Clinical Policy Title:	mitapivat
Policy Number:	RxA.755
Drug(s) Applied:	Pyrukynd®
Original Policy Date:	04/18/2022
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Hemolytic anemia with pyruvate kinase (PK) deficiency (must meet all):

1. Diagnosis of hemolytic anemia with pyruvate kinase (PK) deficiency;
2. Age ≥ 18 years;
3. Prescribed by or in consultation with a hematologist;
4. Member has diagnosis of PKD with at least two mutant alleles in the PKLR gene, of which at least one is a missense mutation;
5. Member is not homozygous for the R479H mutation or had two non-missense variants, without the presence of another missense variant, in the PKLR gene;
6. Documentation required for RBC transfusions for hemolytic anemia due to PKD within the previous year;
7. Member has a current hemoglobin level ≤ 10 mg/dL;
8. Prescribed concurrently with oral folic acid;
9. Dose does not exceed 100 mg/day orally.

Approval Duration
Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

A. Hemolytic anemia in adults with pyruvate kinase (PK) deficiency (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to the therapy as documented by increase in Hb ≥ 1.5 mg/dL over baseline and/or reduction in transfusion burden;
3. If request is for a dose increase, new dose does not exceed 100 mg/day orally.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

References
Not Applicable

Review/Revision History	Review/Revision Date	P&T Approval Date

Policy established.	03/14/2022	04/18/2022
1. Initial Approval Criteria I.A.9: Updated to add prescribed concurrently with oral folic acid. 2. References were reviewed and updated.	3/30/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023