Ohio | Department of Medicaid

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.

Therapeutic Class	Drug Name	Clinical Criteria (Authorization is for 365 days unless otherwise stated)
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

		• 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 • Must meet ONE of the following criteria while compliant with insulin regimen: ▪ HgA1C>7% ▪ History of recurrent hypoglycemia ▪ Wide fluctuations in blood glucose before mealtime ▪ A marked early morning increase in fasting blood sugar (dawn phenomenon-glucose level exceeds 200mg/dL) ▪ History of ketoacidosis ▪ A history of severe glycemic excursions • Must be capable of managing the pump and that the desired improvement in metabolic control can be achieved (or someone assisting the individual) • Must have completed a comprehensive diabetes education program within the previous 365 days • Must submit a letter or documentation indicating patient regularly works with a certified diabetes educator • Subsequent authorizations require documentation of objective evidence of improvement in control of diabetes relative to baseline
Diarylquinoline Antimycobacterial	Sirturo® (bedaq uiline)	• 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

		• 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)	• Must be prescribed by or in consultation with an endocrinologist or oncologist • Must have a documented baseline IGF-I (somatomedin C) level above normal range for age (level should be re-evaluated at 180-day intervals) • Must not have had an adequate clinical response to surgery, radiation, bromocriptine mesylate OR surgical resection is not an option • Initial authorizations will be up to 90 days • Subsequent authorizations require documentation of clinical response
Endocrine-Metabolic Analog	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
Glutarimide 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

		• 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	Zavesca® (miglustat)	• Must be unable to receive enzyme therapy due to an allergy, hypersensitivity, or poor venous access
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 (i.e., absence of recurrence of CRBSI or clearing of established infection)
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:

for RSV		○ **Prematurity** - infants born before 29 weeks, 0 day's gestations who are < 12 months of age at the start of RSV season ○ **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 ▪ 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 ○ **Congenital Heart Disease** - infants who are < 12 months of age with a diagnosis of hemodynamically significant heart disease who will most likely benefit from immuno-prophylaxis: ▪ Infants with acyanotic heart disease receiving drugs to control congestive heart failure and who will require surgery ▪ Infants with moderate to severe pulmonary hypertension receiving drugs to control pulmonary hypertension ▪ Infants with a cyanotic heart defect who are prescribed therapy in consultation with a pediatric cardiologist ○ **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 ○ **Heart Transplant** - patients who are <24 months of age who have a heart transplant during RSV season ○ **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) • Must provide documentation that the patient has not had RSV during the current season • 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
Nasal synthetic vasopressin analogue	Stimate® (desmopressin acetate)	• Must provide documentation of a Stimate challenge test performed prior to initiation • Initial authorizations will be for 30 days • Subsequent authorizations require documentation of clinical response
Oxazolidinone Antibacterial	Zyvox® (linezolid) Sivextro® (tedizolid)	**Zyvox® (linezolid)**

		• 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 **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 • Must have had an inadequate clinical response to linezolid or provide documentation of reasoning the patient cannot be changed to linezolid • Authorizations will be for 6 days
Psoralens	Methoxsalen	• Prescriber must have proper training for use of the UVAR photopheresis system • Must provide documentation of an ophthalmic exam prior to initiation

Retinoid X Receptor Activator	Targretin® (bexarotene)	**Capsules**
		• Must be prescribed by an oncologist
		• Must have had an inadequate clinical response to at least one prior systemic therapy
		• Must provide documentation that the patient has had baseline CBC, fasting lipid profile, liver function tests, and thyroid profile prior to initiation
		Gel
		• Must be prescribed by an oncologist
		• Must have had an inadequate clinical response to at least 3 of the following:
		  ○ Local radiation
		  ○ Phototherapy
		  ○ Topical carmustine
		  ○ Topical corticosteroids
		  ○ Topical imiquimod
		  ○ Topical mechlorethamine (mustard)

Somatostatin Analogue	Signifor® (pasireotide)	**Signifor® (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 **Signifor LAR® (pasireotide)**

		• 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
Spinal Muscular Atrophy (SMA)	Evrysdi™ (risdiplam)	• 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
Tetracycline Antibacterials on UPDL	Demeclocycline	• Must provide documentation of diagnosis and any culture and sensitivity reports showing the infection is caused by an organism resistant to preferred drugs • Authorizations limited to 28 days
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

Topical Retinoid	Panretin®(alitretinoin)	• Initial authorizations will be for 90 days
Vitamin B-12	Nascobal®(cyanocobalamin)	• Must have a contraindication or an inadequate clinical response to all injectable formulations of cyanocobalamin
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