MetroPlus Health

Policy and Procedure

Title: Medicare - Soliris (eculizumab)	Division: Medical Management Department: Pharmacy
Approval Date: 6/27/2022	LOB: Medicare, MAP
Effective Date: 7/30/2021	Policy Number: UM-MP320
Review Date: 6/27/2022	Cross Reference Number:
Retired Date:	Page 1 of 3

1. **POLICY DESCRIPTION:**
   Soliris is a complement inhibitor indicated for:
   - The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
   - The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
   - The treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AchR) antibody positive.
   - The treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

2. **RESPONSIBLE PARTIES:**
   Utilization Management, Pharmacy

3. **DEFINITIONS:**
   Off-label/Unlabeled Use: Use of a drug is defined as a use for a non-FDA approved indication, that is, one that is not listed on the drug's official label/prescribing information.

   Indication: a diagnosis, illness, injury, syndrome, condition, or other clinical parameter for which a drug may be given.

4. **POLICY:**

   Documentation, including chart notes and lab results, MUST be submitted for approval.

   Per CMS regulation, Metroplus Health Plan follows the following Local Coverage Determination (LCD) and Local Coverage Article (LCA):
   1. LCD: L33394
   2. LCA: A54548

5. **LIMITATIONS/ EXCLUSIONS:**
   The use of eculizumab is limited to coverage guidance indicated in the CMS provided LCD/LCA.

6. **APPLICABLE PROCEDURE CODES:**

CPT	Description

J1300	INJECTION, ECULIZUMAB, 10 MG

7. APPLICABLE DIAGNOSIS CODES:

CODE	Description
D59.3	Hemolytic-uremic syndrome
D59.5	Paroxysmal nocturnal hemoglobinuria [Marchiafava-Micheli]
G36.0	Neuromyelitis optica [Devic]
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation
N00.6	Acute nephritic syndrome with dense deposit disease
N01.6	Rapidly progressive nephritic syndrome with dense deposit disease
N02.6	Recurrent and persistent hematuria with dense deposit disease
N03.6	Chronic nephritic syndrome with dense deposit disease
N04.6	Nephrotic syndrome with dense deposit disease
N07.6	Hereditary nephropathy, not elsewhere classified with dense deposit disease
T86.19	Other complication of kidney transplant

8. REFERENCES:

1. Soliris (eculizumab) [package insert]. Boston, Massachusets: Alexion Pharmaceuticals, Inc. November 2020.
2. CMS Local Coverage Determination (LCD): Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394)
3. CMS Local Coverage Article (LCA): Billing and Coding: Omalizumab (A54548)

REVISION LOG:

REVISIONS	DATE
Creation date	7/30/2021
Annual Review	6/27/2022

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Approved: **Date:** Glendon Henry Digitally signed by Glendon Henry Date: 2022.06.28 11:02:01 -04'00'	**Approved:** **Date:** Sanjiv Shah MD Digitally signed by Sanjiv Shah MD Date: 2022.07.06 17:31:35 -04'00'
Glendon Henry, MD **Senior Medical Director**	**Sanjiv Shah, MD** **Chief Medical Officer**

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members.

All coding and website links are accurate at time of publication.

MetroPlus Health Plan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.