Reference number
1035-AMBST

Aetna Medicare Part B Drug Step Criteria

Myasthenia Gravis

Preferred product(s):
Vyvgart (efgartigimod alfa-fcab)
Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)

This criteria document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization. Step criteria are applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Aetna Medicare Part B Drug Criteria. **Find Aetna Medicare Part B Drug Criteria documents**.

This program applies to complement inhibitor products as specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude use of the preferred product and may be based on previous use of a product. The coverage review process will determine situations where a clinical exception can be made. This program applies to all Medicare members who are new to treatment with a targeted product.

For the indications listed below (new starts only):

1. Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive

TABLE. Myasthenia gravis

Status	Product(s)
Preferred*	Vyvgart (efgartigimod alfa-fcab) Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
Non-preferred (targeted)	Bkemv (eculizumab-aeeb) Epysqli (eculizumab-aagh) Imaavy (nipocalimab-aahu) Rystiggo (rozanolixizumab-noli) Soliris (eculizumab) Ultomiris (ravulizumab-cwvz)

*Preferred products may still require a prior authorization review for medical necessity

EXCEPTION CRITERIA

Coverage for the targeted product(s) is provided when the member meets one or more of the following criteria:

1. Member has received an authorized dose of the requested product in the past 365 days (does not include samples or doses administered without prior authorization).
2. Documented inadequate response to a trial of one or more preferred products (documentation required upon request)

3. Documented intolerable adverse event to one or more preferred products (documentation required upon request)
4. The preferred products are contraindicated for the member
5. The member is anti-muscle specific tyrosine kinase (MuSK) antibody positive

REFERENCES

1. Bkemv (eculizumab-aeeb) injection, for intravenous use [package insert]. Thousand Oaks, CA: Amgen Inc.; October 2024.
2. Epysqli (eculizumab-aagh) injection, for intravenous use [package insert]. Parsippany, NJ: Teva Pharmaceuticals; April 2025.
3. Imaavy (nipocalimab-aahu) injection, for intravenous use [package insert]. Horsham, PA: Janssen Biotech Inc.; April 2025.
4. Soliris (eculizumab injection, for intravenous use) [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; February 2024.
5. Ultomiris (ravulizumab-cwvz injection, for intravenous or subcutaneous use) [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; February 2024.
6. Vyvgart (efgartigimod alfa-fcab injection, for intravenous use) [package insert]. Boston, MA: argenx US, Inc.; January 2024.
7. Rystiggo (rozanolixizumab-noli) injection, for subcutaneous use) [package insert]. Smyrna, GA: UCB, Inc.; June 2023.

DOCUMENT HISTORY

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See Evidence of Coverage for a complete description of plan benefits, exclusions, limitations and conditions of coverage. Plan features and availability may vary by service area.
The formulary may change at any time. You will receive notice when necessary.