syndrome-prescribed by or in consultation with an oncologist, endocrinologist or gastroenterologist. All neuroendocrine tumors-prescribed by or in consultation with an oncologist, endocrinologist, or gastroenterologist. Pheochromocytoma/paraganglioma-prescribed by or in consultation with an endo/onc/neuro.
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Acromegaly-approve if the patient has a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory AND the patient meets i., ii., or iii: i. has had an inadequate response to surgery and/or radiotherapy or ii. is not an appropriate candidate for surgery and/or radiotherapy or iii. the patient is experiencing negative effects due to tumor size (e.g., optic nerve compression). Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptide-secreting tumors [VIPomas], insulinomas)-approve. Carcinoid Syndrome-approve.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Pheochromocytoma/paraganglioma

# SOMAVERT

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## Products Affected

- SOMAVERT

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	Prescribed by or in consultation with an endocrinologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Acromegaly-approve if patient meets ONE of the following (i, ii, or iii): i. patient has had an inadequate response to surgery and/or radiotherapy OR ii. The patient is NOT an appropriate candidate for surgery and/or radiotherapy OR iii. The patient is experiencing negative effects due to tumor size (e.g., optic nerve compression) AND patient has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal (ULN) based on age and gender for the reporting laboratory.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# SOVALDI

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## Products Affected

- SOVALDI ORAL TABLET 400 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	N/A
<b>Age Restrictions</b>	Genotype 1 and 4 -18 years or older, Genotype 2 and 3-3 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. And, patients with genotype 1 and 4 must have a trial with Harvoni, Mavyret, Vosevi or Epclusa prior to approval of Sovaldi, unless Harvoni, Mavyret, Vosevi and Epclusa are not specifically listed as an alternative therapy for a specific patient population in the guidelines. Patients with Genotype 2 and 3 must have a trial of Epclusa, Mavyret, or Vosevi prior to approval of Sovaldi, unless Epclusa, Mavyret and Vosevi are not specifically listed as an alternative therapy for a specific patient population in the guidelines.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance

# STELARA

## Products Affected

- STELARA INTRAVENOUS
- STELARA SUBCUTANEOUS SOLUTION
- STELARA SUBCUTANEOUS SYRINGE 45 MG/0.5 ML, 90 MG/ML

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with biologic therapy or targeted synthetic DMARD
<b>Required Medical Information</b>	Diagnosis, concurrent medications, previous drugs tried.
<b>Age Restrictions</b>	PENDING CMS REVIEW
<b>Prescriber Restrictions</b>	PP-Prescr/consult w/derm.PsA-prescr/consult w/rheum or derm.CD/UC-prescr/consult w/gastro.
<b>Coverage Duration</b>	PP/PsA Init-3mo,CD/UC load-approve 1 dose IV,CD/UC post IV load-SC 3 mo,cont tx-SC 3 yr
<b>Other Criteria</b>	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). 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, approve 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. UC initial, approve if the patient has had a trial of one systemic agent for UC.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# SYLATRON

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## Products Affected

- SYLATRON SUBCUTANEOUS KIT  
200 MCG, 300 MCG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist
<b>Coverage Duration</b>	1 year
<b>Other Criteria</b>	Melanoma-approve if the patient has microscopic or gross nodal involvement and has had a complete lymphadenectomy within the past 84 days. Systemic mastocytosis-approve if the patient has aggressive systemic mastocytosis OR systemic mastocytosis with an associated hematologic malignancy OR osteopenia/osteoporosis with refractory bone pain and/or decreasing bone mineral density on bisphosphonate therapy. Myeloproliferative neoplasms-approve if the patient has symptomatic low-risk myelofibrosis or polycythemia vera or essential thrombocythemia.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Systemic mastocytosis, myeloproliferative neoplasms

# SYMDEKO

## Products Affected

- SYMDEKO

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Patients with unknown CFTR gene mutations, Combination therapy with Orkambi, Kalydeco or Trikafta
<b>Required Medical Information</b>	Diagnosis, specific CFTR gene mutations
<b>Age Restrictions</b>	Six 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
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TALTZ

## Products Affected

- TALTZ SYRINGE

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with a Biologic DMARD or Targeted Synthetic DMARD.
<b>Required Medical Information</b>	Diagnosis, Previous medication use
<b>Age Restrictions</b>	PP-6 years and older (initial therapy), all other dx-18 years of age and older (initial therapy)
<b>Prescriber Restrictions</b>	All dx initial therapy only-PP-Prescribed by or in consultation with a dermatologist. PsA prescribed by or in consultation with a rheumatologist or a dermatologist. AS-prescribed by or in consultation with a rheum.
<b>Coverage Duration</b>	Initial authorization will be for 3 months, 3 years continuation.
<b>Other Criteria</b>	PP, approve if the patient has tried two of the following: Enbrel, Humira, Skyrizi, or Stelara. PsA, approve if the patient has tried two of the following: Enbrel, Humira, Stelara. AS, approve if the patient has tried one of the following: Enbrel or Humira. Non-radiographic Axial Spondyloarthritis, approve if the patient has objective signs of inflammation. Continuation-approve if the patient has had a response as determined by the prescriber.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TARGRETIN ORAL

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## Products Affected

- *bexarotene*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies tried
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TARGRETIN TOPICAL

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## Products Affected

- TARGRETIN TOPICAL

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, previous therapies tried
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an oncologist or dermatologist (initial and continuation)
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TAZAROTENE

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## Products Affected

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

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	1 year
<b>Other Criteria</b>	Acne vulgaris after a trial with at least 1 other topical retinoid product (eg, tretinoin cream/gel/solution/microgel, adapalene).
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A



# TECFIDERA

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## Products Affected

- TECFIDERA ORAL  
CAPSULE, DELAYED

RELEASE(DR/EC) 120 MG, 120 MG  
(14)- 240 MG (46), 240 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Concurrent use with other disease-modifying agents used for multiple sclerosis (MS)
<b>Required Medical Information</b>	PENDING CMS REVIEW
<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
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TERIPARATIDE

## Products Affected

- TERIPARATIDE

PA Criteria	Criteria Details
<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>	Auth will be for 2 years of total therapy between Tymlos/teriparatide over pt'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), OR pt has severe renal impairment (CrCL less than 35 mL/min) or has CKD or has had an osteoporotic fracture or fragility fracture.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# THALOMID

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## Products Affected

- THALOMID ORAL CAPSULE 100 MG, 150 MG, 200 MG, 50 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	PENDING CMS REVIEW
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Discoid lupus erythematosus or cutaneous lupus erythematosus, Myelofibrosis, Prurigo nodularis, Recurrent aphthous ulcers or aphthous stomatitis, AIDS related Kaposi's Sarcoma, Castleman's Disease.

# TOPICAL AGENTS FOR ATOPIC DERMATITIS

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## Products Affected

- *tacrolimus topical*

PA Criteria	Criteria Details
Exclusion Criteria	N/A
Required Medical Information	N/A
Age Restrictions	N/A
Prescriber Restrictions	N/A
Coverage Duration	Authorization will be for 12 months.
Other Criteria	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.
Indications	All Medically-accepted Indications.
Off-Label Uses	N/A

# TOPICAL RETINOID PRODUCTS

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## Products Affected

- *avita*
- *tretinoin microspheres topical gel 0.1 %*
- *tretinoin microspheres topical gel with pump 0.1 %*
- *tretinoin topical*

PA Criteria	Criteria Details
<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
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TOPIRAMATE/ZONISAMIDE

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## Products Affected

- *topiramate oral capsule, sprinkle*
- *topiramate oral tablet*
- *zonisamide*

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Coverage is not provided for weight loss or smoking cessation.
<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 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TRANSMUCOSAL FENTANYL DRUGS

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## Products Affected

- *fentanyl citrate buccal lozenge on a handle*

PA Criteria	Criteria Details
<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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# TRELSTAR

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## Products Affected

- TRELSTAR INTRAMUSCULAR  
SUSPENSION FOR RECONSTITUTION

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# TRIENTINE

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## Products Affected

- *trientine*

<b>PA Criteria</b>	<b>Criteria Details</b>
<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: 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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TURALIO

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## Products Affected

- TURALIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	Tenosynovial Giant Cell Tumor (Pigmented Villonodular Synovitis)- approve if, according to the prescriber, the tumor is not amenable to improvement with surgery.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TYMLOS

## Products Affected

- TYMLOS

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concomitant use with other medications for osteoporosis (eg, denosumab [Prolia], bisphosphonates, calcitonin nasal spray [Fortical], Forteo), Evenity except calcium and Vitamin D. Previous use of Tymlos and/or teriparatide 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 yrs of total therapy between Tymlos/teriparatide over a pt'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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# TYSABRI

## Products Affected

- TYSABRI

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use of other disease-modifying agents used for MS. Concurrent use with immunosuppressants (eg, 6-mercaptopurine, azathioprine, cyclosporine, methotrexate) in Crohn's disease (CD) patient
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 and older (initial and continuation)
<b>Prescriber Restrictions</b>	MS: prescribed by, or in consultation with, a neurologist or a physician who specializes in the treatment of MS. (initial and continuation) CD: prescribed by, or in consultation with, a gastroenterologist (initial and continuation)
<b>Coverage Duration</b>	MS-Authorization will be for 1 year.CD, initial-3 mo. CD, cont therapy-1 year.
<b>Other Criteria</b>	Adults with a relapsing form of MS-initial. Patient has had an inadequate response to, or is unable to tolerate, one disease modifying agent used for MS: (eg, interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron, Extavia), glatiramer acetate (Copaxone/Glatopa), Plegridy, fingolimod (Gilenya), Tecfidera, Lemtrada, daclizumab (Zinbryta), Aubagio, Mavenclad, Mayzent, Vumerity, Lemtrada, Ocrevus) OR the patient has highly active or aggressive disease according to the prescribing physician by meeting one of the following-the patient has demonstrated rapidly-advancing deterioration(s) in physical functioning (e.g., loss of mobility/or lower levels of ambulation, severe changes in strength or coordination OR disabling relapse(s) with suboptimal response to systemic corticosteroids OR magnetic resonance imaging (MRI) findings suggest highly-active or aggressive multiple sclerosis (e.g., new, enlarging, or a high burden of T2 lesions or gadolinium lesions) OR manifestation of multiple sclerosis-related cognitive impairment. Adults with CD, initial. Patient has moderately to severely active CD and patient has tried two biologics for CD. CD, continuation therapy. Patient has had a response to Tysabri, as determined by the prescribing physician.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Off-Label Uses</b>	Patients already started on Tysabri for a Covered Use.

# UPTRAVI

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## Products Affected

- UPTRAVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Confirmation of right heart catheterization, 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>	1 year
<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). Patient new to Uptravi therapy 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).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# VALCHLOR

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## Products Affected

- VALCHLOR

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	Cutaneous Lymphomas (Note-includes mycosis fungoides/Sezary syndrome, primary cutaneous B-cell lymphoma, primary cutaneous CD30+ T-cell lymphoproliferative disorders)-approve. Adult T-Cell Leukemia/Lymphoma-approve if the patient has chronic/smoldering subtype of adult T-cell leukemia/lymphoma.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Adults with T-cell leukemia/lymphoma



# VALTOCO

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## Products Affected

- VALTOCO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, other medications used at the same time
<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>	Intermittent Episodes of Frequent Seizure Activity (i.e., seizure clusters, acute repetitive seizures)-approve if the patient is currently receiving maintenance antiepileptic medication(s).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# VANCOMYCIN

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## Products Affected

- *vancomycin oral capsule 125 mg, 250 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	2 weeks
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# VENTAVIS

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## Products Affected

- VENTAVIS

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	B vs D coverage determination
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# VERZENIO

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## Products Affected

- VERZENIO

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	For use with an aromatase inhibitor in postmenopausal women or men as initial endocrine-based therapy, approve if the patient has tried Ibrance. For use with fulvestrant in patients with disease progression following endocrine therapy, approve if the patient has tried Ibrance.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# VITRAKVI

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## Products Affected

- VITRAKVI ORAL CAPSULE 100 MG, 25 MG
- VITRAKVI ORAL SOLUTION

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis, NTRK gene fusion status
<b>Age Restrictions</b>	N/A
<b>Prescriber Restrictions</b>	N/A
<b>Coverage Duration</b>	3 years
<b>Other Criteria</b>	Solid tumors - approve if the tumor has a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation AND the tumor is metastatic or surgical resection of tumor will likely result in severe morbidity AND there are no satisfactory alternative treatments or the patient has disease progression following treatment.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# VOSEVI

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## Products Affected

- VOSEVI

<b>PA Criteria</b>	<b>Criteria Details</b>
<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.
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Indications consistent with current AASLD/IDSA guidance

# XATMEP

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## Products Affected

- XATMEP

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# XCOPRI

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## Products Affected

- XCOPRI
- XCOPRI MAINTENANCE PACK
- XCOPRI TITRATION PACK

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	Approve if the patient has tried one other anticonvulsant therapy (eg, carbamazepine, divalproex sodium, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, topiramate, valproic acid).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# XENAZINE

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## Products Affected

- *tetrabenazine oral tablet 12.5 mg, 25 mg*

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 1 year.
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Tardive dyskinesia (TD). Tourette syndrome and related tic disorders. Hyperkinetic dystonia. Hemiballism.

# XGEVA

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## Products Affected

- XGEVA

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	For initial therapy in the treatment of hypercalcemia of malignancy: trial and failure, contraindication, or intolerance to one intravenous bisphosphonate (e.g. pamidronate, zoledronic acid) is required. For continuation of therapy in the treatment of hypercalcemia of malignancy, approve if patient has already been started on Xgeva. For other medically accepted indication, no trial of alternatives is required.
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# XIAFLEX

## Products Affected

- XIAFLEX

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Retreatment (i.e., treatment beyond three injections per affected cord for those with Dupuytren's Contracture or beyond eight injections for Peyronie's Disease).
<b>Required Medical Information</b>	Diagnosis
<b>Age Restrictions</b>	18 years and older
<b>Prescriber Restrictions</b>	Dupuytren's Contracture-administered by a healthcare provider experienced in injection procedures of the hand and in the treatment of Dupuytren's contracture. Peyronie's Disease -administered by a healthcare provider experienced in the treatment of male urological diseases.
<b>Coverage Duration</b>	Dupuytren's Contracture-3 months, Peyronie's Disease-6 months
<b>Other Criteria</b>	Dupuytren's Contracture-at baseline (prior to initial injection of Xiaflex), the patient had contracture of a metacarpophalangeal (MP) or proximal interphalangeal (PIP) joint of at least 20 degrees AND the patient will not be treated with more than a total of three injections (maximum) per affected cord. Peyronie's Disease-the patient meets ONE of the following (i or ii): i. at baseline (prior to use of Xiaflex), the patient has a penile curvature deformity of at least 30 degrees OR in a patient who has received prior treatment with Xiaflex, the patient has a penile curvature deformity of at least 15 degrees AND the patient has not previously been treated with a complete course (8 injections) of Xiaflex for Peyronie's disease.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# XIFAXAN

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## Products Affected

- XIFAXAN ORAL TABLET 550 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	12 months
<b>Other Criteria</b>	N/A
<b>Indications</b>	All Medically-accepted Indications.
<b>Off-Label Uses</b>	N/A

# XOLAIR

## Products Affected

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

PA Criteria	Criteria Details
<b>Exclusion Criteria</b>	Concurrent use with an Interleukin (IL) Antagonist Monoclonal Antibody
<b>Required Medical Information</b>	Moderate to severe persistent asthma, baseline IgE level of at least 30 IU/mL. For asthma, patient has a baseline 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).
<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 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 corticosteroid and at least one the following: long-acting beta-agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist, or theophylline, and 2) patient's asthma is uncontrolled or was uncontrolled prior to receiving any Xolair or anti-IL-4/13 therapy (Dupixent) therapy as defined by ONE of the following (a, b, c, d, or e): a) The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year OR b) The patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year OR c) Patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted OR d) Patient has an FEV1/forced vital capacity (FVC) less than 0.80 OR e) The patient's asthma worsens upon tapering of oral corticosteroid therapy NOTE: An exception to the requirement for a trial

<b>PA Criteria</b>	<b>Criteria Details</b>
	<p>of one additional asthma controller/maintenance medication can be made if the patient has already received anti-IL-4/13 therapy (Dupixent) used concomitantly with an ICS for at least 3 consecutive months. For continued Tx for asthma - patient has responded to therapy as determined by the prescribing physician and continues to receive therapy with one inhaled corticosteroid or inhaled corticosteroid containing combination product. For CIU cont tx - must have responded to therapy as determined by the prescribing physician.</p>
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# XYREM

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## Products Affected

- XYREM

<b>PA Criteria</b>	<b>Criteria Details</b>
<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 two CNS stimulants (e.g., methylphenidate, dexamethylphenidate, dextroamphetamine), modafinil, or armodafinil and narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT). Cataplexy treatment in patients with narcolepsy- approve if narcolepsy has been confirmed with polysomnography and a multiple sleep latency test (MSLT).
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ZIEXTENZO

## Products Affected

- ZIEXTENZO

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	N/A
<b>Required Medical Information</b>	Diagnosis
<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.
<b>Coverage Duration</b>	Cancer pts receiving chemo-6 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 an intermediate risk of febrile neutropenia (the risk is 10-20% based on the chemotherapy regimen) and the patient has one or more risk factors for febrile neutropenia according to the prescribing physician (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.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A



# ZOLINZA

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## Products Affected

- ZOLINZA

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	Cutaneous T-Cell Lymphoma including Mycosis Fungoides/Sezary Syndrome-approve.
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

# ZTLIDO

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## Products Affected

- ZTLIDO

<b>PA Criteria</b>	<b>Criteria Details</b>
<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>	PENDING CMS REVIEW
<b>Indications</b>	All FDA-approved Indications, Some Medically-accepted Indications.
<b>Off-Label Uses</b>	Diabetic neuropathic pain, chronic back pain

# ZYPREXA RELPREVV

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## Products Affected

- ZYPREXA RELPREVV RECONSTITUTION 210 MG, 300 MG,  
INTRAMUSCULAR SUSPENSION FOR 405 MG

<b>PA Criteria</b>	<b>Criteria Details</b>
<b>Exclusion Criteria</b>	Dementia-related psychosis
<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>	1 year
<b>Other Criteria</b>	N/A
<b>Indications</b>	All FDA-approved Indications.
<b>Off-Label Uses</b>	N/A

## PART B VERSUS PART D

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### Products Affected

- *acetylcysteine*
- *acyclovir sodium intravenous solution*
- *adriamycin intravenous recon soln 10 mg*
- *adriamycin intravenous solution*
- *adrucil intravenous solution 2.5 gram/50 ml*
- *albuterol sulfate inhalation solution for nebulization*
- AMINOSYN II 10 %
- AMINOSYN II 15 %
- AMINOSYN-PF 10 %
- AMINOSYN-PF 7 % (SULFITE-FREE)
- *amiodarone intravenous solution*
- *aprepitant*
- ARRANON
- ARSENIC TRIOXIDE INTRAVENOUS SOLUTION 1 MG/ML
- *arsenic trioxide intravenous solution 2 mg/ml*
- ARZERRA
- *azacitidine*
- BELEODAQ
- BENDEKA
- *bleomycin*
- BLINCYTO INTRAVENOUS KIT
- *budesonide inhalation suspension for nebulization 0.25 mg/2 ml, 0.5 mg/2 ml, 1 mg/2 ml*
- *busulfan*
- *carboplatin intravenous solution*
- *carmustine*
- *cisplatin intravenous solution*
- *cladribine*
- CLINIMIX 5%/D15W SULFITE FREE
- CLINIMIX 4.25%/D10W SULF FREE
- CLINIMIX 4.25%/D5W SULFIT FREE
- CLINIMIX 5%-D20W(SULFITE-FREE)
- CLINIMIX E 4.25%/D10W SUL FREE
- CLINISOL SF 15 %
- *clofarabine*
- *cromolyn inhalation*
- *cyclophosphamide intravenous recon soln*
- *cyclophosphamide oral capsule*
- *cytarabine*
- *cytarabine (pf) injection solution*
- *dacarbazine*
- *dactinomycin*
- *daunorubicin intravenous solution*
- *decitabine*
- *docetaxel intravenous solution 160 mg/16 ml (10 mg/ml), 160 mg/8 ml (20 mg/ml), 20 mg/2 ml (10 mg/ml), 20 mg/ml (1 ml), 80 mg/4 ml (20 mg/ml), 80 mg/8 ml (10 mg/ml)*
- *doxorubicin intravenous recon soln 50 mg*
- *doxorubicin intravenous solution*
- *doxorubicin, peg-liposomal*
- *dronabinol*
- ELLENCE
- EMEND ORAL SUSPENSION FOR RECONSTITUTION
- ENGERIX-B (PF) INTRAMUSCULAR SYRINGE
- ENGERIX-B PEDIATRIC (PF) INTRAMUSCULAR SYRINGE
- *epirubicin intravenous solution*
- ERBITUX
- ERWINAZE
- ETOPOPHOS
- *etoposide intravenous*
- FIRMAGON KIT W DILUENT SYRINGE
- *floxuridine*
- *fludarabine*
- *fluorouracil intravenous*
- FOLOTYN
- FREAMINE HBC 6.9 %
- *freamine iii 10 %*
- *fulvestrant*
- GAMUNEX-C
- *gemcitabine intravenous recon soln*
- *gemcitabine intravenous solution 1 gram/26.3 ml (38 mg/ml), 2 gram/52.6 ml (38 mg/ml), 200 mg/5.26 ml (38 mg/ml)*
- GEMCITABINE INTRAVENOUS SOLUTION 100 MG/ML

- *granisetron hcl oral*
- HEPATAMINE 8%
- HIZENTRA
- HUMULIN R U-500 (CONC) INSULIN
- *idarubicin*
- *ifosfamide*
- INFUGEM
- INFUMORPH P/F
- INTRALIPID INTRAVENOUS EMULSION 20 %, 30 %
- INTRON A INJECTION
- *ipratropium bromide inhalation*
- *ipratropium-albuterol*
- *irinotecan*
- IXEMPRA
- JEVTANA
- KABIVEN
- KYPROLIS
- MARQIBO
- *melphalan hcl*
- *mesna*
- *methotrexate sodium (pf) injection solution*
- *methotrexate sodium injection*
- *mitomycin intravenous*
- *mitoxantrone*
- MORPHINE INTRAVENOUS SYRINGE 10 MG/ML
- NEPHRAMINE 5.4 %
- NIPENT
- *nitroglycerin intravenous*
- *ondansetron*
- *ondansetron hcl oral solution*
- *ondansetron hcl oral tablet*
- *oxaliplatin intravenous recon soln*
- *oxaliplatin intravenous solution 100 mg/20 ml, 50 mg/10 ml (5 mg/ml)*
- *paclitaxel*
- *pentamidine inhalation*
- PERFOROMIST
- PERIKABIVEN
- PLENAMINE
- PORTRAZZA
- *potassium chloride-d5-0.3%nacl intravenous parenteral solution 20 meq/l*
- *prednisone oral tablet*
- PREMASOL 10 %
- PROCALAMINE 3%
- PROLEUKIN
- PROSOL 20 %
- PULMOZYME
- RECOMBIVAX HB (PF)
- SIMULECT
- TEMODAR INTRAVENOUS
- *temsirolimus*
- *tobramycin in 0.225 % nacl*
- *toposar*
- *topotecan intravenous solution 4 mg/4 ml (1 mg/ml)*
- TRAVASOL 10 %
- TREANDA INTRAVENOUS RECON SOLN
- TROPHAMINE 10 %
- *valrubicin*
- *vinblastine intravenous solution*
- *vincasar pfs*
- *vincristine*
- *vinorelbine*
- VYXEOS
- ZALTRAP
- ZANOSAR
- ZOLADEX
- *zoledronic acid intravenous solution*
- *zoledronic acid-mannitol-water*

## 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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