Clinical Policy: Propranolol HCl Oral Solution (Hemangeol)

Reference Number: IL.ERX.PMN.58
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Propranolol HCl oral solution (Hemangeol®) is a beta-adrenergic blocker.

FDA Approved Indication(s)
Hemangeol oral solution is indicated for the treatment of proliferating infantile hemangioma requiring systemic therapy.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions that Hemangeol is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Proliferating Infantile Hemangioma (must meet all)**:**
1. Diagnosis of proliferating infantile hemangioma;
2. Age < 1 year.

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Proliferating Infantile Hemangioma (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Member meets one of the following (a or b):
   a. Member has not received ≥ 12 months of consecutive therapy;
   b. Documentation supports recurrence of hemangioma.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2**):**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HCl: hydrochloride
IH: infantile hemangioma

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed warnings
- Contraindication(s): asthma or history of bronchospasm, heart rate less than 80 beats/min, blood pressure less than 50/30mmHg, pheochromocytoma, hypersensitivity to propranolol or its excipients
- Boxed warning(s): none reported

Appendix D: Management of IH
- IHs are the most common tumors of childhood. While they often involute after proliferation, there are some that rapidly develop complications, resulting in pain, functional impairment, or permanent disfiguration. For such complicated cases of IH, propranolol is a first-line medical therapy.
- Although the most dramatic improvement using propranolol for IH occurs within 3 to 4 months of initiation of therapy, the optimal treatment duration has not been established:
  - The FDA recommends the maintenance dose be maintained for 6 months. This is likely based on the clinical trial for approval which evaluated patients after 6 months of treatment.
  - The American Academy of Pediatrics indicates that many continue therapy until patients reach an age when IH would normally begin to regress without treatment-often until at least 8 to 12 months of age, which, in most studies, equated to 3 to 12 months of therapy.
- While Hemangeol is effective, rebound growth has been observed in 6% to 25% of children. In the Hemangeol clinical trial, 10% of patients deemed successes after 6-months of therapy later required re-treatment for recurrence.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Proliferating infantile hemangioma	0.15 mL/kg (0.6 mg/kg) PO twice daily, increase to 0.3 mL/kg (1.1 mg/kg) twice daily after 1 week, then to a maintenance dose of 0.4 mL/kg (1.7 mg/kg) twice daily	Depends on weight

VI. Product Availability

Oral solution: 4.28 mg/mL

VII. References

1. Hemangeol Prescribing Information. Parsippany, NJ: Pierre Fabre Pharmaceuticals, Inc; May 2015. Available at: http://www.hemangeol.com. Accessed February 5, 2019.
2. Darrow DH, Greene AK, Mancini AJ, et al. American Academy of Pediatrics clinical report (guidance for the clinician in rendering pediatric care): diagnosis and management of infantile hemangioma. Pediatrics. 2015; 136(4): e1060-e1104.
3. Krowchuk DP, Frieden IJ, Mancini AJ, et al: Clinical practice guideline for the management of infantile hemangiomas. Pediatrics 2019; 143(1):e20183475.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.15.21	05.21

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.