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PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Panhematin (hemin for injection)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Panhematin was approved by the FDA in 1983. It is a hemin for injection indicated for amelioration of recurrent attacks of acute intermittent porphyria (AIP) temporally related to the menstrual cycle in susceptible women, after initial carbohydrate therapy is known or suspected to be inadequate. Panhematin is the most effective treatment for the other types of acute porphyria as well, which are hereditary coproporphyria (HCP), variegate porphyria (VP), or aminolevulinic acid dehydratase deficiency porphyria (ADP). Carbohydrate loading is typically only attempted first for mild cases.
Porphyrias are rare genetic disorders characterized by abnormally high levels of porphyrins in the body due to certain enzyme defects in the heme biosynthesis pathway. Neurotoxic intermediates cause potentially life-threatening neurologic attacks. AIP is the most common and severe subtype. Women of childbearing age are the most affected population, and the most common attack symptom is severe abdominal pain. Up to 8% of patients have recurrent attacks, defined as more than 4 attacks per year. Panhematin is also commonly used off label for prophylaxis of recurrent attacks.

Panhematin (hemin for injection) will be considered for coverage when the following criteria are met:

Acute Porphyrias

For **initial** authorization:

1. Member is at least 16 years of age; AND
2. Medication must be prescribed by or in consultation with a neurologist, hematologist, gastroenterologist, or hepatologist; AND
3. Member has a documented diagnosis of an acute porphyria with one of the following types: acute intermittent porphyria (AIP), hereditary coproporphyria (HCP), variegate porphyria (VP), or aminolevulinic acid dehydratase deficiency porphyria (ADP); AND
4. Member presents with clinical features suggestive of an acute porphyric attack such as abdominal, back, and/or limb pain, nausea, vomiting, motor neuropathy, tachycardia, seizures, or hyponatremia; AND
5. Member's diagnosis has been confirmed by labs showing an elevated level of urinary deltaaminolevulinic acid (ALA) or porphobilinogen (PBG) (i.e., ≥4 times the upper limit of the normal) within the past year; AND
6. Member has been assessed for possible attack triggers such as certain drugs, smoking, alcohol, or low carb diets, and counseled to avoid these potential causative factors; AND
7. If requesting off label for prophylactic use, chart notes must include documentation of active recurrent porphyria attacks with 4 or more attacks per year requiring hospitalization, urgent care visit, or IV hemin administration at home.
8. **Dosage allowed/Quantity limit:** IV infusion: 1 to 4 mg/kg/day for 3 to 14 days based on the clinical signs. Do not exceed 6 mg/kg of hematin in any 24-hour period.

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For prophylaxis of recurrent attacks (OFF-LABEL): Varies; consult literature. For example, 1 infusion weekly.

If all the above requirements are met, the medication will be approved for 14 days for an acute attack, or 12 months if meets criterion for prophylactic use.

For **reauthorization**:

1. Chart notes must document a positive clinical response to therapy such as symptom improvement, pain reduction OR
2. If being used off label for prophylaxis, must have documentation of reduced frequency or severity of attacks.

If all the above requirements are met, the medication will be approved for 14 days for an acute attack episode, or an additional 12 months if previously met criteria for prophylactic use.

HAP CareSource considers Panhematin (hemin for injection) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
12/27/2022	New policy for Panhematin created.
01/29/2024	Added new reference. Added max dose from label. For prophylaxis, changed “more than 4 attacks” to “4 or more attacks.”

References:

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4. Anderson KE. Acute hepatic porphyrias: Current diagnosis & management. *Mol Genet Metab*. 2019;128(3):219-227. doi:10.1016/j.ymgme.2019.07.002
5. Kothadia JP, LaFreniere K, Shah JM. Acute Hepatic Porphyria. [Updated 2022 May 8]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537178/
6. Whatley SD, Badminton MN. Acute Intermittent Porphyria. 2005 Sep 27 [Updated 2019 Dec 5]. In: Adam MP, Everman DB, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2022. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1193/
7. Bissell DM, Wang B. Acute Hepatic Porphyria. *J Clin Transl Hepatol*. 2015;3(1):17-26. doi:10.14218/JCTH.2014.00039
8. Wang B, Bonkovsky HL, Lim JK, Balwani M. AGA Clinical Practice Update on Diagnosis and Management of Acute Hepatic Porphyrias: Expert Review. *Gastroenterology*. 2023;164(3):484-491. doi:10.1053/j.gastro.2022.11.034

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