



Clinical Policy: Propranolol HCl Oral Solution (Hemangeol)  
Reference Number: CP.PMN.58  
Effective Date: 05/14  
Last Review Date: 05/17  
Line of Business: Medicaid

[Coding Implications](#)  
[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

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 health plans affiliated with Centene Corporation® 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 ≥ between 5 weeks to 5 months;
3. Weight  $\geq 2$  kg;
4. ~~Request does not exceed 6 months of therapy;~~
5. ~~Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.~~

**Approval duration: 6 months**

### B. Other diagnoses/indications

1. Refer to 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 Previously~~ receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. ~~Member has not received ≥ 6 months of consecutive therapy~~
3. ~~Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit~~
2. Documentation of positive response to therapy (e.g., improvement in hemangioma);
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.

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**Approval duration: ~~approve to allow up to 6 months of total therapy~~**

*The recommended treatment course duration is 6 months. Requests for re-treatment will need to be evaluated using the initial approval criteria.*

**B. Other diagnoses/indications** (must meet 1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less); or**

2. Refer to CP.XXX.## 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 – 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: 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

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	daily after 1 week, then to a maintenance dose of 0.4 mL/kg (1.7 mg/kg) twice daily	
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**VI. Product Availability**  
 Oral solution: 4.28 mg/mL

**VII. Workflow Document**



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**VIII. References**

1. Hemangeol Prescribing Information. Parsippany, NJ: Pierre Fabre Pharmaceuticals, Inc; March 2014. Available at <http://www.hemangeol.com>. Accessed ~~May 18, 2016~~ February 8, 2017.
2. ~~Metry DW. Management of infantile hemangiomas. Levy ML (Ed), UpToDate, Waltham, MA. Accessed May 2016.~~
3. ~~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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template Removed criteria B is allow provider to own this responsibility Removed criteria C due to lack of literature support Added recommended starting age and weight to criteria	08/15	08/15
Updated template and references. Added requirement for previous fulfilment of Centene coverage criteria for continued approval. Changed weight requirement from ≤ 2 kg to ≥ 2 kg in accordance with FDA labeling. Added workflow document.	05/16	08/16
<u>Clinical changes made to criteria</u> <del>- Removed upper age limit as Hemangeol has demonstrated efficacy in older children per literature review</del> <del>- Removed hard stop at 6 months of total treatment and all criteria referencing said hard stop</del> <del>—Added criteria to allow continued therapy for recurrence of hemangioma or for those requiring up to 12 consecutive months of treatment per AAP clinical report</del> <del>—</del> <u>Non-clinical changes to criteria</u> <del>- Converted to new template</del>	<del>03/17</del> <u>03/17</u>	<u>05/17</u>

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
- <a href="#">Updated references</a>		

**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 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.



## CLINICAL POLICY

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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.

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