RX.PA.054.CCH ULTOMIRIS (RAVULIZUMAB-CWVZ)

The purpose of this policy is to define the prior authorization process for Ultomiris® (ravulizumab-cwvz).

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Ultomiris® (ravulizumab-cwvz), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed below:

- Must be at least one month of age
- Must be prescribed by or in consultation with a hematologist, oncologist, immunologist, or genetic specialist
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must be prescribed to treat one of the following:
    - Must have a laboratory confirmed diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) as evidenced by having detectable GPI-deficient hematopoietic clones (Type III PNH RBC) via Flow Cytometry. Documentation of Flow Cytometry pathology report support must indicate presence of PNH-type RBC (red blood cell) and must be submitted.
    - Atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA)
- Must have an LDH level of 1.5 times the upper limit of the normal range (laboratory result with reference range must be submitted)
- Must provide documentation that a meningococcal vaccine was given at least two (2) weeks prior to the administration of the first dose of Ultomiris

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year

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intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

Codes: J Code(s)

Code	Brand	Description
J1303	**Ultomiris**	INJECTION RAVULIZUMAB-CWVZ 10 MG

REFERENCES

1. Ultomiris [prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; January 2022.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial Review	3/22
Updated initial authorization duration to 1 year	02/23

Record Retention

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

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