# Clinical Policy: Hemin (Panhematin)

Reference Number: PA.CP.PHAR.181
Effective Date: 01/2018
Last Review Date: 01/2023

Coding Implications
Revision Log

**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) temporarily 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**
It is the policy of PA Health & Wellness ® that Panhematin is **medically necessary** when one of the following criteria is met:

**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 both of the following (a or 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);
   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 ≥ 16 years;
3. Documentation of member's current body weight (in kg);
4. Prescribed dose does not exceed 6 mg/kg in any 24-hour period.

**Approval duration: 14 days**

**B. Other diagnoses/indications:** Refer to PA.CP.PMN.53

**II. Continued Approval**

**A. Acute Porphyria** (must meet all):
1. Previously received medication via PA Health & Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;

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 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 PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

## III. 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): 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 mcmol/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.*

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

## IV. 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.<br><br>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. |

## V. Product Availability

Single-dose lyophilized powder vial: 350 mg

## VI. References

1. Panhematin. Prescribing Information. Lebanon, NJ: Recordati Rate Disease, Inc. May 2020. Available at https://www.panhematin.com/pdf/Panhematin-PI-May-2020.pdf. Accessed November 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 Porphyrias: Recommendations for Evaluation and Long Term Management. Hepatology 2017; 66(4):1314-1322.

## Coding Implications

The following codes are for informational purposes only. They are current at time of review of this policy. 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 | Approval Date |
|---|---|---|
| Ages added. References reviewed and updated. | 02/2018 | |
| 1Q 2019 annual review: continued approval duration updated to “up to” 14 days; references reviewed and updated. | 01/2019 | |
| 1Q 2020 annual review: references reviewed and updated. | 01/2020 | |
| 1Q 2021 annual review: references reviewed and updated. | 01/2021 | |
| 1Q 2022 annual review: added requirement for documentation of member’s weight for dose calculation purposes, as a previously Corporate P&T-approved approach to ensure appropriate dosing; references reviewed and updated. | 01/2022 | |

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|---|---|
| 1Q 2023 annual review: required labs for diagnosis of porphyria revised to align with Givlaari (PA.CP.PHAR.457); added Appendix D ALA and PBG Laboratory Testing; references reviewed and updated. | 01/2023 | |