Effective Date: 01/01/2020
Last P&T Approval/Version: 04/2022
Next Review Due By: 04/2023
Policy Number: C21109-A

Hemangeol (propranolol hydrochloride oral solution) IL Medicaid Only

PRODUCTS AFFECTED

Hemangeol Solution (propranolol hydrochloride oral solution)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Proliferating infantile hemangioma

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. Proliferating Infantile Hemangioma:
   1. Documentation of a diagnosis of proliferating infantile hemangioma which requires systemic therapy

   AND

   2. Documentation that member is starting treatment between the age of 5 weeks, corrected, and 5 months. NOTE: Member's corrected age can be no less than 5 weeks (see Appendix)

CONTINUATION OF THERAPY:
A. Proliferating infantile hemangioma
   1. Documentation that member meets initial criteria

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DURATION OF APPROVAL:
Initial authorization: 6 months
Continuation of Therapy: 6 months

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
Corrected Age greater than 5 weeks (see appendix) to 5 months, at initiation of therapy.

QUANTITY:
0.6 mg/kg (0.15 mL/kg) twice daily, starting dose
1.7 mg/kg twice daily (0.4 mL/kg) maintenance dose

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Beta-adrenergic blocker

FDA-APPROVED USES:
Indicated for the treatment of proliferating infantile hemangioma requiring systemic therapy

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Hemangeol is contraindicated in members with a corrected age of less than 5 weeks. The corrected age is a calculated age which "corrects" for prematurity. The corrected age may be calculated as the weeks of prematurity subtracted from the chronological age in weeks.[4]

Chronological age (weeks) – [weeks of prematurity]= corrected age (weeks)

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Hemangeol (propranolol hydrochloride) oral solution are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Hemangeol (propranolol hydrochloride) oral solution include: use in a premature infant with a corrected age less than 5 weeks, weight less than 2 kg, know hypersensitivity to propranolol or any of the product's excipients, asthma or history of bronchospasms, heart rate < 80 beats per minute, greater than first degree heart block, decompensated heart failure, blood pressure less than 50/30 mm Hg, and pheochromocytoma.

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therefore, will follow Molina's Off- Label policy.

OTHER SPECIAL CONSIDERATIONS:

Hemangeol (propranolol hydrochloride) oral solution should be dispensed in the original container with the provided oral dosing syringe. Once open, the product may be kept for 2 months.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Hemangeol SOLN 4.28MG/ML

REFERENCES

1. HEMANGEOL (propranolol hydrochloride) Package Insert. Pierre Fabre Pharmaceuticals, Inc., Parsippany, NJ, 08/2021
2. Illinois HFS Drugs with Stipulated PA Language per Contract for MCOs 04.01.2022, revised
3. Bauman, N. M., McCarter, R. J., Guzzetta, P. C., Shin, J. J., Oh, A. K., Preciado, D. A., He, J., Greene, E. A., & Puttgen, K. B. (2014). Propranolol vs prednisolone for symptomatic proliferating infantile hemangiomas: a randomized clinical trial. *JAMA otolaryngology-- head & neck surgery*, *140*(4), 323–330.
4. https://www.healthychildren.org/English/ages-stages/baby/preemie/Pages/Corrected-Age-For-Preemies.aspx#:~:text=Here's%20how%3A,is%20your%20baby's%20corrected%20age

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW COMPLETED- No coverage criteria changes with this annual review.	Q2/2022

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