RX.PA.078.CCH NEONATAL Fc RECEPTOR (FcRn) ANTAGONISTS

The purpose of this policy is to define the prior authorization process for the neonatal Fc Receptor (FcRn) Antagonists used for Myasthenia Gravis.

VYVGART (efgartigimod alfa-fcab) is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

VYVGART HYTRULO is a combination of efgartigimod alfa, a neonatal Fc receptor blocker, and hyaluronidase, an endoglycosidase, indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

RYSTIGGO (rozanolixizumab-noli) is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or antimuscle-specific tyrosine kinase (MuSK) antibody positive.

DEFINITIONS

gMG = generalized Myasthenia Gravis

Myasthenia Gravis Foundation of America (MGFA) Disease Clinical Classification

Class I	Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal.
Class II	Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity. • IIa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles. • IIb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
Class III	Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity. • IIIa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles. • IIIb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
Class IV	Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.

	• IVa. Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles. • IVb. Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both
Class V	Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management. The use of a feeding tube without intubation places the patient in class IVb.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drugs, Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab), and Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc), are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed below:

- Must be age 18 years or older
- Must be prescribed by, or in consultation with, a neurologist
- Must have a diagnosis of myasthenia gravis, Foundation of America class II, III, or IV
- Must have documentation of ONE of the following:
  - Positive test for anti-acetylcholine receptor (AChR) antibody
  - Postive test for anti-muscle-specific tyrosine kinase (MuSK) antibody (applicable for Rystiggo ONLY)
- Must have a trial and failure, contraindication, or intolerance to at least ONE corticosteroid (e.g., prednisone)
- Must have a trial and failure or contraindication to at least ONE of the following (or intolerance of all):
  - At least TWO non-steroidal immunosuppressive therapies (e.g., azathioprine, cyclophosphamide, methotrexate)
  - At least ONE non-steroidal immunosuppressive therapy while on chronic plasmapheresis or plasma exchange

- Must have documentation of a baseline score using a validated gMG instrument [e.g., the MG-QOL 15 tool, the Myasthenia Gravis Activities of Daily Living (MG-ADL) tool]
- Must not be used in combination with other biologic therapies used for myasthenia gravis
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon the following:

- Must have documentation of improvement from the member's baseline score using a validated gMG instrument [e.g., the MG-QOL 15 tool, the Myasthenia Gravis Activities of Daily Living (MG-ADL) tool]
    - For subsequent reauthorizations, stability in the score may be accepted after initial improvement
- Must have documentation or an attestation from the provider that:
    - Vyvgart/Vyvgart Hytrulo: planned administration of each subsequent cycle must be ≥ 50 days since the START of the previous cycle
    - Rystiggo: planned administration of each subsequent cycle must be ≥ 63 days since the START of the previous cycle
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must not be used in combination with other biologic therapies used for myasthenia gravis

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 12 months
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J9332	Vyvgart	Injection, efgartigimod alfa-fcab, 2mg
J9333	Rystiggo	Injection, rozanolixizumab-noli, 1 mg
J9334	Vyvgart Hytrulo	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc

REFERENCES

1. Vyvgart [Prescribing Information]. Zwijnaarde, Belgium: Argenx BV; April 2022.
2. Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase) [prescribing information]. Boston, MA: Argenx US Inc; January 2024.
3. Rystiggo (rozanolixizumab) [prescribing information]. Smyrna, GA: UCB Inc; June 2023.
4. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: executive summary. Neurology. 2016;87(4):419-425. doi:10.1212/WNL.0000000000002790 [PubMed 27358333]

Revision History

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
New Policy	09/23
Addition of Rystiggo and Vyvgart Hytrulo Policy renamed to “Neonatal Fc Receptor Antagonists”	04/2024

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

Disclaimer

CountyCare medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of CountyCare and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

CountyCare reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of Evolent Health. Any sale, copying, or dissemination of said policies is prohibited.