Mass General Brigham
Health Plan

Pyrukynd (mitapivat)
Effective 06/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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 ≤ 10g/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, Glenthoj 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