

Pyrukynd (mitapivat)
Effective 06/01/2023

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange		Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit			<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.			
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671	
	Pharmacy Benefit	Phone: 800-711-4555	Fax: 844-403-1029	
Exceptions	N/A			

Overview
FDA Approved Indications

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

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with Pyrukynd, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for treatment when all the following criteria are met:

1. Diagnosis of hemolytic anemia with PK deficiency
2. Physician documentation of BOTH of the following:
 - a. ONE of the following:
 - i. Enzyme assay demonstrating deficiency in PK enzyme activity
 - ii. Genetic testing demonstrating presence of at least 2 mutant alleles in the PKLR gene, of which at least 1 is a missense mutation
 - b. ONE of the following:
 - i. Documentation of 6 blood transfusion episodes in the last 12 months
 - ii. Hemoglobin (Hb) level of $\leq 10\text{g/dL}$

Continuation of Therapy

Reauthorization may be granted for members who meet the following:

1. Diagnosis of hemolytic anemia with PK deficiency
2. The member has achieved or maintained a positive clinical response to therapy (e.g., improvement in hemoglobin levels, reduction in blood transfusions)

Limitations

1. Initial approvals will be granted for 7 months
2. Reauthorizations will be granted for 12 months

References

1. Pyrukynd [package insert]. Cambridge, MA: Agio Pharmaceuticals, Inc.; February 2022.
2. Al-Samkari H, Galacteros F, Glenthøj A, et al. Mitapivat versus placebo for pyruvate kinase deficiency. *N Engl J Med*. 2022 Apr 14;386(15):1432-1442.
3. A Study Evaluating the Efficacy and Safety of AG-348 in Regularly Transfused Adult Participants with Pyruvate Kinase Deficiency (PKD). *ClinicalTrials.gov*.
<https://clinicaltrials.gov/ct2/show/study/NCT03559699>. Published January 4, 2022. Accessed March 1, 2022.

Review History

03/15/2023 – Reviewed and Created for Feb P&T; Effective 6/1/23

