Clinical Policy: Hemin (Panhematin)

Reference Number: CP.PHAR.181
Effective Date: 02/16
Last Review Date: 03/17

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for hemin for injection (Panhematin®).

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® 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. 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. Prescribed dose does not exceed 6 mg/kg in any 24 hour period.

Approval duration: 14 days

B. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy

II. Continued Approval

A. Acute Intermittent Porphyria (must meet all):
1. Previously received medication via Centene benefit or member has previously met all initial approval criteria;
2. 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 Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

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.

FDA Approved Indications:
Panhematin is an enzyme inhibitor/injectable lyophilized powder indicated for:

- Amelioration of recurrent attacks of acute intermittent porphyria temporally related to the menstrual cycle in susceptible women. Manifestations such as pain, hypertension, tachycardia, abnormal mental status and mild to progressive neurologic signs may be controlled in selected patients with this disorder. Similar findings have been reported in other patients with acute intermittent porphyria, porphyria variegata and hereditary coproporphyria. Panhematin is not indicated in porphyria cutanea tarda.

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
Policy developed	02/16	03/16
Removed requirement that medication is prescribed by a physician experienced in porphyria. Removed warnings against hypersensitivity reactions. Removed exclusion to treatment because of the presence of porphyria cutanea tarda. Added examples of some clinical symptoms. Changed approval duration from 3 months to 14 days per PI.	03/17	03/17

References
1. Panhematin. Prescribing Information. Lebanon, NJ: Recordati Rate Disease, Inc. February 2013. Available at http://recordatirarediseases.com. Accessed February 16, 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. Sood GK, Anderson KE. Pathogenesis, clinical manifestations, and diagnosis of acute intermittent porphyria. Waltham, MA: Walters Kluwer Health; 2015. Available at UpToDate.com Accessed February 17, 2017.
4. Gagan KS, Anderson KE. Management and prognosis of acute intermittent porphyria. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2015. Available at UpToDate.com Accessed February 17, 2017.
5. Ashwani KS, Anderson KE. Porphyria cutanea tarda and hepatoerythropoietic porphyria: Management and prognosis. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2015. Available at UpToDate.com Accessed February 17, 2017.
6. Ashwani KS, Anderson KE. Hereditary coproporphyria. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2014. Accessed February 17, 2017.
7. Ashwani KS, Anderson KE. Variegate porphyria. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2013. Accessed February 17, 2017.

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. The Health Plan 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. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. 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.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.