Clinical Policy: Hemin (Panhematin)

Reference Number: LA.PHAR.181
Effective Date:
Last Review Date: 06.21 **Coding Implications**
Line of Business: 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

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 prophobilinogen (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;**
3. **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**

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 Rate Disease, Inc. July 2017. Available at https://www.panhematin.com/pdf/panhematin-marketing-PI.pdf. Accessed November 25, 2020.
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. Heaptology 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
J1640	Injection, hemin, 1 mg

Reviews, Revisions, and Approvals	Date
Converted corporate to local policy	06.2021

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 by 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 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. 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.