Clinical Policy Title:	propranolol HCl Oral Solution
Policy Number:	RxA.389
Drug(s) Applied:	Hemangeol®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Propranolol HCl oral solution (Hemangeol®) is a beta-adrenergic blocker. It is indicated for the treatment of proliferating infantile hemangioma requiring systemic therapy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Propranolol HCl Oral Solution (Hemangeol®)	Proliferating infantile hemangioma	Starting dose is 0.15 mL/kg (0.6 mg/kg) orally twice daily. After 1 week, increase to 0.3 mL/kg (1.1 mg/kg) twice daily. After 2 weeks, increase to a maintenance dose of 0.4 mL/kg (1.7 mg/kg) twice daily. Note - Monitor heart rate and blood pressure for 2 hours after the first dose or increasing dose.	Depends on weight

Dosage Forms

- Oral solution: 4.28 mg/mL

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. Proliferating Infantile Hemangioma (must meet all)**:**

1. Diagnosis of proliferating infantile hemangioma;
2. Age 5 weeks of age or older;

3. Prescribed by or in consultation with pediatric dermatologist;
4. Weight is 2 kg or more;

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Proliferating Infantile Hemangioma (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
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
Commercial: 6 months
Medicaid: 6 months

III. APPENDICES

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;
  - Pheochromocytoma;
  - Premature infants with corrected age <5 weeks;
  - Infants weighing less than 2 kg;
  - Known hypersensitivity to propranolol or excipients;
  - Bradycardia (<80 beats per minute), greater than first degree heart block, decompensated heart failure;
  - Blood pressure less than 50/30mmHg;

- Boxed warning(s):
  - None reported.

APPENDIX D: General Information
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 6months of therapy later required re-treatment for recurrence.

References

1. Hemangeol Prescribing Information. Parsippany, NJ: Pierre Fabre Pharmaceuticals, Inc; April 2020. Available at: https://www.hemangeol.com/hcp/wp-content/themes/responsive-child/docs/HEMANGEOL-Notice-USA-May-12-2020.pdf . Accessed May 31, 2021.
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. Accessed May 31, 2021.
3. Hemangeol. Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed May 31, 2021.
4. Krowchuk DP, Frieden IJ, Mancini AJ, et al: Clinical practice guideline for the management of infantile hemangiomas. Pediatrics 2019; 143(1):e20183475. Accessed May 31, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1) Policy description table updated 2) Dosing Information updated 3) Continuation therapy criteria II.A.1. rephrased to “Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy” 4) Appendix C, contraindications updated 5) Initial therapy and continued therapy approval duration was updated 6) References were updated	07/14/2020	09/14/2020
Policy was reviewed: 1. Dosing Information dosing regimen was updated to include “Note - Monitor heart rate and blood pressure for 2 hours after the first dose or increasing dose.” 2. Statement about provider sample ‘‘The provision of provider samples does not	5/31/2021	9/14/2021

guarantee coverage…" was added to Clinical Policy. 3. Initial Approval Criteria I.A.3 was updated to include "Prescribed by or in consultation with pediatric dermatologist." 4. References were reviewed and updated.		