

## Clinical Policy: Hemin (Panhematin)

Reference Number: PA.CP.PHAR.181

Effective Date: 01/18

Last Review Date: 07/18

[Coding Implications](#)

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### Description

The intent of the criteria is to ensure that patients follow selection elements established by Pennsylvania Health and Wellness<sup>®</sup> clinical policy for hemin for injection (Panhematin<sup>®</sup>).

### 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).
- Panhematin is not effective in repairing neuronal damage due to progression of porphyria attacks.

### Policy/Criteria

It is the policy of Pennsylvania Health and Wellness<sup>®</sup> 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 coproporphyrinemia [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. For AIP, urine positive for uroporphobilinogen (PBG);
  - b. For VP or HCP, urine positive for PBG; or elevated urinary porphyrins with elevated plasma and/or fecal porphyrins;
2. Age  $\geq$  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 Intermittent 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. Prescribed 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. 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.

**Appendices**

**Appendix A: Abbreviation Key**

AIP: acute intermittent porphyria  
VP: variegate porphyria

HCP: hereditary coproporphyria  
PBG: prophobilinogen

**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	

**References**

1. Panhematin. Prescribing Information. Lebanon, NJ: Recordati Rate Disease, Inc. July 2017. Available at <http://recordatirarediseases.com>. Accessed November 20, 2017.
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. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: <http://www.clinicalpharmacology-ip.com/>.