PRIOR AUTHORIZATION POLICY

POLICY: Hemangeol Prior Authorization with Step Therapy Policy
- Hemangeol® (propranolol hydrochloride oral solution [4.28 mg/mL] – Pierre Fabre)

REVIEW DATE: 11/19/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 and location, are disfiguring (e.g., those present in the facial region), and can 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 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 history 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

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.

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

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 < 6 years of age; AND
   B) If the patient is ≥ 6 months of age, patient has tried generic propranolol.

CONDITIONS NOT COVERED

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

is(are) considered not medically necessary for ANY other use(s); 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	11/13/2024
Annual Revision	No criteria changes.	11/19/2025