SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-800-750-9692** . 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**.

Drug Requested: Zilbrysq® (zilucoplan)

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

Member Name: _____

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

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

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

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

Diagnosis: _____ **ICD Code:** _____

Weight: _____ **Date:** _____

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® 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 ≥ 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 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® 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® and documented risks of delaying Zilbrysq® 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)

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.*

***Approved by Pharmacy and Therapeutics Committee**: 3/21/2024
REVISED/UPDATED/REFORMATTED: 5/15/2024