CENTENE® Corporation

Clinical Policy: Dersimelagon (MT-7117)

Reference Number: CP.PHAR.815
Effective Date: FDA Approval Date
Last Review Date: 11.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

INTERIM POLICY AND INFORMATION IS SUBJECT TO CHANGE

Description

Dersimelagon (MT-7117) is a melanocortin 1 receptor (MC1-R) agonist.

FDA Approved Indication(s) [Pending]

MT-7117 is indicated for the treatment of erythropoietic protoporphyria (EPP) or X-linked protoporphyria (XLP).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that MT-7117 is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Erythropoietic Protoporphyria and X-Linked Protoporphyria (must meet all)**:**

1. Diagnosis of EPP or X-linked protoporphyria (known as XLP or XLEPP) confirmed by both of the following tests (a and b):
   a. Elevated total erythrocyte protoporphyrin (e.g., 300 to 5,000 mcg/dL vs. normal at < 80 mcg/dL);
   b. Erythrocyte fractionation shows ≥ 50% metal-free vs. zinc protoporphyrin (certified laboratories include University of Texas Medical Branch at Galveston - Porphyria Center, and Mayo Medical Laboratories);
2. Prescribed by or in consultation with a dermatologist;
3. Age ≥ 12 years;
4. Evidence of EPP/XLP-associated acute non-blistering cutaneous reactions (e.g., pain, stinging, redness, swelling, blanching) following exposure to sun;
5. Sun avoidance and use of sunscreen, protective clothing, and pain medication have proven inadequate in controlling EPP/XLP-associated painful skin reactions;
6. Member does not have any of the following conditions:
   a. Current basal cell carcinoma, squamous cell carcinoma, or other malignant skin lesions;
   b. Personal history of melanoma;
   c. Presence of history of hepatobiliary disease;
7. MT-7117 is not prescribed concurrently with Scenesse®;

8. Dose does not exceed 200 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Erythropoietic Protoporphyria and X-Linked Protoporphyria (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy as evidenced by any of the following (a or b):
   a. Improvement in acute non-blistering cutaneous reactions (e.g., pain, stinging, redness, swelling, blanching) following exposure to sun;
   b. Improvement on a pain-intensity Likert scale or quality of life questionnaire;
3. Member has received a full skin examination by a dermatologist within the last six months;
4. MT-7117 is not prescribed concurrently with Scenesse;
5. If request is for a dose increase, new dose does not exceed 200 mg per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

INTERIM POLICY AND INFORMATION

a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

DLQI: dermatology of life quality index
EPP: erythropoietic protoporphyria
FDA: Food and Drug Administration
MC1-R: melanocortin 1 receptor
XLP/XLEPP: X-linked protoporphyria/X-linked erythropoietic protoporphyria

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings [Pending]

- Contraindication(s): pending
- Boxed warning(s): pending

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
EPP	200 mg PO QD*	200 mg/day*

VI. Product Availability

Tablet: 200 mg*

VII. References

1. INcreased Sun Exposure Without Pain In Research Participants With EPP or XLP (INSPIRE). *ClinicalTrials.gov*, U.S. National Library of Medicine, ClinicalTrials.gov Identifier NCT06144840, June 4, 2026. Available at: https://clinicaltrials.gov/study/NCT06144840. Accessed October 1, 2026.

INTERNAL USE ONLY AND INFORMATION IS SUBJECT

2. Balwani M, Bonkovsky HL, Levy C, et al.; Endeavor Investigators. Dersimelagon in Erythropoietic Protoporphyrias. N Engl J Med. 2023 Apr 13;388(15):1376-1385. PMID: 37043653.
3. Gou EW, Balwini M, Bissell DM, et al. Pitfalls in erythrocyte protoporphyrin measurement for diagnosis and monitoring of protoporphyrias. Clin Chem. 2015 December; 61(12): 1453–1456. doi:10.1373/clinchem.2015.245456.
4. Erythropoietic protoporphyria and X-linked protoporphyria. National Organization of Rare Disorders. Updated 2018. Available at: https://rarediseases.org/rare-diseases/erythropoietic-protoporphyria/. Accessed: November 6, 2025
5. Balwani M, Bloomer J, Desnick R, et al.; Porphyrias Consortium of the NIH-Sponsored Rare Diseases Clinical Research Network. Erythropoietic protoporphyria, autosomal recessive. Last updated September 7, 2017. Available at: https://www.ncbi.nlm.nih.gov/books/NBK100826/.
6. Balwani M. Erythropoietic protoporphyria and X-linked protoporphyria: Pathophysiology, genetics, clinical manifestations, and management. Mol Genet Metab. 2019 November;123(3):298-303.
7. Dickey AK, Naik H, Keel SB et al. Evidence-based consensus guidelines for the diagnosis and management of erythropoietic protoporphyria and x-linked protoporphyria. J Am Acad Dermatol 2023;89(6):1227-37.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	10.20.26	11.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

INTERNAL POLICY AND INFORMATION IS SUBJECT TO CHANGE

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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