

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

## Interim Criteria for Agents Awaiting PAC Review

February 1, 2026

### Abbreviations:

B	Budgetary Reduction edit for utilization control	Caps	Capsules
I/DD	Intellectual and Developmental Disabilities (I/DD)	Conc	Concentrate
NP	Non-Preferred Agent	Cr	Cream
P	Preferred Agent	Oint	Ointment
PA	Prior Authorization	Soln	Solution
PAC	Pharmacy Advisory Committee	Susp	Suspension
PDL	Preferred Drug List	Tabs	Tablets
QL	Quantity Limit		

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Medication	Prior Authorization Criteria	Quantity Limit
Hernexeos®	<p><b>Initial Criteria:</b></p> <ul style="list-style-type: none"><li>• Diagnosis of unresectable or metastatic non-squamous non-small cell lung cancer (NCSLC); <b>AND</b></li><li>• Patient is positive for HER2 (ERBB2) tyrosine kinase domain activating mutations; <b>AND</b></li><li>• Patient is 18 years of age or older; <b>AND</b></li><li>• Patient has documented disease progression on at least one prior systemic therapy (e.g., platinum and Carboplatin based chemotherapy); <b>AND</b></li><li>• Prescribed by, or in consultation with an oncologist</li></ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"><li>• Patient continues to meet initial criteria; <b>AND</b></li><li>• Patient has positive disease response defined as disease stabilization or decrease in size of tumor or tumor spread; <b>AND</b></li><li>• Patient does not have unacceptable toxicity (e.g., hepatotoxicity, left ventricular dysfunction, interstitial lung disease/pneumonitis)</li></ul>	
Ibtrozi®	<p><b>Initial Criteria:</b></p> <ul style="list-style-type: none"><li>• Diagnosis of locally advanced or metastatic non-small cell lung cancer; <b>AND</b></li><li>• ROS1-positive mutation present; <b>AND</b></li><li>• Prescribed by, or in consultation with, an oncologist</li></ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"><li>• Patient continues to meet initial criteria; <b>AND</b></li><li>• Patient does not show evidence of progressive disease or unacceptable toxicity (e.g., hepatotoxicity, interstitial lung disease, QTc interval prolongation, etc.)</li></ul>	3 capsules/day

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Brinsupri®	<p><b>Initial Criteria:</b></p> <ul style="list-style-type: none"> <li>Diagnosis of non-cystic fibrosis bronchiectasis (NCFB); <b>AND</b></li> <li>Diagnosis has been confirmed by a documented computed tomography (CT) scan; <b>AND</b></li> <li>Prescribed by, or in consultation with, a pulmonologist or infectious disease specialist; <b>AND</b></li> <li>One of the following: <ul style="list-style-type: none"> <li>Patient is 12 to 17 years of age with at least one documented pulmonary exacerbation in the past 12 months requiring systemic antibiotic therapy; <b>OR</b></li> <li>Patient is 18 years of age or older with at least two documented pulmonary exacerbations in the past 12 months requiring systemic antibiotic therapy;</li> </ul> </li> </ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"> <li>Patient demonstrates positive clinical response to therapy (e.g., stabilization or reduction in number of pulmonary exacerbations, reduced cough or sputum)</li> </ul>	1 tablet/day
Wayrilz®	<p><b>Initial Criteria:</b></p> <ul style="list-style-type: none"> <li>Patient is <math>\geq</math> 18 years old; <b>AND</b></li> <li>Patient has a diagnosis of chronic OR persistent immune thrombocytopenia; <b>AND</b></li> <li>Trial and failure (platelet count <math>\geq</math> 50 x 109/L not achieved) of ONE of the following: <ul style="list-style-type: none"> <li>Corticosteroids</li> <li>Thrombopoietin receptor antagonists (e.g., Promacta)</li> <li>Splenectomy</li> <li>Azathioprine (Azasan, Imuran), cyclosporine (Neoral, Sandimmune), cyclophosphamide (Cytoxan), mycophenolate mofetil (CellCept), danazol, or rituximab (Rituxan); <b>AND</b></li> </ul> </li> <li>Patient is not on concomitant therapy with a strong CYP3A4 inducer; <b>AND</b></li> <li>Females must use effective contraception due to embryo-fetal toxicity; <b>AND</b></li> <li>Prescribed by, or in consultation with, a hematologist; <b>AND</b></li> <li>Patient has received a baseline and will receive ongoing routine monitoring that includes: <ul style="list-style-type: none"> <li>Neutropenia (measure ANC monthly)</li> <li>Hepatotoxicity (measure LFTs monthly)</li> </ul> </li> </ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"> <li>Patient has laboratory values documenting platelet response to therapy (platelet count <math>\geq</math> 50 x 109/L); <b>AND</b></li> <li>Patient has not experienced severe adverse effect as a result of Wayrilz® therapy</li> </ul>	2/day
Bluejepa®	<ul style="list-style-type: none"> <li>Diagnosis of uncomplicated urinary tract infection (uUTI); <b>AND</b></li> <li>Patient is 12 years of age or older and weighs at least 40 kg; <b>AND</b></li> <li>Infection has been confirmed to have been caused by one of the following: <ul style="list-style-type: none"> <li><i>Escherichia coli</i></li> <li><i>Klebsiella pneumoniae</i></li> <li><i>Citrobacter freundii complex</i></li> <li><i>Staphylococcus saprophyticus</i></li> <li><i>Enterococcus faecalis</i>; <b>AND</b></li> </ul> </li> <li>Trial and failure, contraindication, intolerance, or resistance to at least 2 of the following agents: <ul style="list-style-type: none"> <li>Sulfamethoxazole/trimethoprim</li> <li>Quinolones</li> <li>Nitrofurantoin; <b>AND</b></li> </ul> </li> <li>Prescribed by, or in consultation with, an infectious disease specialist</li> </ul>	20 tabs/30 days
Modeyso®	<p><b>Initial Criteria:</b></p> <ul style="list-style-type: none"> <li>Diagnosis of diffuse midline glioma; <b>AND</b></li> <li>Patient is positive for H3 K27M mutation; <b>AND</b></li> <li>Patient has progressed on at least one prior therapy (e.g., radiation therapy)</li> <li>Prescribed by, or in consultation with, an oncologist</li> </ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"> <li>Patient continues to meet initial criteria; <b>AND</b></li> <li>Patient has positive disease response defined as disease stabilization or decrease in size of tumor or tumor spread; <b>AND</b></li> <li>Patient does not have unacceptable toxicity (e.g., QT prolongation, Torsades de pointes, polymorphic ventricular tachycardia, confusional state)</li> </ul>	20 caps/28 days

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Medication	Prior Authorization Criteria	Quantity Limit
Harliku®	<p><b>Initial Criteria:</b></p> <ul style="list-style-type: none"><li>• Diagnosis of alkaptonuria (AKU); <b>AND</b></li><li>• Used for the reduction of urine homogentisic acid; <b>AND</b></li><li>• Disease is confirmed by ONE of the following:<ul style="list-style-type: none"><li>○ Presence of a mutation in the homogentisate 1,2-dioxygenase (HGD) gene as detected by an FDA-approved test</li><li>○ Presence of elevated homogentisic acid (HGA) levels in urine greater than 0.4 g/24h; <b>AND</b></li></ul></li><li>• Prescribed by or in consultation with a specialist (i.e., someone experienced with treatment of inborn errors of metabolism, rheumatologist)</li></ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"><li>• Patient demonstrates positive clinical response to therapy (e.g., reduced levels of urinary HGA)</li></ul>	1 tab/day
Orlynvah®	<ul style="list-style-type: none"><li>• Diagnosis of uncomplicated urinary tract infection (uUTI); <b>AND</b></li><li>• Patient is 18 years of age or older; <b>AND</b></li><li>• Infection has been confirmed to have been caused by one of the following:<ul style="list-style-type: none"><li>○ <i>Escherichia coli</i></li><li>○ <i>Klebsiella pneumoniae</i></li><li>○ <i>Proteus mirabilis</i>; <b>AND</b></li></ul></li><li>• Trial and failure, contraindication, intolerance, or resistance to at least 2 of the following agents:<ul style="list-style-type: none"><li>○ Sulfamethoxazole/trimethoprim</li><li>○ Quinolones</li><li>○ Nitrofurantoin; <b>AND</b></li></ul></li><li>• Prescribed by, or in consultation with, an infectious disease specialist</li></ul> <p><b>NOTE:</b> Reserve use for infections caused by drug-resistant pathogens with limited treatment options.</p>	10 tabs/course of therapy

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Medication	Prior Authorization Criteria	Quantity Limit
Wegovy® tablets	<p><b>CV Risk Reduction due to prior MI, prior stroke, or PAD</b></p> <p><b>Initial Criteria (1yr duration)</b></p> <ul style="list-style-type: none"> <li>• Treatment is being requested to reduce the risk of major adverse cardiovascular events; <b>AND</b></li> <li>• Patient must be 18 years of age or older meet labeled age minimum; <b>AND</b></li> <li>• Submitted medical documentation (e.g. chart notes) of initial BMI <math>\geq 27 \text{ kg/m}^2</math>; <b>AND</b></li> <li>• Submitted medical documentation (e.g. chart notes) of ONE of the following: <ul style="list-style-type: none"> <li>◦ Prior myocardial infarction</li> <li>◦ Prior stroke (ischemic and hemorrhagic stroke)</li> <li>◦ Symptomatic peripheral arterial disease as evidenced by intermittent claudication with ankle-brachial index <math>&lt; 0.85</math>, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease; <b>AND</b></li> </ul> </li> <li>• Patient is on optimized guideline-directed therapy including beta-blockers, RAS inhibitors, and lipid lowering agents to ensure reduced cardiovascular risk unless contraindicated (supported by medical documentation or claims history); <b>AND</b></li> <li>• Prescriber attests patient is participating in complementary nutritional and lifestyle changes (e.g. dietary modification, increased physical activity as medically able, structured behavioral intervention, comprehensive weight management); <b>AND</b></li> <li>• Will not be used concomitantly with DPP-4 inhibitors; <b>AND</b></li> <li>• Will not be co-administered with another GLP-1 receptor agonists; <b>AND</b></li> <li>• Submission of medical records (i.e. chart notes) providing a clinically valid reason why patient can't use Wegovy injectable (NOTE: Patient convenience, mild injection site reactions, or needle phobia is NOT an approvable reason. Patient must have contraindication to the excipients in the injectable Wegovy product.)</li> </ul> <p><b>Renewal Criteria (1 year duration)</b></p> <ul style="list-style-type: none"> <li>• 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); <b>AND</b></li> <li>• One of the following: <ul style="list-style-type: none"> <li>◦ Patient is currently on the 25mg once daily maintenance dose; <b>OR</b></li> <li>◦ Submission of medical records (i.e. chart notes) demonstrating a positive clinical response (e.g. decrease in body weight, blood pressure, heart rate, etc.) with no adverse effects (e.g. nausea, diarrhea, constipation, hypoglycemia, acute pancreatitis/gallbladder disease, etc.) at a lower maintenance dose; <b>AND</b></li> </ul> </li> <li>• Prescriber attests patient is participating in complementary nutritional and lifestyle changes (e.g. dietary modification, increased physical activity as medically able, structured behavioral intervention, comprehensive weight management); <b>AND</b></li> <li>• Will not be used concomitantly with DPP-4 inhibitors; <b>AND</b></li> <li>• Will not being co-administered with another GLP-1 receptor agonists (e.g. Byetta, Ozempic, Victoza); <b>AND</b></li> <li>• Patient is on optimized guideline-directed therapy including beta-blockers, RAS inhibitors, and lipid lowering agents to ensure reduced cardiovascular risk unless contraindicated (supported by medical documentation or claims history)</li> </ul> <p><b>Note:</b> Patients not meeting the above renewal criteria may be approved for up to one month to allow for titration off medication.</p> <p><i>Continued below.</i></p>	1 tablet/day

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Medication	Prior Authorization Criteria	Quantity Limit
Wegovy® tablets	<p><b>Weight Management</b></p> <p><b>Initial Criteria: (1-year duration)</b></p> <ul style="list-style-type: none"> <li>• Patient must be 18yrs of age or older; <b>AND</b></li> <li>• Treatment is for the management of obesity; <b>AND</b></li> <li>• One of the following: <ul style="list-style-type: none"> <li>– Submission of medical records (e.g. chart notes) documenting a body mass index (BMI) <math>\geq 30</math> kg/m<sup>2</sup>; <b>OR</b></li> <li>– Submission of medical records (e.g. chart notes) documenting a BMI of greater than 27 kg/m<sup>2</sup> with a weight related comorbidity (e.g. hypertension, dyslipidemia, diabetes, coronary heart disease, MASH/NASH, obstructive sleep apnea); <b>AND</b></li> </ul> </li> <li>• Trial and failure, or contraindication, or intolerance to 2 preferred GLP-1 agonist weight management agents (e.g., appetite and absorption agents, neurobehavioral appetite modulators) and ; <b>AND</b></li> <li>• Prescriber attests patient is participating in complementary nutritional and lifestyle changes (e.g., dietary modification, increased physical activity as medically able, structured behavioral intervention, comprehensive weight management program); <b>AND</b></li> <li>• Medication will not be used in combination with other medications FDA approved for obesity/weight loss; <b>AND</b></li> <li>• Will not be co-administered with another GLP-1 receptor agonist; <b>AND</b></li> <li>• Patient does not have personal or immediate family history of medullary thyroid carcinoma or multiple endocrine neoplasia type 2 (MEN2); <b>AND</b></li> <li>• Trial and failure of 2 preferred GLP-1 agonist weight management agents; <b>AND</b></li> <li>• Submission of medical records (i.e. chart notes) providing a clinically valid reason why patient can't use Wegovy injectable (NOTE: Patient convenience, mild injection site reactions, or needle phobia is NOT an approvable reason. Patient must have contraindication to the excipients in the injectable Wegovy product.)</li> </ul> <p><b>Renewal Criteria:</b></p> <ul style="list-style-type: none"> <li>• Patient has continued participating in complementary nutritional and lifestyle changes (e.g., dietary modification, increased physical activity as medically able, structured behavioral intervention, comprehensive weight management program); <b>AND</b></li> <li>• One of the following: <ul style="list-style-type: none"> <li>○ Patient is currently on the 25mg once daily maintenance dose; <b>OR</b></li> <li>○ Submission of medical records (i.e., chart notes) demonstrating a positive clinical response (e.g., decrease in body weight, blood pressure, heart rate, etc.) with no adverse effects (e.g., nausea, diarrhea, constipation, hypoglycemia, acute pancreatitis/gallbladder disease, etc.) at a lower maintenance dose; <b>AND</b></li> </ul> </li> <li>• Medication will not be used in combination with other medications for obesity/weight loss; <b>AND</b></li> <li>• Submission of medical records (e.g., chart notes) documenting a weight loss of <math>\geq 5\%</math> of baseline body weight</li> </ul> <p><b>Note:</b> Patients not meeting the above renewal criteria may be approved for up to one month to allow for titration off medication.</p>	1 tablet/day