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

## Interim Criteria for Agents Awaiting PAC Review

**May 1, 2024**

| Interim Criteria for Agents Awaiting PAC Review<br>*Approval of NP agents requires trial and failure, contraindication or intolerance of 2 preferred agents, unless otherwise indicated.* | | | |
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| **Medication** | **Prior Authorization Criteria** | **Quantity Limit** | **PA Form** |
| Agamree® | **Initial Criteria:**<br>• Documentation of a confirmed diagnosis of Duchenne muscular dystrophy (DMD); **AND**<br>• Patient is 2 years of age or older; **AND**<br>• Patient retains meaningful voluntary motor function (e.g., patient can speak, manipulate objects using upper extremities, ambulate, etc.); **AND**<br>• Patient has experienced at least ONE of the following unacceptable adverse reactions directly attributable to previous therapy with prednisone:<br>  ○ Patient has experienced significant weight gain (e.g., crossing 2 percentile lines and/or reaching 98th percentile for age and sex)<br>  ○ Patient has manifested significant behavioral changes negatively impacting function at school, home, day care, etc.; **AND**<br>• Patient has tried and failed, contraindication, or intolerance to Emflaza<br>**Renewal Criteria:**<br>• Patient retains meaningful voluntary motor function (e.g., patient can speak, manipulate objects using upper extremities, ambulate, etc.); **AND**<br>• Patient has received benefit from therapy, which may include ONE or more of the following:<br>  ○ Stability or slowing of decline in motor function or respiratory function<br>  ○ 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)**<br>• Diagnosis of locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC); **AND**<br>• Disease is positive for ROS1 gene fusions; **AND**<br>• Patient have received at least one prior therapy; **AND**<br>• Prescribed by, or in consultation with, an oncologist; **AND**<br>• For patients with reproductive potential, prescriber attest to all of the following:<br>  ○ Patient is not pregnant prior to initiation of therapy<br>  ○ Females patients have been advised to use effective contraception during treatment and for 2 months after the final dose<br>  ○ Female patients have been advised to not breastfeed during treatment and 10 days after the final dose<br>  ○ 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<br>**Renewal Criteria**<br>• Patient must continue to meet the initial criteria; **AND**<br>• Patient has positive disease response defined as disease stabilization or decrease in size of tumor or tumor spread; **AND**<br>• 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 |

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| Fabhalta® | **Initial Criteria (6-month duration)**<br>• Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH); **AND**<br>• Diagnosis confirmed by peripheral blood flow cytometry diagnostic testing showing the absence or deficiency of glycosylphosphatidylinositol-anchored proteins; **AND**<br>• Patient has symptoms of PNH (e.g., anemia, extreme fatigue, difficulty swallowing, recurrent abdominal pain, smooth muscle dystonia, thrombosis, chronic kidney disease, organ damage secondary to chronic hemolysis); **AND**<br>• Prescriber is enrolled in the Fabhalta REMS Program; **AND**<br>• Prescribed by, or in consultation with, one of the following:<br>  ○ Hematologist<br>  ○ Oncologist<br>**Renewal Criteria**<br>• 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**<br>• Patient does not have unacceptable toxicity (e.g., serious infections, hyperlipidemia) | 2/day | General PA Form |
| Fruzaqla® | **Initial Criteria**<br>• Diagnosis of metastatic colorectal cancer; **AND**<br>• Patient has tried and failed, contraindication, or intolerance to ALL of the following chemotherapy based regimens:<br>  ○ Fluoropyrimidine,<br>  ○ Oxaliplatin<br>  ○ Irinotecan<br>  ○ Anti- vascular endothelial growth factor (VEGF) therapy (e.g bevacizumab ); **AND**<br>• 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**<br>• Prescribed by or in consultation with an oncologist<br>**Reauth Criteria**<br>• Patient continues to meet initial criteria; **AND**<br>• Patient has positive disease response defined as disease stabilization or decrease in size of tumor or tumor spread; **AND**<br>• Patient does not have unacceptable toxicity (e.g., hypertension, hemorrhagic events) | 5 mg- 21/28 days<br><br>1 mg- 84/28 days | General PA Form |
| Iwilfin® | **Initial Criteria**<br>• Diagnosis of high-risk neuroblastoma (HRNB); **AND**<br>• Patient had a partial response to prior multiagent, multimodality therapy; **AND**<br>• Patient has received anti-GD2 immunotherapy (e.g., dinutuximab); **AND**<br>• Prescribed by or in consultation with an oncologist<br>**Renewal Criteria**<br>• Patient continues to meet initial criteria; **AND**<br>• Patient has positive disease response defined as disease stabilization or decrease in size of tumor or tumor spread; **AND**<br>• Patient is absent of unacceptable toxicity from the medication (e.g., hepatotoxicity, hearing loss) | | General PA Form |
| Ogsiveo® | **Initial Criteria**<br>• Diagnosis of Desmoid tumor (Aggressive fibromatosis); **AND**<br>• Disease is progressing according to Response Evaluation Criteria in Solid Tumors (RECIST); **AND**<br>• Prescriber has reviewed and evaluated appropriate treatment options and attests that the patient requires systemic therapy; **AND**<br>• Prescribed by, or in consultation with, an oncology, hematology, or gastroenterology specialist<br>**Renewal criteria**<br>• 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 |

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| Opfolda® | • Patient is ≥ 18 years old; **AND**<br>• Patient weighs at least 40 kg; **AND**<br>• Diagnosis of late-onset Pompe disease confirmed by ONE of the following:<br>  ○ Documentation demonstrating deficiency of acid alpha-glucosidase (GAA) enzyme activity<br>  ○ Molecular genetic test demonstrating pathogenic variants in GAA; **AND**<br>• Prescriber attest patient did not have clinical improvement on enzyme replacement therapy alglucosidase or avalglucosidase alfa-ngpt; **AND**<br>• Must be used in combination with Pombiliti (cipaglucosidase alfa-atga); **AND**<br>• 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)**<br>• Patient is 9 years of age or older; **AND**<br>• Patient has diagnosis of primary hyperoxaluria type 1 (PH1); **AND**<br>• Documentation of ONE of the following:<br>  ○ Genetic testing demonstrating a mutation alanine-glyoxylate aminotransferase (AGXT) gene<br>  ○ Liver biopsy demonstrating absence or reduced alanine: glyoxylate aminotransferase (AGT) activity; **AND**<br>• Patient has relatively preserved kidney function (e.g., eGFR ≥ 30 mL/min/1.73 $m^2$); **AND**<br>• Trial and failure, contraindication, or intolerance to pyridoxine (vitamin B-6); **AND**<br>• Prescribed by, or in consultation with, a hematologist, nephrologist, urologist or geneticist<br>**Renewal Criteria**<br>• 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**<br>• Patient has hormone receptor-positive, HER2-negative locally advanced or metastatic breast cancer; **AND**<br>• Patient has one or more PIK3CA/AKT1/PTEN-alterations as detected by an FDA-approved test; **AND**<br>• 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**<br>• Agent is being given in combination with fulvestrant; **AND**<br>• Agent is prescribed by, or in consultation with, an oncologist; **AND**<br>• Patient does not have clinically significant abnormalities of glucose metabolism defined by ONE of the following:<br>  ○ Diabetes Type 1 or 2 requiring insulin treatment<br>  ○ HbA1c ≥8%<br>**Renewal criteria**<br>• Patient continues to meet initial criteria; **AND**<br>• Patient has positive disease response defined as disease stabilization or decrease in size of tumor or tumor spread; **AND**<br>• Patient does not have unacceptable toxicity (e.g., hyperglycemia, diarrhea, cutaneous adverse reactions) | 64 tablets per 28 days | General PA Form |

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| Veopoz® | **Initial Criteria:**<br>• Diagnosis of CD55-deficient protein-losing enteropathy (CHAPLE disease); **AND**<br>• Patient has documentation of genetic testing confirming biallelic CD55 loss-of-function mutation; **AND**<br>• Prescriber attest to ALL of the following:<br>  ○ Patient has received Veopoz IV loading dose;<br>  ○ 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**<br>• Prescribed by or in consultation with a clinical specialist knowledgeable in appropriate disease management (e.g., geneticist, gastroenterologist, hematologist)<br>**Renewal Criteria:**<br>• 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 |
| Wegovy® | **Initial Criteria**<br>• Treatment is being requested to reduce the risk of major adverse cardiovascular events; **AND**<br>• Patient is 21 years of age or older; **AND**<br>• Submitted medical documentation (e.g. chart notes) of initial body mass index (BMI) of ≥ 27 kg/m2; **AND**<br>• Submitted medical documentation (e.g. chart notes) of ONE of the following:<br>  ○ Prior myocardial infarction<br>  ○ Prior stroke (ischemic and hemorrhagic stroke)<br>  ○ 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**<br>• Submitted documentation HbA1C ≤ 6.5%; **AND**<br>• Prescriber attests patient is participating in a supervised comprehensive weight management program that encourages behavioral modification, reduced calorie diet, and increased physical activity; **AND**<br>• Patient does not have any of the following:<br>  ○ Diagnosis of type 1 or type 2 diabetes<br>  ○ New York Heart Association class IV heart failure;<br>  ○ Personal or family history of medullary thyroid carcinoma (MTC) OR Multiple Endocrine Neoplasia syndrome type 2 (MEN 2);<br>  ○ History or presence of chronic pancreatitis<br>  ○ End-stage renal disease or currently receiving dialysis; **AND**<br>• For female patients of reproductive potential, the following has been addressed:<br>  ○ Patient is not pregnant or breastfeeding<br>  ○ Patient has been counseled to use highly effective contraceptive method during treatment; **AND**<br>• Medication is not being co-administered with another GLP-1 receptor agonists (e.g. Byetta, Ozempic, and Victoza)<br>**Renewal Criteria**<br>• Patient continues to meet initial criteria; **AND**<br>• 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**<br>• Patient must not have any contraindications or serious adverse effects (e.g., acute gallbladder disease, acute kidney injury, acute pancreatitis);<br>**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 |

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| Xdemvy® | **Approval duration 2 months**<br>• Diagnosis of Demodex blepharitis; **AND**<br>• Patient has collarettes, cylindrical deposits at the base of eyelashes, confirmed by slit lamp examination; **AND**<br>• 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**<br>• Diagnosis of chronic kidney disease (CKD); **AND**<br>• Patient is currently on dialysis; **AND**<br>• Trial and failure, contraindication, or intolerance of TWO preferred agents; **AND**<br>• Agent will be used as adjunctive therapy to reduce serum phosphorus; **AND**<br>• Patient does not have known or suspected mechanical gastrointestinal obstruction | 2/day | General PA Form |
| Zilbrysq® | **Initial Criteria (6- month duration)**<br>• Diagnosis of generalized myasthenia gravis (gMG); **AND**<br>• Documented positive serology for acetylcholine receptor (AChR) autoantibodies; **AND**<br>• Patient has a baseline MG-Activities of Daily Living (MG-ADL) total score of ≥6; **AND**<br>• Patient has tried and failed, or has contraindication, or intolerance to TWO of the following:<br>  ○ Corticosteroids<br>  ○ Azathioprine<br>  ○ Cyclosporine<br>  ○ mycophenolate mofetil<br>  ○ methotrexate<br>  ○ tacrolimus; **AND**<br>• Prescribed by, or in consultation with, a neurologist or neuromuscular specialist; **AND**<br>• Prescriber is enrolled in the Zilbrysq REMS Program; **AND**<br>• Patient has not failed a previous course of Zilbrysq, Ultomiris, or Soliris therapy; **AND**<br>• Patient is not receiving Zilbrysq in combination with another complement inhibitor used for the treatment of gMG (e.g., Soliris, Ultomiris)<br>**Reauth Criteria**<br>• 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 |
| Zoryve® Foam | **Initial Criteria (3-month duration)**<br>• Diagnosis of seborrheic dermatitis; **AND**<br>• Patient is 9 years of age or older; **AND**<br>• Patient does not have moderate to severe liver impairment (Child-Pugh B or C); **AND**<br>• Trial and failure, contraindication, or intolerance to BOTH of the following agents:<br>  ○ topical antifungals (ketoconazole, ciclopirox, miconazole, clotrimazole)<br>  ○ topical corticosteroids<br>**Renewal Criteria**<br>• Patient continues to be monitored for liver impairment; **AND**<br>• Documented clinical improvement in response to treatment (e.g., decreased erythema, scaling, inflammation, size of patches); **AND**<br>• Patient does not have any treatment limiting adverse effects | 60 grams per 30 days | General PA Form |

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| Zurzuvae® | **Approval duration 3 months**<br>• Patient is 18 years of age or older; **AND**<br>• Diagnosis of postpartum depression (PPD); **AND**<br>• Patient's symptoms began in the third trimester or within 4 weeks of delivery; **AND**<br>• Prescriber attests that the PPD requires rapid improvement and resolution of symptoms; **AND**<br>• Prescribed by, or in consultation with, a psychiatrist, psychologist, or an obstetrician-gynecologist; **AND**<br>• The prescriber attests to ALL of the following:<br>  ○ 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<br>  ○ 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 |