

Comprehensive support for your patients on MYALEPT



^aApplicants with federal and state government insurance such as Medicare, Medicaid, VA/DoD, and TRICARE are not eligible.

^bThis program is operated by Aegerion Pharmaceuticals, Inc. and can be modified at any time without notice.

^cSubject to other eligibility criteria.



To speak with a ByMySide Coordinator, call 1-855-6MYALEPT (1-855-669-2537), Monday through Friday, 8 AM to 8 PM ET.

Please see Indication and Important Safety Information on page 2.
Please see accompanying Prescribing Information, including Boxed Warning.


myalept[®]
(metreleptin) for injection 11.3 mg per vial

Indication and Important Safety Information

INDICATION: MYALEPT® (metreleptin) for injection is a leptin analog indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.

LIMITATIONS OF USE: The safety and effectiveness of MYALEPT for the treatment of complications of partial lipodystrophy or for the treatment of liver disease, including nonalcoholic steatohepatitis (NASH), have not been established.

MYALEPT is not indicated for use in patients with HIV-related lipodystrophy. MYALEPT is not indicated for use in patients with metabolic disease, including diabetes mellitus and hypertriglyceridemia, without concurrent evidence of generalized lipodystrophy.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF ANTI-METRELEPTIN ANTIBODIES WITH NEUTRALIZING ACTIVITY AND RISK OF LYMPHOMA

- **Anti-metreleptin antibodies with neutralizing activity have been identified in patients treated with MYALEPT. The consequences are not well characterized but could include inhibition of endogenous leptin action and/or loss of MYALEPT efficacy. Worsening metabolic control and/or severe infection have been reported. Test for anti-metreleptin antibodies with neutralizing activity in patients with severe infections or loss of efficacy during MYALEPT treatment. Call 1-866-216-1526 for neutralizing antibody testing**
- **T-cell lymphoma has been reported in patients with acquired generalized lipodystrophy, both treated and not treated with MYALEPT. Carefully consider the benefits and risks of MYALEPT treatment in patients with significant hematologic abnormalities and/or acquired generalized lipodystrophy**
- **Because of the risks associated with the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or MYALEPT and the risk for lymphoma, MYALEPT is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the MYALEPT REMS PROGRAM**

CONTRAINDICATIONS: MYALEPT is contraindicated in general obesity not associated with congenital leptin deficiency. MYALEPT has not been shown to be effective in treating general obesity. The development of anti-metreleptin neutralizing antibodies have been reported in obese patients treated with MYALEPT. MYALEPT is contraindicated in patients with prior severe hypersensitivity reactions to metreleptin or to any of its components.

WARNINGS AND PRECAUTIONS: A dose adjustment, including possible large reductions, of insulin or insulin secretagogue may be necessary in some patients to minimize risk of hypoglycemia. Closely monitor blood glucose in patients on concomitant insulin, especially those on high doses, or insulin secretagogue.

Cases of progression of autoimmune hepatitis and membranoproliferative glomerulonephritis (associated with massive proteinuria and renal failure) were observed in some patients with acquired generalized lipodystrophy treated with MYALEPT. A causal relationship between MYALEPT and the development and/or progression of autoimmune disease has not been established. Carefully consider the benefits and risks of MYALEPT treatment in patients with autoimmune disease.

Hypersensitivity reactions (e.g., anaphylaxis, urticaria or generalized rash) have been reported. Patient should promptly seek medical advice about discontinuation of MYALEPT if a hypersensitivity reaction occurs.

MYALEPT contains benzyl alcohol when reconstituted with Bacteriostatic Water for Injection. The preservative benzyl alcohol has been associated with serious adverse events and death in pediatric patients, particularly in neonates and premature infants.

Preservative-free Water for Injection is recommended for use in neonates and infants.

ADVERSE REACTIONS: Most common adverse reactions ($\geq 10\%$) in clinical trials were headache, hypoglycemia, decreased weight, and abdominal pain.

Please see accompanying full Prescribing Information.

Tap into insurance support as soon as you prescribe MYALEPT metreleptin

Our team is committed to helping your patients get access to MYALEPT. ByMySide Coordinators are available to provide the information you may need to help get your patients started.



Benefits investigation assistance

- We will verify if your patient's insurance covers MYALEPT
- You will be notified if additional steps are required for coverage (i.e., prior authorization)



Prior authorization support

- We can walk you through the prior authorization process, ensure that your office understands what information and forms are needed, and follow up on the status of existing submissions
- We can also provide a sample letter of medical necessity to help with the process
- We can review all reimbursement materials to help before you submit to your patient's insurance

Patient Diagnosis Code

Type	Code	Description
ICD-10-CM diagnosis code	E88.1	Lipodystrophy, not elsewhere classified



Information about coverage appeals

- If coverage is denied, we'll help you understand the steps involved to appeal an initial coverage denial and follow up on the status of existing appeals
- We can also provide a sample letter of appeal for a denied claim to help with the process



To speak with a ByMySide Coordinator, call 1-855-6MYALEPT (1-855-669-2537), Monday through Friday, 8 AM to 8 PM ET.

Please see Indication and Important Safety Information on page 2.
Please see accompanying Prescribing Information, including Boxed Warning.

Help your patients cover the cost of MYALEPT

We aim to help make MYALEPT affordable for patients by offering financial assistance to eligible patients. A ByMySide Coordinator will help determine which programs are best suited for your patients based on eligibility.



Co-pay assistance^{a,b}

Help your eligible, commercially insured patients obtain **100% coverage of their monthly out-of-pocket costs** (up to an annual maximum) for MYALEPT regardless of their financial status and whether your patients are new to MYALEPT or already on therapy. There are no income requirements.



Free drug assistance^{a,b}

Help your patients **access MYALEPT for free** if they are uninsured or underinsured (e.g., have reached their insurance cap or have insurance that will not cover their MYALEPT treatment).^c

We can also help your uninsured patients explore other insurance plan options.

Third-party assistance programs

Are your patients insured through Medicare or Medicaid or any other state government insurance? We can refer them to alternative independent financial assistance programs. These types of programs may be able to provide financial assistance to eligible patients.

^aApplicants with federal and state government insurance such as Medicare, Medicaid, VA/DoD, and TRICARE are not eligible.

^bThis program is operated by Aegerion Pharmaceuticals, Inc. and can be modified at any time without notice.

^cSubject to other eligibility criteria.


myalept[®]
(metreleptin) for injection 11.3 mg
per vial

Start your patients off right and help keep them motivated to stay on track



Injection support and nurse educators

A ByMySide registered nurse can provide one-on-one training and supervision of MYALEPT reconstitution and self-injection—at no cost—at a location chosen by you and your patient.

- Step-by-step training and supervision of MYALEPT reconstitution and self-injection
- Helpful tips for staying on track with MYALEPT and maintaining a regular dosing schedule
- Distribution of MYALEPT resources—including the Medication Guide and Instructions for Use



Adherence support

- Your patients can request a sharps disposal container to properly dispose of their used syringes and needles
- Patients who need to use MYALEPT away from home can request information and counseling to help ensure medication stability
- Check-in, follow-up, and refill reminder calls are available to help patients stay on MYALEPT therapy as prescribed/directed by their health care provider



Personalized nutrition consultations

- A dedicated ByMySide dietitian can consult with your patients to personalize an eating plan
- This education can take place in person or by phone and includes guidance, tips and tools



In-person generalized lipodystrophy and MYALEPT education

- A ByMySide clinical educator can provide one-on-one disease education, information on how MYALEPT works, and steps to get started
- This education can take place in person or by phone and includes guidance, tips, and tools to help your patients be successful on their treatment plan

**Please see Indication and Important Safety Information on page 2.
Please see accompanying Prescribing Information, including Boxed Warning.**

Utilize key pharmacy services to fulfill your patient's prescription

You and your patients have access to key pharmacy services so your patients can start—and stay on track—with MYALEPT.



The specialty pharmacy provides:

- ✓ **Direct-to-patient** medication and supplies shipments
- ✓ **Assistance** with medication replacement if it is lost or damaged
- ✓ **Help** with MYALEPT refills
- ✓ **24/7** pharmacist and nurse hotline in the event of an emergency



To speak with a ByMySide Coordinator, call 1-855-6MYALEPT (1-855-669-2537), Monday through Friday, 8 AM to 8 PM ET.


myalept[®]
(metreleptin) for injection 11.3 mg per vial

Become Certified in the MYALEPT REMS Program

Because of the risks associated with the development of anti-metresleptin antibodies that neutralize endogenous leptin and/or MYALEPT and the risk for lymphoma, MYALEPT is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the MYALEPT REMS Program.

The MYALEPT REMS Program was developed with the FDA to educate prescribers about:

- the development of anti-metresleptin antibodies that neutralize endogenous leptin and/or MYALEPT and the serious adverse events that may result from these antibodies
- the risk of lymphoma, and
- appropriate patient selection

Healthcare providers who prescribe MYALEPT must review the prescriber training materials to enroll in the MYALEPT REMS Program:

Steps to Prescriber Certification:

1. Review the Prescriber Education Materials
 - MYALEPT Prescribing Information
 - Prescriber Training Module
2. Complete and submit the MYALEPT REMS Program Prescriber Enrollment Form
 - Print and sign the Prescriber Enrollment Form or request a copy by calling 1-855-669-2537
 - Submit the form via fax to 1-877-328-9682
 - A confirmation of your certification in the MYALEPT REMS program will be sent to you so you can begin to prescribe MYALEPT



For additional information about the MYALEPT
REMS Program, visit MYALEPTREMS.com or
call 1-855-6MYALEPT (1-855-669-2537),
Monday through Friday, 8 AM to 8 PM ET.

Get your patients started with MYALEPT

Follow the 3 steps below to get a patient started with MYALEPT treatment:

1 If you haven't already, enroll in the MYALEPT REMS Program:

- Visit MYALEPTREMS.com and review the MYALEPT Prescribing Information and Prescriber Training Module
- Complete, sign, and fax the one-time MYALEPT REMS Program Prescriber Enrollment Form to 1-877-328-9682

2 Write the prescription:

A prescription for MYALEPT can only be written on the MYALEPT REMS Authorization Form.

- Complete, sign and fax the MYALEPT REMS Prescription Authorization Form to 1-877-328-9682 for each new prescription
- Remember to check off the ancillary supplies on the bottom of page 2 of the form. Please be sure to fill out all sections of the form. Incomplete areas may delay the start of treatment

3 Let your patients know they will be receiving a call from ByMySide:

- A ByMySide Coordinator will contact patients from a phone number they might not recognize to complete and fulfill their prescriptions for MYALEPT



To speak with a
ByMySide Coordinator,
call 1-855-6MYALEPT
(1-855-669-2537), Monday
through Friday, 8 AM to 8 PM ET.

**Please see Indication and Important Safety Information on page 2.
Please see accompanying Prescribing Information, including Boxed Warning.**

Aegerion[®]
Pharmaceuticals
A NOVELION THERAPEUTICS COMPANY

©2018 Aegerion Pharmaceuticals, Inc. MYALEPT is a registered trademark and ByMySide is a trademark of Aegerion Pharmaceuticals, Inc. All rights reserved. MYA/US/129 1/18

 myalept[®]
(metreleptin) for injection 11.3 mg
per vial