

Pharmacy

Last Reviewed: March 2012

PRIOR AUTHORIZATION FORM

Last Updated: March 2012

For Prior Authorization, please fax to: (877) 974-4411 toll free, or (616) 942-8206

This form applies to: Commercial Plan Medicaid Plan Medicare Plan

Soliris[®] (eculizumab)

URGENT (life threatening)

A claim involving "urgent care" applies when then standard review time will seriously jeopardize the life or health of the member, or subject the member to severe pain that cannot be managed without the care or treatment requested in the subject of this request. **Priority Health averages between 1 and 3 business days for our standard review response time.**

Non-Urgent (standard review)

Member Information

Member Name:	Member No.:
DOB:	Gender:
Member's PCP:	

Provider Information

Provider Name:	
Office Contact Name:	Provider Phone:
Provider NPI:	Provider Fax:
Provider Address:	

Provider Signature

Date

PRODUCT INFORMATION

Soliris PNH Dose: 600 mg every 7 days for 4 weeks, followed by 900 mg 7 days later, then 900 mg every 14 days.

Other: _____

aHUS Dose: 900 mg every 7 days for 4 weeks, followed by 1,200 mg 7 days later, then 1,200 mg every 14 days. (If < 18 yrs, weight based dosing (see product labeling)).

Start Date: _____

BILLING INFORMATION

Place of administration:

Provider's Office

Outpatient Infusion Center
Center Name: _____

Home Infusion
Agency Name: _____

Billing Options:

Physician buy and bill (J1300, per 10 mg)

Preferred Specialty Vendor

Other: _____

Request: New – Complete Section A
 Continuation – Complete Section B

PRIORITY HEALTH PRECERTIFICATION REQUIREMENTS

Authorization for Soliris® (eculizumab) requires the following information to certify:

Patient must have met the following requirements:

- Diagnosis of either paroxysmal nocturnal hemoglobinuria (PNH) or atypical hemolytic uremic syndrome (aHUS).
 - *For patients with PNH:*
 - Flow cytometric confirmation of at least 10% PNH cells
 - At least 4 or more transfusions in the last 12 months OR disabling symptoms (eg. thrombosis, and/or end organ damage)
 - *For patients with aHUS:*
 - Shiga toxin-related HUS has been ruled out
 - Patient must have received plasma exchange (PE) or plasma infusion (PI) within previous 2 weeks of starting Soliris therapy
 - Patient has a chronic need for either PE/PI or chronic dialysis
- Meningococcal vaccinated at least 2 weeks before treatment initiation

For continuation, patient must have met the following requirements:

For patients with PNH:

- A decrease in the number of transfusions or disabling symptoms
- Stabilization of Hemoglobin levels
- Fewer thrombotic events than prior to therapy
- Improvement in fatigue and quality of life

For patients with aHUS:

- Decrease in signs of TMA (normalization of platelet counts and LDH levels, reduction in serum creatinine)
- Decrease in need for PE/PI or dialysis

SECTION A – NEW THERAPY

PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION

Authorization for Soliris® (eculizumab) requires the following information to certify:

A. What is the patient's diagnosis?

- a. paroxysmal nocturnal hemoglobinuria (PNH)

The following criteria must also be met for use of Soliris in PNH

- i. Flow cytometric confirmation of at least 10% PNH cells
ii. Number of transfusions patient received in the previous 12 months: _____

If the number of transfusions is less than 4, which of the following disabling symptoms are present in the patient (at least 1 must be present):

- thrombosis
 end organ disease
 Other: _____

- b. atypical hemolytic uremic syndrome (aHUS).

The following criteria must also be met for use of Soliris in aHUS:

- i. Shiga toxin-related HUS has been ruled out
ii. Patient received plasma exchange (PE) or plasma infusion (PI) within the previous 2 weeks
and one of the following:
iii. patient has need for chronic PE or PI, or
 patient has need for chronic dialysis

B. Has the patient received the meningococcal vaccine at least 2 weeks prior to treatment initiation?

Yes

No – Rationale for use: _____

SECTION B – CONTINUATION**PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION**

Authorization for continuation of Soliris[®] (eculizumab) requires the following information to certify:

A. What is the patient's diagnosis?

- a. paroxysmal nocturnal hemoglobinuria (PNH)

For patients with PNH, all of the following criteria must be met for continuation:

- i. patient had a decrease in the number of transfusions or disabling symptoms since initiation of Soliris
- ii. patient's Hb levels have stabilized
- iii. patient experienced fewer thrombotic events while on Soliris than prior to therapy
- iv. patient has shown improvement disabling symptoms since initiating Soliris

- b. atypical hemolytic uremic syndrome (aHUS)

For patients with aHUS, all of the following criteria must be met for continuation:

- i. patient has decrease in signs of TMA (normalization of platelet counts and LDH levels, reduction in serum creatinine)
- ii. patient has decrease in need for PE/PI or dialysis

FOR MEDICARE ONLY

If none of the above precertification criteria is applicable to this member, please check off which, if any, of the following apply:

1. All covered Part D drugs on any tier of a plan's formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects
2. The number of doses available under a dose restriction for the prescription drug:
 - a. Has been ineffective in the treatment of the enrollee's disease or medical condition, or
 - b. Based on sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.
3. The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements:
 - a. Has been ineffective in the treatment of the enrollee's disease or medical condition, or
 - b. Based on sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.
 - c. Has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee.
4. None of the above apply

****If you selected 1, 2, or 3 above, supporting evidence/documentation is required for review. If no supporting evidence/documentation is provided, this request will not be approved.**

***** All fields must be complete and legible for Prior Authorization Review*****

**Please fax this request to: (877)974-4411 toll free or (616)942-8206
YOUR OFFICE WILL RECEIVE A RESPONSE VIA FAX**