ALASKA MEDICAID
Prior Authorization Criteria

Fabhalta™ (iptacopan)

FDA INDICATIONS AND USAGE[1]

Fabhalta™ is a complement factor B inhibitor, indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).

APPROVAL CRITERIA[1,2,3]

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with a hematologist **AND**;
3. Patient has the diagnosis of paroxysmal nocturnal hemoglobinuria confirmed by flow cytometry diagnostic testing **AND**;
4. Patient's hemoglobin is <10g/dl **AND**;
5. Documented baseline laboratory values, including:
    a. Serum lipid panel including total cholesterol, LDL-C and triglycerides
    b. Hemoglobin
    c. Serum lactate dehydrogenase (LDH) **AND**;
6. Patient has tried and failed or has an intolerance or contraindication to one of the following complement inhibitors:
    a. eculizumab
    b. pegcetacoplan
    c. ravulizumab-cwvz

DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Patient has not been vaccinated against Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B at least two weeks prior to the first dose of Fabhalta™ **OR**;
3. Patient will use Fabhalta™ in combination with another complement inhibitor **OR**;
4. Patient has an unresolved, serious infection caused by encapsulated bacteria (e.g. Streptococcus pneumoniae)

CAUTIONS[1]

- Fabhalta™ increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by encapsulated bacteria. Vaccination does not eliminate the risk of serious encapsulated bacterial infections, despite development of antibodies following vaccination.
- After discontinuing treatment with Fabhalta™, closely monitor patients for at least 2 weeks after the last dose for signs and symptoms of hemolysis.
- Use of Fabhalta™ in combination with cytochrome P450 2C8 inhibitors is not recommended.

DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- 68 capsules in 34 days

REFERENCES / FOOTNOTES:

1. Fabhalta [prescribing information]. East Hanover, NJ; Novartis; March 2024
2. NCT04558918. Study of Efficacy and Safety of Twice Daily Oral LNP023 in Adult PNH Patients With Residual Anemia Despite Anti-C5 Antibody Treatment (APPLY-PNH). Available at: https://www.clinicaltrials.gov/study/NCT04558918. Accessed April 3, 2024.
3. Brodsky RA. Clinical manifestations and diagnosis of paroxysmal nocturnal hemoglobinuria. UpToDate. Available at: https://www.uptodate.com/contents/clinical-manifestations-and-diagnosis-of-paroxysmal-nocturnal-hemoglobinuria