Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Soliris® (eculizumab)

Effective: December 1, 2023

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988
CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939
☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Neuromyelitis optica spectrum disorder (NMOSD) is an ultra-rare autoimmune disease resulting from inflammation of the central nervous system that is characterized by severe demyelination and axonal damage, predominantly targeting the optic nerves and spinal cord. Patients frequently experience a relapsing disease course. Neurologic damage and disability accumulate with repeated attacks. Approval of Soliris for treatment of NMOSD in anti-AQP4 antibody positive patients was based on the PREVENT trial. Results demonstrated that the time to the first relapse was significantly longer in Soliris-treated patients compared to placebo-treated patients, with or without concomitant treatment. Furthermore, Soliris-treated patients had reduced annualized rates of hospitalizations, of corticosteroid administrations to treat acute relapses, and of plasma exchange treatments.

Myasthenia gravis (MG) is an autoimmune disorder characterized by muscle weakness and fatigue. The degree of muscle weakness can fluctuate and vary in severity from person to person; however, it will generally improve with rest and worsen with physical activity. Most patients with MG develop autoantibodies that attack the acetylcholine receptor (AChR), blocking or destroying the receptors, which prevents muscles from contracting. The REGAIN trial evaluated Soliris in patients with MG with a positive serologic test for anti-AChR antibodies who had failed at least two immunosuppressive therapies. A statistically significant difference favoring Soliris was observed in the mean change from baseline to Week 26 in Myasthenia Gravis-Activities of Daily Living total scores compared to placebo.

Food and Drug Administration-Approved Indications:

Soliris (eculizumab) is a complement inhibitor indicated for the treatment of:

- **Atypical Hemolytic Uremic Syndrome (aHUS)**
  Patients with aHUS to inhibit complement-mediated thrombotic microangiopathy
- **Generalized Myasthenia Gravis (gMG)**

Adult patients with gMG who are anti-acetylcholine receptor antibody positive
- **Neuromyelitis Optica Spectrum Disorder (NMOSD)**
  NMOSD in adult patients who are anti-aquaporin-4 antibody positive
- **Paroxysmal Nocturnal Hemoglobinuria (PNH)**
  Patients with PNH to reduce hemolysis

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Soliris for Members when documentation of the following criteria is met:
Atypical Hemolytic Uremic Syndrome, Paroxysmal Nocturnal Hemoglobinuria

1. Documentation of **one (1)** of the following:
   a. Diagnosis of atypical hemolytic uremic syndrome (aHUS)
   b. Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH)

Generalized Myasthenia Gravis

Initial Authorization Criteria

1. Documented diagnosis of generalized myasthenia gravis

AND

2. Documentation of a positive serologic test for anti-acetylcholine antibodies

AND

3. The prescribing physician is a neurologist

Reauthorization Criteria

1. Documented diagnosis of generalized myasthenia gravis

AND

2. Documentation of a positive serologic test for anti-acetylcholine antibodies

AND

3. The prescribing physician is a neurologist

AND

4. Documentation the Member has experienced a therapeutic response as defined by an improvement of Myasthenia Gravis-Activities of Daily Living (MG-ADL) total score from baseline

Neuromyelitis Optica Spectrum Disorder (NMOSD)

1. Documented diagnosis of neuromyelitis optica spectrum disorder

AND

2. Documentation of a positive serologic test for anti-aquaporin-4 antibodies

Limitations

- Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements.
- Initial coverage of Soliris for generalized myasthenia gravis will be authorized for 6 months. Reauthorization of Soliris will be provided for 12-month intervals.
- Members new to the plan stable on Soliris should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1300	Injection, eculizumab, 10 mg

References

1. Billing and Coding: Eculizumab. Local Coverage Article. (A54548). Centers for Medicare and Medicaid Services (CMS). Accessed 2023 August.
2. Local Coverage Determination (LCD): Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394). Centers for Medicare and Medicaid Services (CMS). Accessed 2023 August.
3. Soliris (eculizumab) [package insert]. Cheshire, CT: Alexion Pharmaceuticals, Inc.; Last updated November 2020.

4. Narayanaswami P, et al. International Consensus Guidance for Management of Myasthenia Gravis 2020 Update. Neurology. 2021; 96:114-22.
5. Kessler RA, et al. Treatment of Neuromyelitis Optica Spectrum Disorder: Acute, Preventive, and Symptomatic. Current Treatment Options in Neurology. 2016;18(2).

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T).

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).

Subsequent endorsement date(s) and changes made:

- September 12, 2023: Removed Step Therapy requirements from Medical Necessity Guideline. Added the Limitation Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements. For PNH, updated criteria to diagnosis only. For aHUS, updated criteria to diagnosis only. For NMOSD, updated criteria for diagnosis and a positive serologic test for anti-aquaporin-4 antibodies. For generalized myasthenia gravis, added Reauthorization Criteria, removed age requirements, added provider specialty requirements, and updated the wording for the requirement to be a positive serologic test for anti-acetylcholine. Removed the Limitations The health plan may authorize initial coverage of Soliris (eculizumab) for up to 12 weeks for the treatment of atypical hemolytic uremic syndrome (aHUS) when coverage criteria are met, The health plan may reauthorize coverage of Soliris (eculizumab) for the treatment of atypical hemolytic uremic syndrome (aHUS) for up to 12 months if reauthorization criteria are met, The health plan may authorize coverage of Soliris (eculizumab) for up to 12 months for the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH), generalized myasthenia gravis (gMG), or neuromyelitis Optica spectrum disorder (NMOSD) when coverage criteria are met, and Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan (effective 12/1/23).
- November 2023: Administrative Updates: Rebranded from Tufts Health Unify to Tufts Health One Care for 2024 and administrative update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic..