Reference number(s)
7585-A

Specialty Guideline Management
Panhematin

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Panhematin	hemin

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Panhematin

Panhematin is 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/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.

Compendial Uses[2-4]

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- Acute hepatic porphyria (e.g., acute intermittent porphyria, variegate porphyria, hereditary coproporphyria)

All other indications are considered experimental/investigational and not medically necessary.

Documentation

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

For initial requests: Elevated porphobilinogen (PBG) in the urine confirmed by a PBG quantitative random urine test, or an elevated porphyrin level (plasma or fecal).

Coverage Criteria

Acute Hepatic Porphyria[1-4,A]

Authorization of 12 months may be granted for treatment of acute hepatic porphyria when all of the following criteria are met:

- The member has a diagnosis of acute hepatic porphyria confirmed by the presence of clinical symptoms (e.g., severe acute abdominal pain, nausea, vomiting, constipation, muscle weakness, neuropathy, tachycardia, and hypertension).
- The member has an elevated urine porphobilinogen (PBG), or an elevated porphyrin level (plasma or fecal).

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment of an indication listed in the coverage criteria section for members who are experiencing benefit from therapy.

References

1. Panhematin [package insert]. Bridgewater, NJ: Recordati Rare Diseases Inc.; August 2025.
2. Wang B, Bonkovsky HL, Lim JK, Balwani M. AGA Clinical Practice Update on Diagnosis and Management of Acute Hepatic Porphyrias: Expert Review. Gastroenterology. 2023 Mar;164(3):484-491.
3. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed August 18, 2026.
4. Clinical Pharmacology powered by ClinicalKey. Elsevier; 2026. Available at: http://www.clinicalkey.com/pharmacology/. Accessed August 18, 2026.

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