Clinical Policy: Hemin (Panhematin)

Reference Number: PA.CP.PHAR.181
Effective Date: 01/2018
Last Review Date: 01/2026

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, 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 ≥ 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. Prevention of Porphyria Attacks (off-label) (must meet all):
1. Diagnosis of acute porphyria (i.e., AIP, variegate porphyria [VP], or hereditary coproporphyria [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

C. 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.PHARM.01) applies;
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 does not exceed 6 mg/kg in any 24-hour period.

Approval duration: Up to 14 days

B. Prevention of Porphyria Attacks (off-label) (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.PHARM.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 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

C. 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.PHARM.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.

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. 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. January 2024. Available at https://www.panhematin.com/pdf/Panhematin-Prescribing-Information-Current.pdf. Accessed 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
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
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
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
1Q 2024 annual review: no significant changes; references reviewed and updated.	01/2024
1Q 2025 annual review: no significant changes; references reviewed and updated.	01/2025
1Q 2026 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.	01/2026