EVH Clinical Guideline 5077.CC for Neonatal Fc Receptor (FcRn) Antagonists

Guideline Number: EVH_CG_5077.CC	**Applicable Codes**	
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Original Date: October 2024	**Last Revised Date:** October 2025	**Implementation Date:** December 2025

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STATEMENT

General Information

- *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.*
- *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.*

Purpose

The purpose of this guideline to define the prior authorization process for the neonatal Fc receptor (FcRn) antagonists.

Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

Plan Design Summary

Requests for FcRn antagonists for the diagnosis of generalized myasthenia gravis are subject to the preferred medical drug list program. This program applies to the products specified in this guideline and only to indications that are FDA-approved for the preferred product (as applicable). Coverage for non-preferred products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made.

Preferred Product Table	
Preferred	Vyvgart Hytrulo
Non-Preferred	Imaavy Rystiggo Vyvgart

INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed under the diagnosis-specific sections below.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) – *Vyvgart Hytrulo ONLY*

- Must be 18 years of age or older
- Must be prescribed by, or in consultation with, a neurologist
- Must have clinical features of typical CIDP, which includes ALL the following:
  - Progressive or relapsing, symmetric, proximal and distal muscle weakness of upper and lower limbs
  - Sensory involvement of at least two limbs
  - Developing over at least 8 weeks
  - Absent or reduced tendon reflexes in all limbs
- Must submit documentation of electrodiagnostic testing (e.g., nerve conduction studies, EMG report) that supports a diagnosis of CIDP
  - **NOTE:** Cerebrospinal fluid (CSF) analysis, MRIs, or ultrasounds can be accepted to support the diagnosis when electrodiagnostic testing is nondiagnostic
- Must have a baseline INCAT score ≥2
- Must have a trial (of at least 3 months) and failure to ONE of the following (or a contraindication/intolerance to all):
  - Glucocorticoids
  - Intravenous immune globulin (IVIG)
  - Plasma exchange (PLEX)
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Generalized Myasthenia Gravis (gMG)

- Must meet the following age requirements:
  - Imaavy – Must be age 12 years or older
  - Rystiggo – Must be age 18 years or older
  - Vyvgart – Must be age 18 years or older
  - Vyvgart Hytrulo – 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
  - Positive test for anti-muscle-specific tyrosine kinase (MuSK) antibody (applicable for Imaavy or Rystiggo ONLY)
- Must have a trial and failure of at least ONE corticosteroid (e.g., prednisone) or a contraindication/intolerance to all corticosteroids
- Must have a trial and failure of at least ONE of the following (or contraindication/intolerance to 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
- **For non-preferred requests**: Must have a trial and failure or intolerance of the preferred product or have a contraindication to the preferred product
  - **NOTE**: Preferred product trial is not required in members younger than 18 years of age

REAUTHORIZATION CRITERIA

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. The request must meet all of the criteria listed under the diagnosis-specific sections below.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) – *Vyvgart Hytrulo ONLY*

- Must have documentation of improvement from the member's baseline INCAT score
  - For subsequent reauthorizations, stability in the score may be accepted after initial improvement
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

Generalized Myasthenia Gravis (gMG)

- 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
- **For non-preferred requests**: Must have a trial and failure or intolerance of the preferred product or have a contraindication to the preferred product
  - **NOTE**: Preferred product trial is not required in members younger than 18 years of age

APPROVAL DURATIONS

Initial Authorization	Up to 1 year
Reauthorization	Same as initial

CODING AND STANDARDS

Codes

Code	Brand	Description
J3590	Imaavy	Nipocalimab-aahu
J9332	Vyvgart	Injection, efgartigimod alfa-fcab, 2mg
J9333	Rystiggo	Injection, rozanolixizumab-noli, 1 mg

Code	Brand	Description
J3590	Imaavy	Nipocalimab-aahu
J9334	Vyvgart Hytrulo	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☐	Commercial
☐	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

BACKGROUND

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 the following:

- Generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive
- Chronic inflammatory demyelinating polyneuropathy (CIDP)

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.

IMAAVY is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.

	Imaavy	Rystiggo	Vyvgart	Vyvgart Hytrulo
gMG	X	X	X	X
CIDP				X

Definitions

Inflammatory Neuropathy Cause and Treatment (INCAT) = A disability scale that assesses the functional ability of the arms and legs in patients with CIDP. Overall disability is measured by the arm disability score plus the leg disability score, which equals the overall score. A score of 10 represents maximum disability and a score of 0 represents no signs of disability.

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 HISTORY

Date	Summary
October 2025	• Addition of Imaavy • Addition of preferred product requirement for myasthenia gravis
October 2024	• Addition of CIDP for Vyvgart Hytrulo
April 2024	• Addition of Rystiggo and Vyvgart Hytrulo

	• Policy renamed to “Neonatal Fc Receptor Antagonists”
September 2023	• New Guideline

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Administrative Services Medical Policy Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members’ health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

REFERENCES

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