

# SENTARA HEALTH PLANS

## 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 1-800-750-9692.** 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<sup>®</sup> (mitapivat)

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

Member Name: \_\_\_\_\_

Member Sentara #: \_\_\_\_\_ 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 hemoglobin
  - 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<sup>®</sup> therapy compared to pre-treatment baseline as demonstrated by at least **ONE** of the following (**check all that apply**):
    - Hemoglobin response defined as a  $\geq 1.5$  g/dL increase in hemoglobin level without transfusion over a four week or longer time period
    - Transfusion reduction response defined as a  $\geq 33\%$  reduction in the number of red blood cell (RBC) units transfused compared to historical transfusion burden
    - Increase in hemoglobin 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.\****