

Clinical Policy: Hemin (Panhematin)

Reference Number: ERX.SPA.298

Effective Date: 03.01.19

Last Review Date: 02.22

Line of Business: Commercial, Medicaid

[Revision Log](#)

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

Description

Hemin for injection (Panhematin[®]) is an enzyme inhibitor derived from processed red blood cells.

FDA Approved Indication(s)

Panhematin is indicated for amelioration of recurrent attacks of acute intermittent porphyria (AIP) temporally related to the menstrual cycle in susceptible women, after initial carbohydrate therapy is known or suspected to be inadequate.

Limitation(s) of use:

- Before administering Panhematin, consider an appropriate period of carbohydrate loading (i.e., 400 g glucose/day for 1 to 2 days).
- Attacks of porphyria may progress to a point where irreversible neuronal damage has occurred. Panhematin therapy is intended to prevent an attack from reaching the critical stage of neuronal degeneration. Panhematin is not effective in repairing neuronal damage.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions[™] that Panhematin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Porphyria (must meet all):

1. Diagnosis of acute porphyria (i.e., acute intermittent porphyria [AIP], variegate porphyria [VP], or hereditary coproporphyria [HCP]) confirmed by presence of clinical symptoms (e.g., abdominal pain, pain in chest, legs or back, peripheral neuropathy, hypernatremia, tachycardia, sweating, tremor, dysuria, incontinence, constipation, nausea, vomiting) and one of the following (a or b):
 - a. For AIP: urine positive for uroporphobilinogen (PBG);
 - b. For VP or HCP: urine positive for PBG, or elevated urinary porphyrins with elevated plasma and/or fecal porphyrins;
2. Age \geq 16 years;
3. Documentation of member's current body weight (in kg);
4. Dose does not exceed 6 mg/kg in any 24-hour period.

Approval duration: 14 days

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Acute Porphyria (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Documentation of member's current body weight (in kg);
4. If request is for a dose increase, new dose does not exceed 6 mg/kg in any 24-hour period.

Approval duration: Up to 14 days

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AIP: acute intermittent porphyria

FDA: Food and Drug Administration

HCP: hereditary coproporphyria

PBG: prophobilinogen

VP: variegate porphyria

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to Panhematin
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Amelioration of recurrent attacks of AIP	1 to 4 mg/kg/day IV for 3 to 14 days based on the clinical signs. The standard dose in clinical practice is 3 to 4 mg/kg/day. Repeat dose in more severe cases no earlier than every 12 hours. Do not exceed 6 mg/kg in any 24-hour period.	6 mg/kg in any 24-hour period.

VI. Product Availability

Single-dose lyophilized powder vial: 350 mg

VII. References

1. Panhematin. Prescribing Information. Lebanon, NJ: Recordati Raritan, Inc. May 2020. Available at: <https://www.panhematin.com/pdf/panhematin-PI-May-2020.pdf>. Accessed November 23, 2021.
2. Stein P, Badminton M, Barth J et al. Best practice guidelines on clinical management of acute attacks of porphyria and their complications. Ann Clin Biochem. 2013 May;50(Pt 3):217-23. doi: 10.1177/0004563212474555.
3. Balwani M, Wang B, Anderson KE, et al. Acute Hepatic Porphyrias: Recommendations for Evaluation and Long Term Management. Hepatology 2017; 66(4):1314-1322.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	10.30.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	10.21.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	12.02.20	02.21
1Q 2022 annual review: no significant changes; added requirement for documentation of member's weight for dose calculation purposes, as a previously P&T-approved approach to ensure appropriate dosing; references reviewed and updated.	11.23.21	02.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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