

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date:	December 2, 2014
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# **HEMANGEOL®** (propranolol oral solution)

## **LENGTH OF AUTHORIZATION:**

**Initial Therapy**: 6 months

Continuation of Therapy: 6 months

### **INITIAL THERAPY:**

- Infant has a diagnosis of proliferating infantile hemangioma.
- Infant's age is in the range of 5 weeks (adjusted gestational age) to 5 months.
- Infant weighs a minimum of 2 kilograms. (Documentation of patient's most recent body weight at baseline must be provided).
- Infant has <u>none</u> of the contraindications as listed below:
  - Known hypersensitivity to propranolol or excipients
  - o Asthma, history of bronchospasm or lower respiratory infection
  - o Bradycardia (< 80 beats per minute)
  - o Greater than first degree heart block
  - o Decompensated heart failure
  - Blood pressure < 50/30 mmHg
  - o Pheochromocytoma

### **CONTINUATION OF THERAPY:**

- Patient met initial review criteria;
- Patient had initial successful treatment with Hemangeol for 6 months resulting in complete or nearly complete resolution of the target hemangioma but has experienced a recurrence;
- Per the FDA approved product labeling, "Safety and effectiveness for infantile hemangioma have not been established in pediatric patients greater than 1 year of age.";
- For dosage adjustments, documentation of patient's most recent body weight must be provided.

#### **DOSING & ADMINISTRATION:**

- Refer to product labeling at <a href="https://www.accessdata.fda.gov/scripts/cder/daf/">https://www.accessdata.fda.gov/scripts/cder/daf/</a>
- Available as a 4.28 mg/ml oral solution (120 ml bottle, discard 2 months after opening).