OPTIMA HEALTH COMMUNITY CARE
AND
OPTIMA FAMILY CARE
(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 1-844-348-3720**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **Incomplete form will delay authorization process.**

Drug Requested: Soliris (eculizumab) **IV (J1300)** **(Medical)**

DRUG INFORMATION: Complete all information below or authorization process will be delayed.

Drug Form/Strength: _____

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

Diagnosis: _____ **ICD Code:** _____

RECOMMENDED DOSAGE:

- **Paroxysmal nocturnal hemoglobinuria (PNH):** IV:Induction: 600mg weekly for 4 doses; Maintenance: 900mg at week 5 then 900 mg every 2 weeks thereafter
- **Atypical hemolytic uremic syndrome (aHUS):** IV Induction:900mg weekly x 4 doses; Maintenance 1200mg at week 5 then 1200mg q 2 weeks thereafter
- **Generalized myasthenia gravis (gMG):** IV Induction:900mg weekly x 4 doses; Maintenance 1200mg at week 5 then 1200mg q 2 weeks thereafter

CLINICAL CRITERIA: Check **ALL** applicable boxes to qualify. **ALL** chart notes, including lab values, **MUST** be submitted with form to ensure authorization will **NOT** be delayed.

For INITIAL APPROVAL OF THERAPY
ALL of the following criteria MUST be met:

- ❑ Patient does not have a systemic infection; **AND**
- ❑ Patients 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; **OR**
- ❑ The member has not received a meningococcal vaccination at least two weeks prior to the initiation of therapy with Soliris and documented the risks of delaying Soliris therapy outweigh the risks of developing a meningococcal infection; **AND**
- ❑ The prescriber must be enrolled in the Soliris Risk Evaluation and Mitigation Strategy (REMS) program; **AND**
- ❑ The member must have **ONE** of the following conditions with the following criteria:

❑ **For Diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH):**

- ❑ Member must have documented diagnosis of paroxysmal nocturnal hemoglobinuria confirmed by flow cytometry testing **(test results must be submitted)** **AND**
- ❑ The prescribing physician must be a hematologist or nephrologist

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❑ For Diagnosis of Atypical Hemolytic Uremic Syndrome (aHUS):

- ❑ Member must have diagnosis of atypical hemolytic uremic syndrome (aHUS) and documentation supporting a confirmed diagnosis (e.g. genetic testing, chart notes/lab results documenting evidence of microangiopathic hemolytic anemia, acute kidney injury and thrombocytopenia) must be submitted **(please attach)** **AND**
- ❑ The prescribing physician must be a hematologist or nephrologist

❑ For Diagnosis of Generalized Myasthenia Gravis (gMG):

- ❑ Patient must be 18 years of age or older; **AND**
- ❑ The prescribing physician must be a neurologist; **AND**
- ❑ Patient must have Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease **(chart note documentation must be submitted)**; **AND**
- ❑ Patient must have a positive serologic test for anti-acetylcholine receptor (AchR) antibodies **(lab results must be submitted)**; **AND**
- ❑ Physician must have assessed the baseline Quantitative Myasthenia Gravis (QMG) score **(results must be submitted)**; **AND**
- ❑ Patient has a MG-Activities of Daily Living (MG-ADL) total score of ≥6 **(results must be submitted)**; **AND**
- ❑ Patient has failed treatment over at least 1 year with at least 2 immunosuppressive therapies (e.g. azathioprine, cyclosporine, mycophenolate, etc), **OR** has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) **(chart notes/pharmacy records must be submitted for documentation)**

Length of Authorization:

- ❑ For diagnosis of PNH and aHUS: Coverage will be provided for twelve months and may be renewed.
- ❑ For diagnosis of gMG: Initial coverage will be provided for 6 months and may be renewed annually thereafter

RENEWAL CRITERIA:
For continuation of therapy, ALL of the following MUST be met:

❑ For Diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH):

- ❑ Documentation of a positive clinical response, such as hemoglobin stabilization or a decrease in the number of red blood cell transfusions, must be submitted **(chart notes/labs must be submitted to document improvement)**

❑ For Diagnosis of Atypical Hemolytic Uremic Syndrome (aHUS):

- ❑ An increase in mean platelet counts or hematologic normalization from baseline must be noted **(labs must be submitted to document improvement)**

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❑ For Diagnosis of Generalized Myasthenia Gravis (gMG):

- ❑ Subsequent 12 month authorizations will require documentation from a neurologist of a decrease in the MG-ADL total score from baseline **(results must be submitted to document improvement)**;

AND

- ❑ 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 **(results must be submitted to document improvement)**;

AND

- ❑ Improvement of at least 5-points from baseline in the Quantitative Myasthenia Gravis (QMG) total score must be documented **(results must be submitted to document improvement)**

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

Medication being provided by (check applicable box(es) below)**:**

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy - PropriumRx**

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.

Patient Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR /NPI #: _____

***Approved by Pharmacy and Therapeutics Committee**: 2/15/2018

REVISED/UPDATED: ~~6/27/2018~~, **8/30/2018**, **10/8/2018**;