Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Aqvesme (mitapivat)

Effective: June 1, 2026

Guideline Type	☒ Prior Authorization ☒ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Aqvesme (mitapivat) is a pyruvate kinase activator indicated for the treatment of anemia in adults with alpha- or beta-thalassemia.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Aqvesme (mitapivat) for Members when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Patient is 18 years of age or older

AND

2. Documented diagnosis of anemia with alpha or beta-thalassemia

AND

3. Hemoglobin is less than or equal to 10g/dL

AND

4. Patient has symptomatic anemia or is transfusion dependent

AND

5. Patient does not have liver cirrhosis

AND

6. Patient does not have documented history of homozygous or heterozygous sickle hemoglobin or hemoglobin C

AND

7. Patient has not had prior exposure to gene therapy for alpha or beta thalassemia (e.g., Casgevy, Zynteglo)

AND

8. Patient has not had prior bone marrow or stem cell transplantation

AND

9. Patient is not on concurrent treatment with any of the following:
    a. Reblozyl (luspatercept-aamt)
    b. Pyrukynd (mitapivat)

AND

10. Prescribed by or in consultation with a hematologist

Reauthorization Criteria

1. Patient demonstrates positive clinical response to therapy (e.g., reduction in RBC transfusion burden, improvement in fatigue, increase in Hb concentration greater than or equal to 1g/dL from baseline)

AND

2. Patient does not have liver cirrhosis

AND

3. Patient does not have documented history of homozygous or heterozygous sickle hemoglobin or hemoglobin C

AND

4. Patient has not had prior exposure to gene therapy for alpha or beta thalassemia (e.g., Casgevy, Zynteglo)

AND

5. Patient has not had prior bone marrow or stem cell transplantation

AND

6. Patient is not on concurrent treatment with any of the following:
    a. Reblozyl (luspatercept-aamt)
    b. Pyrukynd (mitapivat)

AND

7. Prescribed by or in consultation with a hematologist

Limitations

1. Initial approval will be authorized for 12 months. Reauthorization will be provided in 12-month intervals.
2. Members new to the plan stable on the requested medication should be reviewed against Initial Authorization Criteria.
3. Members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against Initial Authorization Criteria.

References

1. Aqvesme (mitapivat) [prescribing information]. Cambridge, MA: Agios Pharmaceuticals, Inc.; December 2025.

Approval And Revision History

May 12, 2026: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.