## Additional Therapeutic Classes with Clinical Criteria

Providers should provide supporting documentation (chart notes, lab work, medication history) to demonstrate criteria is satisfied

All requests must be in compliance with OAC 5160

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Drug Name</th>
<th>Clinical Criteria (Authorization is for 1 year unless otherwise stated)</th>
</tr>
</thead>
</table>
| Adrenocorticotropic hormone (ACTH) analogue           | H.P. Acthar® (≥ 2 years old)   | • Must be prescribed by a specialist AND  
• Must have a diagnosis of multiple sclerosis (experiencing an acute exacerbation) AND  
• Must have failed corticosteroid therapy in the last 30 days or have a contraindication to corticosteroid therapy AND  
• Authorization will be granted for up to 28 days |
| Adrenocorticotropic hormone (ACTH) analogue           | H.P Acthar® (< 2 years old)    | • Must be prescribed by a specialist AND  
• Must have a confirmed diagnosis of infantile spasms AND  
• Must not have or is suspected of having an untreated congenital infection AND  
• Authorization will be granted for up to 28 days |
| Agents for Homozygous familial hypercholesterolemia (HoFH) [non-PCKS9 Inhibitors] | Juxtapid® (lomitapide)         | • Must be 18 years of age or older AND  
• Must have a diagnosis of Homozygous Familial Hypercholesterolemia AND  
• Must have a history of at least 90 days of high-dose statin therapy, ezetimibe and PCSK9 inhibitor in the past 180 days (or a clinical reason that these medications cannot be utilized) AND  
• Initial consultation with a lipid specialist  
• Initial authorization is for 6 months and re-authorization will be granted for 1 year |
| Anabolic steroid                                      | oxandrolone                    | • Must have a diagnosis of cachexia from extensive surgery, chronic infections or severe trauma  
• Must have a diagnosis of COPD with corticosteroid-induced protein catabolism or chronic non-healing wounds without impaired blood flow AND  
• Must have ≥ 10% unintentional weight loss AND  
• Must be on a high protein diet  
• Authorization limited to 30 days with re-authorization granted with documentation of weight gain with therapy |
| Antimycobacterial                                     | Priftin® (rifapentine)         | • Must have a recommendation or consult with an infectious disease specialist, tuberculosis clinic, CDC or state health department AND  
• Must have a diagnosis of tuberculosis AND  
• Must have a claim for another anti-TB drug AND  
• For an active infection must obtain molecular susceptibility testing prior to initiation of therapy |
<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Drug Name</th>
<th>Clinical Criteria (Authorization is for 1 year unless otherwise stated)</th>
</tr>
</thead>
</table>
| Benzothiazole for ALS             | Rilutek® (riluzole)            | • Must be prescribed by or in consultation with a neurologist AND  
• Must have a diagnosis of amyotrophic lateral sclerosis (ALS) without a tracheotomy                                                                                                                                |
| Central Nervous System Agents     | Nuedexta® (dextromethorphan hydrobromide and quinidine sulfate) | • Has a diagnosis of PBA secondary to a neurologic condition AND  
• Has had treatment failure, contraindication, or allergy to a tricyclic antidepressant (TCA) or a selective serotonin reuptake inhibitor (SSRI) AND  
• Is ≥ 18 years old AND  
• Baseline Center for Neurologic Study-Lability Scale (CNS-LS) score > 13 AND  
• Does not exceed 40mg dextromethorphan and 20mg quinidine (2 capsules per day) AND  
• Authorization will be granted for 12 weeks AND  
• For renewal, must respond positively to therapy as evidenced by a decrease in the CNS-LS score of ≥ 3 points from baseline |
| Cortisol Receptor Blocker         | Korlym® (mifepristone)         | • Must have a recommendation or consultation from an endocrinologist AND  
• Must have a diagnosis of Cushing’s Disease AND  
• Must have a history of at least 30 days of therapy with ketoconazole within the past 60 days (or a documented clinical reason the patient cannot use ketoconazole) AND  
• Must have documented hyperglycemia AND  
• Must not be pregnant AND  
• Authorization limited to less than or equal to 4 doses per day with an initial authorization for 60 days and subsequent authorization for 1 year |
<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Drug Name</th>
<th>Clinical Criteria (Authorization is for 1 year unless otherwise stated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetic Insulin Pump</td>
<td>Omnipod®</td>
<td><strong>INITIAL AUTHORIZATION</strong></td>
</tr>
<tr>
<td></td>
<td>V-Go®</td>
<td>- Requests for V-Go will be limited to a diagnosis of Type 2 Diabetes AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Must have completed a comprehensive diabetes education program within the previous 12 months AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Must be adherent to the insulin therapy recommended by an endocrinologist as demonstrated by monitoring logs and claims history maintained for at least 3 months AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- A letter or documentation indicating patient regularly works with a certified diabetes educator AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Insulin injections are required greater than or equal to 3 times a day AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Self-Home glucose monitoring is required greater than or equal to 4 times a day AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Meets one of the following:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- HgA1C&gt;7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- History of recurrent hypoglycemia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Wide fluctuations in blood glucose before mealtime</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- A marked early morning increase in fasting blood sugar (dawn phenomenon-glucose level exceeds 200mg/dL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- History of ketoacidosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- A history of severe glycemic excursions AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Must be capable of managing the pump and that the desired improvement in metabolic control can be achieved (or someone assisting the individual)</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>REAUTHORIZATION</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Prescriber must attest to the following</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Must be able to manage the pump (or someone assisting the individual)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Objective documented evidence of improvement in control of diabetes (specific to baseline status of disease for individual patients)</td>
</tr>
<tr>
<td>Therapeutic Class</td>
<td>Drug Name</td>
<td>Clinical Criteria (Authorization is for 1 year unless otherwise stated)</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------------------</td>
<td>---------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Diarylquinoline Antimycobacterial | Sirturo®(bedaq uiline) | • Must be at least 5 years of age and weigh at least 15 kg AND  
• Must have a diagnosis of pulmonary multi-drug resistant tuberculosis as confirmed by an isolate showing resistance to both isoniazid and rifampin AND  
• Must be prescribed by an Infectious Disease specialist AND  
• ECG, liver enzymes and electrolytes must be obtained prior to administration AND  
• Must be used with at least three drugs to which MDR-TB isolate is susceptible in vitro (or, in the absence of in vitro testing, at least four other drugs to which isolate is likely to be susceptible) AND  
• Initial authorization for two weeks of therapy limited to 28 or 56 of the 100 mg tablets or 140 or 280 of the 20 mg tablets AND  
• For reauthorization, an ECG must have been obtained two weeks after starting the drug and another ECG about 10 weeks later. There must be documentation that the QT interval has been evaluated for continued drug therapy, recommended to be <500 milliseconds. The remaining 22 weeks of therapy limited to 66 or 132 of the 100 mg tablets or 330 or 660 of the 20 mg tablets |
| Dopamine Precursor          | Lodosyn® (carbidopa) | • Approved for 1 year if being prescribed in combination with levodopa OR  
• Approved for 3 months if there is a history of levodopa-containing product in the past 45 days |
| Endocrine-Metabolic Analog  | Sandostatin®(octreotide) | • Must be prescribed by an endocrinologist, or oncologist or prescriber in consultation with one of these specialists AND  
• Must have a diagnosis of acromegaly and be ≥ 18 years of age AND  
• Must have a documented baseline IGF-I (somatomedin C) level above normal range for age (level should be re-evaluated at 6-month intervals) AND  
• Did not have adequate response to surgery, radiation, bromocriptine mesylate OR surgical resection is not an option OR  
• Must have a diagnosis of carcinoid tumor with documented diarrhea and flushing associated with tumor OR  
• Must have a diagnosis of VIP-tumor (VIPoma) with documented profuse watery diarrhea associated with the VIP-secreting tumor AND  
• Authorization for up to 3 months with re-authorization requiring evidence of improvement in condition due to therapy |
<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Drug Name</th>
<th>Clinical Criteria (Authorization is for 1 year unless otherwise stated)</th>
</tr>
</thead>
</table>
| Endocrine-Metabolic Analog                           | Octreotide, Long-Acting Formulation (Sandostatin LAR) | - Must be prescribed by an endocrinologist OR oncologist OR prescriber in consultation with one of these specialists AND  
- Must have previously treated with short-acting injection for at least 2 weeks with documented success AND  
- Initial authorization for up to 6 months with re-authorization requiring documentation of clinical benefit  
- LFT baseline required at initiation of therapy AND  
- Documented success one of these specialists must be prescribed by an endocrinologist OR oncologist OR prescriber in consultation with one of these specialists AND  
- Must have previously treated with short-acting injection for at least 2 weeks with documented success AND  
- Initial authorization for up to 6 months with re-authorization requiring documentation of clinical benefit  
- Must have a confirmed diagnosis of Type 1 Gaucher disease and be of appropriate age (≥4 years old for Eleyso and Vpriv; ≥2 years old for Cerezyme) AND  
- Therapy must be initiated to manage any one of the following: anemia/thrombocytopenia/bone disease/hepatomegaly/splenomegaly [Cerezyme® Only] AND  
- Must not be already receiving another enzyme therapy (e.g. Zavesca, Cerdelga) AND  
- Must have baseline, and at least once annually, hemoglobin level, platelet count, spleen volume and liver volume tests/examination, dexam scan AND  
- Authorizations beyond the initial will require documentation demonstrating benefit from therapy (e.g. decreased liver and spleen volume, increased platelet count, increased hemoglobin concentration) |
| Enzyme Replacement Therapy for disorder caused by mutations in the GBA gene, which results in a deficiency of the lysosomal enzyme beta-glucocerebrosidase | Cerezyme® (imiglucerase) Eleyso® (taliglucerase alfa) Vpriv® (velaglucerase alfa) | - Must have a diagnosis of acromegaly with inadequate response to surgery AND  
- Must have trialed other therapies and/or other therapies must not be appropriate for the patient with documented response and/or reasons to each provided AND  
- LFT baseline required at initiation of therapy AND  
- For renewals, recommended LFT draws must be provided AND  
- Approval for 6 months  
- Must have a diagnosis of Duchenne Muscular Dystrophy AND  
- Is 2 years of age or older AND  
- Has a serum creatinine kinase activity at least 10 times the upper limit of normal prior to initiating treatment AND  
- Must have a trial and failure to 6 months use of prednisone OR  
- Must have an intolerance or contraindication to prednisone AND  
- Prescribed by or in consultation with a neurologist or specialist in Duchenne Muscular Dystrophy AND  
- Dose does not exceed 0.9mg/kg per day (Please provide patient weight on PA request) |
| GH Receptor Antagonist                               | Somavert® (pegvisomant)                        | - Must have a diagnosis of acromegaly with inadequate response to surgery AND  
- Must have trialed other therapies and/or other therapies must not be appropriate for the patient with documented response and/or reasons to each provided AND  
- LFT baseline required at initiation of therapy AND  
- For renewals, recommended LFT draws must be provided AND  
- Approval for 6 months  
- Must have a diagnosis of Duchenne Muscular Dystrophy AND  
- Is 2 years of age or older AND  
- Has a serum creatinine kinase activity at least 10 times the upper limit of normal prior to initiating treatment AND  
- Must have a trial and failure to 6 months use of prednisone OR  
- Must have an intolerance or contraindication to prednisone AND  
- Prescribed by or in consultation with a neurologist or specialist in Duchenne Muscular Dystrophy AND  
- Dose does not exceed 0.9mg/kg per day (Please provide patient weight on PA request) |
| Glucocorticoid                                       | Emflaza® (deflazacort)                         | - Must have a diagnosis of Duchenne Muscular Dystrophy AND  
- Is 2 years of age or older AND  
- Has a serum creatinine kinase activity at least 10 times the upper limit of normal prior to initiating treatment AND  
- Must have a trial and failure to 6 months use of prednisone OR  
- Must have an intolerance or contraindication to prednisone AND  
- Prescribed by or in consultation with a neurologist or specialist in Duchenne Muscular Dystrophy AND  
- Dose does not exceed 0.9mg/kg per day (Please provide patient weight on PA request) |

Last Updated: July 2021
<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Drug Name</th>
<th>Clinical Criteria (Authorization is for 1 year unless otherwise stated)</th>
</tr>
</thead>
</table>
| Glutaminide Immunomodulatory Agent| Thalomid® (thalidomide) | • Must have a diagnosis of leprosy OR  
• Must have a diagnosis of multiple myeloma and medication must be prescribed by an oncologist AND  
• Initial authorization limited to 4 weeks AND  
• Re-authorization occurs automatically based upon claim history for Thalomid in the past 28 days |
| H-2 Antagonist                    | Preferred: Cimetidine (generic of Tagamet®)  
Non-Preferred: nizatidine | • Non-preferred medications will be approved if there is at least a 30-day history of therapy with one preferred agent in the past 90 days written by the same prescriber OR  
• Allergy, contraindication, drug-drug interaction, or history of unacceptable/toxic effects to the preferred drugs OR  
• Patient’s condition is clinically unstable OR  
• Medication was initiated in hospital to treat a GI bleed or other serious acute condition AND  
• Famotidine suspension authorization limited to patient’s less than 12 years of age unless any of the above applies AND  
• Nizatidine indicated for 12 weeks unless diagnosis is duodenal ulcer |
| Inhibitor of glucosylceramide synthase | Zavesca® (miglustat) | • Must have a diagnosis of mild to moderate Type 1 Gaucher disease AND  
• Must be unable to receive enzyme therapy due to an allergy, hypersensitivity, or poor venous access AND  
• Authorization limited to dose ≤ 300mg per day |
| Inhibitor of glucosylceramide synthase | Cerdelga™ (eliglustat) | • Must be ≥ 18 years of age AND  
• Must have a confirmed diagnosis of Type 1 Gaucher disease AND  
• Must have FDA-cleared test to evaluate cytochrome P450 enzyme (CYP)2D6 functionality and be determined not to be an ultra-rapid metabolizer AND  
• Must have baseline, and at least once annually, hemoglobin level, platelet count, spleen volume and liver volume tests/examination AND  
• Authorization will not be granted for any subsequent fill where the condition has not improved with treatment as measured relative to the baseline tests |
| Insulin-like Growth Factors       | Increlex® (mecasermin) | • Must be between the age of 2 to 17 years AND  
• Must have a diagnosis of primary IGF-1 Deficiency (height standard deviation score ≤ -3.0, basal IGF-1 standard deviation score ≤ -3.0 normal or elevated GH) or must have a diagnosis of growth hormone gene deletion with neutralizing antibodies to growth hormone AND  
• Must not have hypothyroidism or nutritional deficiencies or chronic treatment with pharmacological doses of anti-inflammatory corticosteroids AND  
• Must be prescribed by or in consultation with an endocrinologist AND  
• For re-authorization requests evidence must be provided of increase in height velocity |
<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Drug Name</th>
<th>Clinical Criteria (Authorization is for 1 year unless otherwise stated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isotretinoin (oral)</td>
<td>Absorica® (isotretinoin)</td>
<td>• Must have a diagnosis of Severe, Recalcitrant Nodular Acne AND</td>
</tr>
<tr>
<td></td>
<td>Amnesteem® (isotretinoin)</td>
<td>• Must have tried at least 30 days of other anti-acne products within the past 90 days OR</td>
</tr>
<tr>
<td></td>
<td>Claravis™ (isotretinoin)</td>
<td>• Must have a diagnosis of keratinization disorder OR</td>
</tr>
<tr>
<td></td>
<td>Myorisan™ (isotretinoin)</td>
<td>• Must have a diagnosis of Cutaneous T-cell Lymphoma, Leukoplakia, Neuroblastoma, Hidradenitis Suppurativa or tumor prevention</td>
</tr>
<tr>
<td></td>
<td>Sotret® (isotretinoin)</td>
<td>during treatment of squamous cell carcinoma AND</td>
</tr>
<tr>
<td></td>
<td>Zenatane™ (isotretinoin)</td>
<td>• Must be absent oral tretinoin in the past 60 days AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Authorization provided for no more than 5 months at a time</td>
</tr>
<tr>
<td>IV Lock Therapy</td>
<td>Ablysinsol® (dehydrated alcohol)</td>
<td>• Has a history of catheter-related bloodstream infections caused by drug resistant pathogens for which there is not a suitable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>antibiotic lock agent (e.g. fungal) AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Replacement of the catheter is not feasible AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The patient is TPN dependent or on myelosuppressive chemotherapy AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• For approval, pharmacy must prepare prefilled syringes of Ablysinsol diluted to 70% AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• For renewal, provide documentation of effectiveness (i.e. absence of recurrence of CRBSI or clearing of established infection)</td>
</tr>
<tr>
<td>Lipopeptide Antibacterials</td>
<td>Cubicin® (daptomycin)</td>
<td>• Must have a diagnosis of infection of the skin or skin structure caused by gram positive bacterial susceptible to the medication OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Must have a diagnosis of right-sided Endocarditis OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Must have a diagnosis of a MRSA bloodstream infection OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Will be approved as a continuation of therapy if initiated in the hospital AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Authorization provided for up to 6 weeks</td>
</tr>
<tr>
<td>Long-acting Benzodiazepine</td>
<td>Xanax XR® (alprazolam, extended release)</td>
<td>• Must have a diagnosis of panic disorder AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Must have documented inadequate response to other benzodiazepines or is transitioning from other benzodiazepines to alprazolam</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ER AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Initial authorization is for 6 months AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Re-authorization is for 6 months if it is documented the patient’s condition has improved with therapy</td>
</tr>
<tr>
<td>Melatonin receptor agonist</td>
<td>Hetlioz® (tasimelteon)</td>
<td>• Patient must be totally blind AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Patient must have a diagnosis of Non-24-hour Sleep Wake Disorder AND</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Authorization will be limited to 90 days</td>
</tr>
<tr>
<td>Miscellaneous Endocrine and Metabolic Agents</td>
<td>Carnitor® (levocarnitine)</td>
<td>• Automatically approved if there is a history of valproic acid drug use in the past 6 months OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Must have a diagnosis of primary or secondary carnitine deficiency confirmed by testing to verify deficiency OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Must have a diagnosis of mitochondrial disease</td>
</tr>
<tr>
<td>Therapeutic Class</td>
<td>Drug Name</td>
<td>Clinical Criteria (Authorization is for 1 year unless otherwise stated)</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| **Miscellaneous Topical Combination Product** | Tri-Luma® (fluocinolone, hydroquinone, and tretinoin) | • Must have a diagnosis of melasma of the face AND  
  • Authorization limited to 6 months                                                                                                                                                                                                                                                                                                                                                                             |
| **Monoclonal antibody for RSV**    | Synagis® (palivizumab)              | • Medication must be requested for use during the RSV season (November 1st to March 31st) AND  
  • Monthly doses must not exceed 15mg/kg per dose AND  
  Use not to exceed 5 doses per single RSV season or 1 dose per month; whichever is lower AND  
  Patient must have a diagnosis of at least one of the following:  
  O Prematurity  
  ▪ Infants born before 29 weeks, 0 day’s gestations who are < 12 months of age at the start of RSV season  
  O Chronic Lung Disease  
  ▪ Infants gestation age < 32 weeks who are < 12 months of age and require >21% oxygen for at least the first 28 DAYS after birth OR  
  ▪ Infants born at < 32 weeks, 0 day’s gestation who are ≥ 12 to < 24 months of age who required at least 28 days of >21% oxygen after birth and who continue to require supplemental oxygen, diuretics, or chronic systemic corticosteroid therapy within 6 months of the start of the second RSV season  
  O Congenital Heart Disease  
  ▪ Infants who are < 12 months of age with a diagnosis of hemodynamically significant heart disease who will most likely benefit from immunoprophylaxis:  
  ▪ Infants with acyanotic heart disease receiving drugs to control congestive heart failure with a history of at least 30 days of therapy with medications used to control congestive heart failure in the last 180 days and who will require surgery  
  ▪ Infants with moderate to severe pulmonary hypertension and history of at least 30 days of therapy with medications used to control pulmonary hypertension in the past 180 DAYS  
  ▪ Infants with a cyanotic heart defect who are prescribed therapy in consultation with a pediatric cardiologist  
  O Congenital abnormalities of the airway or neuromuscular disease  
  ▪ Infants who are < 12 months of age with a diagnosis of a neuromuscular condition that compromises handling of respiratory secretions  
  O Heart Transplant  
  Patients who are <24 months of age who have a heart transplant during RSV season  
  O Immunocompromised  
  ▪ Patients who are <24 months of age who have a diagnosis that supports they are profoundly immunocompromised during the RSV season (e.g. chemotherapy) |
<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Drug Name</th>
<th>Clinical Criteria (Authorization is for 1 year unless otherwise stated)</th>
</tr>
</thead>
</table>
| **Monoclonal Antibody targeting CD20** | Rituxan® (rituximab) | • Must have a living arrangement in a long-term care facility AND  
• Must have a diagnosis of CD20-positive B-cell Non-Hodgkin’s Lymphoma (NHL) for an 8-week authorization OR  
• Must have a diagnosis of CD20-positive Chronic Lymphocytic Leukemia (CLL) also being treated with fludarabine and cyclophosphamide for a 4-week authorization OR  
• Must have a diagnosis of Wegner’s Granulomatosis or Microscopic Polyangitis for a 4-week authorization OR  
• Must have a diagnosis of moderately to severely active rheumatoid arthritis with a history of methotrexate in the past 30 days and a history of a TNF inhibitor in the past year for a 30-day authorization |
| **Monoclonal Antibody targeting TNFα** | Remicade® (infliximab) | Must not have moderate to severe heart failure (NYHA Class III/IV) AND  
• Must have a diagnosis of Rheumatoid Arthritis AND  
• a history of oral methotrexate in the past 30 days OR  
• a diagnosis of Psoriatic Arthritis AND  
• Must have trialed at least two of the following medications in the past two years: Gold compounds (Myochrysine, Ridaura), Hydroxychloroquine, Kineret, Leflunomide, Methotrexate (oral), NSAIDS, Penicillamine (Cuprimine, Depen), TNF Inhibitors (Remicade, Cimzia, Enbrel, Humira, Orencia, Simponi, etc) OR  
• Must have a diagnosis of Crohn’s Disease AND  
• a history of at least 180 days of therapy with one of the following medications in the past year: oral corticosteroid+mesalamine (Asacol, Apriso, Canasa, Delzicol, Lialda, Pentasa, Rowasa), mercaptopurine, azathioprine OR  
• Must have a diagnosis of Ankylosing Spondylitis AND  
• a history of at least 180 days of therapy with a NSAID in the past year OR  
• Must have a diagnosis of Chronic, Severe Plaque Psoriasis AND  
• a trial of at least one of the following medications in the past year: acitretin (Soriatane), anthralin (Dritho-creme, Zithranol), calcipotriene (Dovonex), calcipotriene/betamethasone (Taclonex), cyclosporine, methoxsalen (8-MOP, Oxsoralen), TNF Inhibitors (Cimzia, Enbrel, Humira, Orencia, Simponi, etc), Tazarotene (Tazorac, Avage, Fabior), Topical steroids OR  
• Must have a diagnosis of Ulcerative Colitis AND  
• a history of at least one of the following medications in the past two years: azathioprine, balsalazide, Celestone Soluspan, cortisone (oral), cyclosporine, dexamethasone (oral), Dipentum, hydrocortisone (oral), mesalamine (Asacol, Apriso, Canasa, Delzicol, Lialda, Pentasa, Rowasa), methylprednisolone (oral), mercaptopurine, Paser, prednisone (oral), prednisolone (oral), sulfadiazine, sulfasalazine AND  Authorization limited to a dose ≤ 5mg/kg |
<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Drug Name</th>
<th>Clinical Criteria (Authorization is for 1 year unless otherwise stated)</th>
</tr>
</thead>
</table>
| Nasal synthetic vasopressin analogue | Stimate® (desmopressin acetate) | • Must have a diagnosis of mild hemophilia A (factor level 5% or greater) and a documented response to DDAVP OR  
• Must have a diagnosis of type 1 or 2 Von Willebrand Disease and a documented response to DDAVP OR  
• Females who are symptomatic carriers of hemophilia A and have a documented response to DDAVP OR  
• Must have a functional platelet disorder (such as storage pool disease) AND  
• Authorization limited to 30 days with re-authorization for 1 year for those with Documented adequate response to treatment                        |
| Oxazolidinone Antibacterial       | Zyvox® (linezolid)             | • Must have a diagnosis of MRSA or VRE OR  
• Medication must have been initiated in the hospital OR  
• Has a history of the linezolid injection in the past 28 days AND  
• Authorization limited to 28 days                                                                                                          |
| Oxazolidinone Antibacterial       | Sivextro® (tedizolid)          | • Must have a diagnosis of an acute bacterial skin and skin structure infection caused by: MRSA, MSSA, S. pyogenes, S. agalactiae, S. anginosus Group (including S. anginosus, S. intermedius, and S. constellatus), E. faecalis, OR VRE OR  
• Medication must have been initiated in the hospital AND  
• Authorization limited to 6 days                                                                                                          |
| Psoralens                         | 8-MOP® (methoxsalen)           | • Prescriber must have proper training for use of the UVAR photopheresis system AND  
• Must not have a diagnosis of a light sensitive disease state OR  
• Must not have a diagnosis of melanoma or a history of melanoma or invasive squamous cell carcinoma                                                                                                    |
| Psoralens                         | Oxsoralen-Ultra® (methoxsalen) | • Must be confirmed to be not pregnant and not planning on becoming pregnant AND  
• Must have a diagnosis of cutaneous manifestations of T-cell lymphoma, non-small cell lung cancer AND  
• Must be prescribed by an oncologist                                                                                                          |
| Retinoid X Receptor Activator     | Targretin® (bexarotene)        | • Must have a diagnosis of Cushing’s Disease AND  
• Must have a history of at least 30 days of therapy with ketoconazole or cabergoline within the past 60 days (or a documented clinical reason the patient cannot use ketoconazole or cabergoline) AND  
• Authorization limited to less than or equal to 2ml per day with an initial authorization for 60 days and subsequent authorization for 1 year                                                                 |
| Somatostatin Analogue             | Signifor® (pasireotide)        |                                                                                                                                                                                                                                                                                                                                 |

Last Updated: July 2021
<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Drug Name</th>
<th>Clinical Criteria (Authorization is for 1 year unless otherwise stated)</th>
</tr>
</thead>
</table>
| Spinal Muscular Atrophy (SMA)  | Evrysdi™ (risdiplam)               | • Member has a diagnosis of type 1, 2 or 3 Spinal Muscular Atrophy (SMA) with both of the following:  
  1. Genetic testing quantifying the copy number of SMN2 gene ≤ 4.  
  2. Member is symptomatic.  
  • Genetic testing confirms one of the following:  
    1. Homozygous deletions of SMN1 gene  
    2. Homozygous mutations in the SMN1 gene  
    3. Compound heterozygous mutations in SMN1 gene  
  • Prescribed by, or in consultation with, a neurologist, AND  
  • Member is two months of age or older AND  
  • Dosing follows FDA approved dose for age and weight AND  
  • Not concomitantly prescribed other treatments for SMA such as Zolgensma or nusinersen AND  
  • If prior treatment with Zolgensma attempted, documentation of poor response (e.g. sustained decrease in CHOP-INTEND score over a 6-month period)  
    • Authorization will be provided for up to 1 year  
    • Renewal for continued use will be based on meeting the requirements of the prior authorization criteria and documentation of clinical efficacy |
| Streptogramin Antibacterial     | Synercid® (quinupristin and dalfopristin) | • Must have a diagnosis of serious and life-threatening vancomycin-resistant enterococcus (VR) infection AND  
  • Authorization limited to 30 days |
| Tetracycline Antibacterial (IV Infusion) | Tygacil® (tigecycline) | • Must be ≥ 18 years of age AND  
  • Must live in assisted living or receiving home healthcare with nursing services AND  
  • Must have a diagnosis of a complicated skin and skin structure infection OR  
  • Must have a diagnosis of drug-resistant complicated intra-abdominal infection AND  
  • Must have documented trials and failed other anti-infectives |
| Tetracycline Antibacterials     | demeclocycline                      | • Will be approved if doxycycline, minocycline or tetracycline are inappropriate to treat the current medical condition clinically AND  
  • Authorization limited to 1 month |
<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Drug Name</th>
<th>Clinical Criteria (Authorization is for 1 year unless otherwise stated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thalidomide Analogue</td>
<td>Revlimid® (lenalidomide)</td>
<td>• Must have a diagnosis of multiple myeloma OR&lt;br&gt;• Must have a diagnosis of transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality OR&lt;br&gt;• Must have a diagnosis of mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included Velcade (bortezomib) AND&lt;br&gt;• Patient and prescriber must be enrolled in the REM program</td>
</tr>
<tr>
<td>Topical agents for Actinic Keratosis</td>
<td>Aldara® (imiquimod)</td>
<td>• Must have a diagnosis of Actinic Keratosis AND&lt;br&gt;• Authorization limited to 36 packets over 16 weeks in 1-year OR&lt;br&gt;• Must have a diagnosis of Superficial Basal Cell Carcinoma AND&lt;br&gt;• Authorization limited to 36 single-use packets over 6 weeks in 1-year OR&lt;br&gt;• Must have a diagnosis of Genital or Perianal Warts AND&lt;br&gt;• Authorization limited to 48 single-use packets over 16 weeks in 1 year</td>
</tr>
<tr>
<td>Topical agents for Actinic Keratosis</td>
<td>Picato® (ingenol mebutate)</td>
<td>• Must have a diagnosis of Actinic Keratosis AND&lt;br&gt;• Must be 18 years of age or older AND&lt;br&gt;• Authorization limited to one claim (MAX QTY of 3 tubes) of the 0.15% gel for treating the face every 180 days OR&lt;br&gt;• Authorization limited to one claim of the 0.05% gel (MAX QTY of 2 tubes) for treating the trunk every 180 days</td>
</tr>
<tr>
<td>Topical agents for Actinic Keratosis</td>
<td>Zyclara® (imiquimod)</td>
<td>• Must have a diagnosis of Actinic Keratosis AND&lt;br&gt;• Authorization limited to 28 packs per year</td>
</tr>
<tr>
<td>Topical Agents: Treatment of Anal Fissure</td>
<td>Rectiv™ (nitroglycerin)</td>
<td>• Must have a diagnosis to treat moderate to severe pain associated with chronic anal fissure AND&lt;br&gt;• Must have trialed laxatives, stool softeners and/or fiber in the past year AND&lt;br&gt;• Must have trialed a topical steroid containing product in the past 60 days AND&lt;br&gt;• Must have trialed a topical vasoconstrictor product containing phenylephrine in the past 60 days AND&lt;br&gt;• Authorization limited to one fill of ≤ 30-gram tube every 6 months</td>
</tr>
<tr>
<td>Topical - astringents / protectants</td>
<td>Qbrexa™ (glycopyrronium)</td>
<td>• Must have a diagnosis of hyperhidrosis of the axillary AND&lt;br&gt;• Must have a one-month trial and failure of either Drysol or Xerac-AC Solution OR&lt;br&gt;• Has an intolerance or contraindication to the use of Drysol and Xerac-AC</td>
</tr>
<tr>
<td>Therapeutic Class</td>
<td>Drug Name</td>
<td>Clinical Criteria (Authorization is for 1 year unless otherwise stated)</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------</td>
<td>---------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| Topical Retinoid  | Panretin® (alitretinoin) | • Must have a diagnosis of cutaneous lesions in patients with AIDS-related Kaposi’s Sarcoma (KS) AND  
• Must have less than 10 lesions in the past month AND  
• Must not have symptomatic lymphedema, symptomatic pulmonary KS or symptomatic visceral involvement |
| Vitamin B-12     | Nascobal® (cyanocobalamin) | • Approved if member has a documented lack of muscle mass that prevents the use of cyanocobalamin injection |
| All Other Therapies Not Listed Here or on the Unified Preferred Drug List (UPDL) | All Other Therapies Not Listed Here or on the Unified Preferred Drug List (UPDL) | • Must be prescribed in accordance with its FDA approved labeling |