Pyrukynd (mitapivat)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial approval duration: 6 months Maintenance therapy requests: 6 months

Medications	Quantity Limit
Pyrukynd (mitapivat) 5mg, 20mg, 50mg tablets Pyrukynd (mitapivat) Taper Packs	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Pyrukynd (mitapivat) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of hemolytic anemia due to pyruvate kinase (PK) deficiency; **AND**
III. Documentation is provided that diagnosis of pyruvate kinase deficiency is confirmed by one (A or B) of the following:
    A. Low levels of red blood cells (RBC) PK enzymatic activity; **OR**
    B. At least two (2) mutations of the pyruvate kinase liver and red blood cell (PKLR) gene known or expected to impair PK activity, one (1) of which is a missense mutation;

AND

IV. Documentation is provided for one of the following (A or B):
    A. Hemoglobin (HGB) 10 g/dL or below (NCT03548220); **OR**
    B. Six (6) or more RBC transfusions for hemolytic anemia due to PKD in the last fifty-two (52) weeks prior to initiation of Pyrukynd (mitapivat) (NCT03559699).

Continuation requests for Pyrukynd (mitapivat) may be approved if the following criteria are met:

I. Documentation is provided that individual has experienced an increase in hemoglobin (HGB) of at least 1.5 g/dL from baseline; **OR**
II. Documentation is provided that individual has decreased RBC transfusion episodes from baseline.

Requests for Pyrukynd (mitapivat) may not be approved for the following:

I. Individual with moderate or severe hepatic impairment; **OR**
II. Individual is currently using strong CYP3A4 inhibitors or inducers.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: March 7, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT03548220, A Study to Evaluate Efficacy and Safety of AG-348 in Not Regularly Transfused Adult Participants With Pyruvate Kinase Deficiency (PKD); 2018 June 7. Available from: https://clinicaltrials.gov/ct2/show/NCT03548220. Accessed March 7, 2022.
6. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT03548220, A Study Evaluating the Efficacy and Safety of AG-348 in Regularly Transfused Adult Participants With Pyruvate Kinase Deficiency (PKD); 2018 June 18. Available from: https://clinicaltrials.gov/ct2/show/NCT03548220. Accessed March 7, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.