Panhematin (hemin)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Panhematin is a hemin for injection indicated for the amelioration of recurrent attacks of acute intermittent porphyria temporally related to the menstrual cycle in susceptible women, after initial carbohydrate therapy is known or suspected to be inadequate.

Limitations of Use:

- Before administering Panhematin, consider an appropriate period of carbohydrate loading (i.e., 400 g glucose per 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 degradation. Panhematin is not effective in repairing neuronal damage due to progression of porphyria attacks.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial Requests:

1. Chart notes, medical record documentation confirming signs and symptoms suggesting diagnosis of acute hepatic porphyria, laboratory work and diagnostic testing confirming elevated porphobilinogen in the urine or plasma or an elevated porphyrin level (plasma or fecal).

B. Continuation Requests:
   1. Chart notes, laboratory values and medical record documentation supporting a positive clinical response to Panhematin therapy from pre-treatment baseline without experiencing serious adverse effects.

Prescriber Specialties

Panhematin must be prescribed by or in consultation with a physician experienced in the management of porphyrias (e.g., gastroenterologist, hematologist, hepatologist, neurologist).

Criteria for Initial Approval

Acute Hepatic Porphyria

Panhematin (hemin) may be considered **medically necessary** for the treatment of acute hepatic porphyria when ALL of the following criteria are met:

1. Member is 16 years of age or older.
2. Member has a documented diagnosis of acute hepatic porphyria (AHP) with one of the following types:
   a. Acute Intermittent Porphyria (AIP)
   b. Aminolevulinic Acid Dehydratase Deficiency Porphyria (ADP)
   c. Hereditary Coproporphyria (HCP)
   d. Variegate Porphyria (VP)
3. Member's diagnosis confirmed with presence of clinical symptoms suggestive of AHP attack (e.g., severe acute abdominal pain, nausea, vomiting, constipation, muscle weakness, neuropathy, tachycardia, hypertension, seizures, hyponatremia).
4. Member has laboratory confirmation of elevated porphobilinogen (PBG) in the urine or plasma, or an elevated porphyrin level (plasma or fecal).

Approval will be for **6 months**.

Continuation of Therapy

Acute Hepatic Porphyria

Panhematin (hemin) may be considered **medically necessary** for the continued treatment of acute hepatic porphyria when ALL of the following criteria are met:

1. Member meets Criteria for Initial Approval.
2. Member has experienced a positive clinical response while on Panhematin therapy as demonstrated by improvement in the signs and symptoms of the disease (e.g., severe acute abdominal pain, nausea, vomiting, constipation, muscle weakness, neuropathy, tachycardia, hypertension, seizures, hyponatremia).
3. Member has not experienced any serious side effects with previous Panhematin therapy (i.e., anaphylactic reactions, renal or hepatic toxicity).

Approval will be for **12 months**.

Panhematin is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Dosing Limits

Drug	Dosing Regimen	Maximum Dose
Panhematin (350 mg Hemin per Vial)	1 to 4 mg/kg/day of hematin for 3 to 14 days based on the clinical signs Standard dose in clinical practice is 3 to 4 mg/kg/day. In more severe cases, dose may be repeated no earlier than every 12 hours.	Not to exceed 6 mg/kg/day of hematin in any 24-hour period.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J1640 – Injection, hemin, 1 mg

REFERENCES

- Panhematin [package insert]. Lebanon, NJ: Recordati Rare Diseases Inc.; January 2024.
- Wang B, Bonkovsky HL, Kim JK, Balwani M. AGA Clinical Practice Update on Diagnosis and Management of Acute Hepatic Porphyrias: Expert Review. Gastroenterology. March 2023; 164(3):484-491.doi:10.1053/j.gastro.2022.11.034. PMID36642627.

POLICY HISTORY

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