AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Soliris® (eculizumab) **IV (J1299) (Medical)**
Generalized Myasthenia Gravis (gMG)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosage:

Patient Body Weight	Induction	Maintenance
40 kg and over	900 mg weekly for the first 4 weeks	1200 mg at week 5; then 1200 mg every 2 weeks
30 kg to less than 40 kg	600 mg for the first 2 weeks	900 mg at week 3; then 900 mg every 2 weeks
20 kg to less than 30 kg	600 mg for the first 2 weeks	600 mg at week 3; then 600 mg every 2 weeks
10 kg to less than 20 kg	600 mg single dose at week 1	300 mg at week 2; then 300 mg every 2 weeks
5 kg to less than 10 kg	300 mg single dose at week 1	300 mg at week 3; then 300 mg every 3 weeks

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Maximum Quantity Limit: 4 vials every 14 days; one 300 mg vial (30 mL) = 150 billable units [1 billable unit per 2 mg]

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Prescribing physician must be a neurologist
- ❑ Prescriber must be enrolled in the Soliris® Risk Evaluation and Mitigation Strategy (REMS) program
- ❑ Member must be 6 years of age or older
- ❑ Member must have Myasthenia gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease and have a positive serologic test for anti-acetylcholine receptor (AchR) antibodies (**chart notes must be submitted**)
- ❑ Physician has assessed objective signs of neurological weakness and fatigability on a baseline neurological examination **(chart notes must be submitted**)
- ❑ Physician must have assessed and submitted a baseline Quantitative Myasthenia Gravis (QMG) score
- ❑ Member has a MG-Activities of Daily Living (MG-ADL) total score of ≥ 6
- ❑ Member has **ONE** of the following **(verified by chart notes or pharmacy paid claims)**:
  - ❑ Member has tried and had an inadequate response to pyridostigmine
  - ❑ Member has an intolerance, hypersensitivity or contraindication to pyridostigmine
- ❑ Member has **ONE** of the following **(verified by chart notes or pharmacy paid claims)**:
  - ❑ Member failed over 1 year of therapy with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate)
  - ❑ Member failed at least 1 immunosuppressive therapy and required chronic plasmapheresis, plasma exchange (PE) or intravenous immunoglobulin (IVIG)
- ❑ Member must meet **ONE** of the following:
  - ❑ Member must have documentation of an inadequate response, contraindication or intolerance to **ALL** the following medications **(verified by chart notes or medical paid claims)**
    - ❑ Vyvgart® (efgartigimod alfa-fcab) or Vyvgart ® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc)
    - ❑ Rystiggo® (rozanolixizumab-noli)
    - ❑ Ultomiris® (ravulizumab-cwvz)
  - ❑ Member is under 18 years of age and all prerequisite therapies above are not FDA-approved for this age group and indication
- ❑ Member will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., aminoglycosides, fluoroquinolones, beta-blockers, botulinum toxins, hydroxychloroquine)

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- ❑ Member does **NOT** have a systemic infection
- ❑ Member meets **ONE** of the following:
  - ❑ Member must be administered a meningococcal vaccine **at least two weeks prior** to initiation of Soliris® therapy and revaccinated according to current medical guidelines for vaccine use
  - ❑ Member has **NOT** received a meningococcal vaccination at least two weeks prior to the initiation of therapy with Soliris® and documented risks of delaying Soliris® therapy outweigh the risks of developing a meningococcal infection
- ❑ Medication will **NOT** be used in combination with other immunomodulatory biologic therapies (e.g., ravulizumab, zilucoplan, efgartigimod alfa-fcab, efgartigimod alfa and hyaluronidase-qvfc, rozanolixizumab-noli, rituximab)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has **NOT** experienced unacceptable toxicity from the drug (e.g., serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections)
- ❑ Member has demonstrated an improvement of at least 3 points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) **(total score must be documented)**
- ❑ Member has demonstrated an improvement of at least 5 points from baseline in the Quantitative Myasthenia Gravis (QMG) **(total score must be documented)**

EXCLUSIONS – Therapy will NOT be approved if member has history of any of the following:

- History of thymoma or other neoplasms of the thymus
- History of thymectomy within 12 months prior to treatment
- MGFA Class I or MG crisis at initiation of treatment (MGFA Class V)
- Use of rituximab within 6 months prior to treatment
- Use of IVIG or PE within 4 weeks prior to treatment
- Any systemic bacterial or significant infections that have not been treated with appropriate antibiotics
- Unresolved meningococcal disease

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Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****