

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date:	December 2, 2014
Revision Date:	January 27, 2023

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
 - Bradycardia (< 80 beats per minute)
 - Greater than first degree heart block
 - Decompensated heart failure
 - Blood pressure < 50/30 mmHg
 - 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 https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as a 4.28 mg/ml oral solution (120 ml bottle, discard 2 months after opening).

