BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.85.066

Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	May 16, 2025
Subject:	Imaavy	**Page:**	1 of 4

Last Review Date: September 19, 2025

Imaavy

Description

Imaavy (nipocalimab-aahu)

Background
Imaavy (nipocalimab-aahu) is a humanized immunoglobulin G1 (IgG1) monoclonal antibody that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG levels. Myasthenia gravis is an autoimmune disease in which immunoglobulin G (IgG) autoantibodies are formed that target neuromuscular junction proteins. In patients treated with Imaavy, there was a reduction in total IgG levels and decreases in AChR autoantibody and MuSK autoantibody levels (1-2).

Regulatory Status
FDA-approved indication: 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 (1).

The International Consensus Guidance for Management of Myasthenia Gravis recommends the use of chronic IVIG and immunosuppressants (3).

Because Imaavy causes transient reduction in IgG levels, immunization with live vaccines is not recommended during treatment with Imaavy. Evaluate the need to administer age-appropriate immunizations according to immunization guidelines before initiation of Imaavy (1).

Imaavy includes warnings regarding infections, hypersensitivity reactions, and infusion-related reactions. During treatment with Imaavy monitor for clinical signs and symptoms of these reactions. If any of these reactions occur, administer the appropriate treatment and consider withholding or discontinuing Imaavy (1).

The safety and effectiveness of Imaavy in pediatric patients less than 12 years of age have not been established (1).

Related policies
Rystiggo, Soliris, Ultomiris, Vyvgart, Zilbrysq

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Imaavy may be considered **medically necessary** if the conditions indicated below are met.

Imaavy may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

1. Generalized myasthenia gravis (gMG)

AND ALL of the following:

a. Presence of autoantibodies against AChR or MuSK
b. Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV
c. Documented baseline score of **ONE** of the following:
    i. Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score ≥ 6 (*http://c.peerview.com/inReview/programs/150204324/downloads/PVI_practiceaids_RMU.pdf)*
    ii. Quantitative Myasthenia Gravis (QMG) total score > 9

(https://myasthenia.org/wp-content/uploads/Portals/0/QMG.pdf)

d. Patient has had an inadequate treatment response, intolerance, or contraindication to **ONE** of the following:
    i. acetylcholinesterase inhibitor
    ii. azathioprine
    iii. cyclosporine
    iv. mycophenolate mofetil
    v. tacrolimus
    vi. methotrexate
    vii. cyclophosphamide
e. **NOT** given concurrently with live or live-attenuated vaccines

Prior – Approval *Renewal* Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following:

1. Generalized myasthenia gravis (gMG)

AND ALL of the following:

a. Decrease of MG-ADL or QMG total score from baseline of ≥ 2 points (*http://c.peerview.com/inReview/programs/150204324/downloads/PVI_practiceaids_RMU.pdf*) *(https://myasthenia.org/wp-content/uploads/Portals/0/QMG.pdf)*
b. **NO** unacceptable toxicity from the drug
c. **NOT** given concurrently with live or live-attenuated vaccines

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Duration 12 months

Rationale

Summary

Imaavy is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody-positive. Imaavy includes warnings regarding infections, hypersensitivity reactions, and infusion-related reactions. The safety and effectiveness of Imaavy pediatric patients less than 12 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Imaavy while maintaining optimal therapeutic outcomes.

References

1. Imaavy [package insert]. Horsham, PA: Janssen Biotech, Inc.; April 2025.
2. Lazaridis K and Tzartos SJ (2020) Autoantibody Specificities in Myasthenia Gravis; Implications for Improved Diagnostics and Therapeutics. Front. Immunol. 11:212.
3. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. *Neurology*. 2016; 87(4):419. Epub 2016 Jun 29.

Policy History

Date	Action
May 2025	Addition to PA
September 2025	Annual review. Per SME, removed double step requirement to t/f immunosuppressive therapy and added QMG score as an optional gMG scoring tool

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.