MASSACHUSETTS

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Pharmacy Medical Policy

Soliris, Ultomiris, and Uplizna Policy

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Policy Number: 093

BCBSA Reference Number: None

Related Policies

- Quality Care Dosing guidelines apply to the following medications and can be found in Medical Policy #**621A**

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

Please refer to the chart below for the formulary and step status of the medications affected by this policy.

Standard Formulary	
Drug	**Formulary Status**
Soliris® (eculizumab)	PA Required
Ultomiris® (ravulizumab)	PA Required
Uplizna™ (Inebilizumab)	PA Required

We may cover Soliris®** (eculizumab) **OR we may cover** Ultomiris®** (ravulizumab) when **all** of the following criteria are met:

1. Paroxysmal nocturnal hemoglobinuria (PNH)
    a. 18 years of age or older
    b. Documented baseline value for serum lactate dehydrogenase (LDH) is ≥1.5 times the upper limit of normal.
    c. **NO** dual therapy with another terminal complement inhibitor such as Ultomiris® (ravulizumab) in combination with Soliris® (eculizumab)
    d. Vaccination against Neisseria meningitides, pneumococcus, haemophilus and meningococcal prior to initiation [unless treatment cannot be delayed])
    e. Prescribing physician is enrolled in Soliris REMS program and or the Ultomiris REMS program

2. Atypical hemolytic uremic syndrome (aHUS)
    a. Documented baseline value for serum lactate dehydrogenase (LDH) ≥ Upper Level of Normal (ULN) unless the patient has been receiving plasma exchange
    b. **NO** dual therapy with another terminal complement inhibitor such as Ultomiris® (ravulizumab) in combination with Soliris® (eculizumab)
    c. Vaccination against Neisseria meningitides, pneumococcus, haemophilus and meningococcal prior to initiation [unless treatment cannot be delayed]
    d. Does **NOT** have Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)
    e. Prescribing physician is enrolled in Soliris REMS program and or the Ultomiris REMS program

We may cover Soliris®** (eculizumab) when **all** of the following criteria are met:

I. Myasthenia Gravis (gMG)
    a. 18 years of age or older
    b. Positive serologic test for anti-AChR antibodies
    c. Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II to IV
    d. Documented baseline MG-Activities of Daily Living (MG-ADL) total score ≥ 6 (*https://info.soliris.net/wp-content/uploads/2017/12/Assessment_Tool_Booklet.pdf*)
    e. Vaccination against Neisseria meningitides, pneumococcus, haemophilus and meningococcal prior to initiation [unless treatment cannot be delayed]
    f. Prescribing physician is enrolled in Soliris REMS program.

II. Neuromyelitis optica spectrum disorder (NMOSD)
    a. 18 years of age or older
    b. Anti-aquaporin-4 (AQP4) antibody positive
    c. Vaccination against Neisseria meningitides, pneumococcus, haemophilus and meningococcal prior to initiation [unless treatment cannot be delayed]
    d. Prescribing physician is enrolled in Soliris REMS program.

Prior – Approval *Continuation* Requirements
Diagnoses

1. Paroxysmal nocturnal hemoglobinuria (PNH)
    a. 18 years of age or older
    b. Decrease in serum LDH from pretreatment baseline
    c. **NO** dual therapy with another terminal complement inhibitor such as Ultomiris® (ravulizumab) in combination with Soliris® (eculizumab)
    d. Prescribing physician is enrolled in Soliris REMS program and or the Ultomiris REMS program
    e. Absence of unacceptable toxicity from the drug

2. Atypical hemolytic uremic syndrome (aHUS)
    a. Decrease in serum LDH from pretreatment baseline
    b. **NO** dual therapy with another terminal complement inhibitor such as Ultomiris® (ravulizumab)

in combination with Soliris® (eculizumab)
c. Does **NOT** have Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS)
d. Prescribing physician is enrolled in Soliris REMS program and or the Ultomiris REMS program
e. Absence of unacceptable toxicity from the drug

3. Myasthenia Gravis (gMG)
a. 18 years of age or older
b. Decrease of (MG-ADL) total score from baseline (*https://info.soliris.net/wp-content/uploads/2017/12/Assessment_Tool_Booklet.pdf*)
c. Prescribing physician is enrolled in Soliris REMS program and or the Ultomiris REMS program
d. Absence of unacceptable toxicity from the drug

4. Neuromyelitis optica spectrum disorder (NMOSD)
a. 18 years of age or older
b. Patient has had fewer relapses while on Soliris therapy
c. Prescribing physician is enrolled in Soliris REMS program and or the Ultomiris REMS program
d. Absence of unacceptable toxicity from the drug

We may cover Uplizna™** (inebilizumab) for the treatment of neuromyelitis optica spectrum disorder (NMOSD) when **all** of the following criteria are met:

- Confirmed diagnosis of Neuromyelitis optica spectrum disorder (NMOSD), **AND**
- 18 years of age or older, **AND**
- Anti-aquaporin-4 (AQP4) antibody positive

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

For non-formulary/non-covered medications, requests must meet criteria above and the member must have had a previous treatment failure with or a contraindication to two covered formulary alternatives when available.

We do not cover the medications listed above for other conditions not listed above.

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There is no specific CPT code for this service.

Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances

may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Managed Care Authorization Information

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization. Pharmacy Operations: (800)366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.

PPO and Indemnity Authorization Information

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization. Pharmacy Operations: (800)366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.

Policy History

Date	Action
9/2020	Updated to include Uplizna™ and to change the policy name.
7/2020	Implement a policy for both Ultomiris® & Soliris®

References

1. Soliris® [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.: 7/2019.
2. Ultomiris® [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.: 10/2019.
3. Uplizna™ [package insert]. Gaithersburg, MD: Viela Bio, Inc.: 6/2020.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf