



Efgartigimod Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
02-15-2026

Date of Origin
05-15-2025

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Vyvgart hytrulo	efgartigimod alf-hyalur-qvfc pref syr	1000-10000 MG-UNT/5ML	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
Vyvgart hytrulo	efgartigimod alf-hyalur-qvfc pref syr	1000-10000 MG-UNT/5ML	4	Syringes	28	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Vyvgart hytrulo	efgartigimod alf-hyalur-qvfc pref syr	1000-10000 MG-UNT/5ML	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 HMO Performance Quarterly ; 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
Vyvgart hydrulo	efgartigimod alf-hyalur-qvfc pref syr	1000-10000 MG-UNT/5ML	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 HMO Performance Quarterly ; 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 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 5 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. 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 patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR B. 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

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	<p>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</p> <p>B. The patient has 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</p> <p>C. The patient has 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</p> <p>D. The patient has 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</p> <p>E. The patient required chronic intravenous immunoglobulin (IVIG) OR</p> <p>F. The patient required chronic plasmapheresis/plasma exchange AND</p> <p>6. The patient will NOT be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Soliris (eculizumab), Bkembv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Zilbrysq (zilucoplan) or Imaavy (nipocalimab-aahu) OR</p> <p>B. The patient has a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP), AND ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient's disease course is progressive or relapsing and remitting for at least 2 months AND 2. The patient has progressive or relapsing motor sensory impairment of more than one limb AND 3. The patient has electrodiagnostic findings indicating demyelination with at least ONE of the following: <ol style="list-style-type: none"> A. Prolonged distal motor latency in at least 2 motor nerves OR B. Reduced motor conduction velocity in at least 2 motor nerves OR C. Prolonged F-wave latency in at least 2 motor nerves OR D. Absent F-wave in at least 2 motor nerves plus one other demyelination criterion listed here in at least 1 other nerve OR E. Partial motor conduction block in at least 2 motor nerves or in 1 nerve plus one other demyelination criterion listed here OR F. Abnormal temporal dispersion conduction in at least 2 motor nerves OR G. Distal CMAP duration increase in at least 1 nerve plus one other demyelination criterion listed here in at least 1 other nerve AND 4. The patient has ONE of the following: <ol style="list-style-type: none"> A. Tried and had an inadequate response to at least a 3-month trial of ONE standard of care therapy (i.e., corticosteroids, immunoglobulins, plasma exchange) OR B. An intolerance or hypersensitivity to ONE standard of care therapy (i.e., corticosteroids, immunoglobulins, plasma exchange) OR C. An FDA labeled contraindication to ALL standard of care therapies (i.e., corticosteroids, immunoglobulins, plasma exchange) OR <p>C. 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> <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR

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	<p>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., neurologist), 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</p> <p>BCBSIL, BCBSMT, and BCBSTX: 12 months</p> <p>Other plans: 6 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS MT Fully Insured or MT HIM member AND <ol style="list-style-type: none"> A. The patient is under the age of 18 years old AND B. The patient does NOT have any FDA labeled contraindications to the requested agent AND C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] 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] AND D. There is support for an age in the patient’s given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). 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] OR 2. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 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>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</p> <p>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. If the patient has a diagnosis of generalized Myasthenia Gravis (gMG), then the patient will NOT be using the requested agent in combination with Rystiggo (rozanolixizumab-noli), Soliris (eculizumab), Bkembv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Zilbrysq (zilucoplan), 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</p> <p>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:

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication <p>Length of Approval:</p> <p>INITIAL: BCBSIL: 12 months, all other plans: 6 months</p> <p>RENEWAL: 12 months</p>