

PRIOR AUTHORIZATION POLICY

POLICY: Hemangeol Prior Authorization with Step Therapy Policy

- Hemangeol[®] (propranolol hydrochloride oral solution [4.28 mg/mL] – Pierre Fabre)

REVIEW DATE: 11/13/2024

OVERVIEW

Hemangeol, a beta-adrenergic blocker, is indicated for the treatment of proliferating infantile hemangioma requiring systemic therapy.¹ Initiate treatment at ages 5 weeks to 5 months.

Disease Overview

Infantile hemangiomas are common pediatric vascular tumors;^{2,3} they may occur in up to 5% of infants.⁴ The pathogenesis is not clearly known but may be due to the proliferation of endothelial cells present in the chorionic villi of the placenta.³ Onset may occur as early as a few weeks after birth. The most significant growth occurs between 1 month to 3 months of age.⁴ Although hemangiomas may occur anywhere on the body, most occur on the head and neck. Some are small and resolve on their own without treatment.²⁻⁴ Others, due to their size the location, are disfiguring (e.g., those present in the facial region), cause functional impairment (e.g., periorbital infantile hemangiomas), or lead to permanent skin changes (scarring).²⁻⁴ Early active interventions should be sought for infantile hemangiomas that are problematic (ideally by before 5 weeks of age).³

Guidelines

The American Academy of Pediatrics published clinical practice guidelines for the management of infantile hemangiomas in 2019.⁴ Regarding pharmacological therapy, oral propranolol is the treatment of choice for problematic infantile hemangiomas that require systemic treatment. Oral prednisolone or prednisone may be used for infantile hemangiomas if there are contraindications or if patients have experienced an inadequate response to propranolol. Intralesional injection of triamcinolone and/or betamethasone may be used to treat focal, bulky infantile hemangiomas during proliferation or in selected critical anatomic locations (e.g., the lip). Topical timolol may be utilized to treat some thin and/or superficial infantile hemangiomas. Surgery and/or laser treatment may be used for selected patients. Early intervention (ideally by 1 month of age) is recommended for infants who may have problematic infantile hemangiomas. It is notable that infantile hemangiomas have a maximum growth potential between 1 and 3 months of age; the majority of growth is complete by 5 months of age. However, deeper infantile hemangiomas may have a slightly later onset and more prolonged duration of growth. By 5 to 12 months of age, most infantile hemangiomas have stopped growing and are beginning to involute. Changes in color of the infantile hemangiomas may change from red to milky-white or gray. Lesions gradually flatten and shrink. In general, infantile hemangioma involution is complete by 4 years of age in 90% of patients. Extended therapy may need to account for the remainder of the infantile hemangiomas.

Safety

Hemangeol is contraindicated in the following conditions; premature infants with corrected age < 5 weeks; infants weighing less than 2 kg; asthma or of bronchospasm; heart rate < 80 beats per minute, greater than first degree heart block, or decompensated heart failure; blood pressure < 50/30 mmHg; and pheochromocytoma.

POLICY STATEMENT

11/13/2024

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Prior Authorization is recommended for prescription benefit coverage of Hemangeol. There is also a Step Therapy component which applies only to a patient ≥ 6 months of age. When Step Therapy applies, a trial of generic propranolol is required prior to Hemangeol.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Hemangeol recommended in those who meet the following criteria:

FDA-Approved Indication

- 1. Infantile Hemangioma, Proliferating.** Approve for 1 year if the patient meets BOTH of the following (A and B):
 - A)** Patient is less than 6 years of age; AND
 - B)** If the patient is greater than or equal to 6 months of age, patient has tried generic propranolol.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Hemangeol is not recommended in the following situations:

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Hemangeol[®] oral solution [prescribing information]. Parsippany, NJ: Pierre Fabre; June 2021.
2. Hasbani DJ, Hamie L. Infantile hemangiomas. *Dermatol Clin.* 2022;40:383-392.
3. Sebaratnam DF, Rodriquez Bandera AI, Wong LF, Wargon O. Infantile hemangioma. Part 2: management. *J Am Acad Dermatol.* 2021;85(6):1395-1404.
4. Krowchuk DP, Frieden IL, Mancini AJ, et al. Clinical practice guideline for the management of infantile hemangiomas. *Pediatrics.* 2019;143(1):e20183475.