

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Mitapivat (Pyrukynd)

Notes:

- Quantity Limits: Yes

Initiation (new start) criteria: Formulary **mitapivat (Pyrukynd)** will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Patient is at least 18 years of age
- Patient has a diagnosis of Pyruvate Kinase Deficiency (PKD) AND hemolytic anemia
- Medication is prescribed by a hematologist/oncologist
- Patient is NOT homozygous for the R479H mutation
- Patient has 2 mutant alleles in the PKLR gene and at least 1 of them is a missense mutation
- Patient is transfusion-dependent (required 6 or more transfusions in the past 365 days) – **OR** – has hemoglobin less than or equal to 10 g/dL

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Formulary **mitapivat (Pyrukynd)** will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Patient is at least 18 years of age
- Patient has a diagnosis of Pyruvate Kinase Deficiency (PKD) AND hemolytic anemia
- Medication is prescribed by a hematologist/oncologist

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Formulary **mitapivat (Pyrukynd)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient is at least 18 years of age
- Patient has a diagnosis of Pyruvate Kinase Deficiency (PKD) AND hemolytic anemia
- Medication is prescribed by a hematologist/oncologist

Continued use criteria (6 months after initiation): Formulary **mitapivat (Pyrukynd)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient is at least 18 years of age

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Mitapivat (Pyrukynd)

- Patient has a diagnosis of Pyruvate Kinase Deficiency (PKD) AND hemolytic anemia
- Medication is prescribed by a hematologist/oncologist
- Decrease in number of red blood cell units transfused of 33% or greater compared to baseline* **-OR-** increase in hemoglobin level of 1.5 g/dL or greater compared to baseline **-OR-** mitapivat (Pyrukynd) dose was increased by the prescriber in the past 4 weeks

*Baseline period for transfusions is defined as the 6-month period prior to initiation of mitapivat (Pyrukynd)