

Guideline Number: Hemangeol (propranolol hydrochloride oral solution) (PG135, Ver. 3)

## Hemangeol (propranolol hydrochloride oral solution)

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

### Summary

Infantile hemangioma is a common benign tumor of infancy that affects the blood vessels. It is the most common type of vascular tumor in children and is estimated to occur in 4-10% of infants. Infantile hemangioma typically appears as a raised, red or purple bump on the skin and can vary in size and location.

The exact cause of infantile hemangioma is unknown, but it is believed to be related to an abnormal proliferation of blood vessels during early infancy. It is more common in female infants and in premature infants. Diagnosis of infantile hemangioma is usually made based on the characteristic appearance of the lesion and the patient's age and medical history. In some cases, a biopsy may be performed to confirm the diagnosis.

Treatment for infantile hemangioma is generally not needed for small, asymptomatic lesions. However, if a larger lesion causes symptoms or interferes with daily activities and developmental milestones, drug therapy options such as beta blockers and corticosteroids (oral, intralesional, or topical) may be

considered. Active monitoring is typically required for most lesions, with treatment being necessary in cases of ulceration, vital structure interference, or potential disfigurement. Complications of cutaneous hemangiomas depend on factors like size, location, and shape, and can include ulceration, cosmetic disfigurement, and functional issues like eye complications, airway obstruction, feeding difficulties, limited mobility, and, rarely, heart failure. Hemangeol (propranolol hydrochloride oral solution) is a beta-adrenergic blocker indicated for treating proliferating infantile hemangioma that requires systemic therapy. Its safety and effectiveness have not been established for pediatric patients older than 1 year of age.

### Definitions

**"Infantile hemangioma (IH)"** is a benign (noncancerous) tumor that affects the blood vessels and is the most common type of vascular tumor in children. It typically appears as a raised, red or purple bump on the skin and can vary in size and location.

**"Asthma"** is a chronic respiratory condition that is characterized by inflammation and narrowing of the airways, leading to difficulty breathing.

**"Bronchospasm"** is a sudden contraction or narrowing of the muscles in the walls of the bronchial tubes, making it difficult to breathe.

**"Bradycardia"** is a medical condition in which the heart beats at a slower rate than normal.

**"Decompensated Heart Failure"** is a medical condition in which the heart is unable to pump enough blood to meet the body's demands, leading to symptoms such as shortness of breath, fatigue, and swelling in the legs and ankles.

**"Premature infant"** is a baby born before 37 weeks of gestation.

**"Pheochromocytoma"** is a rare type of tumor that affects the adrenal glands and produces excess amounts of catecholamines, which can lead to high blood pressure and other symptoms.

### Medical Necessity Criteria for Initial Authorization

The Plan considers **Hemangeol (propranolol hydrochloride oral solution)** medically necessary when **ALL** of the following criteria are met:

1. Prescribed by or in consultation with a specialist with experience treating hemangioma (e.g., pediatric dermatologist); **AND**

2. The member is between the ages of 5 weeks (i.e., 35 days) to 1 year of age; **AND**
3. The member has a confirmed diagnosis of proliferating infantile hemangioma; **AND**
4. The member does not have documentation of **ANY** of the following:
  - a. Asthma or history of bronchospasm; **or**
  - b. Blood pressure <50/30 mmHg; **or**
  - c. Bradycardia (<80 beats per minute); **or**
  - d. Decompensated heart failure; **or**
  - e. Greater than first degree heart block; **or**
  - f. Is a premature infant with corrected age <5 weeks; **or**
  - g. Pheochromocytoma; **or**
  - h. Weighing less than 2 kg; **AND**
5. Hemangeol (propranolol hydrochloride oral solution) will be dosed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature **AND BOTH** of the following:
  - a. Treatment will be initiated between ages 5 weeks to 5 months; **and**
  - b. Treatment will not extend beyond 1 year of age; **AND**
6. Recent clinical chart documentations (within the last month) are provided for review to substantiate the above listed requirements.

**If the above prior authorization criteria are met, the requested medication will be approved for 6 months.**

#### **Medical Necessity Criteria for Reauthorization**

**Reauthorization for 6 months or up to 1 year of age (whichever is less)** will be granted if **BOTH** of the following are met:

1. the member still meets the applicable initial criteria; **AND**
2. chart documentation shows **BOTH** of the following:
  - a. recurrence of hemangiomas; **and**
  - b. the member has shown a clinical improvement (e.g., resolution of the target hemangioma) in symptoms since starting the requested medication.

### Experimental or Investigational / Not Medically Necessary

Hemangeol (propranolol hydrochloride oral solution) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Akathisia, antipsychotic-induced; **or**
- Angina, chronic stable; **or**
- Atrial fibrillation/flutter; **or**
- Essential tremor; **or**
- Hypertension; **or**
- Migraine, prevention; **or**
- Myocardial infarction, early treatment and secondary prevention; **or**
- Infantile hemangioma in pediatric patients greater than 1 year of age. Safety and effectiveness for infantile hemangioma have not been established in pediatric patients greater than 1 year of age; **or**
- Initiating treatment at ages less than 5 weeks or greater than 5 months; **or**
- Infants weighing less than 2 kg; **or**
- Performance anxiety disorder; **or**
- Pheochromocytoma; **or**
- Postural orthostatic tachycardia syndrome; **or**
- Premature infants with corrected age <5 weeks; **or**
- Supraventricular tachycardia; **or**
- Thyroid storm; **or**
- Thyrotoxicosis; **or**
- Treatment for cosmetic improvement rather than focusing on the patient's functionality, such as:
  - Situations where the lesions do not require medical or surgical intervention; **or**
  - Instances where small, localized, non facial lesions without ulceration can be safely managed through active observation; **or**
  - Cases where allowing lesions to follow their natural involution process is expected to result in the most favorable cosmetic outcome; **or**
- Tremor, lithium-induced, moderate to severe; **or**
- Variceal hemorrhage prophylaxis; **or**
- Ventricular arrhythmias.

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#### Clinical Guideline Revision / History Information

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