

Clinical Policy: Hemin (Panhematin)

Reference Number: LA.PHAR.181

Effective Date: 09.18.21

Last Review Date: 07.2206.02.23

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®) 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~~both of the following (a and b):

- a. 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):~~
- b. ~~For AIP: urine positive for porphobilinogen~~
- c. ~~For VP or HCP: urine positive for PBG; or elevated urinary porphyrins with elevated plasma and/or fecal porphyrins;~~

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

- 1. Refer to the off-label use policy if 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): LA) AND criterion 1 above does not apply, refer to the off-label use policy 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. 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 Louisiana Healthcare Connections benefit and documentation supports positive response to therapy. Approval duration: Duration of request or 6 months (whichever is less); or
- 1. Refer to the off-label use policy if 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): LA) AND criterion 1 above does not apply, refer to the off-label use policy 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
[ALA: 5-aminolevulinic acid](#)
 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.

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 mmol/L.*

○ ALA = 40 mg/L (reference range 0.0-5.4 mg/L);

○ PBG = 90 mg/L (reference range 0.0-2.0 mg/L).

See LabCorp (www.labcorp.com) and Mayo Medical Laboratories (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 acute intermittent porphyria 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 Rare Disease, Inc. May 2020. Available at <https://www.panhematin.com/pdf/Panhematin-PI-May-2020.pdf>. Accessed November ~~23, 2021~~ 16, 2022.
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.

HCPSC Codes	Description
J1640	Injection, hemin, 1 mg

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	03.21	<u>09.18.21</u>
Added requirement for documentation of member's weight for dose calculation purposes to ensure appropriate dosing; references reviewed and updated.	07.22	<u>08.19.22</u>
<u>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.</u> <u>Added verbiage this policy is for medical benefit only.</u>	<u>06.02.23</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 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.

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