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

Interim Criteria for Agents Awaiting PAC Review

September 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®	**Initial Criteria:**
	• 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:
	  ○ 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
	Renewal Criteria:
	• 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:
	  ○ 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®	**Initial Criteria (6-month duration)**
	• One of the following:
	  ○ Diagnosis of Dystrophic Epidermolysis bullosa (EB);
	  ○ Diagnosis of Junctional Epidermolysis bullosa (EB); **AND**
	• Prescriber attest the target wound(s) meet ALL of the following:
	  ○ Target wound is clean in appearance and does not appear to be infected
	  ○ Target wound is 10 cm^2 to 50 cm^2
	  ○ 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 appropriate wound management and avoiding skin trauma; **AND**
	• Prescribed by or in consultation with a dermatologist or wound management;
	Reauth Criteria
	• Patient has a clinical response to therapy (e.g., decreased wound size, decreased frequency of wound dressing changes, reduction in pain)
	Note: New wounds not previously treated with Filsuvez or recurrent reopened wounds are subject to initial criteria.
		15 tubes/ per 30 days	General PA Form

Iwilfin®	**Initial Criteria** • 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 **Renewal Criteria** • 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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Mircera®	**Initial Criteria**
	• Lab values obtained within 30 days of the date of administration; **AND**
	• Adequate iron stores demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20%; **AND**
	• One of the following:
	  ○ Diagnosis of anemia secondary to chronic kidney disease (CKD) in adult patients and ALL of the following:
	  – Patient is 18 years of age or older
	  – Hemoglobin (Hb) is ≤ 10 g/dL
	  ○ Diagnosis of anemia secondary to chronic kidney disease (CKD) in pediatric patients and ALL of the following:
	  – Patient is between 3 months and 17 years of age
	  – Patient's hemoglobin stabilized following administration of another erythropoietin stimulating agent (ESA) (e.g., Retacrit, Aranesp, Procrit, Epogen); **AND**
	• Patient will not use Mircera in combination with another ESA agent; **AND**
	• Other causes of anemia (e.g., hemolysis, bleeding, vitamin deficiency, etc.) have been ruled out
	Renewal Criteria
	• Last dose < 60 days ago; **AND**
	• Patient will not use Mircera in combination with another ESA agent; **AND**
	• Lab values obtained within 30 days of the date of administration demonstrating BOTH of the following:
	  ○ Adequate iron stores as demonstrated by serum ferritin ≥ 100 ng/mL (mcg/L) and transferrin saturation (TSAT) ≥ 20% measured within the previous 3 months;
	  ○ Increase or stabilization of hemoglobin from baseline
			General PA Form

Ojemda®	**Initial Criteria:** • Diagnosis of relapsed or refractory pediatric low-grade glioma (PLGG); **AND** • Patient has BRAF fusion or rearrangement or BRAF V600 mutation; **AND** • Prescribed by, or in consultation with, an oncologist **Renewal Criteria:** • Patient demonstrates disease stabilization or clinical response to therapy (e.g., stabilized or decrease tumor size, decreased pain, improved vision, increased quality of life)	24 tablets/28 days 96 mL/28 days	General PA Form

Rezdiffra®	**Initial Criteria**
	• 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:
	  ○ 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
	Renewal Criteria
	• 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

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Rivfloza®	**Initial Criteria (6-month duration)**
	• 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:
	  ○ 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 m^2); **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
	Renewal Criteria
	• 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

Spevigo®	**Initial Criteria**
	• 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:
	  ○ 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:
	  ○ 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):
	  ○ A TNF inhibitor (e.g. adalimumab, infliximab, and etanercept)
	  ○ Taltz; **AND**
	• Prescribed by, or in consultation with, a dermatologist
	Renewal Criteria
	• 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)
	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.
		2 per 28 days	General PA Form

Vonjo®	**Initial Criteria** • 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 10^9/L **Renewal Criteria:** • 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

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Voquezna®	• Patient is 18 years of age or older; **AND**
	• One of the following diagnoses:
	  ○ Active treatment of erosive esophagitis **(2- month approval duration); OR**
	  ○ Maintenance treatment of healed erosive esophagitis **(6- month approval duration); AND**
	  – Request is for Voquezna 10 mg tablets; **OR**
	  ○ Non-erosive gastroesophageal reflux disease **(1- month approval duration); AND**
	  – Request is for Voquezna 10 mg tablets; **AND**
	• Trial and failure, contraindication, or intolerance to TWO preferred proton pump inhibitors (e.g. Dexilant, esomeprazole, lansoprazole, omeprazole, and pantoprazole)
		1/day	General PA Form

Voydeya®	**Initial Criteria (6-month duration)**
	• 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;
	  ○ Hemoglobin levels less than or equal to 9.5 g/dL
	  ○ Absolute reticulocyte count greater than or equal to 120 × 10^9 /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:
	  ○ Hematologist
	  ○ Oncologist
	Renewal Criteria
	• 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

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Wegovy®	**Initial Criteria**
	• 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:
	  ○ 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 ≤ 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:
	  ○ 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:
	  ○ 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)
	Renewal Criteria
	• 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);
	Note: If patient's HbA1C ≥ 6.5% the patient should use a GLP-1 Receptor Agonists FDA approved for the treatment of diabetes (e.g., Byetta, Ozempic, Victoza).
			General PA Form

Winrevair®	• 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:
	  ○ Endothelin receptor antagonist (e.g. ambrisentan, bosentan)
	  ○ Phosphodiesterade-5 inhibitors (e.g. sildenafil, tadalafil)
	  ○ Prostacyclin analogue or receptor agonist (e.g., treprostinil, epoprostenol, Uptravi, Ventavis); **AND**
	• Winrevair will be used in combination with other PAH therapies;
		1 kit per 21 days	General PA Form

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Zymfentra®	**Initial Criteria**
	• Patient is 18 years of age or older; **AND**
	• Diagnosis of ONE of the following:
	  ○ 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
	Renewal Criteria
	• Diagnosis of ONE of the following:
	  ○ 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