UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2277-2
Program	Prior Authorization/Medical Necessity
Medication	Pyrukynd® (mitapivat)
P&T Approval Date	5/2022, 5/2023
Effective Date	8/1/2023; Oxford only: 8/1/2023

1. Background:

Pyrukynd® (mitapivat) is a pyruvate kinase activator indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.

2. Coverage Criteria[a]:

A. Initial Authorization

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

   a. Diagnosis of pyruvate kinase (PK) deficiency based on **all** of the following:

      (1) Presence of at least 2 variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least 1 is a missense variant

      -AND-

      (2) Patient is not homozygous for the c.1436G>A (p.R479H) variant

      -AND-

      (3) Patient does not have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene

      -AND-

   b. Used for the treatment of hemolytic anemia

      -AND-

   c. **One** of the following:

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

         i. Baseline hemoglobin less than or equal to 10 g/dL

         -AND-

         ii. Patient has had no more than 4 transfusions in the previous 52 weeks and no transfusions in the preceding 3-month period

-OR-

(2) Patient has had a minimum of 6 transfusion episodes in the preceding 52 weeks

-AND-

d. Prescribed by a nephrologist or hematologist

Authorization will be issued for 6 months.

2. Reauthorization

a. **Pyrukynd** will be approved based on **one** of the following criteria:

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

i. Documentation of positive clinical response to Pyrukynd therapy based on **one** of the following:

- A ≥ 1.5 g/dL increase in hemoglobin from baseline sustained at 2 or more scheduled assessments 4 weeks apart during the initial 24 week period without any transfusions

-OR-

- Reduction in transfusions of ≥ 33% in the number of red blood cell units transfused during the initial 24 week period compared with the patient's historical transfusion burden

-OR-

- Patent has been on Pyrukynd for greater than 52 weeks and has maintained a positive clinical response to therapy

-AND-

ii. Prescribed by, or in consultation with, a nephrologist or hematologist

Authorization will be issued for 12 months.

-OR-

(2) Documentation does not provide evidence of positive clinical response to Pyrukynd therapy, allow for dose titration with discontinuation of therapy

Authorization will be issued for 4 weeks.

[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. Pyrukynd [package insert]. Cambridge, MA: Agios Pharmaceuticals, Inc.; February 2022.

Program	Prior Authorization/Medical Necessity – Pyrukynd® (mitapivat)
Change Control	
5/2022	New program.
5/2023	Annual review. No changes.