

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
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This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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