Clinical Policy: Hemin (Panhematin)

Reference Number: PA.CP.PHAR.181
Effective Date: 01/18
Last Review Date: 01/19

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 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 Pennsylvania Health and 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 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. 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 Pennsylvania Health and 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. 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 Pennsylvania Health and 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

Background

Description/Mechanism of Action:

Hemin for injection is an enzyme inhibitor derived from processed red blood cells. Hemin inhibits the enzyme (delta)-aminolevulinic acid synthetase. In normal patients, heme inhibits this enzyme and limits the rate of the porphyrin/heme biosynthetic pathway. Administration of hemin results in effects similar to heme and limits the hepatic and/or marrow synthesis of porphyrin. The exact mechanism by which hemin improves symptoms in patients with acute episodes of the hepatic porphyrias has not been determined.

III. 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

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

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.	02/18	
1Q 2019 annual review: continued approval duration updated to "up to" 14 days; references reviewed and updated.	01/19	

References

1. Panhematin. Prescribing Information. Lebanon, NJ: Recordati Rate Disease, Inc. July 2017. Available at http://recordatirarediseases.com. Accessed October 30, 2018.
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.