PriorityHealth

Medical prior authorization form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☒ **Commercial (Traditional)** ☒ **Commercial Individual (Optimized)** ☒ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Soliris® (eculizumab)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product and Billing Information

☐ New Request ☐ Continuation Request

Drug product: ☐ Soliris 300 mg/30 mL

Start date (or date of next dose): _____

Date of last dose (if applicable): _____

Date of next dose (if applicable): _____

Dose:_____ **Dose Frequency**:_____

Place of administration:

☐ Physician's office

☐ Outpatient infusion

Facility: _____ NPI:_____ Fax:_____

☐ Home infusion

Agency: _____ NPI:_____ Fax:_____

Billing:

☐ Physician to buy and bill

☐ Facility to buy and bill

☐ Specialty Pharmacy

Pharmacy:_____ NPI:_____ Fax:_____

ICD-10 Diagnosis code(s): _____

Drug cost information

The wholesale acquisition cost for each 1 mL (10 mg) of Soliris is $203.70. The annual cost of treatment with this drug will vary depending on the patient's circumstances, but may cost more than $482,000 for PHN and $663,000 for aHUS).

All fields must be complete and legible for review. Your office will receive a response via fax.

Updated 06/2018
Last reviewed 05/2019

Precertification Requirements

Before this drug is covered, the patient must meet all of the requirements for one of the following conditions:

1. Paroxysmal nocturnal hemoglobinuria (PNH)
   - Must have received meningococcal vaccine at least two weeks before starting Soliris treatment
   - Must have flow cytometric confirmation ≥10% granulocyte clone cells
   - Or have symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, end organ damage)

2. Atypical hemolytic uremic syndrome (aHUS)
   - Must have received meningococcal vaccine at least two weeks before starting Soliris treatment
   - Shiga toxin-related HUS and Thrombotic Thrombocytopenia Purpura (TTP) must be ruled out

3. Refractory generalized myasthenia gravis (MG)
   - Must have received meningococcal vaccine at least two weeks before starting Soliris treatment
   - Must meet all the following criteria with documentation provided:
     a. Anti-acetylcholine receptor antibody (AChR-Ab) positive disease
     b. Myasthenia Gravis Foundation of America (MGFA[1]) Clinical Classification Class II – IV
     c. Myasthenia Gravis Activities of Daily Living (MG-ADL[2]) total score greater than or equal to 6
     d. Provide baseline quantitative myasthenia gravis (QMG[3]) total score
     e. Progressive disease on a therapeutic trial of at least FOUR or more of the following:
        i. azathioprine
        ii. cyclosporine
        iii. mycophenolate mofetil
        iv. tacrolimus
        v. methotrexate
        vi. cyclophosphamide
     f. Continued progressive disease on a therapeutic trial of:
        i. IVIG
     g. Prescribed by or in consultation with a neurologist
   - Initial authorization duration is 12 weeks. If continuation criteria is met, authorization may be extended for 12 months

For continuation, patient must meet all of the requirements for one of the following conditions:

1. Paroxysmal nocturnal hemoglobinuria (PNH)
   - Must have a decrease disabling symptoms
   - Hemoglobin levels must be stabilized
   - Patient has experienced an improvement in fatigue and quality of life
2. Atypical hemolytic uremic syndrome (aHUS)
   - Must have decreased signs of thrombotic microangiopathy (normalization of platelet counts and LDH levels, reduction in serum creatinine)
3. Refractory generalized myasthenia gravis (MG)
   - Must have documented response as evidenced by BOTH of the following:
     a. Improved MG-ADL total score from baseline
     b. Improved (QMG) total score from baseline

Commercial/Individual members: On and after January 1, 2017, infusion of Soliris is not covered at hospital-affiliated infusion centers. Patients age 17 and younger may choose to have this drug administered at a hospital-affiliated infusion center.
Medicaid members: Requirement to receive the medication by home infusion.

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

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New request
Priority Health Precertification Documentation

A. What condition is this drug being requested for?

- ☐ Atypical hemolytic uremic syndrome (aHUS)
- ☐ Paroxysmal nocturnal hemoglobinuria (PNH)
- ☐ Refractory generalized myasthenia gravis (MG)
- ☐ *Other – the patient's condition is:* _____
  Rationale for use: _____

For patients with aHUS, which of the following apply?

1. Was shiga toxin-related HUS and TTP ruled out?
   ☐ Yes ☐ No
2. When did the patient receive the meningococcal vaccine? _____

For patients with PNH, which of the following apply?

1. What percent of PNH granulocyte clone cells does cytometry confirm? _____
2. How many transfusions has the patient had in the last 12 months? _____
3. What disabling symptoms is the patient experiencing?
   - ☐ End organ damage
   - ☐ Frequent paroxysms of pain (abdominal pain, chest pain, other)
   - ☐ Shortness of breath
   - ☐ Thrombosis
   - ☐ Other: _____
4. When did the patient receive the meningococcal vaccine? _____

For patients with MG, which of the following apply?

- ☐ Laboratory assay showing confirmed presence of binding AChR-Ab is provided
- ☐ Documentation supporting patient has met MGFA[1] Clinical Classification Class II – IV is provided
  MGFA Class:_____
- ☐ Documentation supporting patient has MG-ADL[2] score ≥ 6 is provided
  MG-ADL score:_____
- ☐ Documentation of baseline quantitative myasthenia gravis (QMG[3]) total score is provided
  QMG total score:_____
- ☐ Patient has received meningococcal vaccine
  Date provided:_____
- ☐ The patient has used the following medications:

Drug	Dose	Dates of Use	Response to Therapy

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Updated 06/2018
Last reviewed 05/2019

Request for continuation
Priority Health Precertification Documentation

For patients with aHUS, which of the following apply?

- ☐ The patient's platelet counts and LDH levels have normalized and his or her serum creatinine has decreased

For patients with PNH, which of the following apply?

- ☐ The patient had a decrease in disabling symptoms since initiation of Soliris
- ☐ The patient's hemoglobin levels have stabilized
- ☐ The patient experienced fewer thrombotic events after starting Soliris
- ☐ The patient has shown improvement in both fatigue and quality of life since starting Soliris

For patients with MG, which of the following apply?

- ☐ Improved MG-ADL total score from baseline
  - Baseline MG-ADL:_____
  - Current MG-ADL: _____
- ☐ Improved (QMG) total score from baseline
  - Baseline QMG: _____
  - Current QMG: _____

[1]MGFA Clinical Classification

Class I:	Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal.
Class II:	Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
A. IIa.	Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
B. IIb.	Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
Class III:	Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
A. IIIa.	Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
B. IIIb.	Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
Class IV:	Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
A. IVa.	Predominantly affecting limb, axial muscles, or both. May also have lesser involvement of oropharyngeal muscles.
B. IVb.	Predominantly affecting oropharyngeal, respiratory muscles, or both. May also have lesser or equal involvement of limb, axial muscles, or both.
Class V:	Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management. The use of a feeding tube without intubation places the patient in class IVb.

[2]MG-ADL Profile (total score = summation of items 1-8)

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

Total score (summation of items 1-8):_____

[3]QMG: Manual with testing forms and instructions for appropriate testing administration are available through the Myasthenia Gravis Foundation and are available for download at www.myasthenia.org.

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