Ohio Department of Medicaid

Last Updated: April 2018

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

Therapeutic Class	Drug Name	Clinical Criteria (Authorization is for 1 year unless otherwise stated)
Interferon gamma-1b	Actimmune® (interferon gamma-1b solution)	• Patient must have a diagnosis of Chronic Granulomatosis disease **OR** • Patient must have a diagnosis of Severe Malignant Osteopetrosis
Topical agents for Actinic Keratosis	Aldara® (imiquimod)	• Patient must have a diagnosis of Actinic Keratosis **AND** • Authorization limited to 36 packets over 16 weeks in 1 year **OR** • Patient must have a diagnosis of Superficial Basal Cell Carcinoma **AND** • Authorization limited to 36 single-use packets over 6 weeks in 1 year **OR** • Patient must have a diagnosis of Genital or Perianal Warts **AND** • Authorization limited to 48 single-use packets over 16 weeks in 1 year
	Picato® (ingenol mebutate)	• Patient must have a diagnosis of Actinic Keratosis **AND** • Patient must be 18 years of age or older **AND** • Authorization limited to one claim (MAX QTY of 3 tubes) of the 0.015% gel for treating the face every 180 days **OR** • Authorization limited to one claim of the 0.05% gel (MAX QTY of 2 tubes) for treating the trunk every 180 days

	Zyclara® (imiquimod)	• Patient must have a diagnosis of Actinic Keratosis **AND** • Authorization limited to 28 packets per year
Sublingual Allergen Extract	Grastek ® (timothy grass pollen allergen extract) Ragwitek® (short ragweed pollen allergen extract)	• Patient must not be a candidate to receive allergy shots **AND** • Patient must not have a history of daily asthma medication (inhaled corticosteroid or leukotriene modifier) **AND** • Patient must be between the age 5 and 65 **AND** • Patient must have a history of at least 90 days of therapy with two or more different anti-allergy classes in the past 6 months **AND** • Patient must test positive to the appropriate allergen **AND** • Patient must have symptoms present ≥ 120 DAYS during the last allergy season (January to June for Grastek; March to September for Ragwitek) **AND** • Authorization will be limited to allergy season (January to June for Grastek; March to September for Ragwitek)
Anabolic steroid for anemia	Anadrol®-50 (oxymetholone tablet)	• Patient must have a diagnosis of anemia **AND** • Prescriber must provide a monitoring plan **AND** • Authorization will be limited to 6 months with re-authorization dependent upon documentation of patient improvement (lab test and RBC count)

Miscellaneous Endocrine and Metabolic Agents	Carnitor® (levocarnitine)	• Medication automatically approved if there is a history of valproic acid drug use in the past 6 months **OR** • Patient must have a diagnosis of primary or secondary carnitine deficiency confirmed by testing to verify deficiency **OR** • Patient must have a diagnosis of mitochondrial disease
Lipopeptide Antibacterials	Cubicin® (daptomycin)	• Patient must have a diagnosis of infection of the skin or skin structure caused by gram positive bacterial susceptible to the medication **OR** • Patient must have a diagnosis of right-sided Endocarditis **OR** • Patient must have a diagnosis of a MRSA bloodstream infection **OR** • Medication will be approved as a continuation of therapy if initiated in the hospital **AND** • Authorization limited to 28 days
Tetracycline Antibacterials	demeclocycline	• Medication will be approved if doxycycline, minocycline or tetracycline are inappropriate to treat the current medical condition clinically **AND** • Authorization limited to 1 month

Recombinant human parathyroid hormone	Forteo® (teriparatide)		• Patient must not be at risk for osteosarcoma **AND** • Patient must have a history of fracture, multiple risk factors for fractures, or patient has failed or is intolerant to other therapy **AND** • Patient must have a diagnosis of osteoporosis for postmenopausal woman **OR** • Patient must have a diagnosis of osteoporosis primary or hypogonadal in men to increase bone mass **OR** • Patient must have a diagnosis of osteoporosis related corticosteroid therapy receiving at least 5mg of prednisone (or equivalent) per day
H-2 Antagonist	Preferred	Non-Preferred	• 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** • There is an allergy, contraindication, drug-drug interaction, or history of unacceptable/ toxic effects to the preferred drugs **AND** • The patient's condition is clinically unstable **AND** • The mediation was initiated in the hospital to treat a GI bleed or other serious acute condition **AND** • Ranitinde Syrup authorization limited to patient's less than 12 years of age unless any of the above applies
	Cimetidine (generic of Tagamet®) Famotidine (generic of Pepcid®) Ranitidine (generic of Zantac®)	Axid AR™ (nizatidine)	

Hepatitis B Immune Globulin	Hepagam B® (hepatitis b immune globulin (human)) HyperHEP B® (hepatitis b immune globulin (human)) Nabi-HB® (human hepatitis b virus immune globulin)	• For patients less than or equal to 12 months of age authorization is limited to those exposed to others with hepatitis B and to 14 days **OR** • Patient must have a diagnosis requiring post-exposure prophylaxis and authorization will be limited to 2 months **OR** • Patient must have had a sexual encounter with a hepatitis B positive individual within the last two weeks and authorization will be limited to 14 days **OR** • Patients must have had a liver transplant and using Hepgam B® to prevent hepatitis B recurrence and authorization will be approved for 1 year
Melatonin receptor agonist	Hetlioz® (tasimelteon)	• Patient must be totally blind **AND** • Patient must have a diagnosis of Non-24-hour Sleep Wake Disorder **AND** • Authorization will be limited to 90 days
Immune Globulins	Atgam® (equine thymocyte immune globulin) Bivigam™ (human immunoglobulin g) Carimune® NF (human immunoglobulin g) Cytogam® (human cytomegalovirus immune globulin) Flebogamma® DIF (immune globulin (human))	• Patient must have an immune deficiency diagnosis **AND** • Requested therapy must be approved to treat the diagnosis

	GamaSTAN® (immune globulin (human)) Gammagard® (human immunoglobulin g) Gammaked™ (human immunoglobulin g) Gammgard® S/D (human immunoglobulin g) Gammaplex® (human immunoglobulin g) Gamunex®-C (immune globulin (human)) HyperRAB® S/D (rabies immune globulin (human)) HyperRHO® (rho(d) immune globulin (human)) HyperTET ® (tetanus immune globulin (human)) Hyqvia® (human immune globulin g and hyaluronidase) Micrhogam® (human rho(d) immune globulin) Octagam® (human immune globulin) Privigen® (human immunoglobulin g) Rhogam® (human rho(d) immune globulin)

	WinRho® (rho(d) immune globulin) Varizig® (varicella zoster immune globulin)	
Insulin-like Growth Factors	Increlex® (mecasermin)	• Patient must be between the age of 2 to 17 years **AND** • Patient must have a diagnosis of primary IGF-1 Deficiency (height standard deviation score ≤ -3.0 AND normal or elevated GH) **AND** • Patient must have a diagnosis of growth hormone gene deletion with neutralizing antibodies to growth hormone **AND** • Patient must not have uncorrected thyroid or nutritional deficiencies **AND** • Prescriber must be familiar with treating patients with growth disorder • For re-authorization requests evidence must be provided of increase in height velocity
Human Chorionic Gonadotropin (HCG)	HCG (human chorionic gonadotropin) Novarel® (gonadotrophin, chorionic) Ovidrel® (choriogonadotropin alfa) Pregnyl® (choriogonadotropin alfa)	• Patient must have a diagnosis of hypogonadism **OR** • Patient must have a diagnosis of Prepubertal Cryptorchidism not due to anatomical obstruction

Isotretinoin (oral)	Absorica® (isotretinoin) Amnesteem® (isotretinoin) Claravis™ (isotretinoin) Myorisan™ (isotretinoin) Sotret® (isotretinoin) Zenatane™ (isotretinoin)	• Patient must have a diagnosis of Severe, Recalcitrant Nodular Acne **AND** • Patient must have tried at least 30 days of other anti-acne products within the past 90 days **OR** • Patient must have a diagnosis of keratinization disorder **OR** • Patient must have a diagnosis of Cutaneous T-cell Lymphoma, Leukoplakia, Neuroblastoma, Hidradenitis Suppurativa or tumor prevention during treatment of squamous cell carcinoma **AND** • Patient must be absent oral tretinoin in the past 60 days **AND** • Authorization provided for no more than 5 months at a time
Agents for Homozygous familial hypercholesterolemia (HoFH) [non-PCKS9 Inhibitors]	Juxtapid® (lomitapide) Kynamro™ (mipomersen)	• Patient must be 18 years of age or older **AND** • Patient must have a diagnosis of Homozygous Familial Hypercholesterolemia **AND** • Patient must have a history of at least 90 days of high-dose statin therapy in the past 180 days (or a clinical reason that statins cannot be utilized) **AND** • Patient must have a LDL > 400mg/dL **AND** • Initial authorization is for 6 months and re-authorization will be granted for 1 year

Cortisol Receptor Blocker	Korlym® (mifepristone)	• Patient must have a diagnosis of Cushing's Disease **AND** • Patient 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** • Patient must have documented hyperglycemia **AND** • Patient 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
Somatostatin Analogue	Signifor® (pasireotide)	• Patient must have a diagnosis of Cushing's Disease **AND** • Patient 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
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

Vitamin B-12	Nascobal® (cyanocobalamin)	• Approved if member has a documented lack of muscle mass that prevents the use of cyanocobalamin injection
Hydroxyphenyl-pyruvate dioxygenase inhibitor	Orfadin® (nitisinone)	• Patient must have a diagnosis of hereditary tyrosinemia type-1 (HT-1) **AND** • Medication must be prescribed by an endocrinologist or pediatrician or consulting a specialist who has knowledge in treating patients with HT-1
Anabolic steroid	Oxandrin (oxandrolone)	• Patient must have a diagnosis of AIDS Wasting Syndrome • Patient must have a diagnosis of cachexia from multiple abdominal surgeries • Patient must have a diagnosis of COPD with corticosteroid-induced protein catabolism or chronic non-healing wounds without impaired blood flow **AND** • Patient must have ≥ 10% unintentional weight loss **AND** • Patient must be on a high protein diet • Authorization limited to 30 days with re-authorization granted with documentation of weight gain with therapy
Topical Retinoid	Panretin® (alitretinoin)	• Patient must have a diagnosis of cutaneous lesions in patients with AIDS-related Kaposi's Sarcoma (KS) **AND** • Patient must have less than 10 lesions in the past month **AND** • Patient must not have symptomatic lymphedema, symptomatic pulmonary KS or symptomatic visceral involvement
Antimycobacterial	Priftin® (rifapentine)	• Patient must have a diagnosis of tuberculosis **AND** • Patient must have a claim for another anti-TB drug in the past 45 days

Human Recombinant Interleukin-2	Proleukin® (aldesleukin)	• Patient must have a diagnosis of metastatic renal cell carcinoma (metastatic RCC) or metastatic melanoma **AND** • Patient must have normal cardiac, pulmonary, hepatic and CNS function **AND** • Patient must have pulmonary function and thallium cardiac stress test with normal results **AND** • Patient must not have any organ allografts **AND** • Patient must have a serum creatinine ≤ 1.5mg/dL
Agents to Promote Wakefulness	Provigil® (modafinil) Nuvigil® (armodafinil)	• Patient must not be pregnant or planning to become pregnant **AND** • Patient must not have a history of drug dependence or substance abuse **AND** • Patient must have a diagnosis of narcolepsy **OR** • Patient must have a diagnosis of Shift Work Disorder (SWD) **OR** • Patient must have a diagnosis of fatigue related to Multiple Sclerosis **OR** • Patient must have a diagnosis of excessive sleepiness associated with obstructive sleep apnea **AND** • Must not be a candidate for CPAP or have had a trial of CPAP and now using both modalities **AND**

		• Patient must have failed other treatment modalities (i.e. short acting stimulants) **AND** • Authorization will be granted for 6 months
Psoralens	8-MOP® (methoxsalen) Oxsoralen-Ultra® (methoxsalen)	• Prescriber must have proper training for use of the UVAR photopheresis system **AND** • Patient must have a diagnosis of a light sensitive disease state **OR** • Patient must have a diagnosis of melanoma or a history of melanoma or invasive squamous cell carcinoma
Topical Agents: Treatment of Anal Fissure	Rectiv™ (nitroglycerin)	• Patient must have a diagnosis to treat moderate to severe pain associated with chronic anal fissure **AND** • Patient must have trialed laxatives, stool softeners and/or fiber in the past year **AND** • Patient must have trialed a topical steroid containing product in the past 60 days **AND** • Patient must have trialed a topical vasoconstrictor product containing phenylephrine in the past 60 days **AND** • Authorization limited to one fill of ≤ 30 gram tube every 6 months

Topical recombinant platelet-derived growth factor	Regranex® (becaplermin)	• Patient must have a history of use of an antidiabetic agent in the past 90 days **AND** • Patient must have a wound care plan documented **AND** • Patient must have an ulcer located in the lower extremity that extends into the subcutaneous tissue or beyond (stage III or IV) and that has an adequate blood supply **AND** • Authorization limited to 10 weeks for the initial fill. A second fill up to 10 weeks will be authorized if the ulcer size is documented to decrease by at least 30%. **AND** • Authorization is limited to 20 weeks in a 6 month period
Monoclonal Antibody targeting TNFα	Remicade® (infliximab)	• Patient must not have moderate to severe heart failure (NYHA Class III/IV) **AND** • Patient must have a diagnosis of Rheumatoid Arthritis **AND** ○ a history of oral methotrexate in the past 30 days **OR** • Patient must have 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) **OR** • Patient 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

- Patient 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

- Patient 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-crème, Zithranol), calcipotriene (Dovonex), calcipotriene/betamethasone (Taclonex), cyclosporine, methoxsalen (8-MOP, Oxsoralen), TNF Inhibitors (Cimzia, Enbrel, Humira, Orencia, Simponi), Tazarotene (Tazorac, Avage, Fabior), Topical steroids

OR

- Patient 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
Thalidomide Analogue	Revlimid® (lenalidomide)	• Patient must have a diagnosis of multiple myeloma **OR** • Patient 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** • Patient 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** • Patient and prescriber must be enrolled in the REM program
Benzothiazole for ALS	Rilutek® (riluzole)	• Patient must have a diagnosis of amyotrophic lateral sclerosis (ALS) without a tracheotomy
Monoclonal Antibody targeting CD20	Rituxan® (rituximab)	• Patient must have a living arrangement in a long-term care facility **AND** • Patient must have a diagnosis of CD20-positive B-cell Non-Hodgkin's Lymphoma (NHL) for an 8-week authorization **OR** • Patient must have a diagnosis of CD20-positive Chronic Lymphocytic Leukemia (CLL) also being treated with fludarabine and cyclophosphamide for a 4-week authorization **OR** • Patient must have a diagnosis of Wegner's Granulomatosis or Microscopic Polyangitis for a 4-week authorization **OR** • Patient 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
Diarylquinoline Antimycobacterial	Sirturo® (bedaquiline)	• Patient must have a diagnosis of pulmonary multi-drug resistant tuberculosis (confirmed by culture and sensitivity) **AND** • Patient must have a history of at least 30 days each with three different anti-TB agents in the past 30 days **AND** • Medication must be prescribed by an Infectious Disease specialist **AND** • Initial authorization limited to one fill of a prescribed quantity ≤ 68 tablets for a 28-day supply. Subsequent authorizations limited to a prescribed quantity ≤ 24 tablets for a 28-day supply
Oxazolidinone Antibacterial	Zyvox® (linezolid)	• Patient must have a diagnosis of MRSA or VRE **OR** • Medication must have been initiated in the hospital **OR** • Patient has a history of the linezolid injection in the past 28 days **AND** • Authorization limited to 28 days
	Sivextro® (tedizolid)	• Patient 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

GH Receptor Antagonist	Somavert® (pegvisomant)	• Patient must have a diagnosis of acromegaly with inadequate response to surgery **AND** • Patient 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
Kinase Inhibitor	Sprycel® (dasatinib)	• Patient must have a diagnosis of chronic myeloid leukemia (CML) **OR** • Patient must have a diagnosis of Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) **AND** • Authorization for 1 year for either treatment naïve or patient's whose response to prior therapy was intolerance or resistance
Nasal synthetic vasopressin analogue	Stimate® (desmopressin acetate)	• Patient must have a diagnosis of hemophilia A **OR** • Patient must have a diagnosis of von Willebrand's disease (Type I) both with Factor VIII coagulant activity levels greater than 5% **OR** • Patient must have a congenital factor VIII disorder (in women) **OR** • Patient must have granule storage pool deficiency **OR** • Patient must have episodes of spontaneous or trauma induced injuries **AND** • Authorization limited to 30 days with re-authorization for those with documented adequate response to treatment

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: ○ **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 **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 ○ **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 ○ **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)
Streptogramin Antibacterial	Synercid® (quinupristin and dalfopristin)	• Patient must have a diagnosis of serious and life threatening vancomycin-resistant enterococcus (VR) infection **AND** • Authorization limited to 30 days
Retinoid X Receptor Activator	Targretin® (bexarotene)	• Patient must be confirmed to be not pregnant and not planning on becoming pregnant **AND** • Patient must have a diagnosis of cutaneous manifestations of T-cell lymphoma, non-small cell lung cancer

		AND • Medication must be prescribed by an oncologist
Glutarimide Immunomodulatory Agent	Thalomid® (thalidomide)	• Patient must have a diagnosis of leprosy **OR** • Patient must have a diagnosis of cancer 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
Miscellaneous Topical Combination Product	Tri-Luma® (fluocinolone, hydroquinone, and tretinoin)	• Patient must have a diagnosis of melisma of the face **AND** • Authorization limited to 6 months
IV Infusion Tetracycline Antibacterial	Tygacil® (tigecycline)	• Patient must be ≥ 18 years of age **AND** • Patient must live in assisted living or receiving home healthcare with nursing services **AND** • Patient must have a diagnosis of a complicated skin and skin structure infection **OR** • Patient must have a diagnosis of drug-resistant complicated intra-abdominal infection **AND** • Patient must have documented trials and failed other anti-invectives

Long-acting Benzodiazepine	Xanax XR® (alprazolam, extended release)	• Patient must have a diagnosis of panic disorder **AND** • Patient must have documented inadequate response to other benzodiazepines or is transitioning from other benzodiazepines to alprazolam ER **AND** • Initial authorization is for 6 months **AND** • Re-authorization is for 6 months provided that it is documented the patient's condition has improved with therapy
Anti-Cataplectic Agents	Xyrem® (sodium oxybate)	• Patient must have a diagnosis of cataplexy or narcolepsy
Inhibitor of glucosylceramide synthase	Zavesca® (miglustat)	• Patient must have a diagnosis of mild to moderate Type 1 Gaucher disease **AND** • Patient must be unable to receive enzyme therapy due to an allergy, hypersensitivity, or poor venous access **AND** • Authorization limited to dose ≤ 300mg per DAY
	Cerdelga™ (eliglustat)	• Patient must be ≥ 18 years of age **AND** • Patient must have a confirmed diagnosis of Type 1 Gaucher disease **AND** • Therapy must be initiated for management of one of the following conditions with appropriate supporting documentation: radiologic evidence of skeletal disease, platelet count <60,000microl, liver >2.5 times normal size, spleen >15 times normal size, hemoglobin ≤ 11.5g/dl (females) or ≤12.5g/dl (males) **AND** • Patient must be unable to receive enzyme therapy due to an allergy, hypersensitivity or due to poor venous access **AND**

		• Patient must have FDA-cleared test to evaluate cytochrome P450 enzyme (CYP)2D6 functionality **AND** • Patient 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 progressed as defined by all the of following occurring: Hemoglobin level decreased >1.5 g/dL from baseline, platelet count decreased >25% from baseline, spleen volume increased >25% from baseline, and liver volume increased >20% from baseline
Inhibitor of histone deacetylases	Zolinza® (vorinostat)	• Patient must have a diagnosis of progressive, persistent or recurrent cutaneous T-cell lymphoma **AND** • Patient must either be currently receiving two of the following therapies concurrently or have received two of the following in the past year: topical high potency corticosteroids, Doxorubicin, Etoposide, Gemcitabine, Leukine, Nipent, Ontak, Proleukinm Imiquimod cream, Interferon, alpha or gamma, methotrexate, topical nitrogen mustard, topical (mechlorethamine, carmustine), Psoralens (8-MOP, methoxsalen), oral Retinoids **AND** • Initial authorization limited to ≤ 4 capsules per DAY and 6 months at a time **AND** • Re-authorization limited to those claims with evidence of at least a 50% reduction in the affected surface area, dose ≤ 4 capsules per DAY, and 6 months at a time

Enzyme Replacement Therapy for disorder caused by mutations in the GBA gene, which results in a deficiency of the lysosomal enzyme beta-glucocerebrosidase	Elelyso® (taliglucerase alfa) Vpriv® (velaglucerase alfa)	• Patient must have a confirmed diagnosis of Type 1 Gaucher disease and be of appropriate age (>4 years old for Elelyso 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 **AND** • Patient must not be already receiving other enzyme therapy (e.g. Zavesca, Cerdelga) **AND** • Patient must have baseline, and at least once annually, hemoglobin level, platelet count, spleen volume and liver volume tests/examination **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)
Intravenous (IV) Antifungals	*Azole Antifungals* • Cresemba (isavuconazonium) Powder for Injection: 372mg • Diflucan (fluconazole) in Dextrose 5% Solution for Injection: 200mg, 400mg • Diflucan (fluconazole) in Sodium Chloride 0.9%	• Authorization will be granted for completing a course of therapy initiated in the hospital or from a prior carrier **AND** • Medication must be prescribed by an infectious disease specialist, oncologist, organ transplant specialist or a prescriber in consultation with one of these specialist **AND** • Patient must be severely immunocompromised or otherwise critically ill (e.g. hematopoietic stem cell transplant [HSCT] recipient, hematologic malignancy, prolonged neutropenia from chemotherapy, high-risk solid organ (lung, heart-lung, liver, pancreas, small bowel) transplant)

	Solution for Injection: 200mg, 400mg • Fluconazole in Sodium Chloride 0.9% for Injection: 100mg/50ml [2mg/ml] • Vfend (voriconazole) Powder for Injection: 200mg • Noxafil (posaconazole) Solution for Injection: 300mg/16.7ml • Sporanox (itraconazole) Solution for Injection: 250mg/25ml *Echinocandins Antifungals* • Cancidas (caspofungin) Powder for Injection: 50mg, 70mg • Eraxis (anidulafungin) Powder for Injection: 50mg, 100mg • Mycamine (micafungin) Powder for Injection: 50mg, 100mg	**AND** • Medication must be prescribed for an indication within the product labeling **AND** • Patient must have completed a trial with fluconazole or not be a candidate for fluconazole therapy (e.g. resistance to fluconazole, allergy, significant drug-drug interactions, etc) **AND** • Authorization limited to 30 days initially with subsequent authorization granted if within the last 30 days has an effort been made and was unsuccessful to switch the medication to an oral formulation OR has it been determined that the patient is not a candidate for oral therapy

	Polyene Antifungals • Amphocin (amphotericin B) Powder for Injection: 50mg, 100mg • Fungizone (amphotericin B) Powder for Injection: 50mg • Abelcet (amphotericin B-lipid formulation) Suspension for Injection: 100mg/20ml • Ambisome (amphotericin B-lipid formulation) Powder for Injection: 50mg	
Adrenocorticotropic hormone (ACTH) analogue	H.P. Acthar (≥ 2 years old)	• Medication must be prescribed by a specialist **AND** • Patient must have a diagnosis of one of the following: multiple sclerosis (experiencing an acute exacerbation), psoriatic arthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, systemic lupus erythematosus, systemic dermatomyositis, severe erythema multiforme, Stevens-Johnson syndrome, serum sickness, keratitis, iritis, iridocyclitis, diffuse

		posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation, OR sarcoidosis **AND** • Patient 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 21 days
	H.P Acthar (< 2 years old)	• Medication must be prescribed by a specialist **AND** • Patient must have a confirmed diagnosis of infantile syndrome (West Syndrome) **AND** • Patient must have or is suspected of having congenital infections **AND** • Authorization will be granted for up to 14 days
Endocrine-Metabolic Analog	Sandostatin® (octreotide)	• Medication must be prescribed by an endocrinologist, or oncologist **or** prescriber in consultation with one of these specialists **AND** • Patient must have a diagnosis of acromegaly and be ≥ 18 years of age **AND** ○ Patient 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** • Patient must have a diagnosis of carcinoid tumor with documented diarrhea and flushing associated with tumor **OR**

		• Patient 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
	Octreotide, Long-Acting Formulation	• Medication must be prescribed by an endocrinologist **OR** oncologist **OR** prescriber in consultation with one of these specialists **AND** • Patient must have previously treated with short-acting injection with documented success **AND** • Authorization for up to 3 months with re-authorization requiring evidence of improvement in condition due to therapy

Diabetic Testing Supplies	Continuous Glucose Monitoring Systems (CGMS)	**INITIAL AUTHORIZATION** • Patient must have a diagnosis of Type I Diabetes **AND** • Patient must be 2 years of age or older **AND** • The patient must have completed a comprehensive diabetes education program within the previous 12 months **AND** • The patient is adherent to the insulin therapy recommended by an endocrinologist as demonstrated by monitoring logs and claims history maintained for at least 3 months **AND** • A letter or documentation indicating the patient regularly works with a certified diabetes educator **AND** • Insulin injections are required greater than or equal to 3 times a day or on an insulin pump **AND** • Self-Home glucose monitoring is required greater than or equal to 4 times a day **AND** • The patient meets one of the following: ○ HgA1C greater than or equal to 7% despite diligent adjustments to therapy based on previous short-term CGMS and self-monitoring ○ History of recurrent hypoglycemia (<55 mg/dL) or hypoglycemic unawareness despite diligent adjustments to therapy based on previous short-term CGMS and self-monitoring ○ The patient is pregnant with poorly controlled type 1 diabetes; poorly controlled is defined as unexplained

		hypoglycemic episodes, hypoglycemic unawareness, suspected post-prandial hyperglycemia, or recurrent diabetic ketoacidosis
		AND
		• Authorization will be provided for up to 1 year for sensors and transmitters with the following limits: 1 receiver per every 4 years; 1 transmitter every three months; 4 sensors per month.
		REAUTHORIZATION
		• Continuation of CGMS use after one year or device replacement is considered medically necessary for the following:
		  • If for replacement, the device is malfunctioning and out of warranty
		  • There is objective documented evidence of improvement in control of diabetes (specific to baseline status of disease for individual patients)
		  • There is documented evidence of compliance to CMGS defined as at least 80% use rate of device (must be based on log data of the device)
		AND
		• Authorization will be provided for up to 1 year for sensors and transmitters with the following limits: 1 receiver per every 4 years; 1 transmitter every three months; 4 sensors per month.

Agents for Tardive Dyskinesia	Austedo (deutetrabenazine) Ingrezza (valbenzine)	• Diagnosis of Moderate to Severe Tardive Dyskinesia **AND** • Prescriber has reduced the dosage or cessation of all offending medications including antipsychotic medication and metoclopramide (Reglan) or attests that dose reduction or cessation is contraindicated for member • Authorization will be provided for up to 1 year

All Other Therapies Not Listed Here or on the Preferred Drug List (PDL)	All Other Therapies Not Listed Here or on the Preferred Drug List (PDL)	• Medication must be prescribed in accordance with its FDA approved labeling

Unless otherwise stated, generics preferred over brands when available

To request brand name use over generic the patient must:

- Have an allergy, contraindication or ineffectiveness with the generic
  OR
- Have tried the generic for at least 30 DAYS in the past 90 DAYS