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

Interim Criteria for Agents Awaiting PAC Review

April 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

Augtyro®	**Initial Criteria (6- month duration)**
	• Diagnosis of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC); **AND**
	• Disease is positive for ROS1 gene fusions; **AND**
	• Patient have received at least one prior therapy; **AND**
	• Prescribed by, or in consultation with, an oncologist; **AND**
	• For patients with reproductive potential, prescriber attest to all of the following:
	  ○ Patient is not pregnant prior to initiation of therapy
	  ○ Females patients have been advised to use effective contraception during treatment and for 2 months after the final dose
	  ○ Female patients have been advised to not breastfeed during treatment and 10 days after the final dose
	  ○ Male patients with female partners of reproductive potential have been advised to use effective contraception during treatment and for 4 months after the final dose
	Renewal Criteria
	• Patient must continue to meet the initial criteria; **AND**
	• Patient has positive disease response defined as disease stabilization or decrease in size of tumor or tumor spread; **AND**
	• Patient does not have unacceptable toxicity (e.g., hepatotoxicity, central nervous system effects [e.g., cognitive impairment, mood disorders, dizziness, sleep disturbances], hyperuricemia, skeletal fractures, creatine phosphokinase elevation, interstitial lung disease/pneumonitis)
		8/day	General PA Form

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**

Fabhalta®	**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 symptoms of PNH (e.g., anemia, extreme fatigue, difficulty swallowing, recurrent abdominal pain, smooth muscle dystonia, thromboses, chronic kidney disease, organ damage secondary to chronic hemolysis); **AND**
	• Prescriber is enrolled in the Fabhalta 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. improvement in signs and symptoms of the disease); **AND**
	• Patient does not have unacceptable toxicity (e.g., serious infections, hyperlipidemia)
		2/day	General PA Form

Fruzaqla®	**Initial Criteria**
	• Diagnosis of metastatic colorectal cancer; **AND**
	• Patient has tried and failed, contraindication, or intolerance to ALL of the following chemotherapy based regimens:
	  ○ Fluoropyrimidine,
	  ○ Oxaliplatin
	  ○ Irinotecan
	  ○ Anti- vascular endothelial growth factor (VEGF) therapy (e.g bevacizumab); **AND**
	• If RAS wild-type, patient has tried and failed, contraindication, or intolerance to anti-epidermal growth factor receptor (EGFR) therapy (e.g., cetuximab, panitumumab); **AND**
	• Prescribed by or in consultation with an oncologist
	Reauth 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 does not have unacceptable toxicity (e.g., hypertension, hemorrhagic events)
		5 mg- 21/28 days
		
		1 mg- 84/28 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
Ogsiveo®	**Initial Criteria** • Diagnosis of Desmoid tumor (Aggressive fibromatosis); **AND** • Disease is progressing according to Response Evaluation Criteria in Solid Tumors (RECIST); **AND** • Prescriber has reviewed and evaluated appropriate treatment options and attests that the patient requires systemic therapy; **AND** • Prescribed by, or in consultation with, an oncology, hematology, or gastroenterology specialist **Renewal criteria** • Patient demonstrates disease stabilization or positive clinical response to therapy (e.g., decrease tumor size, decreased pain, improved physical function, increased quality of life)	6/day	General PA Form

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**

Opfolda®	• Patient is ≥ 18 years old; **AND**
	• Patient weighs at least 40 kg; **AND**
	• Diagnosis of late-onset Pompe disease confirmed by ONE of the following:
	  ○ Documentation demonstrating deficiency of acid alpha-glucosidase (GAA) enzyme activity
	  ○ Molecular genetic test demonstrating pathogenic variants in GAA; **AND**
	• Prescriber attest patient did not have clinical improvement on enzyme replacement therapy alglucosidase or avalglucosidase alfa-ngpt; **AND**
	• Must be used in combination with Pombiliti (cipaglucosidase alfa-atga); **AND**
	• Prescribed by, or in consultation with, a neurologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders
		8 capsules per 28 days	General PA Form

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

Truqap®	**Initial Criteria**
	• Patient has hormone receptor-positive, HER2-negative locally advanced or metastatic breast cancer; **AND**
	• Patient has one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test; **AND**
	• Patient has experienced disease progression on after an endocrine based regimen for advanced disease OR has relapsed disease within 12 months after completion of adjuvant endocrine therapy; **AND**
	• Agent is being given in combination with fulvestrant; **AND**
	• Agent is prescribed by, or in consultation with, an oncologist; **AND**
	• Patient does not have clinically significant abnormalities of glucose metabolism defined by ONE of the following:
	  ○ Diabetes Type 1 or 2 requiring insulin treatment
	  ○ HbA1c ≥8%
	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 does not have unacceptable toxicity (e.g., hyperglycemia, diarrhea, cutaneous adverse reactions)
		64 tablets per 28 days	General PA Form

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**

Veopoz®	**Initial Criteria:**
	• Diagnosis of CD55-deficient protein-losing enteropathy (CHAPLE disease); **AND**
	• Patient has documentation of genetic testing confirming biallelic CD55 loss-of-function mutation; **AND**
	• Prescriber attest to ALL of the following:
	  ○ Patient has received Veopoz IV loading dose;
	  ○ Patient has completed or updated meningococcal vaccination at least 2 weeks prior to administering the first dose of Veopoz unless the risk of delaying therapy outweighs the risk; **AND**
	• Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease management (e.g., geneticist, gastroenterologist, hematologist)
	Renewal Criteria:
	• Patient has positive clinical response to therapy (e.g normalization of serum albumin, decreased abdominal pain, diarrhea, facial edema, and peripheral edema)
		8 vials per 28 days	General PA Form

Xdemvy®	**Approval duration 2 months** • Diagnosis of Demodex blepharitis; **AND** • Patient has collarettes, cylindrical deposits at the base of eyelashes, confirmed by slit lamp examination; **AND** • Prescribed by or in consultation with an ophthalmologist or optometrist;	10 mL (1 bottle)/ 50 days	General PA Form
Xphozah®	• Patient is 18 years of age or older; **AND** • Diagnosis of chronic kidney disease (CKD); **AND** • Patient is currently on dialysis; **AND** • Trial and failure, contraindication, or intolerance of TWO preferred agents; **AND** • Agent will be used as adjunctive therapy to reduce serum phosphorus; **AND** • Patient does not have known or suspected mechanical gastrointestinal obstruction	2/day	General PA Form

Zilbrysq®	**Initial Criteria (6- month duration)**
	• Diagnosis of generalized myasthenia gravis (gMG); **AND**
	• Documented positive serology for acetylcholine receptor (AChR) autoantibodies; **AND**
	• Patient has a baseline MG-Activities of Daily Living (MG-ADL) total score of ≥6; **AND**
	• Patient has tried and failed, or has contraindication, or intolerance to TWO of the following:
	  ○ Corticosteroids
	  ○ Azathioprine
	  ○ Cyclosporine
	  ○ mycophenolate mofetil
	  ○ methotrexate
	  ○ tacrolimus; **AND**
	• Prescribed by, or in consultation with, a neurologist or neuromuscular specialist; **AND**
	• Prescriber is enrolled in the Zilbrysq REMS Program; **AND**
	• Patient has not failed a previous course of Zilbrysq, Ultomiris, or Soliris therapy; **AND**
	• Patient is not receiving Zilbrysq in combination with another complement inhibitor used for the treatment of gMG (e.g., Soliris, Ultomiris)
	Reauth Criteria
	• Submission of medical records (e.g., chart notes) documenting a positive clinical response to therapy (e.g. reduction in MG-ADL score or improvement in talking, chewing, swallowing, breathing, double vision, eyelid drop, movement)
		1/day	General PA Form

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**

Zoryve® Foam	**Initial Criteria (3-month duration)**
	• Diagnosis of seborrheic dermatitis; **AND**
	• Patient is 9 years of age or older; **AND**
	• Patient does not have moderate to severe liver impairment (Child-Pugh B or C); **AND**
	• Trial and failure, contraindication, or intolerance to BOTH of the following agents:
	  ○ topical antifungals (ketoconazole, ciclopirox, miconazole, clotrimazole)
	  ○ topical corticosteroids
	Renewal Criteria
	• Patient continues to be monitored for liver impairment; **AND**
	• Documented clinical improvement in response to treatment (e.g., decreased erythema, scaling, inflammation, size of patches); **AND**
	• Patient does not have any treatment limiting adverse effects
		60 grams per 30 days	General PA Form

Zurzuvae®	**Approval duration 3 months**
	• Patient is 18 years of age or older; **AND**
	• Diagnosis of postpartum depression (PPD); **AND**
	• Patient's symptoms began in the third trimester or within 4 weeks of delivery; **AND**
	• Prescriber attests that the PPD requires rapid improvement and resolution of symptoms; **AND**
	• Prescribed by, or in consultation with, a psychiatrist, psychologist, or an obstetrician-gynecologist; **AND**
	• The prescriber attests to ALL of the following:
	  ○ Patient has been advised not to drive or operate machinery until at least 12 hours after administration due central nervous system (CNS) depressant effects such as somnolence and confusion
	  ○ Females of reproductive potential should be advised to use effective contraception during treatment and for 1 week after the final dose due to potential risk to fetus and to notify healthcare provider if they become pregnant during treatment
		1 treatment course/ year	General PA Form