Corporate Medical Policy: Neonatal Fc Receptor (FcRn) Blockers **"Notification"** **POLICY EFFECTIVE JANUARY 1, 2026**

Restricted Product(s):

- efgartigimod alfa-fcab (Vyvgart®) intravenous infusion for administration by a healthcare professional
- efgartigimod alfa and hyaluronidase-qvfc (Vyvgart® Hytrulo) subcutaneous injection for administration by a healthcare professional
- nipocalimab-aahu (Imaavy®) intravenous infusion for administration by a healthcare professional
- rozanolixizumab-noli (Rystiggo®) subcutaneous infusion for administration by a healthcare professional

FDA Approved Use:

- Efgartigimod alfa-fcab (Vyvgart®)
  - For the treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) antibody positive

- Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart® Hytrulo)
  - For the treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) antibody positive
  - For the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP)

- Nipocalimab-aahu (Imaavy®)
  - 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

- Rozanolixizumab-noli (Rystiggo®)
  - For the treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

Initial Criteria for Approval:

1. The patient has a diagnosis of **generalized myasthenia gravis (gMG)**; **AND**
   a. ONE of the following:
      i. The patient is 18 years of age or older; **OR**

   ii. If the request is for nipocalimab (Imaavy), the patient is 12 years of age or older; **AND**

b. ONE of the following:
   i. If the request is for efgartigimod alfa (Vyvgart, Vygart Hytrulo), the patient has a positive serological test for anti-acetylcholine receptor (AChR) antibodies **[medical record documentation required]**; **OR**
   ii. If the request is for nipocalimab (Imaavy) or rozanolixizumab (Rystiggo), the patient has a positive serological test for anti-AChR antibodies OR anti-muscle-specific tyrosine kinase (MuSK) antibodies **[medical record documentation required]**; **AND**

c. The patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II to IVb, or as scored by a comparable standardized rating scale that reliably measures MG disease severity; **AND**

d. The patient has the following Myasthenia Gravis Activities of Daily Living (MG-ADL) total score (or as scored by a comparable standardized rating scale that reliably measures MG disease severity):
   i. If the request is for efgartigimod alfa (Vyvgart, Vygart Hytrulo): MG-ADL total score of 5 or higher; **OR**
   ii. If the request is for nipocalimab (Imaavy): MG-ADL total score of 6 or higher; **OR**
   iii. If the request is for rozanolixizumab (Rystiggo): MG-ADL total score of 3 or higher AND at least 3 points are from non-ocular symptoms; **AND**

e. ONE of the following:
   i. The prescriber has assessed the patient's current medications and discontinued any medications known to exacerbate myasthenia gravis (e.g., beta blockers, procainamide, quinidine, magnesium, anti-programmed death receptor-1 monoclonal antibodies, hydroxychloroquine, aminoglycosides); **OR**
   ii. The prescriber has provided clinical rationale indicating that discontinuation of the offending agent is not clinically appropriate **[medical record documentation required]**; **AND**

f. ONE of the following:
   i. The patient has tried and had an inadequate response to at least ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **[medical record documentation required]**; **OR**
   ii. The patient has an intolerance or hypersensitivity to ONE conventional agent used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **[medical record documentation required]**; **OR**
   iii. The patient has an FDA labeled contraindication to ALL conventional agents used for the treatment of myasthenia gravis (i.e., corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide) **[medical record documentation required]**; **OR**
   iv. The patient required chronic intravenous immunoglobulin (IVIG) (i.e., at least every 3 months over 12 months without symptom control) **[medical record documentation required]**; **OR**

v. The patient required chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control) **[medical record documentation required]**; **AND**

g. ONE of the following:
   i. The request is for efgartigimod alfa (Vyvgart, Vygart Hytrulo) or rozanolixizumab (Rystiggo); **OR**
   ii. The request is for nipocalimab (Imaavy) AND the patient is 18 years of age or older, AND ONE of the following:
      1. The patient is anti-AChR antibody positive AND BOTH of the following:
         a. The patient has tried and had an inadequate response to ONE of the following: efgartigimod alfa (Vyvgart, Vyvgart Hytrulo) OR rozanolixizumab (Rystiggo) **[medical record documentation required]**; **OR**
            i. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to both efgartigimod alfa (Vyvgart, Vyvgart Hytrulo) AND rozanolixizumab (Rystiggo) **[medical record documentation required]**; **AND**
         b. The patient has tried and had an inadequate response to ravulizumab (Ultomiris) **[medical record documentation required]**; **OR**
            i. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ravulizumab (Ultomiris) **[medical record documentation required]**; **OR**
      2. The patient is anti-MuSK antibody positive AND ONE of the following:
         a. The patient has tried and had an inadequate response to rozanolixizumab (Rystiggo) **[medical record documentation required]**; **OR**
         b. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to rozanolixizumab (Rystiggo) **[medical record documentation required]**; **AND**

h. The patient will NOT be using the requested agent in combination with other immunotherapy or complement inhibitors (e.g., eculizumab products [e.g., Soliris, Bkemv, Epysqli], efgartigimod alfa (Vyvgart, Vyvgart Hytrulo), immunoglobulins, nipocalimab (Imaavy), ravulizumab (Ultomiris), rozanolixizumab (Rystiggo), or zilucoplan (Zilbrysq) used to treat the requested indication; **OR**

2. The patient has a diagnosis of **chronic inflammatory demyelinating polyneuropathy (CIDP)**; **AND**
   a. The request is for efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo); **AND**
   b. The patient is 18 years of age or older; **AND**
   c. The patient has progressive or relapsing and remitting symptoms present for at least 2 months; **AND**
   d. The patient has progressive or relapsing motor sensory impairment of more than one limb; **AND**
   e. The patient has electrodiagnostic findings indicating demyelination with at least ONE of the following **[medical record documentation required]**:
      i. Motor distal latency prolongation in at least 2 motor nerves; **OR**
      ii. Reduction of motor conduction velocity in at least 2 motor nerves; **OR**
      iii. Prolongation of F-wave latency in at least 2 motor nerves; **OR**

iv. Absence of F-waves in at least 2 motor nerves plus at least one other demyelination criterion listed here (i.-vii.) in at least 1 other nerve; **OR**
v. Partial motor conduction block in at least 2 motor nerves, or in 1 nerve plus at least one other demyelination criterion listed here (i.-vii.) in at least 1 other nerve; **OR**
vi. Abnormal temporal dispersion in at least 2 motor nerves; **OR**
vii. Distal CMAP duration prolongation in at least 1 motor nerve plus at least one other demyelination criterion listed here (i.-vii.) in at least 1 other nerve; **AND**

f. ONE of the following:
   i. The patient has tried and had an inadequate response to immunoglobulin (intravenous or subcutaneous) OR plasma exchange therapy used in the treatment of CIDP for at least 3-months **[medical record documentation required]**; **OR**
   ii. The patient has an intolerance or hypersensitivity to immunoglobulin (intravenous or subcutaneous) OR plasma exchange therapy used in the treatment of CIDP **[medical record documentation required]**; **OR**
   iii. The patient has an FDA labeled contraindication to immunoglobulin (intravenous or subcutaneous) AND plasma exchange therapy used in the treatment of CIDP **[medical record documentation required]**; **AND**

3. If the request is for efgartigimod alfa-fcab (Vyvgart) or efgartigimod alfa and hyaluronidase-qvfc (Vygart Hytrulo), the patient has a physical or cognitive limitation that makes utilization of the self-administered formulation of efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) unsafe or otherwise not feasible, as demonstrated by BOTH of the following **[medical record documentation required]**:
   a. Inability to self-administer the medication; **AND**
   b. Lack of caregiver or support system for assistance with administration of self-administered products; **AND**
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
5. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
6. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval: 180 days (6 months)

Continuation Criteria for Approval:

1. The patient was approved through Blue Cross NC initial criteria for approval; **OR**
2. The patient would have met initial criteria for approval at the time they started therapy; **AND**
3. For patients with a diagnosis of **generalized myasthenia gravis (gMG)**:

a. The patient has demonstrated clinical benefit with the requested agent (e.g., improved MG-ADL total score, improved quantitative myasthenia gravis total score, improved score of another comparable standardized rating scale that reliably measures MG disease severity) **[medical record documentation required]**; **AND**
b. ONE of the following:
    i. The request is for efgartigimod alfa (Vyvgart, Vygart Hytrulo) or rozanolixizumab (Rystiggo); **OR**
    ii. The request is for nipocalimab (Imaavy) AND the patient is 18 years of age or older, AND ONE of the following:
        1. The patient is anti-AChR antibody positive AND BOTH of the following:
            a. The patient has tried and had an inadequate response to ONE of the following: efgartigimod alfa (Vyvgart, Vyvgart Hytrulo) OR rozanolixizumab (Rystiggo) **[medical record documentation required]**; **OR**
                i. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to both efgartigimod alfa (Vyvgart, Vyvgart Hytrulo) AND rozanolixizumab (Rystiggo) **[medical record documentation required]**; **AND**
            b. The patient has tried and had an inadequate response to ravulizumab (Ultomiris) **[medical record documentation required]**; **OR**
                i. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ravulizumab (Ultomiris) **[medical record documentation required]**; **OR**
        2. The patient is anti-MuSK antibody positive AND ONE of the following:
            a. The patient has tried and had an inadequate response to rozanolixizumab (Rystiggo) **[medical record documentation required]**; **OR**
            b. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to rozanolixizumab (Rystiggo) **[medical record documentation required]**; **AND**
c. The patient will NOT be using the requested agent in combination with other immunotherapy or complement inhibitors (e.g., eculizumab products [e.g., Soliris, Bkemv, Epysqli], efgartigimod alfa (Vyvgart, Vyvgart Hytrulo), immunoglobulins, nipocalimab (Imaavy), ravulizumab (Ultomiris), rozanolixizumab (Rystiggo), or zilucoplan (Zilbrysq) used to treat the requested indication; **OR**

4. For patients with a diagnosis of **chronic inflammatory demyelinating polyneuropathy (CIDP)**:
    a. The request is for efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo); **AND**
    b. The patient has demonstrated clinical benefit with the requested agent (e.g., improved or stabilized upper and/or lower limb function, improved symptoms) **[medical record documentation required]**; **AND**
5. If the request is for efgartigimod alfa-fcab (Vyvgart) or efgartigimod alfa and hyaluronidase-qvfc (Vygart Hytrulo), the patient has a physical or cognitive limitation that makes utilization of the self-administered formulation of efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo) unsafe or otherwise not feasible, as demonstrated by BOTH of the following **[medical record documentation required]**:
    a. Inability to self-administer the medication; **AND**
    b. Lack of caregiver or support system for assistance with administration of self-administered products; **AND**

6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
7. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
8. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval: 365 days (1 year)

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
efgartigimod alfa-fcab (Vyvgart®) intravenous (IV) infusion	gMG in patients ≥ 18 years old who are anti-AChR antibody positive	IV: 10 mg/kg once weekly for 4 weeks. For patients ≥ 120 kg, 1,200 mg per infusion. Subsequent treatment cycles may be administered based on clinical evaluation.	J9332	Initial: 9,600 Continuation: 19,200
efgartigimod alfa and hyaluronidase-qvfc (Vyvgart® Hytrulo) subcutaneous (SC) injection	gMG in patients ≥ 18 years old who are anti-AChR antibody positive CIDP in patients ≥ 18 years old	gMG: 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase SC once weekly for 4 weeks. Subsequent treatment cycles may be administered based on clinical evaluation. CIDP: 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase SC once weekly	J9334	**gMG** Initial: 8,064 Continuation: 16,128 **CIDP** Initial: 13,104 Continuation: 26,208
nipocalimab-aahu (Imaavy®) intravenous (IV) infusion	gMG in patients ≥ 12 years old who are anti-AChR or anti-MuSK antibody positive	Initial dose: 30 mg/kg IV one-time loading dose Maintenance dose: 15 mg/kg IV starting 2 weeks after initial loading dose, then 15 mg/kg IV every 2 weeks thereafter	C9305 J3490** J3590**	Initial: 21,000 Continuation: 39,000

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
rozanolixizumab-noli (Rystiggo®) subcutaneous (SC) infusion	gMG in patients ≥ 18 years old who are anti-AChR or anti-MuSK antibody positive	SC: Administered once weekly for 6 weeks at a recommended dose based on body weight. • < 50 kg: 420 mg (3 mL) • 50 kg to < 100 kg: 560 mg (4 mL) • ≥ 100 kg: 840 mg (6 mL) Subsequent treatment cycles may be administered based on clinical evaluation but no sooner than 63 days from start of previous treatment cycle.	J9333	Initial: 15,120 Continuation: 30,240

***Maximum units allowed for duration of approval**
****Non-specific assigned HCPCS codes, must submit requested product NDC**

***Site of Care Medical Necessity Criteria**

1. For requests for injection or infusion administration in an **inpatient setting**, the injection or infusion may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the injection or infusion; **OR**
2. For requests for injection or infusion administration in an **outpatient hospital setting**, the injection or infusion may be given if the above medical necessity criteria are met AND ONE of the following must be met:
    a. History of a severe adverse event following the injection or infusion of the requested medication (i.e., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure); **OR**
    b. Conditions that cause an increased risk for severe adverse event (i.e., unstable renal function, cardiopulmonary conditions, unstable vascular access); **OR**
    c. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
    d. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
    e. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**
    f. Re-initiation of therapy, defined as ONE of the following:

   i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; **OR**
   ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**
 g. Requirement of a change in the requested restricted product formulation; **AND**
3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Antozzi C, Vu T, Ramchandren S, et al.; Vivacity-MG3 Study Group. 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 Feb;24(2):105-116.
2. Barnett C, Herbelin L, Dimachkie MM, et al. Measuring clinical treatment response in myasthenia gravis. *Neurol Clin*. 2018 May;36(2):339-353.
3. Bril V, Druzdz 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 May;22(5):383-394.
4. Howard JF Jr, Bril V, Vu T, et al. Safety, efficacy, and tolerability of efgartigimod in patients with generalised myasthenia gravis (ADAPT): a multicentre, randomised, placebo-controlled, phase 3 trial. *Lancet Neurol*. 2021 Jul;20(7):526-536.
5. Narayanaswami P, Sanders DB, Wolfe GI, et al. International consensus guidance for management of myasthenia gravis: 2020 update. *Neurology*. 2021;96(3):114-122.
6. Sanders DB, Wolfe GI, Benatar M, et al. International consensus guidance for management of myasthenia gravis: executive summary. *Neurology*. 2016;87:419-425.
7. Van den Bergh PYK, van Doorn PA, Hadden RDM, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint Task Force — Second revision. *J Peripher Nerv Syst*. 2021;26(3):242-268.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q4 annually.

January 2026: Original medical policy criteria issued. Consolidated “Efgartigimod Alfa (Vyvgart, Vyvgart Hytrulo)”, “Nipocalimab-aahu (Imaavy)”, and Rozanolixizumab-noli (Rystiggo)” medical policies into the following “Neonatal Fc Receptor (FcRn) Blockers” medical policy. For Vyvgart and Vyvgart Hytrulo, added to initial and continuation criteria the requirement for use of self-administered Vyvgart Hytrulo unless

certain criteria are met. For Imaavy for treatment of gMG in patients ≥18 years old, added to initial and continuation criteria the requirement for trial of Vyvgart/Vyvgart Hytrulo or Rystiggo plus trial of Ultomiris for anti-AChR antibody positive patients, OR trial of Rystiggo for anti-MuSK antibody positive patients. For gMG: Updated list of drugs not to be used in combination for clarity. For CIDP: Updated electrodiagnostic requirements to align with guidelines. Added Site of Care medical necessity criteria. **Policy notification given 11/1/2025 for effective date 1/1/2026**.
*Further historical criteria changes and updates for Corporate Medical Policies for each individual drug are available upon request from Medical Policy and/or Corporate Pharmacy.