bymyside™ Enrollment Instructions

myalept® (metreleptin) for injection 11.3 mg per vial

For Healthcare Providers

All prescribers of Myalept must be certified in the Myalept REMS Program prior to prescribing Myalept.

To Certify follow these steps:

If you are already certified in the Myalept REMS program you may skip to the prescribe section.

1. **Review** the Myalept Prescribing Information and Prescriber Training Module at **www.myaleptrems.com**.
2. **Complete, sign, and fax** the Myalept REMS Program Prescriber Enrollment Form to **1-877-328-9682**. Your REMS ID number will be e-mailed to you.

To Prescribe follow these steps:

1. **Complete and sign** the Myalept REMS Prescription Authorization Form found at **www.myaleptrems.com**. *Please be sure to fill out all sections of the form. Incomplete areas may delay the start of treatment.*
2. **Complete and sign** the ByMySide Enrollment Form (on page 4) to provide your patient access to comprehensive services including insurance coverage information, financial assistance (if eligible), injection training, fulfillment support, nutrition and dietician services, and adherence support.
3. **Have your patients complete and sign** the ByMySide Patient Authorization Form (on page 5) to allow a ByMySide Coordinator to work with your patients to navigate their access and affordability options and coordinate their Myalept shipments.
4. **Fax the following completed and signed forms to 1-877-328-9682**
   - ☐ Myalept REMS Prescription Authorization Form
   - ☐ ByMySide Enrollment Form
   - ☐ ByMySide Patient Authorization Form
   - ☐ Copy of patient's medical and pharmacy insurance cards (front and back)
   - ☐ Clinical notes including documentation of recent medications

Please see Indication and Important Safety Information on page 3 and accompanying full Prescribing Information including Medication Guide and Boxed Warning.

QUESTIONS? To speak with a ByMySide Coordinator, call 1-855-6MYALEPT (1-855-669-2537), Monday-Friday 8am-8pm ET

For Patients

1. **Read and sign** the enclosed Patient Authorization Form (on page 5) if you would like to receive Myalept product support services from ByMySide such as insurance coverage information, financial assistance (if eligible), injection training, fulfillment support, nutrition and dietitian services, and adherence support.

What's Next?

2. Your Healthcare Provider will fax the necessary paperwork to us.

3. You will be contacted by a ByMySide Care Manager within 2 business days to confirm your insurance coverage and delivery details, and to coordinate additional ByMySide support services. *Please note this call might come from an unfamiliar phone number.*

ByMySide Support

To help you add Myalept to your current treatment plan, we offer a personalized support program called ByMySide with a team that's built around you. ByMySide provides the support services and resources you need when you need them. When you sign up for the ByMySide program, you can access these support services at no cost to you:

- Insurance and financial assistance (if eligible)
- Nurse education sessions
- Specialty pharmacy services
- Nutrition and dietitian services
- Ongoing support

Please see Indication and Important Safety Information on page 3 and accompanying full Prescribing Information including Medication Guide and Boxed Warning.

QUESTIONS? To speak with a ByMySide Coordinator, call 1-855-6MYALEPT (1-855-669-2537), Monday-Friday 8am-8pm ET

bymyside™ Indication and Important Safety Information

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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.

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 (eg, 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 (≥10%) in clinical trials wereheadache, hypoglycemia, decreased weight, and abdominal pain.

Please see accompanying full Prescribing Information including Medication Guide and Boxed Warning.

bymyside™ Enrollment Form

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HEALTHCARE PROVIDER: Please complete all sections of this form and fax to 1-877-328-9682.

I. PATIENT INFORMATION

Patient is (choose one): ☐ New ☐ Currently Receiving Myalept

Patient Name (First MI Last): _____

Address: _____ City: _____ State: _____ Zip: _____

Date of Birth: _____ /_____ / _____ Gender: ☐ Male ☐ Female Email: _____

Primary Contact: ☐ Patient ☐ Legal Representative (if applicable): _____

Preferred Phone: _____ ☐ OK to leave message Alternate Phone: _____ ☐ OK to leave message

II. INSURANCE INFORMATION

Please send a copy of the front and back of the medical and pharmacy insurance cards. If not available, please complete the fields below.

Medical Insurance

Policy Holder Name: _____

Medical Insurance Phone: _____

Medical Policy #: _____ Group # _____

Prescription Insurance

Policy Holder Name: _____

Prescription Insurance Phone: _____

Prescription Policy #: _____ Group # _____

III. MEDICAL ASSESSMENT

REMS Attestation:

☐ Patient has clinical/laboratory diagnosis consistent with generalized lipodystrophy (GL)

ICD-10 Diagnosis Code:

☐ E88.1 Lipodystrophy

☐ Other: _____ /_____

Allergies: ☐ None or ☐ Specify: _____

Height: _____ inches **Weight:** _____ pounds

Pretreatment Lab Information:

Test	Result	Date
A1c	%	
Triglycerides	mg/dL	
Fasting Glucose	mg/dL	
Leptin Assay Type ____	ng/mL	

Patient's Current Medications:

Patient's Past Medical History:

Does the patient have a family history of generalized lipodystrophy? ☐ Yes ☐ No

Attempted Antidiabetic and Lipid-Lowering Therapies:

Diabetes Therapies (check all that apply)

- ☐ Long-acting Insulin
- ☐ Intermediate-acting Insulin
- ☐ Fast-acting Insulin
- ☐ U500 Regular Insulin
- ☐ Biguanides-Metformin
- ☐ Thiazolidinediones
- ☐ Sulfonylurea
- ☐ SGLT2 inhibitor
- ☐ DDP4 inhibitor
- ☐ GLP-1 receptor agonist
- ☐ Alpha-glucosidase inhibitors
- ☐ Meglitinides
- ☐ Amylin agonist

Lipid-Lowering Therapies (check all that apply)

- ☐ Statin
- ☐ Ezetimibe
- ☐ Fibrate
- ☐ Niacin
- ☐ Fish oil
- ☐ Bile acid sequestrants
- ☐ Phytosterols
- ☐ PCSK9 inhibitor

Physical Findings:

- Acromegalic features ☐ Yes ☐ No
- Hepatomegaly ☐ Yes ☐ No
- Splenomegaly ☐ Yes ☐ No
- Acanthosis nigricans ☐ Yes ☐ No
- Hirsutism ☐ Yes ☐ No
- Menstrual abnormalities ☐ Yes ☐ No
- Hyperphagia ☐ Yes ☐ No

IV. PRESCRIBER INFORMATION

Prescriber Name: _____

Prescriber Specialty: _____

Phone: _____ Fax: _____

NPI #: _____ Lic #: _____

Office Contact Name: _____

Office Contact Phone: _____

Office Contact Email: _____

Tax ID #: _____

REVIEW AND SIGN THE ACKNOWLEDGMENT AND AUTHORIZATION

☐ I acknowledge that I have obtained any required authorization or other permission necessary to release the patient's protected health information and the information on this form and any prescription to Aegerion Pharmaceuticals, its affiliates and their representatives, agents, and contractors ("Aegerion"), for the purposes of providing product support services, including but not limited to conveying personal information to dispensing pharmacies. I further certify that any service provided through ByMySide on behalf of any patient is not made in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use MYALEPT or any other Aegerion product or service for anyone, and any decision to prescribe MYALEPT was and will in the future be based solely on my determination of medical necessity, and that I will not seek reimbursement for any medication or service provided by or through ByMySide from any government program or third-party insurer.

☐ I understand that my patient may authorize Aegerion to provide GL and MYALEPT education, including compliance and persistency support. I understand that this program does not include individual treatment or medical advice to the patient, and it does not replace the medical treatment and care provided by me the patient's healthcare provider. I acknowledge that the education provided by Aegerion does not replace any obligation I have to inform the patient of the risks associated with MYALEPT or any other treatment I may prescribe.

Prescriber Signature: _____ Date: _____

Please see accompanying full Prescribing Information including Medication Guide and Boxed Warning.

bymyside™ Patient Authorization Form

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The purpose of this Authorization form is to permit ByMySide participants to receive additional disease education and information ("Patient Support") from Aegerion Pharmaceuticals, its affiliates, representatives, agents and contractors ("Aegerion"). Please read this form carefully and ask any questions that you may have.

To be read, completed, and signed by patient or patient's personal representative.

PLEASE FAX TO 1-877-328-9682

I. AUTHORIZATION TO SHARE PROTECTED HEALTH INFORMATION

By signing this Authorization, I authorize Accredo Specialty Pharmacy ("Accredo") to disclose my contact information and protected health information (or "PHI") related to my disease management, including but not limited to my name, medical and pharmacy records and information relating to payment for my disease management, care management and health insurance, as well as all information provided on any Myalept prescription or prescription related to my disease management, to Aegerion Pharmaceuticals, Inc., and those working on its behalf (collectively, "Aegerion") to provide the Patient Support.

II. PURPOSE OF AUTHORIZATION

The purpose of this Authorization to enable me to obtain patient support from Aegerion, including:

- Investigation of my insurance coverage
- Coordination of benefits and reimbursement support
- Investigation of financial support services and programs, or comparable programs for Myalept that may help me
- Facilitating claims adjudication and submission of claims to third party payers for payment
- Education and access to patient programs related to my disease management including medication adherence support, nutrition support and access to a registered dietitian, treatment and medication reminders and injection training
- Participation in surveys and quality assessment activities to evaluate the effectiveness of the Patient Support

The Authorization also enables me to receive Marketing communications from Aegerion or those acting on its behalf offering programs, services or products of interest to patients taking Myalept.

Aegerion is authorized to contact me by mail, e-mail, text, telephone, and/or any alternative communication method that I request in connection with the Patient Support.

Once my PHI has been disclosed to Aegerion, I understand that federal privacy laws may no longer protect that PHI. However, Aegerion will take reasonable steps to protect my PHI by using and disclosing it only for the purposes described in this Authorization or as otherwise authorized by law.

I understand that I may refuse to sign this Authorization, and that doing so will not affect my ability to participate in ByMySide or to receive treatment or benefits to which I am otherwise entitled. I understand that I am entitled to a copy of this Authorization, and that I may revoke this Authorization at any time, by mailing a letter requesting revocation to: Accredo Health Group, Inc. c/o The Myalept Program, 1640 Century Center Parkway Memphis, TN 38134.

I understand that expiration of or revoking this Authorization will end further use and disclosure of my PHI but that it will not affect use or disclosure of PHI that has already been disclosed by Accredo in reliance upon this Authorization.

This Authorization will expire upon my revocation or one year after I receive my last prescription.

AGREED:

Patient Signature: _____ Date: _____

Patient Name (please print): _____

Personal Representative or Guardian Signature (if applicable): _____

Personal Representative or Guardian Name (please print): _____

Relationship to Patient, including the authority for status as Personal Representative: _____

Address of Patient or Personal Representative: _____

Telephone Number: _____ Email Address: _____

Please see accompanying full Prescribing Information including Medication Guide and Boxed Warning.