SmartPA Criteria Proposal

Drug/Drug Class:	Vyvgart Clinical Edit
First Implementation Date:	October 20, 2022
Revised Date:	November 2, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Vyvgart™ (efgartigimod alfa-fcab).

Why Issue Selected: Vyvgart™ (efgartigimod alfa-fcab) was FDA-approved on December 17, 2021, for the treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) antibody positive. Myasthenia gravis is a chronic autoimmune neuromuscular condition that causes muscle weakness, most commonly affecting the eyes, face, neck, and limb muscles. gMG is a more severe form of myasthenia gravis that involves muscle groups besides just the eyes. About 80% of all cases are caused by autoantibodies targeting AChRs involved in nerve-muscle communication. Myasthenia gravis is considered a rare neurological disease, in North America the incidence is estimated at 3 to 9.1 cases per million. Treatment has traditionally consisted of acetylcholinesterase inhibitors, immunosuppressants, and rapid immunomodulatory therapies such as IVIG and plasma exchange.

Vyvgart is a human Immunoglobulin G1 (IgG1) antibody fragment that binds to the neonatal Fc receptor, which is responsible for protecting IgG from breakdown and keeping it in circulation longer. By blocking this receptor, Vyvgart results in decreased levels of IgG in circulation leading to less breakdown of acetylcholine within the neuromuscular junction. It is available as an IV infusion and dosed based on weight. One treatment cycle of Vyvgart consists of weekly infusions for 4 weeks, and the time between treatment cycles should be at least 50 days.

Due to the high cost and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Vyvgart.

Program-Specific Information:

Date Range FFS 4-1-22 to 3-31-23			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
VYVGART 400 MG/20 ML VIAL	38	$457,133.47	$12,029.83

Type of Criteria:

☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

Data Sources:

☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Vyvgart™ (efgartigimod alfa-fcab)
- Age range: All appropriate MO HealthNet participants aged 18 years and older

Approval Criteria

Initial Therapy

- Prescribed by or in consultation with neurologist, rheumatologist, or other specialist in the treated disease state **AND**
- Participant aged ≥ 18 years **AND**
- Participant has documented diagnosis of generalized myasthenia gravis **AND**
- Documented disease classification as Myasthenia Gravis Foundation of America (MGFA) Class II, III, or IV **AND**
- Documented positive anti-acetylcholine receptor (AChR) antibody test **AND**
- Documented baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) score of greater than or equal to 6 **OR**
- Documented baseline Quantitative Myasthenia Gravis (QMG) score of greater than or equal to 12 **AND**
- Adequate therapeutic trial of 2 immunosuppressants (e.g., glucocorticoids, azathioprine, mycophenolate, tacrolimus, cyclosporine, methotrexate) (90/120 days)
- Initial approval period: 3 months

Continuation of Therapy

- Subsequent cycles to be administered if:
  - MG-ADL score is greater than or equal to 6 **OR**
  - QMG score is greater than or equal to 12 **OR**
  - Participant was a MG-ADL/QMG responder initially, but no longer has a clinically meaningful improvement (defined as < 2-point improvement in total MG-ADL score or < 3-point improvement in total QMG score) **AND**
- Treatment has a sustained effect for at least 4 weeks after the end of the previous treatment cycle **AND**
- Minimum time between treatment cycles should be no less than 50 days from the start of previous treatment cycle and the start of the next treatment cycle
- Continuation approval period: 6 months

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant is currently pregnant
- Dose exceeds 1,200 mg (60 mL) per infusion
- Therapy exceeds 24 infusions per year

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

3 months

References

- Vyvgart (efgartigimod alfa-fcab) [package insert]. Argenx: April 2022.
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- IPD Analytics: New Drug Review: Vyvgart (efgartigimod alfa-fcab). Date accessed 01/06/2022.
- Dresser L, Wlodarski R, Rezania K, Soliven B. Myasthenia Gravis: Epidemiology, Pathophysiology and Clinical Manifestations. *JClinMed*, 2021;*10*(11), 2235. https://doi.org/10.3390/jcm10112235
- Farmakidis C, Pasnoor M, Dimachkie M, Barohn RJ. Treatment of Myasthenia Gravis. *NeurolClin*, 2018;*36*(2);311–337. https://doi.org/10.1016/j.ncl.2018.01.011
- Lascano AM, Lalive PH. Update in immunosuppressive therapy of myasthenia gravis. *AutoimmunRev*, 2021;*20*(1);102712. https://doi.org/10.1016/j.autrev.2020.102712