

Policy Name:	Myalept (metreleptin)	Policy #:	2301P
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Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of Myalept.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Myalept under the specialty pharmacy benefit when the criteria below have been met.

Criteria

- 1. Coverage Criteria for the Treatment of Leptin Deficiency, in Addition to Diet, in Patients with Congenital or Acquired Generalized Lipodystrophy**
 - 1.1 Diagnosis of congenital or acquired generalized lipodystrophy (abnormal fat tissue distribution) caused by leptin deficiency
 - 1.2 Ordered by a specialist enrolled in the Myalept Risk Evaluation and Mitigation Strategy (REMS) Program
- 2. Exclusion Criteria**
 - 2.1 All other indications
 - 2.2 Not indicated for use in patients with HIV-related lipodystrophy
 - 2.3 Not indicated for use in patients with metabolic disease, without concurrent evidence of generalized lipodystrophy
- 3. Approval Period**
 - 3.1 Initial: 12 months
 - 3.2 Reauthorization: 12 months with documented benefit from therapy

CPT Codes

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HCPCS Codes

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References

1. Myalept [package insert]. Cambridge, MA: Aegerion Pharmaceuticals, Inc. February 2022.
2. Chan JL, Lutz K, Cochran E, et al. Clinical effects of long-term metreleptin treatment in patients with lipodystrophy. *Endocr Pract* 2011; 17:922.

Created Date: 06/04/14
Effective Date: 06/04/14
Posted to Website: 01/01/22
Revision Date: 06/05/24

DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.