

Mitapivat

Adjudication Guideline

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Approved by: Daman	Responsible: Pharmaceutical Standards	Related Adjudication Guidelines: N/A & Governance		

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1. Abstract

1.1 For Members

Mitapivat is indicated for the treatment of haemolytic anemia in adults(18 years and older) with pyruvate kinase (PK) deficiency, an inherited disease that causes red blood cells to break down faster than normal.

1.2 For Medical Professionals

Mitapivat will be reviewed by High-cost team, relevant reports pertaining to treatment history, frequency, and dosage for the indications should be delivered upon request for further review.

Relevant clinicians are only permitted to order the medication.

Current Dose	DOSE TAPER SCHEDULE		
	Day 1-7	Day 8-14	Day 15
5 mg twice daily	5 mg once daily	Discontinue	N/A
20 mg twice daily	20 mg once daily	5 mg once daily	Discontinue
50 mg twice daily	50 mg once daily	20 mg once daily	Discontinue

Dose Titration Schedule:

Duration	Check	Dosage
Week 1 through Week 4	N/A	5mg twice daily.
Week 5 through Week 8	If Hb is below normal range or patient has required a transfusion within the last 8 weeks.	Increase to 20 mg twice daily and maintain for 4 weeks.
	If Hb is within normal range and patient has not required a transfusion within the last 8 weeks.	Maintain 5 mg twice daily.
Week 9 through Week 12	If Hb is below normal range or patient has required a transfusion within the last 8 weeks	Increase to 50 mg twice daily and maintain thereafter.
	If Hb is within normal range and patient has not required a transfusion within the last 8 weeks	Maintain current dose (5 mg twice daily or 20 mg twice daily).
Maintenance	If Hb decreases.	consider up-titration to the maximum of 50 mg twice daily as per the above schedule.

2. Scope

This Adjudication Rule highlights the coverage and payment requirements by Daman as per policy terms and conditions for Mitapivat. It also highlights the medical criteria for coverage.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

- Mitapivat is indicated for the treatment of haemolytic anemia in adults(18 years and older) with pyruvate kinase (PK) deficiency, an inherited disease that causes red blood cells to break down faster than normal.
- The safety and efficacy of Mitavipat in Pediatric patients has not been established.
- The eligible ordering clinicians are haematologists, Internal medicine.
- It has plan-wise coverage and can be billed based on medical necessity.
- Mitapivat dosage frequency is twice daily regardless of the dose 5mg, 20mg or 50mg as it requires monthly evaluation. Reports with levels of Hb, transfusion details if required should be documented.

3.2 Requirements for Coverage

All the relevant documents should be submitted upon request, also providing the history of treatment, the frequency or dosage related to the same.

- **Genetic Test Results:** Confirming the diagnosis of pyruvate kinase deficiency.
- **Medical History:** Detailed medical history including previous treatments and responses.
- **Laboratory Reports:** Recent complete blood count (CBC) and reticulocyte count.
- **Specialist Report:** Evaluation and recommendation from a hematologist or relevant specialist.
- **Treatment Plan:** Detailed treatment plan including dosage and administration schedule.

3.3 Non-Coverage

- Covered by all plans except visitor's plan.

3.4 Payment and Coding Rules

Please apply regulator payment rules and regulations and relevant coding manuals for ICD, CPT, etc. Kindly code the ICD-10 and the CPT codes to the highest level of specificity.

Table 1: Eligible clinicians

Eligible Ordering Grouping
Hematologists
Internal medicine

4. Denial Codes

DOH denial codes with description are elaborated for reference. These are specialized codes directed by DOH, that explains the reason of rejection of the service by DAMAN to the providers.

Code	Code Description
MNEC 003	Diagnoses are not covered
MNEC 004	Service is not clinically indicated based on good clinical practice
CODE-010	Activity/diagnosis inconsistent with clinician's specialty
CLN-001	Activity/diagnosis inconsistent with clinician specialty
NCOV-003	Service(s) is (are) not covered

5. Appendices

5.1 References

<https://www.ema.europa.eu/en/medicines/human/EPAR/pyrukynd>
<https://go.drugbank.com/drugs/DB16236>
https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/216196s000lbl.pdf

5.2 Revision History

Date	Version No.	Change(s)
30/08/2023	V1.0	Release of V1.0
30/10/2024	V2.0	Add relevant documents
24/09/2025	V2.0	Guideline review/No update

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