AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Fabhalta (iptacopan)	Page:	1 of 2
Effective Date:	3/26/2024	Last Review Date:	01/26/2024
Applies to:	☒Illinois ☒Maryland ☐Michigan	☐Florida ☒Florida Kids ☒Virginia	☒New Jersey ☒Pennsylvania Kids ☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Fabhalta under the patient's prescription drug benefit.

Description:

FDA-Approved Indication
Fabhalta is indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Fabhalta

Policy/Guideline:

Documentation
Submission of the following information is necessary to initiate the prior authorization review for new requests for treatment of:

A. For initial requests:
   Flow cytometry used to show results of glycosylphosphatidylinositol-anchored proteins (GPI-APs) deficiency.
B. For continuation requests:
   Chart notes or medical record documentation supporting positive clinical response.

Criteria for Initial Approval

Paroxysmal nocturnal hemoglobinuria

Authorization may be granted for treatment of paroxysmal nocturnal hemoglobinuria (PNH) when ALL of the following criteria are met:

A. The diagnosis of PNH was confirmed by detecting a deficiency of glycosylphosphatidylinositol-anchored proteins (GPI-APs) as demonstrated by either of the following:
   1. At least 5% PNH cells
   2. At least 51% of GPI-AP deficient poly-morphonuclear cells
B. Flow cytometry is used to demonstrate GPI-APs deficiency.

Continuation of Therapy

Paroxysmal nocturnal hemoglobinuria

Authorization may be granted for continued treatment when the following crierter are met:

A. There is no evidence of unacceptable toxicity or disease progression while member is on the current regimen and demonstrates a positive response to therapy (e.g., improvement in hemoglobin levels, normalization of lactate dehydrogenase [LDH] levels).

Approval Duration and Quantity Restrictions:

Initial Approval: 6 Months
Renewal Approval: 12 Months

Quantity Level Limit:

Fabhalta (iptacopan) 200mg capsules	60 capsules per 30 days	200mg orally twice daily without regard to food

References:

1. Fabhalta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2023.
2. Parker CJ. Management of paroxysmal nocturnal hemoglobinuria in the era of complement inhibitory therapy. Hematology. 2011; 21-29.
3. Borowitz MJ, Craig F, DiGiuseppe JA, et al. Guidelines for the Diagnosis and Monitoring of Paroxysmal Nocturnal Hemoglobinuria and Related Disorders by Flow Cytometry. Cytometry B Clin Cytom. 2010: 78: 211-230.
4. Preis M, Lowrey CH. Laboratory tests for paroxysmal nocturnal hemoglobinuria (PNH). Am J Hematol. 2014;89(3):339-341.
5. Parker CJ. Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria. Hematology Am Soc Hematol Educ Program. 2016;2016(1):208-216.
6. Dezern AE, Borowitz MJ. ICCS/ESCCA consensus guidelines to detect GPI-deficient cells in paroxysmal nocturnal hemoglobinuria (PNH) and related disorders part 1 - clinical utility. Cytometry B Clin Cytom. 2018 Jan;94(1):16-22.