Reference number(s)
6985-A

Standard Medicare Part B Management Imaavy

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Imaavy	nipocalimab-aahu

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Imaavy is 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.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

- For initial requests: chart notes, medical records, or claims history documenting:

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    - Positive anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody test.
    - Myasthenia Gravis Foundation of America (MGFA) clinical classification.
    - MG activities of daily living score.
    - Previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reasons to avoid therapy.
- For continuation requests: Chart notes or medical record documentation supporting benefit from therapy.

Exclusions

The requested medication will not be used in combination with another neonatal Fc receptor blocker (e.g., Rystiggo, Vyvgart, Vyvgart Hytrulo) or complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq).

Coverage Criteria

Generalized Myasthenia Gravis (gMG)[1-3]

Authorization of 6 months may be granted for treatment of generalized myasthenia gravis (gMG) when all of the following criteria are met:

- Anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive.
- Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV.
- MG activities of daily living (MG-ADL) total score of greater than or equal to 5.
- Meets one of the following:
    - Member has had an inadequate response or intolerable adverse event to at least two immunosuppressive therapies over the course of at least 12 months (e.g., azathioprine, corticosteroids, cyclosporine, methotrexate, mycophenolate, tacrolimus).
    - Member has had an inadequate response or intolerable adverse event to at least one immunosuppressive therapy and intravenous immunoglobulin (IVIG) over the course of at least 12 months.
    - Member has a documented clinical reason to avoid therapy with immunosuppressive agents and IVIG.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

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Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy (e.g., improvement in MG-ADL score, MG Manual Muscle Test (MMT), MG Composite).

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Imaavy.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- International consensus guidance for management of myasthenia gravis.

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Imaavy are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for Myasthenia Gravis Activities of Daily Living (MG-ADL) total score of greater than or equal to 5 can be found in the trials associated with Vyvgart and Vyvgart Hytrulo. Most clinical trials of myasthenia gravis agents required a MG-ADL of greater than or equal to 6, however, to align myasthenia gravis programs the baseline requirement will be greater than or equal to 5. MG-ADL is a scale that assesses the impact of myasthenia gravis on daily functions. This scale was used as an assessment tool to evaluate response to myasthenia gravis treatment from baseline in the clinical trials.

Support for the trial of immunosuppressive agents and IVIG before initiating therapy with Imaavy can be found in the 2020 update to the international consensus guidance for management of myasthenia gravis. The update was completed prior to the approval of several new myasthenia gravis agents; however, the guidance includes recommendations for initiating treatment with a complement inhibitor (eculizumab [Soliris]). The recommendations indicate that eculizumab should be considered in the treatment of severe, refractory myasthenia gravis (after trials of other immunotherapies have been unsuccessful in meeting treatment goals).

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Currently there are no treatment guidelines or literature supporting the concomitant use of complement inhibitors (e.g., Soliris, Ultomiris, Zilbrysq) or neonatal Fc receptor blockers (e.g., Rystiggo, Vyvgart, Vyvgart Hytrulo).

References

1. Imaavy [package insert]. Horsham, PA: Janssen Biotech, Inc.; May 2025.
2. Sanders D, Wolfe G, Benatar M et al. International consensus guidance for management of myasthenia gravis. Neurology. 2021; 96 (3) 114-122.
3. Barnett C, Herbelin L, Dimachkie MM, Barohn RJ. Measuring Clinical Treatment Response in Myasthenia Gravis. Neurol Clin. 2018 May;36(2):339-353.

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