

## Clinical Policy: Hemin (Panhematin)

Reference Number: LA.PHAR.181

Effective Date: 09.18.21

Last Review Date: ~~02.18.26~~02.21.25

Line of Business: Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**\*\*Please note: This policy is for medical benefit\*\***

### Description

Hemin for injection (Panhematin<sup>®</sup>) 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.*

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 both of the following (a and b):
  - a. Presence of clinical symptoms (e.g., abdominal pain, pain in chest, legs or back, peripheral neuropathy, hyponatremia, tachycardia, sweating, tremor, dysuria, incontinence, constipation, nausea, vomiting);
  - b. History of at least a four-fold increase of 5-aminolevulinic acid (ALA) or porphobilinogen (PBG) using a random urine sample within the past year (*see Appendix D*);
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. Prevention of Porphyria Attacks (off-label) (must meet all):**

1. Diagnosis of acute porphyria (i.e., AIP, variegate porphyria [VP], or hereditary coproporphryria [HCP]) confirmed by history of at least a four-fold increase of 5-aminolevulinic acid (ALA) or porphobilinogen (PBG) using a random urine sample within the past year (see Appendix D);
2. Age > 16 years;
3. Member has experienced 4 or more porphyria attacks per year (i.e., requirement of hospitalization, urgent healthcare visit or intravenous administration of Panhematin)
4. Panhematin, as a prophylactic treatment, is not prescribed concurrently with Givlaari;
5. Documentation of member's current body weight (in kg);
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).\*

*\*Prescribed regimen must be FDA-approved*

**Approval duration: 12 months**

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**B.C. 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 LA.PMN.255
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 LA.PMN.53

**II. Continued Therapy**

**A. Acute Porphyrria (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. Documentation of member's current body weight (in kg);
4. **Member has not received more than 14 days of treatment with Hemin;**
5. 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**

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**B. Prevention of Porphyria Attacks (off-label) (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. Documentation of member's current body weight (in kg);
4. If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed

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literature for the relevant off-label use (prescriber must submit supporting evidence). \*  
*\*Prescribed regimen must be FDA-approved*

**Approval duration: 12 months**

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**B.C. 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 LA.PMN.255
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 LA.PMN.53

**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

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

AIP: acute intermittent porphyria	HCP: hereditary coproporphyrin
ALA: 5-aminolevulinic acid	PBG: porphobilinogen
FDA: Food and Drug Administration	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

*Appendix D: ALA and PBG Laboratory Testing*

Concentrations of ALA or PBG in a random urine sample greater than four times the upper limit of normal establish the diagnosis of AHP (Wang 2019). Variations in reference ranges and reporting (e.g., with or without creatinine correction) may differ across U.S. laboratories; however, four times the upper limit of normal based on a random urine sample remains an appropriate evaluative tool.

Examples of laboratory reporting variations:\*

*\*ALA/PBG values below are chosen for demonstration purposes only and do not reflect actual required values.*

- Corrected for creatinine: \*  
*\*Additional units applicable here include mg/mmol creatinine.*
  - ALA = 38 mg/g creatinine (reference range 0-7 mg/g creatinine);
  - PBG = 85 mg/g creatinine (reference range 0-4 mg/g creatinine).*See Wang et al (2019) for additional information.*
- Uncorrected for creatinine: \*  
*\*Additional units applicable here include mcml/L.*
  - ALA = 40 mg/L (reference range 0.0-5.4 mg/L);

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- PBG = 90 mg/L (reference range 0.0-2.0 mg/L).  
 See LabCorp ([www.labcorp.com](http://www.labcorp.com)) and Mayo Medical Laboratories ([www.mayoclinicalabs.com](http://www.mayoclinicalabs.com)) testing information for additional information.

Wang B, Rudnick S, Cengia B, Bonkovsky HL. Acute hepatic porphyrias: Review and recent progress. *Hepatology Communications*, 2019; 3(2): 193:206.

**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 Rata Disease, Inc. January 2024. Available at: <https://www.panhematin.com/pdf/Panhematin-Prescribing-Information-Current.pdf>. Accessed ~~October 18, 2024~~ **November 6, 2025**.
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.
4. Anderson KE, Bloomer JR, Bonkovsky HL, et al. Recommendations for the diagnosis and treatment of the acute porphyrias. *Ann Intern Med*. 2005; 142:439-450.
5. Wang B, Bonkovsky HL, Lim JK, and Balwani M. AGA Clinical practice update on diagnosis and management of acute hepatic porphyrias: Expert review. *Gastroenterology* 2023;164:484-491.

**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
J1640	Injection, hemin, 1 mg

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Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	03.21	09.18.21
Added requirement for documentation of member’s weight for dose calculation purposes to ensure appropriate dosing; references reviewed and updated.	07.22	08.19.22
Template changes applied to other diagnoses/indications and continued therapy section. Required labs for diagnosis of porphyria revised to align with Givlaari (LA.PHAR.457); added Appendix D ALA and PBG Laboratory Testing; references reviewed and updated. Added verbiage this policy is for medical benefit only.	06.02.23	10.05.23
No significant changes; corrected “hypernatremia” to “hyponatremia” in examples of clinical symptoms of acute porphyria in section I.A.1.a. references reviewed and updated.	05.26.24	07.29.24
No significant changes; references reviewed and updated.	02.21.25	<u>05.19.25</u>
<u>Annual review: added off-label indication for prevention of porphyria attacks; for acute porphyria continued therapy, added criterion to ensure member has not received more than 14 days of treatment; references reviewed and updated</u>	<u>02.18.26</u>	

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**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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined LHCC. 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. LHCC retains the right to change, amend or

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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.

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