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 ≥ 18 years of age.
- Patient must have a diagnosis of hemolytic anemia due to pyruvate kinase deficiency.
- Patient must have ≥ 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 ≤ 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 ≥1.5g/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.