

## Clinical Policy: Hemin (Panhematin)

Reference Number: LA.PHAR.181

Effective Date: 09.21

Last Review Date: 07~~3.22~~4

Line of Business: Medicaid

Coding Implications  
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

**Prior authorization is required.** 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 Louisiana Healthcare Connections 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., 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 ≥ 16 years;
- 2.3. Documentation of member's current body weight (in kg);
- 3.4. Dose does not exceed 6 mg/kg in any 24-hour period.

**Approval duration: 14 days**

**B. Other diagnoses/indications**

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Acute Porphyria (must meet all):**

1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. 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 Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.  
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.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 policy – LA.PMN.53 for Medicaid 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): Do not use in patients with known hypersensitivity to Panhematin
- Boxed warning(s): none reported

## CLINICAL POLICY

### Hemin

#### V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Amelioration of recurrent attacks of acute intermittent porphyria	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 Rare Disease, Inc. ~~May~~<sup>July</sup> 2020~~17~~. Available at <https://www.panhematin.com/pdf/panhematin-marketing-PI.pdf>. Accessed November 23~~5~~<sup>10</sup>, 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 Porphyrrias: Recommendations for Evaluation and Long Term Management. Hepatology 2017; 66(4):1314-1322.

#### Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
<b>J1640</b>	<b>Injection, hemin, 1 mg</b>

Reviews, Revisions, and Approvals	Date
<b>Converted corporate to local policy</b>	<b>03.2021</b>
<u>Added requirement for documentation of member's weight for dose calculation purposes to ensure appropriate dosing; references reviewed and updated.</u>	<u><b>07.22</b></u>

#### 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

## CLINICAL POLICY

### Hemin

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## CLINICAL POLICY

### Hemin

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