Pharmacy Drug Policy & Procedure

Policy Name:	Pyrukynd (mitapivat)	Policy #:	3167P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Pyrukynd (mitapivat).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Pyrukynd (mitapivat) under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Hemolytic Anemia related to Pyruvate Kinase Deficiency (PKD)

1.1 Diagnosis of hemolytic anemia related to Pyruvate Kinase Deficiency (PKD) as evidenced by genetic testing
- Genetic testing must support at least two mutant alleles of the PKLR gene of which at least one is a missense mutation

1.2 Age 18 years or older

1.3 Prescribed by or in consultation with a hematologist (blood disorder doctor) or specialist in hemolytic anemia

1.4 Patient has required red blood cell transfusions within the last year

1.5 Hemoglobin level ≤ 10 mg/dL

1.6 Currently taking folic acid 0.8mg daily

2. Exclusion Criteria

2.1 Patients homozygous for the R479H mutation

2.2 Patients with 2 non-missense mutations in PKLR, without another missense mutation (these patients did not demonstrate benefit from therapy in clinical trials)

3. Managed Dose Limit

3.1 #60 tablets per 30 days

4. Approval Period

4.1 Initial: 12 months

4.2 Reauthorization: 12 months with documented clinical benefit as evidenced by increase in hemoglobin or decrease in transfusion requirements

CPT Codes

HCPCS Codes

References

1. Pyrukynd (mitapivat) [prescribing information]. Cambridge, MA: Agios Pharmaceuticals Inc; February 2022.
2. Grace RF, Barcellini W. Management of pyruvate kinase deficiency in children and adults. Blood. 2020;136(11):1241-1249.
3. Grace RF, Rose C, Layton DM, et al. Safety and efficacy of mitapivat in pyruvate kinase deficiency. N Engl J Med. 2019;381(10):933-944
4. Al-Samkari H, Galactéros F, Glenthøj A, et al. Mitapivat versus Placebo for Pyruvate Kinase Deficiency. N Engl J Med 2022; 386:1432.

Created Date: 02/01/23
Effective Date: 02/01/23
Posted to Website: 02/01/23
Revision Date: 02/05/25

DISCLAIMER
This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.