

Clinical Criteria, Step Therapy, and Quantity Limits for TennCare Preferred Drug List (PDL):

Interim Criteria for Agents Awaiting PAC Review

July 1, 2024

Interim Criteria for Agents Awaiting PAC Review			
Approval of NP agents requires trial and failure, contraindication or intolerance of 2 preferred agents, unless otherwise indicated.			
Medication	Prior Authorization Criteria	Quantity Limit	PA Form
Agamree®	<p>Initial Criteria:</p> <ul style="list-style-type: none"> Documentation of a confirmed diagnosis of Duchenne muscular dystrophy (DMD); AND Patient is 2 years of age or older; AND Patient retains meaningful voluntary motor function (e.g., patient can speak, manipulate objects using upper extremities, ambulate, etc.); AND Patient has experienced at least ONE of the following unacceptable adverse reactions directly attributable to previous therapy with prednisone: <ul style="list-style-type: none"> Patient has experienced significant weight gain (e.g., crossing 2 percentile lines and/or reaching 98th percentile for age and sex) Patient has manifested significant behavioral changes negatively impacting function at school, home, day care, etc.; AND Patient has tried and failed, contraindication, or intolerance to Emflaza <p>Renewal Criteria:</p> <ul style="list-style-type: none"> Patient retains meaningful voluntary motor function (e.g., patient can speak, manipulate objects using upper extremities, ambulate, etc.); AND Patient has received benefit from therapy, which may include ONE or more of the following: <ul style="list-style-type: none"> Stability or slowing of decline in motor function or respiratory function Stability or slowing of decline in diminished strength of stabilizing musculature (e.g., scoliosis) 	10 mL/day	General PA Form
Filsuvez®	<p>Initial Criteria (6-month duration)</p> <ul style="list-style-type: none"> One of the following: <ul style="list-style-type: none"> Diagnosis of Dystrophic Epidermolysis bullosa (EB); Diagnosis of Junctional Epidermolysis bullosa (EB); AND Prescriber attest the target wound(s) meet ALL of the following: <ul style="list-style-type: none"> Target wound is clean in appearance and does not appear to be infected Target wound is 10 cm² to 50 cm² Target wound is ≥ 21 days and <9 months old; Squamous cell and/or basal cell carcinoma has been ruled out for the target wound; AND Patient will continue standard treatments for EB such as such as appropriate wound management and avoiding skin trauma; AND Prescribed by or in consultation with a dermatologist or wound management; <p>Reauth Criteria</p> <ul style="list-style-type: none"> Patient has a clinical response to therapy (e.g., decreased wound size, decreased frequency of wound dressing changes, reduction in pain) <p>Note: New wounds not previously treated with Filsuvez or recurrent reopened wounds are subject to initial criteria.</p>	23.4 grams/ per 30 days	General PA Form
Iwifin®	<p>Initial Criteria</p> <ul style="list-style-type: none"> Diagnosis of high-risk neuroblastoma (HRNB); AND Patient had a partial response to prior multiagent, multimodality therapy; AND Patient has received anti-GD2 immunotherapy (e.g., dinutuximab); AND Prescribed by or in consultation with an oncologist <p>Renewal Criteria</p> <ul style="list-style-type: none"> Patient continues to meet initial criteria; AND Patient has positive disease response defined as disease stabilization or decrease in size of tumor or tumor spread; AND Patient is absent of unacceptable toxicity from the medication (e.g., hepatotoxicity, hearing loss) 		General PA Form

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Rezdiffra®	<p>Initial Criteria</p> <ul style="list-style-type: none"> • Patient is 18 years or older; AND • Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) or metabolic dysfunction associated steatohepatitis (MASH); AND • Submission of medical records (e.g. chart notes) confirming disease is fibrosis stage F2 or F3 as confirmed by ONE of the following: <ul style="list-style-type: none"> ○ FibroScan ○ Fibrosis-4 index (FIB-4) ○ Magnetic Resonance Elastography (MRE); ○ Liver Biopsy; AND • Prescriber attests patient is participating in a supervised comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity; AND • Patient does not have decompensated cirrhosis (Child-Pugh Class B or C); AND • Prescribed by or in consultation with a gastroenterologist or hepatologist <p>Renewal Criteria</p> <ul style="list-style-type: none"> • Prescriber attest patient is participating in a supervised comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity; AND • Submission of medical records (e.g., chart notes) documenting a positive clinical response to therapy (e.g. NASH resolution, fibrosis stage improvements) 	1/day	General PA Form
Rivfloza®	<p>Initial Criteria (6-month duration)</p> <ul style="list-style-type: none"> • Patient is 9 years of age or older; AND • Patient has diagnosis of primary hyperoxaluria type 1 (PH1); AND • Documentation of ONE of the following: <ul style="list-style-type: none"> ○ Genetic testing demonstrating a mutation alanine-glyoxylate aminotransferase (AGXT) gene ○ Liver biopsy demonstrating absence or reduced alanine: glyoxylate aminotransferase (AGT) activity; AND • Patient has relatively preserved kidney function (e.g., eGFR ≥ 30 mL/min/1.73 m²); AND • Trial and failure, contraindication, or intolerance to pyridoxine (vitamin B-6); AND • Prescribed by, or in consultation with, a hematologist, nephrologist, urologist or geneticist <p>Renewal Criteria</p> <ul style="list-style-type: none"> • Patient has positive clinical response to therapy (e.g. decreased urinary oxalate excretion or plasma concentration, decreased number or size of kidney stones, improved kidney function) 	1 per 28 days	General PA Form

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Spevigo®	<p>Initial Criteria</p> <ul style="list-style-type: none"> • Patient is 12 years of age and older; AND • Patient weights at least 40 kg; AND • Diagnosis of Generalized pustular psoriasis (GPP) confirmed by ONE of the following: <ul style="list-style-type: none"> ○ Presence of sterile, macroscopically visible pustules on non-acral skin and pustulation is NOT restricted to psoriatic plaques (i.e. occurs outside of psoriatic plaques) ○ Skin biopsy confirming presence of Kogoj’s spongiform pustules; ○ Genetic confirmation of IL36RN, CARD14, or AP1S3 mutation; AND • Prescriber attest to ALL of the following: <ul style="list-style-type: none"> ○ Treatment is NOT for an active GPP flare ○ Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment ○ Patient will not receive live vaccines during therapy and 16 weeks after treatment; AND • Trial and failure to BOTH of the following (or have an intolerance or contraindication to all agents): <ul style="list-style-type: none"> ○ A TNF inhibitor (e.g. adalimumab, infliximab, and etanercept) ○ Taltz; AND • Prescribed by, or in consultation with, a dermatologist <p>Renewal Criteria</p> <ul style="list-style-type: none"> • Submission of medical records (e.g. chart notes) documenting disease response to therapy and tolerability compared to baseline (e.g., decreased number of GPP flares) <p>Note: The Spevigo subcutaneous formulation is not FDA approved for the treatment of GPP flare and will not be approved for that diagnosis. A SQ loading dose is not required following treatment of a GPP flare with IV Speviago.</p>	2 per 28 days	General PA Form

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Wegovy®	<p>Initial Criteria</p> <ul style="list-style-type: none"> • Treatment is being requested to reduce the risk of major adverse cardiovascular events; AND • Patient is 21 years of age or older; AND • Submitted medical documentation (e.g. chart notes) of initial body mass index (BMI) of ≥ 27 kg/m²; AND • Submitted medical documentation (e.g. chart notes) of ONE of the following: <ul style="list-style-type: none"> ○ Prior myocardial infarction ○ Prior stroke (ischemic and hemorrhagic stroke) ○ Symptomatic peripheral arterial disease as evidenced by intermittent claudication with ankle-brachial index <0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease; AND • Submitted documentation HbA1C $\leq 6.5\%$; AND • Prescriber attests patient is participating in a supervised comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity; AND • Patient does not have any of the following: <ul style="list-style-type: none"> ○ Diagnosis of type 1 or type 2 diabetes ○ New York Heart Association class IV heart failure; ○ Personal or family history of medullary thyroid carcinoma (MTC) OR Multiple Endocrine Neoplasia syndrome type 2 (MEN 2); ○ History or presence of chronic pancreatitis ○ End-stage renal disease or currently receiving dialysis; AND • For female patients of reproductive potential, the following has been addressed: <ul style="list-style-type: none"> ○ Patient is not pregnant or breastfeeding ○ Patient has been counseled to use highly effective contraceptive method during treatment; AND • Medication is not being co-administered with another GLP-1 receptor agonists (e.g. Byetta, Ozempic, and Victoza) <p>Renewal Criteria</p> <ul style="list-style-type: none"> • Patient continues to meet initial criteria; AND • Submission of medical records (e.g., chart notes) documenting a positive clinical response to therapy (e.g., patient has not had a major cardiovascular event within the past 12 months, decreased body weight or waist circumference from baseline, decrease blood pressure, total cholesterol, LDL, or triglyceride levels from baseline); AND • Patient must not have any contraindications or serious adverse effects (e.g., acute gallbladder disease, acute kidney injury, acute pancreatitis); <p>Note: If patient's HbA1C $\geq 6.5\%$ the patient should use a GLP-1 Receptor Agonists FDA approved for the treatment of diabetes (e.g., Byetta, Ozempic, Victoza).</p>		General PA Form
Winrevair®	<ul style="list-style-type: none"> • Patient is 18 years of age or older; AND • Diagnosis of Pulmonary arterial hypertension (PAH)/ elevated pulmonary vascular resistance or primary pulmonary hypertension; AND • Patient is Functional Class II or III; AND • Trial and failure of one agent with persistent signs and symptoms from TWO different classes for PAH such as: <ul style="list-style-type: none"> ○ Endothelin receptor antagonist (e.g. ambrisentan, bosentan) ○ Phosphodiesterase-5 inhibitors (e.g. sildenafil, tadalafil) ○ Prostacyclin analogue or receptor agonist (e.g., treprostinil, epopostenol, Upravi, Ventavis); AND • Winrevair will be used in combination with other PAH therapies; 	1 kit per 21 days	General PA Form

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Vonjo®	<p>Initial Criteria</p> <ul style="list-style-type: none"> • Patient has a diagnosis of primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis; AND • Patient is considered intermediate risk or high-risk; AND • Platelet count is below 50 x 10⁹/L <p>Renewal Criteria:</p> <ul style="list-style-type: none"> • Patient has positive clinical response to therapy (e.g., reduction in symptoms, decreased spleen size, decreased number of transfusions); AND • Absence of unacceptable toxicity (e.g., thrombocytopenia, major adverse cardiovascular events, thrombosis, and malignancies) 	4/day	General PA Form
Voydeya®	<p>Initial Criteria (6-month duration)</p> <ul style="list-style-type: none"> • Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); AND • Diagnosis confirmed by peripheral blood flow cytometry diagnostic testing showing the absence or deficiency of glycosylphosphatidylinositol-anchored proteins; AND • Patient has clinically significant extravascular hemolysis (EVH) defined by BOTH of the following: <ul style="list-style-type: none"> ○ Hemoglobin levels less than or equal to 9.5 g/dL ○ Absolute reticulocyte count greater than or equal to 120 x 10⁹ /L; AND • Prescriber attests Voydeya will be used in combination with Ultomiris or Soliris; AND • Prescriber is enrolled in the Voydeya REMS Program; AND • Prescribed by, or in consultation with, one of the following: <ul style="list-style-type: none"> ○ Hematologist ○ Oncologist <p>Renewal Criteria</p> <ul style="list-style-type: none"> • Submission of medical records (e.g., chart notes) documenting a positive clinical response to therapy (e.g. hemoglobin stabilization, decreased number of blood transfusions, improvement in signs and symptoms of the disease); AND • Patient does not have unacceptable toxicity (e.g., serious infections, hepatic enzyme increases, hyperlipidemia) 	6/day	General PA Form
Zymfentra®	<p>Initial Criteria</p> <ul style="list-style-type: none"> • Patient is 18 years of age or older; AND • Diagnosis of ONE of the following: <ul style="list-style-type: none"> ○ Moderately to severely active Crohn’s disease ○ Moderately to severely active Ulcerative Colitis; AND • Prescriber attest that patient has received three intravenous (IV) doses of infliximab prior to transitioning to subcutaneous therapy; AND • Submission of medical records demonstrating a positive clinical response following a treatment minimum of 10 weeks of infliximab IV <p>Renewal Criteria</p> <ul style="list-style-type: none"> • Diagnosis of ONE of the following: <ul style="list-style-type: none"> ○ Moderately to severely active Crohn’s disease ○ Moderately to severely active Ulcerative Colitis; AND • Disease response to therapy and tolerability compared to baseline (e.g., decreased UC disease activity index, endoscopic remission, decreased number of soft stools, decreased abdominal pain, etc) 	2 per 28 days	General PA Form