



Zilbrysq Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
12-15-2025

Date of Origin
11-09-2023

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Zilbrysq	ziluocplan sodium subcutaneous soln pref syr	16.6 MG/0.416ML ; 23 MG/0.574ML ; 32.4 MG/0.81ML	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
Zilbrysq 16.6 mg/0.416 mL	ziluocplan	16.6 MG/0.416ML	28	Syringes	28	DAYS			
Zilbrysq 23 mg/0.574 mL	ziluocplan	23 MG/0.574ML	28	Syringes	28	DAYS			
Zilbrysq 32.4 mg/0.81 mL	ziluocplan	32.4 MG/0.81ML	28	Syringes	28	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Zilbrysq	ziluocplan sodium subcutaneous soln pref syr	16.6 MG/0.416ML ; 23 MG/0.574ML ; 32.4 MG/0.81ML	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 ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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
Zilbrysq 16.6 mg/0.416 mL	zilucoplan	16.6 MG/0.416ML	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
Zilbrysq 23 mg/0.574 mL	zilucoplan	23 MG/0.574ML	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
Zilbrysq 32.4 mg/0.81 mL	zilucoplan	32.4 MG/0.81ML	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 ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			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				
	<table border="1"> <thead> <tr> <th>Preferred Target Agent(s)</th> <th>Non-Preferred Target Agent(s)</th> </tr> </thead> <tbody> <tr> <td> Ultomiris (ravulizumab-cwvz) Rystiggo (rozanolixizumab-noli) Vyvgart (efgartigimod) Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) Epysqli (eculizumab-aagh) </td> <td>Zilbrysq (zilucoplan)</td> </tr> </tbody> </table> <p>*Preferred Agents may be targeted in another Utilization Management program and require Prior Authorization</p> <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 generalized Myasthenia Gravis (gMG) AND ALL of the following: <ol style="list-style-type: none"> 1. The patient has a positive serological test for anti-AChR antibodies (medical records required) AND 2. The patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II-IVb AND 3. The patient has a MG-Activities of Daily Living total score of greater than or equal to 6 AND 4. ONE of the following: <ol style="list-style-type: none"> A. The patient's current medications have been assessed and any medications known to exacerbate myasthenia gravis (e.g., beta blockers, procainamide, quinidine, magnesium, anti-programmed death receptor-1 monoclonal antibodies, hydroxychloroquine, aminoglycosides) have been discontinued OR B. Discontinuation of the offending agent is NOT clinically appropriate AND 5. The patient has ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. 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 B. The prescriber has submitted documentation that the patient has been diagnosed with stage four 	Preferred Target Agent(s)	Non-Preferred Target Agent(s)	Ultomiris (ravulizumab-cwvz) Rystiggo (rozanolixizumab-noli) Vyvgart (efgartigimod) Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) Epysqli (eculizumab-aagh)	Zilbrysq (zilucoplan)
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	<p style="text-align: center;">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</p> <ol style="list-style-type: none"> 2. 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 <ol style="list-style-type: none"> B. Tried and had an inadequate response to at least ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) OR C. An intolerance or hypersensitivity to ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) OR D. An FDA labeled contraindication to ALL conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) OR E. The patient required chronic intravenous immunoglobulin (IVIG) OR F. The patient required chronic plasmapheresis/plasma exchange AND <ol style="list-style-type: none"> 6. The patient has ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. 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 B. 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 2. 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 B. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR C. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR D. Tried and had an inadequate response to ONE preferred agent [chart notes required] OR E. ONE preferred agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR F. An intolerance or hypersensitivity to ONE preferred agent [chart notes required] OR G. The patient has an FDA labeled contraindication to ALL preferred agent(s) OR H. ONE preferred agent is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant

Module	Clinical Criteria for Approval
	<p>barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <ol style="list-style-type: none"> I. ALL preferred agent(s) are NOT in the best interest of the patient based on medical necessity [chart notes required] OR J. Tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR <ol style="list-style-type: none"> B. The patient has another FDA labeled indication for the requested agent and route of administration AND <ol style="list-style-type: none"> 2. If the patient has an FDA approved indication, then ONE of the following: <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. The patient will NOT be using the requested agent in combination with Rystiggo (rozanolizumab-noli), Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), or Imaavy (nipocalimab-aahu) AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</p> <p>BCBSOK: 36 months BCBSIL, BCBSMT, and BCBSTX: 12 months ALL other plans: 3 months</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> <ol style="list-style-type: none"> 1. The member resides in Ohio AND 2. The plan is Fully Insured or HIM Shop (SG) AND 3. The patient does NOT have any FDA labeled contraindications to the requested agent AND 4. ONE of the following: <ol style="list-style-type: none"> A. The patient has another FDA labeled indication for the requested agent and route of administration OR B. The patient has another indication that is supported in compendia for the requested agent and route of administration OR C. 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>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p>

Module	Clinical Criteria for Approval
	<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. The patient has had clinical benefit with the requested agent AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. The patient will NOT be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Soliris (eculizumab), Bkembv (eculizumab-aeab), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc), or Imaavy (nipocalimab-aahu) AND 5. The patient does NOT have any FDA labeled contraindications to the requested agent <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 requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR C. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND

Module	Clinical Criteria for Approval
	<p data-bbox="483 180 1341 239">2. There is support for therapy with a higher dose for the requested indication</p> <p data-bbox="232 279 500 310">Length of Approval:</p> <p data-bbox="232 346 472 378">BCBSIL: 12 months</p> <p data-bbox="232 413 886 445">ALL other plans: Initial 3 months, Renewal 12 months</p>