Updated: 05/2018
DMMA Approved: 05/2018

Request for Prior Authorization for Soliris (eculizumab)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Soliris (eculizumab) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Soliris Prior Authorization Criteria:

For all requests for Soliris (eculizumab) all of the following criteria must be met:

- Prescriber must be enrolled in the Soliris REMS program
- The requested dose and frequency is within FDA-approved dosing recommendations

Coverage may be provided with a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) and the following criteria are met:

- Member is 18 years of age or older
- Medication is prescribed by, or in consultation with, a hematologist, oncologist, immunologist, or genetic specialist
- Member has a diagnosis of PNH confirmed by flow cytometry testing. Flow Cytometry pathology report must be supplied and demonstrate at least 2 different GPI protein deficiencies within 2 different cell lines from granulocytes, monocytes, or erythrocytes.
- Member is transfusion dependent as defined by having a transfusion within the last 12 months and one of the following:
    - Member's hemoglobin is less than or equal to 7 g/dL
    - Member has symptoms of anemia and the hemoglobin is less than or equal to 9 g/dL
- Must have a Lactate dehydrogenase (LDH) level of 1.5 times the upper limit of the normal range (laboratory results with reference range must be submitted)
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Documentation of a recent (within 3 months) LDH level that shows a reduction from baseline
    - Documentation from the provider that the member has stabilized hemoglobin levels as supported by the following:
        - Member did not require a transfusion **AND**
        - Member maintained a hemoglobin concentration above 7 g/dL **OR** maintained a hemoglobin concentration above 9 g/dL if they had a baseline hemoglobin level above 7 g/dL but below 9 g/dL
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of atypical hemolytic uremic syndrome (aHUS) and the following criteria are met:

- The member is 2 months of age or older and has a weight of at least 5 kilograms
- Medication is prescribed by, or in consultation with, a hematologist, oncologist, immunologist, genetic specialist, or nephrologist
- The diagnosis of aHUS is supported by the absence of Shiga toxin-producing *E.coli* infection
- **Initial Duration of Approval:** 6 weeks
- **Reauthorization criteria**
    - Documentation from the provider that the member had a positive clinical response as evidenced by any of the following:
        - An increase in platelet count from baseline
        - Maintenance of normal platelet counts and LDH levels for at least four weeks
        - A 25% reduction in serum creatinine for a minimum of four weeks
        - Absence for at least 12 weeks of a decrease in platelet count of >25% from baseline, plasma exchange or plasma infusion, and new dialysis requirement
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of generalized Myasthenia Gravis (gMG) and the following criteria are met:

- The member is 18 years of age or older
- The prescribing physician is a neurologist
- Documentation of a positive serologic test for anti-acetylcholine antibodies
- Documentation the member meets the Myasthenia Gravis Foundation of America Clinical Classification II to IV generalized myasthenia gravis
- Documentation the member has a Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score ≥6
- Documentation of at least one of the following:
    - Failed treatment over 1 year or more with 2 or more immunosuppressive therapies either in combination or as monotherapy (e.g. azathioprine, cyclophosphamide, methotrexate)
    - Failed treatment of at least 1 immunosuppressive therapy while on chronic plasmapheresis or plasma exchange (PE)
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - First reauthorization criteria (member on therapy for 0 to 6 months)
        - Documentation from the provider that the member had a positive clinical response and tolerates Soliris therapy supported by at least one of the following:
            - A 3 point improvement in the member's total MG-ADL score
            - A 5 point improvement in QMG total score

  - Subsequent reauthorization criteria (member on therapy ≥ 6 months)
    - Documentation from the prescriber indicating stabilization or improvement in condition.
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.