AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Pyrukynd® (mitapivat)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Quantity Limits: 60 tablets per 30 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Member is 18 years of age or older
- ❑ Prescribed by or in consultation with a hematologist or specialist in treating members with pyruvate kinase deficiency
- ❑ Member has a confirmed diagnosis of PK-Deficiency as defined by the documented presence of at least 2 variant alleles in the PKLR gene, of which at least 1 was a missense variant
- ❑ Other causes of member's hemolytic anemia have been ruled out (i.e. immune hemolysis, enzyme deficiencies, vitamin/mineral deficiencies)
- ❑ Member is **NOT** homozygous for the c.1436G>A (p.R479H) variant

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- ❑ Member does **NOT** have 2 non-missense variants (without the presence of another missense variant) in the PKLR gene
- ❑ Member's baseline serum hemoglobin level measured < 10 g/dL or required more than 5 transfusions in the prior year
- ❑ Member does **NOT** have hepatic impairment (moderate or severe)
- ❑ Provider has submitted documentation to confirm **ALL** of the following baseline laboratory markers of hemolytic anemia:
  - ❑ Low hemaglobin
  - ❑ Elevated unconjugated bilirubin
  - ❑ Low haptoglobin
  - ❑ Elevated reticulocytes

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Unacceptable toxicity has **NOT** been reported during treatment with requested medication
- ❑ Select **ONE** of the following:
  - ❑ Member has experienced a positive clinical response to Pyrukynd® therapy compared to pre-treatment baseline as demonstrated by at least **ONE** of the following **(check all that apply)**:
    - ❑ Hemoglobin response defined as a ≥1.5 g/dL increase in hemoglobin level without transfusion over a four week or longer time period
    - ❑ Transfusion reduction response defined as a ≥ 33% reduction in the number of red blood cell (RBC) units transfused compared to historical transfusion burden
    - ❑ Increase in hemaglobin and/or decrease in transfusion requirement, to a lesser extent than the above, **AND** also an improvement in the signs and symptoms (e.g., fatigue, jaundice, shortness of breath) and/or markers of hemolysis (e.g., indirect bilirubin, reticulocyte count, LDH, haptoglobin)

      OR
  - ❑ No benefit has occurred and member requires treatment to taper dose for discontinuation

Medication being provided by Specialty Pharmacy - PropriumRx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*