



Empaveli Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date

12-15-2025

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Empaveli	pegcetacoplan subcutaneous soln	1080 MG/20ML	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Empaveli	pegcetacoplan subcutaneous soln	1080 MG/20ML	8	Vials	28	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Empaveli	pegcetacoplan subcutaneous soln	1080 MG/20ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Empaveli	pegcetacoplan subcutaneous soln	1080 MG/20ML	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) AND ALL of the following: <ol style="list-style-type: none"> 1. The diagnosis was confirmed by flow cytometry with at least 2 independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient’s peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (lab tests required) AND 2. The patient will NOT be using the requested agent in combination with Soliris (eculizumab), Bkempv (eculizumab-aeeb), or Epysqli (eculizumab-aagh) (NOTE: if the patient is switching from Soliris, Bkempv, or Epysqli then Soliris, Bkempv, or Epysqli should be continued for the first 4 weeks after starting the requested agent and then Soliris, Bkempv, or Epysqli should be discontinued) AND 3. The patient will NOT be using the requested agent in combination with Fabhalta (iptacopan), Ultomiris (ravulizumab-cwvz), or Piasky (crovalimab-akkz) OR B. The patient has a diagnosis of complement 3 glomerulopathy (C3G) confirmed by kidney biopsy AND ONE of the following: <ol style="list-style-type: none"> 1. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR 2. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used

Module	Clinical Criteria for Approval
	<p style="text-align: center;">to treat an associated condition related to stage four advanced metastatic cancer [chart notes required] AND</p> <p>B. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR</p> <p>2. ALL of the following:</p> <p>A. ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient has a urine protein-to-creatinine ratio (UPCR) greater than 0.88 g/g OR 2. The patient has proteinuria greater than 1.0 g/day AND <p>B. The patient's eGFR is greater than or equal to 30 mL/min/1.73 m² AND</p> <p>C. ONE of the following:</p> <ol style="list-style-type: none"> 1. BOTH of the following: <ol style="list-style-type: none"> A. The patient is currently treated with a maximally tolerated angiotensin-converting-enzyme inhibitor (ACEi, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an ACEi or ARB for at least a 90-day duration of therapy AND B. The patient will continue maximally tolerated ACEi, or ARB, or a combination medication containing an ACEi or ARB therapy in combination with the requested agent OR 2. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL ACEi, ARB, and combination medications containing an ACEi or ARB AND <p>D. The patient will NOT be using the requested agent in combination with Fabhalta (iptacopan) OR</p> <p>C. The patient has a diagnosis of Immune-complex membranoproliferative glomerulonephritis (IC-MPGN) confirmed by kidney biopsy AND ALL of the following:</p> <ol style="list-style-type: none"> 1. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR 2. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes required] AND B. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR 2. ALL of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The patient has a urine protein-to-creatinine ratio (UPCR) greater than 0.88 g/g OR 2. The patient has proteinuria greater than 1.0 g/day AND B. The patient's eGFR is greater than or equal to 30 mL/min/1.73 m² AND C. ONE of the following: <ol style="list-style-type: none"> 1. BOTH of the following: <ol style="list-style-type: none"> A. The patient is currently treated with a maximally tolerated angiotensin-converting-enzyme

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	<p style="text-align: right;">inhibitor (ACEi, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an ACEi or ARB for at least a 90-day duration of therapy AND</p> <p style="padding-left: 40px;">B. The patient will continue maximally tolerated ACEi, or ARB, or a combination medication containing an ACEi or ARB therapy in combination with the requested agent OR</p> <p style="padding-left: 20px;">2. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL ACEi, ARB, and combination medications containing an ACEi or ARB OR</p> <p style="padding-left: 40px;">D. The patient has another FDA labeled indication for the requested agent and route of administration AND</p> <p>2. If the patient has an FDA labeled indication, then ONE of the following:</p> <p style="padding-left: 20px;">A. The patient's age is within FDA labeling for the requested indication for the requested agent OR</p> <p style="padding-left: 20px;">B. There is support for using the requested agent for the patient's age for the requested indication AND</p> <p>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>4. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months BCBSIL, BCBSMT and BCBSTX: 12 months ALL other plans: 6 months for C3G & IC-MPGN ; 12 months for all other indications</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when the following are met:</p> <p>1. ALL of the following:</p> <p style="padding-left: 20px;">A. The member resides in Ohio AND</p> <p style="padding-left: 20px;">B. The plan is Fully Insured or HIM Shop (SG) AND</p> <p style="padding-left: 20px;">C. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p style="padding-left: 20px;">D. ONE of the following:</p> <p style="padding-left: 40px;">1. The patient has another FDA labeled indication for the requested agent and route of administration OR</p> <p style="padding-left: 40px;">2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR</p> <p style="padding-left: 40px;">3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</p> <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p>

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	<p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis Paroxysmal Nocturnal Hemoglobinuria (PNH) AND BOTH of the following: <ol style="list-style-type: none"> 1. The patient has had improvements or stabilization with the requested agent (e.g., decreased requirement of RBC transfusions, stabilization/improvement of hemoglobin, reduction of lactate dehydrogenase [LDH], stabilization/improvement of symptoms) (medical records required) AND 2. The patient will NOT be using the requested agent in combination with Fabhalta (iptacopan), Soliris (eculizumab), Bkembv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), or Plasky (crovalimab-akkz) OR B. The patient has a diagnosis of complement 3 glomerulopathy (C3G) AND ONE of the following: <ol style="list-style-type: none"> 1. BOTH of the following: <ol style="list-style-type: none"> A. ONE of the following: <ol style="list-style-type: none"> 1. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR 2. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes required] AND B. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR 2. ALL of the following: <ol style="list-style-type: none"> A. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: <ol style="list-style-type: none"> 1. Decrease from baseline (prior to treatment with the requested agent) of urine protein-to-creatinine (UPCR) ratio OR 2. Decrease from baseline (prior to treatment with the requested agent) in proteinuria AND B. ONE of the following: <ol style="list-style-type: none"> 1. BOTH of the following:

Module	Clinical Criteria for Approval
	<ul style="list-style-type: none"> A. The patient is currently treated with a maximally tolerated angiotensin-converting-enzyme inhibitor (ACEi, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an ACEi or ARB within the past 90 days AND B. The patient will continue maximally tolerated ACEi, or ARB, or a combination medication containing an ACEi or ARB therapy in combination with the requested agent OR 2. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL ACEi, ARB, and combination medications containing an ACEi or ARB AND C. The patient will NOT be using the requested agent in combination with Fabhalta (iptacopan) OR C. The patient has a diagnosis of Immune-complex membranoproliferative glomerulonephritis (IC-MPGN) AND ONE of the following: <ul style="list-style-type: none"> 1. BOTH of the following: <ul style="list-style-type: none"> A. ONE of the following: <ul style="list-style-type: none"> 1. The prescriber has stated that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR 2. The prescriber has submitted documentation that the patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes required] AND B. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR 2. BOTH of the following: <ul style="list-style-type: none"> A. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: <ul style="list-style-type: none"> 1. Decrease from baseline (prior to treatment with the requested agent) of urine protein-to-creatinine (UPCR) ratio OR 2. Decrease from baseline (prior to treatment with the requested agent) in proteinuria AND B. ONE of the following: <ul style="list-style-type: none"> 1. BOTH of the following: <ul style="list-style-type: none"> A. The patient is currently treated with a maximally tolerated angiotensin-converting-enzyme inhibitor (ACEi, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an ACEi or ARB within the past 90 days AND B. The patient will continue maximally tolerated ACEi, or ARB, or a combination medication containing an ACEi or ARB therapy in combination with the requested agent OR 2. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL ACEi, ARB, and combination medications containing an ACEi or ARB AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., hematologist, nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	<p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The patient has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) and BOTH of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) exceeds the program quantity limit AND B. ONE of the following: <ol style="list-style-type: none"> 1. The patient has a lactate dehydrogenase (LDH) level greater than 2X the upper limit of normal (lab test required) OR 2. ALL of the following: (medical records required) <ol style="list-style-type: none"> A. The patient had a prior LDH greater than 2X the upper limit of normal and required a dose increase AND B. The patient is currently using the requested quantity (dose) AND C. The requested quantity (dose) does NOT exceed 1,080 mg every three days <p>Length of Approval: 12 months NOTE: If approving for every three days dosing approve a quantity of 10 vials/30 days for 12 months</p>