Medical Benefit Drug Policy

Neonatal Fc Receptor Blockers (Imaavy, Rystiggo, Vyvgart & Vyvgart Hytrulo)

Policy Number: MC/PC 026
Effective Date: August 1, 2026

Instructions for Use

Table of Contents **Page**

Related Policies

- N/A

Coverage Rationale

Generalized Myasthenia Gravis (gMG)

For Initial coverage of Imaavy (nipocalimab-aahu) injection, the following will be required:

- Diagnosis of generalized myasthenia gravis (gMG) **and**
- One of the following:
  - Both of the following:
    - Patient is anti-acetylcholine receptor (AChR) antibody positive **and**
    - One of the following:
      - Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids [e.g., prednisone], azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) **or**
      - Both of the following:
        - Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids [e.g., prednisone], azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) **and**
        - Trial and failure, contraindication, or intolerance to one of the following:
          - Chronic plasmapheresis or plasma exchange (PE)
          - Intravenous immunoglobulin (e.g., IVIG)
          - Rituximab **or**
  - Both of the following:
    - Patient is anti-muscle-specific tyrosine kinase (MuSK) antibody positive **and**
    - One of the following:
      - Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids [e.g., prednisone], azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) **or**

- Both of the following:
    - Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids [e.g., prednisone], azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus)
    - Trial and failure, contraindication, or intolerance to one of the following:
        - Chronic plasmapheresis or plasma exchange (PE)
        - Intravenous immunoglobulin (e.g., IVIG)
        - Rituximab **and**
- Patient is 12 years of age or older **and**
- Prescribed by or in consultation with a neurologist **and**
- Requested medication is not being used in combination with any one of the following for the indication of Generalized Myasthenia Gravis (gMG):
    - Another neonatal Fc receptor (FcRn) blocker (e.g., Vyvgart, Vyvgart Hytrulo, Rystiggo)
    - Complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq)
    - Immune globulin (e.g., IVIG)

For reauthorization coverage of Imaavy, the following will be required:

- Patient demonstrates positive clinical response to therapy
- Requested medication is not being used in combination with any one of the following for the indication of Generalized Myasthenia Gravis (gMG):
    - Another neonatal Fc receptor (FcRn) blocker (e.g., Vyvgart, Vyvgart Hytrulo, Rystiggo)
    - Complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq)
    - Immune globulin (e.g., IVIG)

For Initial coverage of Rystiggo (rozanolixizumab-noli) injection, the following will be required:

- Diagnosis of generalized myasthenia gravis (gMG) **and**
- One of the following:
    - Both of the following:
        - Patient is anti-acetylcholine receptor (AChR) antibody positive **and**
        - One of the following:
            - Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) **or**
            - Both of the following:
                - Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) **and**
                - Trial and failure, contraindication, or intolerance to one of the following:
                    - Chronic plasmapheresis or plasma exchange (PE)
                    - Intravenous immunoglobulin (e.g., IVIG)
                    - Rituximab **or**
    - Both of the following:
        - Patient is anti-muscle-specific tyrosine kinase (MuSK) antibody positive **and**
        - One of the following:
            - Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) **or**
            - Both of the following:

        - Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) **and**
        - Trial and failure, contraindication, or intolerance to one of the following:
            - Chronic plasmapheresis or plasma exchange (PE)
            - Intravenous immunoglobulin (e.g., IVIG)
            - Rituximab **and**
- Prescribed by or in consultation with a neurologist
- Requested medication is not being used in combination with any one of the following:
    - Another neonatal Fc receptor (FcRn) blocker (e.g., Imaavy, Vyvgart, Vyvgart Hytrulo)
    - Complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq)
    - Immune globulin (e.g., IVIG)

For reauthorization coverage of Rystiggo, the following will be required:

- Patient demonstrates positive clinical response to therapy
- Requested medication is not being used in combination with any one of the following:
    - Another neonatal Fc receptor (FcRn) blocker (e.g., Imaavy, Vyvgart, Vyvgart Hytrulo)
    - Complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq)
    - Immune globulin (e.g., IVIG)

For Initial coverage of Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) injection*, the following will be required:

***Vyvgart Hytrulo prefilled syringe, when used for self-administered subcutaneous injection would be obtained under the pharmacy benefit.**

- Diagnosis of generalized myasthenia gravis (gMG) **and**
- One of the following:
    - Trial and failure, contraindication, or intolerance to two immunosuppressive therapies (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) **or**
    - Both of the following:
        - Trial and failure, contraindication, or intolerance to one immunosuppressive therapy (e.g., glucocorticoids, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, tacrolimus) **and**
        - Trial and failure, contraindication, or intolerance to one of the following:
            - Chronic plasmapheresis or plasma exchange (PE)
            - Intravenous immunoglobulin (e.g., IVIG)
            - Rituximab **and**
- Prescribed by or in consultation with a neurologist **and**
- Requested medication is not being used in combination with any one of the following:
    - Another neonatal Fc receptor (FcRn) blocker (e.g., Imaavy, Rystiggo)
    - Complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq)
    - Immune globulin (e.g., IVIG)

For reauthorization coverage of Vyvgart and Vyvgart Hytrulo, the following will be required:

- Patient demonstrates positive clinical response to therapy
- Requested medication is not being used in combination with any one of the following:
    - Another neonatal Fc receptor (FcRn) blocker (e.g., Imaavy, Rystiggo)
    - Complement inhibitor (e.g., Soliris, Ultomiris, Zilbrysq)

- Immune globulin (e.g., IVIG)

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J9256	Injection, nipocalimab-aahu, 3 mg
J9332	Injection, efgartigimod alfa-fcab, 2 mg
J9334	Injection, efgartigimod alfa, 2 mg and hyaluronidase-qvfc
J9333	Injection, rozanolixizumab-noli, 1 mg

ICD-10 Code	Description
G70	Myasthenia gravis and other myoneural disorders
G70.0	Myasthenia gravis
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation

Background

Myasthenia gravis (MG) is the most common disorder of neuromuscular transmission. In the United States (U.S.), MG has an incidence of approximately 68 cases per million (per person-years) and an adjusted mean prevalence of 316 cases per million. Within the Medicaid-insured population, slightly lower numbers emerged with the adjusted incidence of 50 new cases per million person-years, and the adjusted prevalence rate of 203.7 cases per million (Ye et al. 2024).

Hallmark symptoms of MG include a fluctuating degree and variable combination of weakness in ocular, bulbar, limb, and respiratory muscles. Weakness is the result of an antibody-mediated, T cell-dependent immunologic attack directed at proteins in the postsynaptic membrane; the majority of patients with MG have autoantibodies against the anti-acetylcholine receptor (AChR) (Dresser et al. 2021). These autoantibodies are directly pathogenic at the postsynaptic membrane of the neuromuscular junction by accelerating endocytosis and degradation of AChRs, as well as inducing complement-mediated membrane damage and inflammation (Howard et al. 2017).

The goal of therapy for MG is to reduce patient symptoms while minimizing side effects (Dellarocca 2024). The acetylcholinesterase (AChE) inhibitor pyridostigmine is generally used as initial first-line treatment for symptomatic MG (Sanders et al. 2016). Most patients will also require some form of immunotherapy, including prednisone or glucocorticoid-sparing therapies for long-term maintenance. Glucocorticoid alternatives include azathioprine, mycophenolate mofetil, tacrolimus, or biologic therapies (Bird 2025[a])

Approximately 10% of patients with severe MG are refractory to, or intolerant of the first-line glucocorticoid-sparing therapies and may require ongoing rescue therapy with intravenous immunoglobulins (IVIG) or plasma exchange (PE), or experience frequent myasthenic crises while on immunosuppressive therapy. For patients with refractory MG, the complement inhibitor eculizumab, rituximab, or cyclophosphamide may be treatment options; there is limited clinical experience with other biologic therapies (ie, ravulizumab, rozanolixizumab, zilucoplan) for refractory disease (Bird

2025[a]). Thymectomy may also lead to clinically meaningful benefits in patients with AChR antibody-positive MG (Gronseth et al. 2020).

The Fc receptor (FcRn) blockers are a class of antibody fragment that targets the neonatal FcRn, preventing it from recycling immunoglobulin G (IgG) back into the blood; this causes a reduction in overall IgG levels, including the abnormal AChR antibodies that are present in MG (Vyvgart prescribing information 2025). Agents include Vyvgart (efgartigimod alfa), Rystiggo (rozanolixizumab-noli) and Imaavy (nipocalimab). Of note, nipocalimab and rozanolixizumab-noli have also demonstrated reductions in the muscle-specific tyrosine kinase (MuSK) antibody.

Clinical Evidence

Imaavy (nipocalimab-aahu)

- The efficacy of nipocalimab in adults with antibody-positive refractory gMG was evaluated in a 24-week, DB, MC, PC, RCT (VIVACITY-MG3 trial). In this study, 88% of patients were AChR-positive, 11% were MuSK-positive. Included patients were on a stable dose of standard of care therapy prior to baseline (ie, AChE inhibitor, steroids or non-steroidal immunosuppressive therapies with suboptimal response), were Myasthenia Gravis Foundation of America (MGFA) class II to IV, and had a MG-ADL score of ≥ 6. A total of 196 patients were randomized to receive nipocalimab or placebo (n = 98 for both groups). The primary efficacy endpoint was the difference in the mean change from baseline over weeks 22, 23, and 24 on the MG-ADL total score (Antozzi et al. 2025).
    - Treatment with nipocalimab demonstrated a statistically significant difference in the primary end point (-4.70 with nipocalimab vs -3.25 with placebo; difference, -1.45; 95% CI, -2.38 to -0.52; p = 0.0024). An OLE study is underway.
    - An ongoing, Phase 2/3, open-label, single arm study in pediatric patients ≥ 12 years of age demonstrated reduced serum immunoglobulin G (IgG) levels at 24 weeks (primary endpoint) and improvements in MG-ADL and QMC scales (Strober et al. 2024).

Rystiggo (rozanolixizumab-noli)

- Efficacy and safety of rozanolixizumab in adults with anti-AChR or anti-MuSK antibody-positive gMG was evaluated in the Phase 3, DB, PC, MC, RCT (MycarinG). Included patients were diagnosed as MGFA class II to IV, had a MG-ADL ≥ 3 from non-ocular symptoms, and QMG ≥ 11. A total of 200 patients were randomized to receive rozanolixizumab 7 mg/kg, rozanolixizumab 10 mg/kg, or placebo. The primary endpoint was Change in MG-ADL from baseline through day 43 (Bril et al. 2023).
    - Overall, reductions in MG-ADL score from baseline to day 43 were greater in both the rozanolixizumab 7 mg/kg and rozanolixizumab 10 mg/kg groups compared to placebo (LSM, -3.37 vs -3.40 vs -0.78, respectively; p < 0.0001 for both); rozanolixizumab was effective in patients with AChE and MuSK autoantibody-positive gMG types.
    - A pooled analysis of MycarinG and 2 OLE studies demonstrated consistent and clinically meaningful improvements in MG-ADL, myasthenia gravis composite (MGC), and QMG scores at the end of the first cycle (day 43) and subsequent cycles (Bril et al. 2025).

Vyvgart (efgartigimod alfa-fcab)

- Efficacy and safety of efgartigimod alfa-fcab were established in the 26-week, Phase 3, double-blind, multicenter, placebo-controlled, randomized controlled ADAPT trial (Howard et al. 2021). The trial included 167 adults with gMG with anti-AChR antibody-positive or negative status with a baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) total score of ≥ 5, with > 50% related to non-ocular symptoms. Patients were on stable doses of acetylcholinesterase inhibitors, corticosteroids, or nonsteroidal immunosuppressives (in combination or as monotherapy) at baseline and were randomized to placebo or efgartigimod alfa-fcab 10 mg/kg administered IV weekly for 4 weeks. Repeated cycles were initiated depending on clinical response with MG-ADL scores ≥ 5 and no earlier than 8 weeks after the initiation of the previous cycle. The primary endpoint was the proportion of MG-ADL responders, defined as ≥ 2-point MG-ADL improvement sustained for ≥ 4 weeks

in anti-AChR antibody-positive patients in cycle 1. Key secondary endpoints were the proportion of Quantitative Myasthenia Gravis score (QMG) responders, defined as ≥ 3-point improvement over 4 consecutive weeks starting by week 4, and the proportion of MG-ADL responders in cycle 1 in the overall population.
    - The proportion of MG-ADL responders in cycle 1 in the anti-AChR antibody-positive patients were significantly higher in the efgartigimod alfa-fcab group (44/65 [68%]) compared with placebo (19/64 [30%]) (odds ratio [OR], 4.95; 95% CI, 2.21 to 11.53; $p < 0.0001$).
    - Patients in the efgartigimod alfa-fcab group had a higher rate of response on QMG in cycle 1 compared with the placebo group (41/65 [63%] vs 9/64 [14%], respectively; OR, 10.84; 95% CI, 4.18 to 31.20; $p < 0.0001$).
    - The proportion of MG-ADL responders in cycle 1 in the overall population was significantly higher in the efgartigimod alfa-fcab group (57/84 [68%]) compared with placebo (31/83 [37%]; OR, 3.70; 95% CI, 1.85 to 7.58; $p < 0.0001$).
- The ADAPT-SC trial was a 10 week non-inferiority trial that compared the efficacy of subcutaneous (SC) efgartigimod to IV efgartigimod in patients with gMG for 1 treatment cycle (4 once-weekly administrations of either formulation); SC efgartigimod was shown to be noninferior to IV efgartigimod in lowering total IgG at 4 weeks. Interim open-label extension results (up to 6 cycles) confirmed consistent IgG reduction (Howard et al. 2024).

Supplementary Evidence

- Three meta-analyses (MAs) evaluating FcRn blockers (+/- other targeted therapies) in adult patients with gMG have been published (Gu et al. 2024, Zhong et al. 2024, and Ma et al. 2024). Overall, authors concluded that FcRn blockers were effective therapies for gMG, ranking above complement inhibitors and off-label targeted therapies (eg, rituximab) in efficacy as measured by MG-ADL and/or QMG. In all MAs, rozanolixizumab and efgartigimod were among the most effective therapies (data from VIVACITY-MG3 [nipocalimab] data were not incorporated into these MAs).

- Another systematic review and MA of 8 RCTs evaluated the efficacy of various FcRn blockers (ie, efgartigimod, rozanolixizumab, satralizumab [not FDA approved for MG], batoclimab [not available in the U.S.], and nipocalimab) in MG patients. Key findings included significantly improved clinical outcomes with FcRn inhibitors compared to placebo across several MG-specific scales including MG-ADL (mean difference [MD], -1.45) and QMG (MD, -2.33). In terms of safety, rozanolixizumab was associated with higher rates of AEs (Akhtar et al. 2025).

- The Institute for Clinical and Economic Review (ICER) evaluated the Phase 3 studies supporting eculizumab (REGAIN study) and efgartigimod (ADAPT study) for the treatment of gMG (Howard et al. 2017, Howard et al. 2021, Tice et al. 2021). Evidence supporting rituximab and IVIG were also reviewed. A network meta-analysis comparing eculizumab, efgartigimod, and placebo at 4 weeks in patients with anti-AChR antibody-positive gMG showed that both eculizumab and efgartigimod significantly improved MG-ADL and QMG. At 8 weeks, the results for efgartigimod had returned to near baseline due to the dosing schedule and were lower than those for eculizumab.

Clinical Guidelines

MG is a heterogeneous disease state with no internationally accepted standard of care. International consensus guidance for the management of MG recommends pyridostigmine as initial symptomatic treatment for most patients with MG (Narayanaswami et al. 2021, Sanders et al. 2016). The treatment goal for MG is to achieve minimal manifestation status or better. Pyridostigmine should be part of the initial treatment in most patients and adjusted as needed based on symptoms. Corticosteroids and/or other immunosuppressive therapy (eg, azathioprine, cyclosporine, mycophenolate mofetil, methotrexate [MTX], tacrolimus) should be used in patients who have not met treatment goals after an adequate trial of pyridostigmine. The dose of pyridostigmine should be titrated and individualized based on symptoms. Patients with refractory MG may require chronic IVIG or PE, cyclophosphamide, or rituximab; eculizumab

should be considered in patients with severe, refractory gMG. Once patients achieve treatment goals, corticosteroids should be tapered, and in many patients, a low-dose of corticosteroids long-term can help maintain disease control. IVIG and PE are used as short-term treatments for patients with MG with life-threatening signs such as respiratory insufficiency or dysphagia; in preparation for surgery; for rapid response when other therapies are ineffective; or prior to beginning corticosteroids if deemed necessary to prevent or minimize exacerbations. The choice between IVIG and PE is based on patient characteristics. IVIG and PE are likely equally effective. The guidelines were published prior to the approval of FcRn blockers, ravulizumab, and zilucoplan for the indication of gMG.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Imaavy (nipocalimab) 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.

Rystiggo (rozanolixizumab-noli) is a neonatal Fc receptor blocker 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.

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

Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

References

1. Akhtar M, Akhtar M, Farooqi HA, et al. Efficacy and safety of FcRn inhibitors in patients with Myasthenia gravis: An updated systematic review and meta-analysis. *Clin Neurol Neurosurg*. 2025:254:108910. doi: 10.1016/j.clineuro.2025.108910.
2. Antozzi C, Vu T, Ramchandren S, et al. Safety and efficacy of nipocalimab in adults with generalised myasthenia gravis (Vivacity-MG3): a phase 3, randomised, double-blind, placebo-controlled study. *Lancet Neurol*. 2025;24(2):105-116. doi: 10.1016/S1474-4422(24)00498-8.
3. Bird SJ. Chronic immunotherapy for myasthenia gravis. UpToDate Web site. www.uptodate.com. Updated March 24, 2025. Accessed October 23, 2025.
4. Bird SJ. Overview of the treatment of myasthenia gravis. UpToDate Web site. www.uptodate.com. Updated September 26, 2025. Accessed October 23, 2025.
5. Bird SJ. Pathogenesis of myasthenia gravis. UpToDate Web site. www.uptodate.com. Updated February 12, 2025. Accessed June 26, 2025.
6. Bril V, Benatar M, Andersen H, et al. on behalf of the MG0002 Investigators. Efficacy and safety of rozanolixizumab in moderate to severe generalized myasthenia gravis: a phase 2 randomized control trial. *Neurology*. 2021;96:3853-e865.
7. Bril V, Drużdż A, Grosskreutz J, et al. Rozanolixizumab in generalized myasthenia gravis: Pooled analysis of the Phase 3 MycarinG study and two open-label extensions. *J Neuromuscul Dis*. 2025;12(2):218-230. doi:10.1177/22143602241305511

8. Bril V, Drużdż A, Grosskreutz J, et al. Safety and efficacy of rozanolixizumab in patients with generalised myasthenia gravis (MycarinG): a randomised, double-blind, placebo-controlled, adaptive phase 3 study. *Lancet Neurol*. 2023;22(5):383-394. doi:10.1016/S1474-4422(23)00077-7
9. Dellarocca MA. The treatment of myasthenia gravis. *US Pharm*. 2024;49(1):4-8.
10. Dresser L, Wlodarski R, Rezania K, Soliven B. Myasthenia gravis: epidemiology, pathophysiology and clinical manifestations. *J Clin Med*. 2021;10(11):2235.
11. Gronseth GS, Barohn R, Narayanaswami P. Practice advisory: thymectomy for myasthenia gravis (practice parameter update). Report of the guideline development, dissemination, and implementation subcommittee of the American Academy of Neurology. *Neurology*. 2020;94:705-709. doi: 10.1212/WNL.0000000000009294
12. Gu J, Qiao Y, Huang R, Cong S. Efficacy and safety of immunosuppressants and monoclonal antibodies in adults with myasthenia gravis: a systematic review and network meta-analysis. *J Transl Med*. 2024;22(1):955. Published 2024 Oct 21. doi:10.1186/s12967-024-05751-1
13. Howard JF Jr, Utsugisawa K, Benatar M, et al; REGAIN Study Group. Safety and efficacy of eculizumab in anti-acetylcholine receptor antibody-positive refractory generalized myasthenia gravis (REGAIN): a phase 3, randomised, double-blind, placebo-controlled, multicentre study. *Lancet Neurol.* 2017;16(12):976-986.
14. Howard JF, Bresch S, Genge A, et al. for the RAISE Study team. Safety and efficacy of zilucoplan in patients with generalized myasthenia gravis (RAISE): a randomized, double-blind, placebo-controlled, phase 3 study. *Lancet Neurol.* 2023[b];22:395-406.
15. Howard JF, Bril V, Karam C, et al. for the ADAPT Investigator Study Group. Safety, efficacy, and tolerability of efgartigimod in patients with generalized myasthenia gravis (ADAPT): a multcentre, randomized, placebo-controlled, phase 3 trial. *Lancet Neurol*. 2021;20:526-536.
16. Howard J, Li G, Vu T, et al. for the ADAPT-SC Investigator Study Group. Long-term safety, tolerability, and efficacy of subcutaneous efgartigimod PH20 in patients with generalized myasthenia gravis: Interim results of the ADAPT-SC+ study (P1-5.014) [abstract]. *Neurology*. 2023[a];100(17 Suppl 2). https://n.neurology.org/content/100/17_Supplement_2/4181.abstract. Accessed April 24, 2024.
17. Howard JF, Vu T, Li G, et al. Subcutaneous efgartigimod PH20 in generalized myasthenia gravis: A phase 3 randomized noninferiority study (ADAPT-SC) and interim analyses of a long-term open-label extension study (ADAPT-SC+). *Neurotherapeutics*. 2024;21(5):e00378. doi:10.1016/j.neurot.2024.e00378.
18. Imaavy [package insert], Horsham, PA: Janssen Biotech, Inc.; April 2025.
19. Ma Y, Nie X, Zhu G, Qi W, Hao L, Guo X. The Efficacy and Safety of Different Targeted Drugs for the Treatment of Generalized Myasthenia Gravis: A Systematic Review and Bayesian Network Meta-analysis. *CNS Drugs*. 2024;38(2):93-104. doi:10.1007/s40263-024-01062-7
20. Narayanaswami P, Sanders DB, Wolfe G, et al. International consensus guidance for management of myasthenia gravis. *Neurology*. 2021;96:114-122.
21. Rystiggo (rozanolixizumab-noli) injection, for subcutaneous use [package insert]. Smyrna, GA: UCB, Inc; December 2025.
22. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: Executive summary. *Neurology*. 2016;87(4):419-425.
23. Strober J, et al. Safety and effectiveness of nipocalimab in adolescent participants in the open label Phase 2/3 Vibrance-MG clinical study. Presentation at American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) Annual Meeting. October 2024. Accessed October 23, 2025. https://www.mdaconference.org/abstract-library/safety-and-effectiveness-of-nipocalimab-in-adolescent-participants-in-the-open-label-phase-2-3-vibrance-mg-clinical-study/
24. Tice JA, Touchette DR, Nikitin D, et al. Eculizumab and efgartigimod for the treatment of myasthenia gravis: effectiveness and value; final report. Institute for Clinical and Economic Review, October 20, 2021.

https://icer.org/wp-content/uploads/2021/03/ICER_Myasthenia-Gravis_Final-Report_102021-1.pdf. Accessed April 24, 2024.

25. Vyvgart [package insert], Boston, MA: Argenx UC, Inc.; October 2025.
26. Vyvgart Hytrulo [package insert], Boston, MA: Argenx UC, Inc.; March 2026.
27. Ye Y, Murdock DJ, Chen C, Liedtke Knox CA, et al. Epidemiology of myasthenia gravis in the United States. *Front Neurol*. 2024:15:1339167. doi: 10.3389/fneur.2024.1339167.
28. Zhong H, Li Z, Li X, et al. Initiation response, maximized therapeutic efficacy, and post-treatment effects of biological targeted therapies in myasthenia gravis: a systematic review and network meta-analysis. *Front Neurol*. 2024;15:1479685. doi:10.3389/fneur.2024.1479685

Policy History/Revision Information

Date	Summary of Changes
9/20/2023	Approved by OptumRx P&T Committee
02/15/2024	Annual Review. Background section updated due to updated references. Under clinical guidelines, added rozanolixizumab and zilucoplan to list of drugs not yet included in guidelines
6/19/2024	Added Rystiggo to policy. Changed policy name from Vyvgart (efgartigimod alfa-fcab) injection to Neonatal Fc receptor Blockers (Vyvgart & Rystiggo) to reflect changes. Added in approval criteria for Rystiggo and updates were made to background and clinical guidelines to reflect the addition of Rystiggo to policy. Updates made to references.
7/16/2024	Added Vyvgart Hytrulo to policy. Updates made to references.
7/16/2025	Annual Review. Updated background section. Updated references.
5/14/2026	Added Imaavy to policy. Added in approval criteria for Imaavy and updates were made to background and clinical guidelines to reflect the addition of Imaavy to policy. For both Rystiggo and Vyvgart/Vyvgart Hytrulo , added rituximab as a step option for AChR+ disease, and added criterion to preclude concomitant use with other FcRn blockers, complement inhibitors, or immune globulin. Updates made to references.
7/15/2026	Removed requirement for AChR antibody positivity for Vyvgart/Vyvgart Hytrulo to align with updated indication.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).