



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 16, 2022

## **PYRUKYND® (mitapivat)**

**LENGTH OF AUTHORIZATION:** Up to 6 months

**REVIEW CRITERIA:**

- Patient must be  $\geq 18$  years of age.
- Patient must have a diagnosis of hemolytic anemia due to pyruvate kinase deficiency.
- Patient must have  $\geq 2$  variant alleles (at least 1 must be a missense variant) in the pyruvate kinase liver and red blood cell (PKLR) gene. (*Diagnostic testing results must be included with submission*)
- Patient must have hemoglobin  $\leq 10$  g/dL or receives regular blood transfusions (at least 6 in the past year).
- The patient is on concurrent folic acid therapy.
- Patient is not and will not be receiving hematopoietic-stimulating therapy while on Pyrukynd.
- Patient does not have any of the following:
  - Moderate or severe hepatic impairment.
  - A history of splenectomy or will undergo splenectomy while taking Pyrukynd.
  - Prior bone marrow or stem cell transplant.

**RENEWAL CRITERIA:**

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response as demonstrated by either of the following:
  - Hemoglobin has increased  $\geq 1.5$ g/dL from baseline; **OR**
  - Documented reduction in RBC transfusions from baseline
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

**DOSING AND ADMINISTRATION:**

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as 5mg, 20mg and 50mg tablets.