

Ultomiris™ (ravulizumab-cwvz)

When requesting Ultomiris™ (elapegademase-lvlr), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Ultomiris is indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

Coverage Guidelines

Paroxysmal nocturnal hemoglobinuria (PNH)

For an initial authorization:

- The diagnosis of PNH has been confirmed by peripheral blood flow cytometry results showing the absence or deficiency of glycosyl phosphatidylinositol (GPI)-anchored proteins on at least 2 cell lineages
- An individual is 18 years of age or older
- Ultomiris is prescribed by or in consultation with a hematologist

For re-authorization:

- An individual is continuing to receive benefits from Ultomiris (e.g., stabilization of hemoglobin levels, decreased transfusion requirement/transfusion independence, reduction in hemolysis)

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Recommendations

Ultomiris is only administered as an intravenous infusion.

Body Weight Range (kg)	Loading Dose (mg)	Maintenance Dose (mg)
Greater or equal to 40 to less than 60	2,400	3,000
Greater than or equal to 60 to less than 100	2,700	3,300
Greater than or equal to 100	3,000	3,600

References

1. Ultomiris™ injection [prescribing information]. New Haven, CT: Alexion Pharmaceuticals, Inc.; December 2018.
2. Brodsky RA. Paroxysmal nocturnal hemoglobinuria. *Blood*. 2014;124(18):2804–2811.