Panhematin® (heme for injection) intravenous solution

Humana

Pharmacy Coverage Policy

Effective Date: January 01, 2025
Revision Date: January 01, 2025
Review Date: November 14, 2024
Line of Business: Medicaid - Louisiana
Policy Type: Prior Authorization

Products Affected

Panhematin intravenous solution

Listed Indications

Acute Intermittent Porphyria

Acute Intermittent Porphyria	
Does the member meet all of the following criteria?	
Criteria #1	The member is using Panhematin for the amelioration of attacks of acute intermittent porphyria that are temporally related to the menstrual cycle.
Criteria #2	The member's diagnosis has been confirmed by quantitative measurement of porphobilinogen (PBG) in urine sample.
Criteria #3	One of the following applies to the member: • The member has tried and failed carbohydrate therapy (i.e., 400 grams glucose/day for 1 to 2 days) OR • Carbohydrate therapy is expected to be inadequate/ineffective per the provider's clinical judgment.
Approval Duration	
Initial	plan year duration
Renewal	plan year duration

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Background

This is a prior authorization policy about Panhematin (hemin) for injection.

Panhematin is a hemin for injection indicated for:

- 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.

Acute intermittent porphyria
Porphyrins are naturally occurring chemicals that originate in either the liver or bone marrow. In porphyria, cells fail to convert porphyrins and their precursors into heme. In acute porphyrias, the accumulation of porphyrins causes sudden attacks of pain and neurological symptoms. The most common acute porphyria is acute intermittent porphyria (AIP). AIP is a hepatic form of porphyria characterized by a partial deficiency of a specific enzyme, but this deficiency alone is insufficient to produce symptoms in most individuals. Additional factors such as hormonal changes, using certain prescribed or recreational drugs, excess alcohol consumption, infection and fasting/dietary changes are typically needed to trigger symptoms.

Screening tests to measure the levels of the porphyrin precursor porphobilinogen (PBG) in urine are essential to confirm a diagnosis of acute porphyria. If urinary PBG excretion is increased, then further testing (fecal and blood porphyrin measurement) is necessary to distinguish AIP from

other acute types. There is also evidence that once urine PBG excretion is increased in AIP it takes many years to return to normal, so increased urine PBG excretion in a known AIP patient does not therefore prove that a patient is having an acute attack.

Current strategies of attack prevention include trigger avoidance, early ingestion of carbohydrate (glucose) therapy, and suppression of ovulation (GnRH analog or low dose oral contraceptive). Hemin for injection (previously known as hematin) is an enzyme inhibitor derived from processed red blood cells. Prophylactic use of hemin is not recommended as it may produce dependence on exogenous heme. For moderate to severe attacks, immediate hemin treatment is recommended. Its use in the acute porphyrias is not curative as symptoms generally return after discontinuation. However, in some cases remission has been prolonged with hemin for injection and some neurological symptoms have improved weeks to months after therapy although response was not noted at the time of treatment.

Limitations 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.

Hemin for injection (lyophilized) is available as:

- Panhematin 48 ml SDV (7 mg/mL after reconstitution)
- Each vial contains the equivalent of 350mg hemin, 240mg sodium bicarbonate, and 335mg sorbitol.
- Panhematin requires reconstitution with sterile water immediately before use as it contains no preservative and undergoes rapid chemical decomposition in solution.

Recommended Dosage and Administration:

- Panhematin should only be used by or in consultation with physicians experienced in the management of porphyria.
- The dose is 1 to 4 mg/kg/day of hemin for injection for 3 to 14 days based on the clinical signs.
- Do not exceed 6 mg/kg of hemin for injection in any 24-hour period.

Dosage Calculation Table
1 mg hematin equivalent = 0.14 mL PANHEMATIN
2 mg hematin equivalent = 0.28 mL PANHEMATIN
3 mg hematin equivalent = 0.42 mL PANHEMATIN
4 mg hematin equivalent = 0.56 mL PANHEMATIN

Please see product package insert(s) for full prescribing information.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

References

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5. Merative Micromedex® DRUGDEX [database online]. Ann Arbor, MI: Merative L.P.; URL: https://www.micromedexsolutions.com/. Updated periodically.
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