Clinical Policy: Propranolol HCl Oral Solution (Hemangeol)

Reference Number: PA.CP.PMN.58
Effective Date: 01/18
Last Review Date: 04/19

Coding Implications
Revision Log

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

FDA approved indication
Hemangeol is indicated for the treatment of proliferating infantile hemangioma (IH) requiring systemic therapy.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® 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 ≥ 5 weeks;
3. Weight ≥ 2 kg.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 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 Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 health plan benefit or the Continuity of Care policy (PA.LTSS.PHAR.01) applies and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to PA.CP.PMN.53 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 – PA.CP.PMN.53 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) twice daily, increase to 0.3 mL/kg (1.1 mg/kg) twice	Depends on weight

	daily after 1 week, then to a maintenance dose of 0.4 mL/kg (1.7 mg/kg) twice daily	

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
2Q 2018 annual review: references reviewed and updated.	02.06.18	
2Q 2019 annual review: added clinical practice guidelines for management of infantile hemangiomas to references; added contraindications; references reviewed and updated.	04.17.19	