Nipocalimab-aahu (Imaavy™)

Requires Step Therapy See "Step Therapy Requirements for Provider Administered Specialty Medications" Document at: https://www.bcbst.com/docs/providers/Comm_BC_PAD_Step_Therapy_Guide.pdf

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

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

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.
- Warm autoimmune hemolytic anemia (wAIHA) in adult and pediatric patients 12 years of age and older currently or previously treated with corticosteroids.

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- For initial requests, chart notes, medical records, or claims history documenting:
  - Generalized myasthenia gravis:
    - 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 (MG-ADL) score.
    - Previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reasons to avoid therapy.
  - Warm autoimmune hemolytic anemia (wAIHA):
    - Hemoglobin <10 g/dL.
    - Evidence of hemolysis confirmed by one of the following:
      - Lactic dehydrogenase [LDH] above upper limit of normal.

  - Indirect bilirubin above the upper limit of normal.
  - Haptoglobin below the lower limit of normal.
- Direct antiglobulin test (DAT) positive for immunoglobulin G (IgG) with or without complement component 3d (C3d).
- Current or previous treatments for wAIHA.

- For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
- Generalized myasthenia gravis (gMG): neurologist.
- Warm autoimmune hemolytic anemia (wAIHA): hematologist.

COVERAGE CRITERIA

Generalized Myasthenia Gravis (gMG)

Authorization of 12 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.
- The requested medication will not be used in combination with another neonatal Fc receptor blocker (e.g., Rystiggo, Vyvgart, Vyvgart Hytrulo), complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq) or Uplizna.

Warm Autoimmune Hemolytic Anemia (wAIHA)

Authorization of 12 months may be granted for treatment of warm autoimmune hemolytic anemia (wAIHA) when all of the following criteria are met:
- Member has a diagnosis of wAIHA for at least 3 months as confirmed by all of the following:
  - Hemoglobin <10 g/dL.
  - Evidence of hemolysis confirmed by one of the following:
    - Lactic dehydrogenase [LDH] above upper limit of normal.
    - Indirect bilirubin above the upper limit of normal.

    - Haptoglobin below the lower limit of normal.
    - Direct antiglobulin test (DAT) positive for immunoglobulin G (IgG) with or without complement component 3d (C3d).
- Member is currently receiving treatment for wAIHA or has previously received treatment for wAIHA (e.g., corticosteroids, rituximab, azathioprine, mycophenolate mofetil, methotrexate).
- Member has not been diagnosed with cold antibody autoimmune hemolytic anemia (AIHA), cold agglutinin syndrome, mixed type (that is, warm and cold) AIHA, or paroxysmal cold hemoglobinuria.

CONTINUATION OF THERAPY

Generalized Myasthenia Gravis (gMG)

Authorization of 12 months may be granted for continued treatment of generalized myasthenia gravis (gMG) in members requesting reauthorization when all of the following criteria are met:

- There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
- Member demonstrates a positive response to therapy (e.g., improvement in MG-ADL score, MG Manual Muscle Test (MMT), MG Composite).
- The requested medication will not be used in combination with another neonatal Fc receptor blocker (e.g., Rystiggo, Vyvgart, Vyvgart Hytrulo), complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq) or Uplizna.

Warm Autoimmune Hemolytic Anemia (wAIHA)

Authorization of 12 months may be granted for treatment of warm autoimmune hemolytic anemia (wAIHA) when all of the following criteria are met:

- There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
- Member demonstrates a positive response to therapy (e.g., improvement in hemoglobin levels, improvement in markers of hemolysis, improvement in fatigue).

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Imaavy [package insert]. Horsham, PA: Janssen Biotech, Inc.; August 2026.

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.
4. Johnson & Johnson Innovative Medicine. IMAAVY - Effect on Fatigue in Patients with Warm Autoimmune Hemolytic Anemia. J&J Medical Connect. https://www.jnjmedicalconnect.com/products/imaavy/medical-content/imaavy-effect-on-fatigue-in-patients-with-warm-autoimmune-hemolytic-anemia. Published August 24, 2026. Accessed September 2, 2026.

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