COLORADO
Department of Health Care Policy & Financing

1570 Grant Street
Denver, CO 80203

Health First Colorado (Colorado's Medicaid Program) Coverage Standards for Ultomiris (ravulizumab-cwvz)

September 2023

Ultomiris (ravulizumab-cwvz) requests will be evaluated for medical necessity and reviewed on a case-by-case basis for all Health First Colorado Members based on the following coverage standards. If request is for use outside of stated coverage standards, support with peer reviewed medical literature and/or subsequent clinical rationale shall be provided and will be evaluated at the time of request.

a. Member is diagnosed with either Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS), or Generalized Myasthenia Gravis (gMG) AND
b. Member has been vaccinated for meningococcal disease according to current ACIP guidelines at least two weeks prior to medication initiation OR
c. Member is receiving 2 weeks of antibacterial drug prophylaxis if meningococcal vaccination cannot be administered at least 2 weeks prior to starting requested medication AND
d. Member does not have unresolved *Neisseria meningitidis* or any systemic infection
e. Prescriber is enrolled in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program AND
f. Medication is administered by or in consultation with a hematologist for PNH and by or in consultation with a hematologist or nephrologist for aHUS and by or in consultation with a neurologist for gMG AND
g. Member meets criteria listed below for specific diagnosis:
    i. <u>Paroxysmal nocturnal hemoglobinuria (PNH)</u>
        1. Member is one month of age or older if prescribing the IV formulation OR is ≥ 18 years of age if prescribing the subcutaneous formulation AND
        2. Diagnosis of PNH must be accompanied by detection of PNH clones by flow cytometry diagnostic testing AND
        3. Baseline values are documented for the following:
            - ❑ Serum lactate dehydrogenase (LDH)
            - ❑ Hemoglobin levels
            - ❑ Packed RBC transfusion requirement

        AND
        4. Member has one of the following indications for therapy:
            - ❑ Presence of a thrombotic event
            - ❑ Presence of organ dysfunction secondary to chronic hemolysis
            - ❑ Member is transfusion dependent
            - ❑ Member has uncontrolled pain secondary to chronic hemolysis
    ii. <u>Atypical hemolytic uremic syndrome (aHUS)</u>
        1. Member is one month of age or older if prescribing the IV formulation OR is ≥ 18 years of age if prescribing the subcutaneous formulation AND
        2. Member does not have Shiga toxin E. coli related HUS (STEC-HUS) AND

3. Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS13 level or a trial of plasma exchange did not result in clinical improvement AND
4. Baseline values are documented for the following:
    - ❑ Serum LDH
    - ❑ Serum creatinine/eGFR
    - ❑ Platelet count
    - ❑ Dialysis requirement

iii. <u>Generalized myasthenia gravis</u>

1. Member is 18 years of age or older AND
2. Member has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies
3. Member has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; AND
4. Member has a MG-Activities of Daily Living (MG-ADL) total score of ≥6; AND
5. Member has trial and failure of treatment over at least 1 year with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate, etc.), or has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG)