

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2413-1
Program	Prior Authorization/Medical Necessity
Medication	Aqvesme™ (mitapivat)
P&T Approval Date	4/2026
Effective Date	7/1/2026

1. Background:

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

2. Coverage Criteria^a:

A. Initial Authorization

1. Aqvesme will be approved based on **all** of the following criteria:

a. Diagnosis of alpha- or beta-thalassemia

-AND-

b. **One** of the following:

(1) **All** of the following:

(a) Patient has had 5 or less red blood cell (RBC) transfusions in the previous 24 weeks

-AND-

(b) Patient has a baseline hemoglobin (Hb) ≤ 10 g/dL

-AND-

(c) Patient demonstrates fatigue-related symptoms from anemia associated with thalassemia

-OR-

(2) Patient is considered transfusion-dependent, requiring a minimum of 6 RBC transfusion episodes in the preceding 24 weeks

-AND-

c. Patient has not had prior exposure to gene therapy or prior bone marrow or stem cell transplantation for treatment of thalassemia

-AND-

- d. Patient will not be taking **Aqvesme** in combination with Reblozyl (luspatercept)

-AND-

- e. Prescribed by or in consultation with a hematologist or other specialist with expertise in the diagnosis and management of thalassemia

Authorization will be issued for 12 months.

B. Reauthorization

1. **Aqvesme** will be approved based on **all** of the following criteria:

- a. Documentation of positive clinical response to **Aqvesme** therapy (e.g., for transfusion-dependent thalassemia, a transfusion reduction response $\geq 50\%$ over a minimum of a 12-week period; in non-transfusion-dependent thalassemia, a decrease in fatigue or an increase in baseline hemoglobin)

-AND-

- b. Prescribed by or in consultation with a hematologist or other specialist with expertise in the diagnosis and management of thalassemia

-AND-

- c. Patient is not taking **Aqvesme** in combination with Reblozyl (luspatercept)

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Aqvesme [prescribing information]. Agios Pharmaceuticals, Inc. Cambridge, MA. December 2025.
2. Taher AT, Farmakis D, Porter JB, Cappellini MD, Musallam KM, eds. Guidelines for the Management of Transfusion-Dependent β -Thalassaemia (TDT). 5th ed. Nicosia, Cyprus: Thalassaemia International Federation; 2025.

3. Ali A, Ashutosh L, Coates TD, Fucharoen S, eds. Guidelines for the Management of α -Thalassaemia. 1st ed. Nicosia, Cyprus: Thalassaemia International Federation; 2023.

Program	Prior Authorization/Medical Necessity – Aqvesme™ (mitapivat)
Change Control	
4/2026	New program.