

Reference number(s) 6651-D

#### This criteria applies to the following:

Formulary	Applies
Standard Control (SF)	<b>V</b>
Standard Control - Choice (SCCF)	<b>V</b>
Preferred Drug Plan Design (PDPD)	
Advanced Control Specialty (ACSF)	<b>V</b>
Advanced Control Specialty - Choice (ACSCF)	<b>V</b>
Managed Medicaid Template (MMT)	
Marketplace (MF)	
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	
Aetna Individual Lives (IVL)	
Value (VF)	

Formulary	Applies
New to Market (NTM)	
Standard Formulary Chart (SFC)	
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	
Advanced Control Specialty Formulary Chart (ACSFC)	
Value Formulary Chart (VFC)	
Medical Benefit	
Medical Benefit: Advanced Biosimilars First	
Medical Benefit: Managed Medicaid (MMMB)	
Medicare Part B	
Medicare Part B: Advanced Biosimilars First	

# Exceptions Criteria Myasthenia Gravis Products

This criteria informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control – Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF).

## **Plan Design Summary**

This criteria applies to the myasthenia gravis products specified in this criteria. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This criteria applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) criteria implemented for the client.

#### Table. Myasthenia Gravis Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

Specialty Exceptions Myasthenia Gravis SF-SCCF-ACSF-ACSCF 6651-D P2025b.docx

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	Products
Preferred	<ul><li>Vyvgart (efgartigimod alfa)</li><li>Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)</li></ul>
Target	<ul><li>Soliris (eculizumab)</li><li>Ultomiris (ravulizumab-cwvz)</li><li>Zilbrysq (zilucoplan)</li></ul>

# **Exception Criteria**

This criteria applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a targeted product is provided when any of the following criteria are met:

- Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with either of the preferred products.
- Member has a documented clinical reason to avoid therapy with either of the preferred products.

### References

- 1. Soliris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; June 2024.
- 2. Ultomiris [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; August 2024.
- 3. Vyvgart [package insert]. Boston, MA: Argenx US, Inc.; August 2024.
- 4. Vyvgart Hytrulo [package insert]. Boston, MA: Argenx US. Inc.; August 2024.
- 5. Zilbrysq [package insert]. Smyrna, GA: UCB, Inc.; April 2024.