

Clinical Policy Title:	propranolol HCl
Policy Number:	RxA.389
Drug(s) Applied:	Hemangeol®
Original Policy Date:	03/06/2020
Last Review Date:	07/18/2022
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	<p>Starting dose is 0.15 mL/kg (0.6 mg/kg) orally twice daily.</p> <p>After 1 week, increase to 0.3 mL/kg (1.1 mg/kg) twice daily.</p> <p>After 2 weeks, increase to a maintenance dose of 0.4 mL/kg (1.7 mg/kg) twice daily.</p> <p>Note - Monitor heart rate and blood pressure for 2 hours after the first dose or increasing dose.</p>	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;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

2. Age ≥ 5 weeks;
3. Prescribed by or in consultation with a pediatric dermatologist;
4. Weight ≥ 2 kg.

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 50/30 mmHg;

*Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- 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 disfigurement. 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; June 2021. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=b6f9dd2a-632b-87eb-70f0-b2064d7ed48a&type=display#section-8.1> . Accessed March 23, 2022.
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. Available at: <https://publications.aap.org/pediatrics/article/136/4/e1060/73846/Diagnosis-and-Management-of-Infantile-Hemangioma> .Accessed March 23, 2022.
3. Hemangeol. Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: <http://online.lexi.com> . Accessed March 23, 2022.
4. Krowchuk DP, Frieden IJ, Mancini AJ, et al: Clinical practice guideline for the management of infantile hemangiomas. Pediatrics 2019; 143(1):e20183475. Available at: <https://publications.aap.org/pediatrics/article/143/1/e20183475/37268/Clinical-Practice-Guideline-for-the-Management-of> .Accessed March 23, 2022.

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	5/31/2021	9/14/2021

<p>rate and blood pressure for 2 hours after the first dose or increasing dose.”</p> <ol style="list-style-type: none"> 2. Statement about provider sample “The provision of provider samples does not 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. 		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Clinical Policy Title: Updated from " propranolol HCl Oral Solution" to " propranolol HCl ". 2. Disclaimer about contraindications "Contraindications listed reflect statements made in the manufacturer's package insert..." was added to Appendix C. 3. References were reviewed and updated. 	<p>03/23/2022</p>	<p>07/18/2022</p>