

**Clinical Policy: PROPRANOLOL HCL ORAL SOLUTION (HEMANGEOL)**

Reference Number: IL.PMN.58

Effective Date: 08.01.20

Last Review Date: 04.14.23

[Revision Log](#)

Line of Business: Medicaid

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Propranolol HCl oral solution (Hemangeol<sup>®</sup>) 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 Centene Corporation<sup>®</sup> 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  $\geq$  5 weeks ;

**Approval duration: 6 months**

**B. Other diagnoses/indications**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the PDL (Medicaid), CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

**II. Continued Therapy**

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

1. Member meets one of the following (a or b):

- a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy;
  3. Member meets one of the following (a or b):
    - a. Member has not received  $\geq$  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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the PDL (Medicaid), CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the PDL (Medicaid), CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace and CP.PMN.53 for Medicaid.

**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 policies – CP.PMN.53 for Medicaid 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): premature infants with corrected age of less than 5 weeks, infants weighing less than 2 kg, asthma or history of bronchospasm, heart rate less than 80 beats/min, greater than first degree heart block, decompensated heart failure, blood pressure less than 50/30 mmHg, 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 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 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 after 2 weeks	Depends on weight

**VI. Product Availability**

Oral solution: 4.28 mg/mL

**VII. References**

1. Hemangeol Prescribing Information. Parsippany, NJ: Pierre Fabre Pharmaceuticals, Inc; June 2021. Available at: <http://www.hemangeol.com>. Accessed January 11, 2023.
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, adapted from CP.PMN.58 Propranolol (Hemangeol) for migration to HFS PDL. Changed age requirement to be younger than 1 year old.	2.27.2020	
Q2 2021 annual review and changes: ; updated age requirement Age ≥ 5 weeks; updated table for Dosing and Administration; updated <i>Appendix C</i> :	6.29.21	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
<i>Contraindications/Boxed warnings</i> ; reviewed and updated references		
1Q 2021 Annual Review: No significant changes. References reviewed and updated.	3.14.22	
2Q2023 Annual review: Template changes applied to other diagnoses/indications and continued therapy section; updated appendix C, references reviewed and updated.	4.14.23	

**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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to

## CLINICAL POLICY

### Propranolol HCl Oral Solution



recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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#### **Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**For Health Insurance Marketplace (HIM) members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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