Clinical Policy Title:	hemin
Policy Number:	RxA.442
Drug(s) Applied:	Panhematin®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Hemin for injection (Panhematin®) is 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.

Limitation(s) 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
hemin (Panhematin®)	Amelioration of recurrent attacks of acute intermittent porphyria	1 to 4 mg/kg/day intravenously for 3 to 14 days based on the clinical signs. The standard dose in clinical practice is 3 to 4 mg/kg/day. Repeat dose in more severe cases no earlier than every 12 hours.	6 mg/kg per 24 hours.

Dosage Forms

- Single-dose lyophilized powder vial (Solution Reconstituted IV): 350 mg hemin, 240 mg sodium carbonate and 335 mg of sorbitol.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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 or b):
   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. Age ≥ 16 years;
3. Dose does not exceed 6 mg/kg in any 24-hour period.

Approval Duration
Commercial: 14 days
Medicaid: 14 days

II. Continued Therapy Approval

A. Acute Porphyria (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 6 mg/kg in any 24-hour period.

Approval Duration
Commercial: 14 days
Medicaid: 14 days

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
AIP: acute intermittent porphyria
FDA: Food and Drug Administration
HCP: hereditary coproporphyria
PBG: prophobilinogen
VP: variegate porphyria
UPG: uroporphyrinogen
ALA: (delta)-aminolevulinic acid

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Do not use in patients with known hypersensitivity to Panhematin®.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- May consider hemin after an appropriate period of alternate therapy (i.e., 400 g glucose/day for 1 to 2

days).

- .Monitor hemin therapy by a decrease in urinary concentrations of 1 or more of the following compounds: (delta)-aminolevulinic acid (ALA), uroporphyrinogen (UPG), porphobilinogen (PBG), or coproporphyrin.

References

1. Panhematin® Prescribing Information. Lebanon, NJ: Recordati Rare Diseases Group, Inc. July 2017. Available at https://www.panhematin.com/ . Accessed June 28, 2021.
2. Stein P, Badminton M, Barth J, Rees D, Stewart MF. Best practice guidelines on clinical management of acute attacks of porphyria and their complications. Ann Clin Biochem. 2013 May;50(Pt 3):217-23.Available at: https://pubmed.ncbi.nlm.nih.gov/23605132/ . Accessed July 01, 2021.
3. Hemin. Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed June 28, 2021.
4. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2021. Accessed with subscription at: http://www.clinicalkey.com. Accessed June 28, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated 2. Background was updated to include: "Panhematin® is not effective in repairing neuronal damage due to progression of porphyria attacks" in Limitation(s) of use 3. Updated verbiage in Dosing Information 4. Clinical policy was updated: Updated approval duration verbiage and updated item #1 verbiage in Continued Therapy Approval 5. Appendix: D was updated 6. References were updated	06/29/2020	09/14/2020
Policy was reviewed: 1. Background was updated to remove "is an enzyme inhibitor derived from processed red blood cells." 2. Dosage Forms was updated to include "hemin, 240 mg sodium carbonate and 335 mg of sorbitol." 3. Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. 4. Continued Therapy Approval criteria II.A.1 was	6/28/2021	09/14/2021

rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 5. Appendix A was updated to include abbreviationsALA and UPG. 6. References reviewed and updated.		