

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2025 P 1387-4 |
| Program | Prior Authorization/Notification |
| Medication | Pyrukynd® (mitapivat) |
| P&T Approval Date | 5/2022, 5/2023, 5/2024, 5/2025 |
| Effective Date | 8/1/2025 |

1. Background:

Pyrukynd® (mitapivat) is a pyruvate kinase activator indicated for the treatment of hemolytic anemia in adults with pyruvate kinase (PK) deficiency.

2. Coverage Criteria^a:**A. Initial Authorization**

1. **Pyrukynd** will be approved based on **both** of the following criteria:

- a. Diagnosis of pyruvate kinase (PK) deficiency

-AND-

- b. Used for the treatment of hemolytic anemia

Authorization will be issued for 12 months.

B. Reauthorization

1. **Pyrukynd** will be approved based on **one** of the following criteria:

- a. Documentation of positive clinical response to Pyrukynd therapy

Authorization will be issued for 12 months.

-OR-

- b. Documentation does not provide evidence of positive clinical response to Pyrukynd therapy, allow for dose titration with discontinuation of therapy

Authorization will be issued for 4 weeks.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Pyrukynd [package insert]. Cambridge, MA: Agios Pharmaceuticals, Inc.; February 2022.

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| Change Control | |
| 5/2022 | New program |
| 5/2023 | Annual review. Added state mandate footnote. |
| 5/2024 | Annual review. Updated initial criteria approval to 12 months. |
| 5/2025 | Annual review. No changes to coverage criteria. |