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Myasthenia Gravis Agents Drug Use Criteria

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Includes:

Approved for *AChR+* MG:

Vyvgart© (*efgartigimod alfa-fcab*)
Vyvgart Hytrulo© (*efgartigimod alfa; hyaluronidase*)
Ultomiris© *(Ravulizumab)**
Soliris© *(Eculizumab)**
Zilbrysq© (*zilucoplan*)

Approved for *AChR+* **OR** *MuSK-Ab+* MG:

Rystiggo© (*rozanolixizumab-noli*)

*Ultomiris (*ravulizumab*) and Soliris (*eculizumab*) have other FDA-approved indications in addition to the treatment of myasthenia gravis. The below criteria is to be use used when prescribed for the treatment of MG.

GUIDELINE FOR USE:

Initial Request:

1. Does the member have an OHP-funded condition?
    a. If yes, go to 2
    b. If no, deny as BTL

2. Is the prescribed medication and dose supported by the FDA approved package insert indications for use and dosing guideline for the prescribed product?
    a. If yes, go to 2
    b. If no, deny as not meeting criteria. Off label use of medication is not a covered benefit on OHP

3. Is the request for a member greater than 18 years old?
    a. If yes, go to 4
    b. If no, deny as not meeting criteria. The requested medication is not FDA-approved for use in pediatric patients.

4. Is the prescription written by a neurology specialist?
    a. If yes, go to 5
    b. If no, deny as not meeting criteria. Please refer patient to a neurologist for further evaluation.

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5. Is the MG-ADL total score greater than or equal to 5?
    a. If yes, go to 6
    b. If no, deny as not meeting criteria.

6. Is the member established on a current dose of MG therapy (ex: pyridostigmine, corticosteroids, or other immunosuppressants like Azathioprine, Mycophenolate Mofetil, Cyclosporine, Tacrolimus?
    a. If yes, go to 7
    b. If no, deny as not meeting criteria. Please trial with first-line therapies.

7. Does the submitted documentation support MGFA clinical classification class II to IV
    a. If yes, go to 8
    b. If no, deny as not meeting criteria

8. Does the patient have a positive serological test for anti-AChR antibodies?
    a. If yes, go to 9
    b. If no, go to 10

9. Is the request for **Zilbrysq®** (*zilucoplan*)?
    a. If yes, go to 13
    b. If no, go to 12

10. Is the request for rozanolixizumab-noli?
    a. If yes, go to 11
    b. If no, deny as not meeting criteria.

11. Does the member have a positive serological test for anti-muscle-specific tyrosine kinase antibody (MuSK-Ab+)
    a. If yes, go to 12
    b. If no, deny as not meeting criteria

12. Are the member's IgG levels of ≥5.5 g/L (rozanolixizumab) or ≥6.0 g/L (efgartigimod)
    a. If yes, go to 14
    b. If no, deny as criteria not met

13. Has the member had adequate trial of (or contraindication to) one corticosteroid?
    a. If yes, go to 14
    b. If no, deny as not meeting criteria

14. Is the request for dosing that corresponds to FDA labeling?
    a. If yes, approve for up to 2 cycles
    b. If no, deny as not meeting criteria

Renewal Request:

1. Is the renewal request for efgartigimod?

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a. If yes, go to 2
b. If no, go to 3

2. Has there been 50 days or more from the start of the previous efgartigimod treatment cycle?
   a. If yes, go to 3
   b. If no, deny as not meeting criteria

3. Has the member demonstrated clinical benefit including the following: (a) reduction in symptoms of at least 2 points from MG-ADL total baseline score, (b)reduced hospitalizations, (c) reduced steroid use?
   a. If yes, approve for up to 7 cycles
   b. If no, deny as not meeting criteria

Rationale: To define a process for covering agents used in the treatment of myasthenia gravis that is consistent with clinical practice guidelines and medical evidence while ensuring that less costly formulary options are trialed first.

FDA Approved Indications: Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive or anti-muscle-specific tyrosine kinase antibody (MuSK-Ab+).

References:

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5. Vyvgart (Prescribing information). Boston, MA. Argenx US, Inc. 2021
6. Narayanaswami P, Sanders DB, Wolfe G, et al. International Consensus Guidance for Management of Myasthenia Gravis: 2020 Update. *Neurology*. 2021;96(3):114-122. doi:10.1212/WNL.0000000000011124.
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8. UCB Pharma. UCB Announces US FDA Approval of Zilbrysq (Zilucoplan) for the Treatment of Adults with Generalized Myasthenia Gravis. *UCB Press Release*. October 2023.
9. AstraZeneca. Ultomiris (Ravulizumab) Approved in the US for Adults with Generalized Myasthenia Gravis. *AstraZeneca Press Release*. April 2022.
10. Myasthenia Gravis Foundation of America (MGFA). Treatment Overview for Myasthenia Gravis. *MGFA Patient Education Resource*. 2023.