

# AvMed

## PHARMACY 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 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

**Drug Requested:** Zilbrysq<sup>®</sup> (zilucoplan)

**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: \_\_\_\_\_

Weight (if applicable): \_\_\_\_\_ Date weight obtained: \_\_\_\_\_

**Recommended Dosage:** Weight-based dosage regimen administered as a subcutaneous injection once daily.

Body Weight Range (kg)	Once Daily Dose (mg)
<56 kg	16.6 mg
56 kg to < 77 kg	23 mg
≥ 77 kg and above	32.4 mg

**Quantity Limit:** 1 syringe per day (all strengths)

**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

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- Prescriber must be enrolled in the Zilbrysq<sup>®</sup> Risk Evaluation and Mitigation Strategy (REMS) program
- Member must be 18 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  $\geq 6$  (**results must be submitted**)
- 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 will avoid or use with caution medications known to worsen or exacerbate symptoms of MG (e.g., aminoglycosides, fluoroquinolones, beta-blockers, botulinum toxins, hydroxychloroquine)
- 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 Zilbrysq<sup>®</sup> 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 Zilbrysq<sup>®</sup> and documented risks of delaying Zilbrysq<sup>®</sup> therapy outweigh the risks of developing a meningococcal infection
- Medication will **NOT** be used in combination with other immunomodulatory biologic therapies (e.g., rituximab, eculizumab, ravulizumab, efgartigimod alfa-fcab, efgartigimod alfa and hyaluronidase-qvfc, rozanolixizumab-noli, nipocalimab-aahu, inebilizumab-cdon)

**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)

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- ❑ Member has demonstrated an improvement of at least 2 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 3 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:**

- MGFA Class I or MG crisis at initiation of treatment (MGFA Class V)
- Any systemic bacterial or significant infections that have not been treated with appropriate antibiotics
- Unresolved meningococcal disease

**Medication being provided by Specialty Pharmacy – Proprium Rx**

***\*\*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.\****