Effective Date: 3/1/2025
Reviewed: 1/25, 8/25
Pharmacy Scope: Medicaid

NON-ONCOLOGY AND NON-HEMATOLOGY POLICY

FABHALTA (iptacopan)

For oncology and hematology indications, please refer to Neighborhood's Fabhalta Oncology/Hematology Policy

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Fabhalta is indicated for:

A. 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*.
B. Treatment of adults with complement 3 glomerulopathy (C3G), to reduce proteinuria.

*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.

II. CRITERIA FOR INITIAL APPROVAL

A. Primary immunoglobulin A nephropathy (IgAN)
Authorization of 6 months may be granted for treatment primary immunoglobulin A nephropathy (IgAN) when all of the following criteria are met:

1. Documentation that member has a kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).
2. The medication must be prescribed by or in consultation with a nephrologist.
3. Documentation with laboratory report and/or chart note(s) indicating the member has proteinuria greater than or equal to 1 g/day or baseline urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g based on a 24-hour urine collection.
4. Documentation that member's eGFR ≥20 mL/min/1.73 m^2
5. Member is receiving 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.

6. Member is receiving a stable dose of maximally tolerated sodium-glucose cotransporter-2 (SGLT2) inhibitor for at least 3 months prior to initiation of therapy, or member has an intolerance or contraindication to SGLT2 inhibitors.
7. Member has experienced a documented inadequate response from a 30-day trial, intolerance, or contraindication to an oral glucocorticoid (e.g., prednisone).
8. Member has experienced a documented inadequate response, intolerance, or contraindication to Filspari or Vanrafia.
9. Member is not using medication in combination with Filspari, Vanrafia or Tarpeyo.
10. Member is not currently receiving dialysis and has not undergone kidney transplant.

B. Complement 3 Glomerulopathy (C3G)

Authorization of 6 months may be granted for treatment of complement 3 glomerulopathy when all of the following criteria are met:

1. Documentation that member has a kidney biopsy confirming a diagnosis of complement 3 glomerulopathy.
2. Documentation with laboratory report and/or chart note(s) indicating the member has proteinuria greater than or equal to 1 g/day or baseline urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.0 g/g based on a 24-hour urine collection.
3. Documentation that member's eGFR ≥30 mL/min/1.73 m^2
4. Documentation that the member has reduced serum C3 (defined as less than 0.85 times the lower limit of normal per the reference ranges provided) at baseline.
5. Member is receiving 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.
6. Member is receiving a stable dose of maximally tolerated sodium-glucose cotransporter-2 (SGLT2) inhibitor for at least 3 months prior to initiation of therapy, or member has an intolerance or contraindication to SGLT2 inhibitors.

III. CONTINUATION OF THERAPY

A. Primary immunoglobulin A nephropathy (IgAN)

Authorization of 6 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. Documentation with laboratory report and/or chart note(s) indicating 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.
3. Documentation that member's eGFR remains ≥20 mL/min/1.73 m^2.
4. Member is not using medication in combination with Filspari, Vanrafia or Tarpeyo.

B. Complement 3 Glomerulopathy

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization when all of the following criteria are met:

5. There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
6. Documentation with laboratory report and/or chart note(s) indicating 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.
7. Documentation that member's eGFR remains ≥30 mL/min/1.73 m^2.

IV. QUANTITY LIMIT

Fabhalta 200mg capsule has a quantity limit of 2 capsules per day.

V. REFERENCES

1. Fabhalta [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2025.
2. 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.
3. Kidney Disease: Improving Global Outcomes (KDIGO). KDIGO 2024 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV) Public Review Draft August 2024 [Accessed at https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2024-IgAN-IgAV-Guideline-Public-Review-Draft.pdf].
4. Caster DJ, Lafayette RA. The Treatment of Primary IgA Nephropathy: Change, Change, Change. Am J Kidney Dis. 83(2):229-240. Published online September 23, 2023.