

## **Pharmacy Drug Policy Checklist**

POLICY NAME Pyrukynd (mitapivat) POLICY # 3167P

## Criteria

| 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                                                             |
|                                                              | <ul> <li>Genetic testing must support at least two mutant alleles of the PKLR gene of which at least<br/>one is a missense mutation</li> </ul>                            |
|                                                              | 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                                                                                                                               |
| Exclusion Criteria – Any of the following prevents coverage  |                                                                                                                                                                           |
|                                                              | 2.1 Patients homozygous for the R479H mutation                                                                                                                            |
|                                                              | <b>2.2</b> Patients with 2 non-missense mutations in PKLR, without another missense mutation (these patients did not demonstrate benefit from therapy in clinical trials) |