Updated: 03/2019
PARP Approved: 03/2019

Prior Authorization Criteria

C5b Complement inhibitors

All requests for C5b Complement inhibitors require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

C5b Complement Inhibitor Medications addressed in this policy include: Soliris (eculizumab), and Ultomiris (ravulizumab-cwvz). New products with this classification will require the same documentation.

ATTACHMENTS

Attachment 1. Myasthenia Gravis Activities of Daily Living (MG-ADL) profile
Attachment 2. Quantitative Myasthenia Gravis scale (QMG) scale
Attachment 3. Myasthenia Gravis Foundation of America Clinical Classification

For all requests C5b Complement inhibitors all of the following criteria must be met:

- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

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 has 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 **(Soliris only)**
    - Member has symptoms of anemia and the hemoglobin is less than or equal to 10 g/dL **(Ultomiris only)**
- Must have a Lactate dehydrogenase (LDH) level at least 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 each of the following:
        - Documentation of a recent (within 3 months) LDH level that shows a reduction from baseline
        - Documentation that hemoglobin has not dropped by more than 2 g/dL from baseline.
            - If baseline hemoglobin was less than 9g/dL, then the most recent hemoglobin must remain above 7g/dL
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of atypical hemolytic uremic syndrome (aHUS) **(Soliris (eculizumab) ONLY)** 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 months
- **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
        - The member has not experienced one of the following for at least 12 weeks after initiation of treatment:
            - A decrease in platelet count of >25% from baseline
            - Decrease in plasma exchange or plasma infusion
            - New dialysis requirement
- **Reauthorization Duration of Approval:** 12 months

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

- The member is 18 years of age or older
- Medication is prescribed by, or in consultation with 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 over 1 year or more with 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.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Attachment 1. MG Activities of Daily Living (MG-ADL) profile

Grade	0	1	2	3	Score
Talking	Normal	Intermittent slurring or nasal speech	Constant slurring or nasal, but can be understood	Difficult to understand speech	
Chewing	Normal	Fatigue with solid food	Fatigue with soft food	Gastric tube	
Swallowing	Normal	Rare episode of choking	Frequent choking necessitating changes in diet	Gastric tube	
Breathing	Normal	Shortness of breath with exertion	Shortness of breath at rest	Ventilator dependence	
Impairment of ability to brush teeth or comb hair	None	Extra effort, but no rest periods needed	Rest periods needed	Cannot do one of these functions	
Impairment of ability to arise from a chair	None	Mild, sometimes uses arms	Moderate, always uses arms	Severe, requires assistance	
Double vision	None	Occurs, but not daily	Daily, but not constant	Constant	
Eyelid droop	None	Occurs, but not daily	Daily, but not constant	Constant	

Total score _____

Attachment 2. Quantitative Myasthenia gravis scale

Test Items Weakness	None	Mild	Moderate	Severe
Double vision on lateral gaze **right** or **left** (circle one)	61	11–60	1–10	spontaneous
Ptosis (upward gaze)	61	11–60	1–10	spontaneous
Facial muscles	normal lid	complete, weak, some resistance	complete, without resistance	incomplete
Swallowing 4 oz. water (½ cup)	normal	Minimal coughing or throat clearing	severe coughing/ choking or nasal regurgitation	cannot swallow (test not attempted)
Speech following counting aloud from 1 to 50 (onset of dysarthria)	none at #50	dysarthria at #30–49	dysarthria at #10–29	dysarthria at #9
Right arm outstretched (90° sitting)	240	90–239	10–89	0–9
Left arm outstretched (90° sitting)	240	90–239	10–89	0–9
Vital capacity (% predicted)	≥80%	65–79%	50–64%	<50%
Right hand grip (kg)				
male	≥45	15–44	5–14	0–4
female	≥30	10–29	5–9	0–4
Left hand grip (kg)				
male	≥35	15–34	5–14	0–4
female	≥25	10–24	5–9	0–4
Head lifted (45° supine)	120	30–119	1–29	0
Right leg outstretched (45° supine)	100	31–99	1–30	0
Left leg outstretched (45° supine)	100	31–99	1–30	0

[a]Total QMG score range 0–39.

Attachment 3. Myasthenia Gravis Foundation of America Clinical Classification

Class	Clinical symptoms
I	Any ocular weakness
II	Mild Weakness. May also have ocular muscle weakness of any severity
II A	Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal, respiratory muscles or both
II B	Predominantly affecting orорpharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles or both
III	Moderate weakness affecting other than ocular muscles. May also have ocular muscle weakness of any severity
III A	Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal, respiratory muscles or both
III B	Predominantly affecting orорpharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles or both
IV	Severe weakness affecting other than ocular muscles. May also have ocular muscle weakness of any severity
IV A	Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal, respiratory muscles or both
IV B	Predominantly affecting orорpharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles or both
V	Defined by intubation, with or without mechanical ventilation, except when employed during routine postoperative management

Updated: 03/2019
PARP Approved: 03/2019

C5B COMPLEMENT INHIBITORS (SOLIRIS AND ULTOMIRIS) PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis: _____

For Paroxysmal Nocturnal Hemoglobinuria (PNH) only:
Is the member's flow cytometry pathology report included? ☐ Yes ☐ No
Has the patient had a blood transfusion within the last 12 months? ☐ Yes ☐ No
Does the patient have symptoms of anemia? ☐ Yes ☐ No

For Atypical Hemolytic Uremic Syndrome only:
Has the absence of Shiga toxin-producing *E.coli* been confirmed? ☐ Yes ☐ No

For generalized Myasthenia Gravis only:
Does the patient have anti-acetylcholine antibodies? ☐ Yes ☐ No
What is the member's Myasthenia Gravis Foundation of America Clinical Classification? _____ ☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

Gateway Health

Updated: 03/2019
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C5B COMPLEMENT INHIBITORS (SOLIRIS AND ULTOMIRIS)
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REFERENCE VALUES

Lab	Initial (Pre-Treatment) Value	Reference Range	Date	Post-Therapy Value (Reauthorization only)	Reference Range	Date
Hemoglobin (Hgb)						
Lactate dehydrogenase (LDH)						
Platelet count						
Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score		**N/A**			**N/A**	
Quantitative Myasthenia Gravis (QMG) total score		**N/A**			**N/A**	

REAUTHORIZATION

For Paroxysmal Nocturnal Hemoglobinuria (PNH) only:
Has the patient had a blood transfusion since taking Soliris? ☐ Yes ☐ No

For Atypical Hemolytic Uremic Syndrome only:
Has the patient been able to maintain a normal platelet or LDH level for at least four weeks? ☐ Yes ☐ No
Has the patient experienced a 25% serum creatinine reduction for at least four weeks? ☐ Yes ☐ No
Has the patient not had a decrease in platelet count of >25% from baseline, plasma exchange, plasma infusion, or new dialysis requirement for at least 12 weeks? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date