## Additional Therapeutic Classes with Clinical Criteria

Prescribers must provide supporting documentation (chart notes, lab work, medication history) to demonstrate all criteria is satisfied unless specified otherwise. All requests must be in compliance with OAC 5160 & prescribed in accordance with its FDA approved labeling unless specified otherwise.

<table>
<thead>
<tr>
<th>Therapeutic Class</th>
<th>Drug Name</th>
<th>Clinical Criteria (Authorization is for 365 days unless otherwise stated)</th>
</tr>
</thead>
</table>
| Adrenocorticotropic hormone (ACTH) analogue | Acthar®                            | • Must be prescribed by an appropriate specialist  
• Must have had an inadequate clinical response in the last 30 days or a contraindication to corticosteroid therapy for multiple sclerosis diagnosis  
• Authorizations will be for up to 28 days |
| Anabolic steroid                           | Oxandrolone                        | • Must provide documentation that the patient has had ≥ 10% unintentional weight loss AND must be on a high protein diet  
• Initial authorizations will be for 30 days  
• Subsequent authorizations require documentation of weight gain with therapy |
| Antimycobacterial                          | Priftin® (rifapentine)             | • Must be prescribed by or in consultation with an infectious disease specialist, tuberculosis clinic, CDC or state health department  
• Must provide documentation of molecular susceptibility testing prior to initiation for an active infection |
| Benzothiazole for ALS                     | Rilutek® (riluzole)                | • Must be prescribed by or in consultation with a neurologist |
| Central Nervous System Agents              | Nuedexta® (dextromethorphan hydrobromide and quinidine sulfate) | • Must have had an inadequate clinical response or contraindication to a tricyclic antidepressant (TCA) or a selective serotonin reuptake inhibitor (SSRI)  
• Must provide documentation that patient’s baseline Center for Neurologic Study-Lability Scale (CNS-LS) score>13  
• Initial authorizations will be for 84 days  
• Subsequent authorizations require documentation of a positive response to therapy as evidenced by a decrease in the CNS-LS score of ≥3 points from baseline |
| Cortisol Receptor Blocker                  | Korlym® (mifepristone)             | • Must be prescribed by or in consultation with an endocrinologist  
• Must have documented hyperglycemia secondary to hypercortisolism  
• Must have had an inadequate clinical response to at least 30 days within the past 60 days or a contraindication to ketoconazole  
• Initial authorizations will be for 60 days |
| Diabetic Insulin Pump                      | Omnipod® V-Go®                    | • Omnipod may be authorized for diagnoses of Type 1 or 2 Diabetes; V-Go will be limited to a diagnosis of Type 2 Diabetes  
• Must require insulin injections greater than or equal to 3 times a day and self-home glucose monitoring greater than or equal to 4 times a day |

Updated: June 2022
| **Diarylquinoline Antimycobacterial** | Sirturo® (bedaquiline) | Must be prescribed by an Infectious Disease specialist  
Must provide documentation of ECG, liver enzymes and electrolytes level prior to authorization  
Initial authorizations will be for 14 days and limited to a quantity of 28 or 56 of the 100 mg tablets or a quantity of 140 or 280 of the 20 mg tablets  
Subsequent authorizations require documentation of an ECG obtained 2 weeks after initiation 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 a quantity of 66 or 132 of the 100 mg tablets or a quantity of 330 or 660 of the 20 mg tablets |
| **Duchenne Muscular Dystrophy Agents** | Amondys 45 (casimersen)  
Exondys 51 (eteplirsen)  
Viltepso (viltolarsen)  
Vyondys 53 (golodirsen) | Must be prescribed by or in consultation with a neurologist or specialist in Duchenne Muscular Dystrophy  
Must receive concurrent corticosteroids unless contraindicated or intolerant  
Must provide documentation of genetic testing showing diagnosis with confirmed mutations amenable to exon skipping and the patient’s weight  
Must provide documentation of appropriate function tests including functional vital capacity (FVC), Brooke Upper Extremity Function score, or equivalent test that demonstrates treatment is likely to improve outcomes  
Must provide documentation that drug will be administered at-home |
<table>
<thead>
<tr>
<th><strong>Endocrine-Metabolic Analog</strong></th>
<th>Sandostatin® (octreotide)</th>
</tr>
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</table>
|                                | • Initial authorizations will be for 180 days  
|                                | • Subsequent authorizations will be for 180 days and requires documentation of appropriate function tests demonstrating clinical improvement or stabilization without deterioration |

- **Endocrine-Metabolic Analog**
  - **Sandostatin® (octreotide)**
  - **Octreotide, Long-Acting Formulation (Sandostatin LAR)**
  - Must be prescribed by or in consultation with an endocrinologist or oncologist
  - Must have previously treated with short-acting injection for at least 14 days with documented success
  - Initial authorizations will be for 180 days
  - Subsequent authorizations require documentation of clinical response

- **Enzyme Replacement Therapy for GBA gene mutation disorder**
  - Cerezyme® (imiglucerase)
  - Elelyso® (taliglucerase alfa)
  - Vpriv® (velaglucerase alfa)
  - Must not be already receiving another enzyme therapy (e.g., Zavesca, Cerdelga)
  - Must have baseline, and at least annual, hemoglobin, platelet count, spleen volume and liver volume tests/examination, DEXA scan
  - Subsequent authorizations require documentation of clinical response (e.g., decreased liver and spleen volume, increased platelet count, increased hemoglobin concentration)

- **GH Receptor Antagonist**
  - Somavert® (pegvisomant)
  - Must have had an inadequate clinical response or contraindication to other therapies
  - Must provide documentation of baseline LFTs
  - Initial authorizations will be for 180 days
  - Subsequent authorizations will be for 180 days and require documentation of LFTs

- **Glucocorticoid**
  - Emflaza® (deflazacort)
  - Must be prescribed by or in consultation with a neurologist or specialist in Duchenne Muscular Dystrophy
  - Must have had an inadequate clinical response of at least 180 days or contraindication to prednisone
  - Must provide documentation of patient’s weight

- **Glutamimide Immunomodulatory Agent**
  - Thalomid® (thalidomide)
  - Patient and prescriber must be enrolled in the REMS program

- **H-2 Antagonist**
  - Nizatidine
  - Must have had an inadequate clinical response to at least 30 days or a contraindication with one preferred drug in the past 90 days OR
| Inhibitor of glucosylceramide synthase | Zavesca® (miglustat) | • Patient’s condition is clinically unstable or was initiated in hospital to treat a GI bleed or other serious acute condition
• Authorizations will be for 84 days unless diagnosis is duodenal ulcer

| Inhibitor of glucosylceramide synthase | Cerdelga™ (eliglustat) | • Must provide documentation of FDA-cleared test to evaluate cytochrome P450 enzyme (CYP)2D6 functionality and be determined not to be an ultra-rapid metabolizer
• Must have baseline, and at least annual, hemoglobin level, platelet count, spleen volume and liver volume tests/examination
• Subsequent authorizations require documentation of clinical response or stabilization

| Insulin-like Growth Factors | Increlex® (mecasermin) | • Must be prescribed by or in consultation with an endocrinologist
• Must not have hypothyroidism or nutritional deficiencies or chronic treatment with pharmacological doses of anti-inflammatory corticosteroids
• Subsequent authorizations require documentation of increase in height velocity

| IV Lock Therapy | Ablysinol® (dehydrated alcohol) | • Must have a history of catheter-related bloodstream infections caused by drug resistant pathogens for which there is not a suitable antibiotic lock agent (e.g., fungal)
• Replacement of the catheter is not feasible
• The patient is TPN dependent or on myelosuppressive chemotherapy
• Pharmacy must prepare prefilled syringes of Ablysinol diluted to 70%
• Subsequent authorization requires documentation of clinical response or stabilization

| Lipopeptide Antibacterials | Cubicin® (daptomycin) | • Authorizations will be up to 42 days as a continuation of therapy if initiated in the hospital

| Long-acting Benzodiazepine | Xanax XR® (alprazolam, extended release) | • Must have had an inadequate clinical response to other benzodiazepines or is transitioning from other benzodiazepines to alprazolam ER
• Initial authorizations will be for 180 days
• Subsequent authorizations will be for 180 days and requires documentation of clinical response

| Melatonin receptor agonist | Hetlioz® (tasimelteon) | • Must be prescribed by or in consultation with a physician who specializes in the treatment of sleep disorder
• Initial and subsequent authorizations will be for 120 days

| Miscellaneous Endocrine and Metabolic Agents | Carnitor® (levocarnitine) | • Must have an inadequate clinical response to valproic acid in the past 180 days

| Monoclonal antibody | Synagis® (palivizumab) | • Must have a diagnosis of at least one of the following:

Updated: June 2022
### Nasal synthetic vasopressin analogue

<table>
<thead>
<tr>
<th>Stimate® (desmopressin acetate)</th>
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<tbody>
<tr>
<td>Must provide documentation of a Stimate challenge test performed prior to initiation</td>
</tr>
<tr>
<td>Initial authorizations will be for 30 days</td>
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<tr>
<td>Subsequent authorizations require documentation of clinical response</td>
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</tbody>
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### Oxazolidinone Antibacterial

<table>
<thead>
<tr>
<th>Zyvox® (linezolid)</th>
<th>Sivextro® (tedizolid)</th>
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<tbody>
<tr>
<td>Must provide documentation that the patient has not had RSV during the current season</td>
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<tr>
<td>Medication must be requested for use during the RSV season (November 1st to March 31st) AND not to exceed 5 doses per single RSV season or 1 dose per month; whichever is lower</td>
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**Updated:** June 2022
<table>
<thead>
<tr>
<th>Psoralens</th>
<th>Methoxsalen</th>
<th><strong>Capsules</strong></th>
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<tr>
<td></td>
<td></td>
<td><strong>Must be prescribed by an oncologist</strong>&lt;br&gt;<strong>Must have had an inadequate clinical response to at least one prior systemic therapy</strong>&lt;br&gt;<strong>Must provide documentation that the patient has had baseline CBC, fasting lipid profile, liver function tests, and thyroid profile prior to initiation</strong></td>
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<tr>
<td>Retinoid X Receptor Activator</td>
<td>Targretin® (bexarotene)</td>
<td><strong>Gel</strong></td>
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<td><strong>Must be prescribed by an oncologist</strong>&lt;br&gt;<strong>Must have had an inadequate clinical response to at least 3 of the following:</strong>&lt;br&gt;  - Local radiation&lt;br&gt;  - Phototherapy&lt;br&gt;  - Topical carmustine&lt;br&gt;  - Topical corticosteroids&lt;br&gt;  - Topical imiquimod&lt;br&gt;  - Topical mechlorethamine (mustard)</td>
</tr>
<tr>
<td>Somatostatin Analogue</td>
<td>Signifor® (pasireotide)</td>
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<td></td>
<td><strong>Must have a contraindication or an inadequate clinical response of at least 30 days of therapy with ketoconazole, cabergoline, metyrapone, or octreotide within the past 60 days</strong>&lt;br&gt;<strong>Must provide documentation that the patient had baseline fasting plasma glucose, hemoglobin A1c, liver function tests, electrocardiogram, gall bladder ultrasound, and electrolyte levels prior to initiation</strong>&lt;br&gt;<strong>Initial authorizations will be for 60 days</strong>&lt;br&gt;<strong>Subsequent authorizations require documentation of a cortisol level checked 60 days after initiation of therapy</strong></td>
</tr>
</tbody>
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**Sivextro® (tedizolid)**
- Must provide documentation of diagnosis and any culture and sensitivity reports showing the infection is caused by an organism resistant to preferred drugs
- For MRSA infections, must have medically valid reason why vancomycin cannot be used
- Authorizations will be for 28 days

**Somatostatin Analogue**
- **Signifor LAR® (pasireotide)**
  - Must have a contraindication or an inadequate clinical response of at least 30 days of therapy with ketoconazole, cabergoline, metyrapone, or octreotide within the past 60 days
  - Must provide documentation that the patient had baseline fasting plasma glucose, hemoglobin A1c, liver function tests, electrocardiogram, gall bladder ultrasound, and electrolyte levels prior to initiation
  - Initial authorizations will be for 60 days
  - Subsequent authorizations require documentation of a cortisol level checked 60 days after initiation of therapy
<table>
<thead>
<tr>
<th>Condition</th>
<th>Product/Compound</th>
<th>Requirements</th>
</tr>
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</table>
| Spinal Muscular Atrophy (SMA)                   | Evrysdi® (risdiplam)                                                             | • Must provide clinical rationale for prescribing Signifor LAR instead of Signifor  
• Must have had inadequate clinical response to surgery or surgery is not an option  
• Must provide documentation that the patient had baseline fasting plasma glucose, hemoglobin A1c, liver function tests, electrocardiogram, gall bladder ultrasound, and electrolyte levels prior to initiation |
| Tetracycline Antibiotics on UPDL                 | Demeclocycline                                                                   | • Must provide documentation of genetic testing  
• Must be prescribed by or in consultation with a neurologist  
• Must not be concomitantly prescribed other treatments for SMA such as Zolgensma or nusinersen  
• Must provide documentation of inadequate clinical response or contraindication to Zolgensma (e.g., sustained decrease in CHOP-INTEND score over a 6-month period)  
• Initial authorizations will be up to 365 days  
• Subsequent authorizations require documentation of clinical response or stabilization |
| Thalidomide Analogue                             | Revlimid® (lenalidomide)                                                          | • Patient and prescriber must be enrolled in the REMS program                                                                                                                                     |
| Topical agents for Actinic Keratosis            | Aldara® (imiquimod)                                                              | • Must have had an inadequate clinical response to generic imiquimod 5%  
• Authorizations limited to 36 single-use packets in a 16-week period for actinic keratosis  
• Authorizations limited to 36 single-use packets in a 6-week period for superficial basal cell carcinoma  
• Authorizations limited to 48 single-use packets in a 16-week period for genital or perianal warts |
| Topical agents for Actinic Keratosis            | Zyclara® (imiquimod)                                                             | • Must have had an inadequate clinical response to generic imiquimod 5%  
• Authorizations limited to 56 single-use packets (or two 2.5% or 3.75% 7.5 gram pump bottles) in a 6-week period for actinic keratosis  
• Authorizations limited to 56 single-use packets (or two 3.75% 7.5 gram pump bottles) in an 8-week period for external genital or perianal warts for a total of 16 weeks if needed |
| Topical Agents: Treatment of Anal Fissure        | Rectiv™ (nitroglycerin)                                                           | • Must have had an inadequate clinical response to 14 days of a combination with 3 of the following alternatives: stool softeners, fiber, topical steroid containing product, or topical calcium channel blocker containing product in the past 60 days  
• Authorizations limited to one fill of ≤ 30-gram tube every 60 days |
| Topical - astringents / protectants             | Qbrexza™ (glycopyrronium)                                                        | • Must have a contraindication or an inadequate clinical response of at least 30 days with either Drysol or Xerac-AC Solution  
• Authorizations limited to 30 cloths per 30 days |

Updated: June 2022
<table>
<thead>
<tr>
<th>Topical Retinoid</th>
<th>Panretin® (alitretinoin)</th>
<th>• Initial authorizations will be for 90 days</th>
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<tbody>
<tr>
<td>Vitamin B-12</td>
<td>Nascobal® (cyanocobalamin)</td>
<td>• Must have a contraindication or an inadequate clinical response to all injectable formulations of cyanocobalamin</td>
</tr>
<tr>
<td>All Other Therapies Not Listed Here or on the Unified Preferred Drug List (UPDL)</td>
<td>All Other Therapies Not Listed Here or on the Unified Preferred Drug List (UPDL)</td>
<td>• Must be prescribed in accordance with its FDA approved labeling</td>
</tr>
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</table>