CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines
Medical Benefit Drugs
Ultomiris® (ravulizumab-cwvz)

Effective: December 1, 2023

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

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, 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

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. Approval of Ultomiris for MG was based on a trial in which patients with MG with a positive serologic test for anti-AChR antibodies treated with Ultomiris achieved a statistically significant change in the Myasthenia Gravis-Activities of Daily Living and Quantitative MG total scores from baseline at Week 26 compared to placebo.

Food and Drug Administration-Approved Indications:

Ultomiris (ravulizumab-cwvz) is a complement inhibitor indicated for the treatment of:

Atypical Hemolytic Uremic Syndrome (aHUS):

Adults and pediatric patients one month of age and older with aHUS to inhibit complement- mediated thrombotic microangiopathy (TMA)

Paroxysmal Nocturnal Hemoglobinuria (PNH):

Adults and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria

Generalized Myasthenia Gravis:

Adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Ultomiris for Members when the following criteria are met:

Atypical Hemolytic Uremic Syndrome, Paroxysmal Nocturnal Hemoglobinuria

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

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

Limitations

- Initial coverage of Ultomiris for generalized myasthenia gravis will be authorized for 6 months. Reauthorization of Ultomiris will be provided for 12-month intervals,
- Members new to the plan stable on Ultomiris should be reviewed against Reauthorization Criteria.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1303	Injection, ravulizumab-cwvz, 10 mg

References

1. Ultomiris (ravulizumab-cwvz) [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc. April 2022.
2. Narayanaswami P, et al. International Consensus Guidance for Management of Myasthenia Gravis 2020 Update. Neurology. 2021;96:114-22.

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 “The Member will be receiving Ultomiris at a REMS certified health care facility.” Removed the Limitation “Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan.” For generalized myasthenia gravis, added Reauthorization Criteria, added provider specialty requirements, and updated the wording for the requirement to be a positive serologic test for anti-acetylcholine antibodies for generalized myasthenia gravis (effective 12/1/23).
- November 2023: 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..