AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Fabhalta (iptacopan)	Page:	1 of 3
Effective Date:	2/7/2025	Last Review Date:	2/7/2025
Applies to:	☒New Jersey		

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:

A. Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH) – Reference the New Jersey State guideline: *PNH products approved protocol addendum 10-24*
B. To reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g*.

*This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether Fabhalta slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

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:

A. Initial requests:
    a. Primary immunoglobin A nephropathy (IgAN):
        i. Kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).
        ii. Laboratory report and/or chart note(s) indicating the member has proteinuria greater than or equal to 1 g/day or baseline UPCR greater than or equal to 0.8 g/g based on a 24-hour urine collection.
B. Continuation requests:
    a. Primary immunoglobin A nephropathy (IgAN): Laboratory report and/or chart note(s) indicating the member has decreased levels of proteinuria or UPCR from baseline based on a 24-hour urine collection.

Criteria for Initial Approval

A. Primary immunoglobulin A nephropathy (IgAN)
Authorization of 10 months may be granted for treatment primary immunoglobulin A nephropathy (IgAN) when all of the following criteria are met:
1. Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy.
2. Member has proteinuria greater than or equal to 1 g/day or UPCR greater than or equal to 0.8 g/g based on a 24-hour urine collection.
3. Member has received a stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy (e.g., angiotensin converting enzyme inhibitor [ACEI] or angiotensin II receptor blocker [ARB]) for at least 3 months prior to initiation of therapy, or member has an intolerance or contraindication to RAS inhibitors.
4. Member has experienced an intolerance to oral glucocorticoid (e.g., prednisone).

Continuation of Therapy

A. Primary immunoglobulin A nephropathy (IgAN)
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when all of the following criteria are met:
1. There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
2. The member is experiencing benefit from therapy as evidenced by either of the following:
   i. Decreased levels of proteinuria from baseline on a 24-hour urine collection.
   ii. Decrease in UPCR from baseline based on a 24-hour urine collection.

Approval Duration and Quantity Restrictions:

Initial Approval: Primary immunoglobulin A nephropathy (IgAN): 10 months

Renewal Approval: 12 Months

Quantity Level Limit:

Fabhalta 200mg caps	60 caps per 30 days	200mg orally twice daily without regard to food

References:

1. Fabhalta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2024.
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.
7. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021 Oct; 100 (4S): S1-S276. doi: 10.1016/j.kint.2021.05.021.