myalept® (metreleptin) for injection 11.3mg per vial

MYALEPT® REMS Program
Prescription Authorization Form

INSTRUCTIONS
All fields are required.

For each new prescription, you must:

- Confirm the patient has a diagnosis consistent with generalized lipodystrophy.
- Complete this Prescriber Attestation by checking the box adjacent to each statement below to indicate that you attest to each statement.
- Sign and date at the bottom of the Attestation.
- THEN, complete the prescription and patient information on reverse side.

PRINT and FAX both pages of the completed form to MYALEPT REMS at 1-877-328-9682.

This prescription for MYALEPT is valid for dispensing only if received by fax.

PATIENT INFORMATION

Full Name (first, middle, last)	Date of Birth

☐ Existing Patient ☐ New Patient

Indication for Use: ☐ congenital generalized lipodystrophy ☐ acquired generalized lipodystrophy

PRESCRIBER ATTESTATION

☐ I understand that MYALEPT is indicated as an adjunct to diet as replacement therapy to treat the complications of leptin-deficiency in patients with congenital or acquired generalized lipodystrophy.

☐ I affirm that my patient has a clinical diagnosis consistent with generalized lipodystrophy, and that my patient (or their caregiver) has been properly informed of the benefits and risks of MYALEPT therapy.

☐ I understand that MYALEPT is not indicated for:

- the treatment of complications of partial lipodystrophy.
- the treatment of liver disease, including non-alcoholic steatohepatitis (NASH).
- use in patients with HIV-related lipodystrophy.
- use in patients with metabolic disease including diabetes mellitus and hypertriglyceridemia without concurrent evidence of congenital or acquired generalized lipodystrophy.

☐ I understand that MYALEPT is contraindicated in patients with general obesity not associated with congenital leptin deficiency.

☐ I understand that MYALEPT is associated with serious adverse events due to the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or MYALEPT.

☐ I agree to test for neutralizing antibodies in patients who experience severe infections or if I suspect MYALEPT is no longer working (e.g., loss of glycemic control, or increases in triglycerides).

☐ I understand that MYALEPT is associated with a risk of lymphoma.

☐ I understand I must carefully consider the risks of treatment with MYALEPT in patients with significant hematological abnormalities and/or acquired generalized lipodystrophy.

SIGN HERE	Physician/Prescriber Signature	Date

PRESCRIBER INFORMATION

Full Name (first, middle, last)			
Practice/Facility Name			
Address 1			
Address 2 (optional)	City	State	Zip
Phone	Fax	Email	

OFFICE CONTACT

Full Name (first last)		

If different from above:

Phone	Fax	Email

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PATIENT INFORMATION

Full Name (first, middle, last)	Gender ☐ Male ☐ Female	Date of Birth
Address	City	State / Zip
Preferred Phone / Alternate Phone	Preferred time to contact (check one): ☐ Day ☐ Evening	
Email	Parent/Guardian (if applicable)	
Alternate Caregiver/ Contact Name	Alternate Caregiver/ Contact Email	
Alternate Caregiver/ Contact Phone	OK to leave message with Alternate Caregiver/Contact? ☐ Yes ☐ No	

INSURANCE INFORMATION – Please copy both sides and attach all medical and prescription insurance cards.

Insurance Company Phone	Insured Employer
Insured Name	Relationship to Patient
Insurance Policy #	Insurance Group # (if applicable)
Prescription Card? ☐ Yes ☐ No If yes, carrier_____	Is the patient eligible for Medicare? ☐ Yes ☐ No
Medicare Policy #	Medicare Group # (if applicable)

SHIPPING INFORMATION

Recipient Name (first last)	Send initial shipment to prescribing doctor's office ☐ Yes ☐ No		
Address (if different from above)	City	State	Zip

MYALEPT 5 mg/mL INJECTION PRESCRIPTION

Starting Dose: ☐ 0.06 mg/kg ☐ 2.5 mg ☐ 5 mg ► Convert dose for syringe type _____ ☐ mL ☐ units

Maintenance Dose: _____ ☐ mg **OR** _____ ☐ mg/kg ► Convert dose for syringe type _____ ☐ mL ☐ units

Days Supply	Refills #	Patient Weight (lbs)	Date Weight Taken

Directions: Inject _____ mL under the skin _____ times(s) daily (e.g., by subcutaneous injection)

Attach or List Concomitant Meds	Allergies ☐ No Known Drug Allergies (NKDA)

MYALEPT SUPPLIES PRESCRIPTION

Required supplies (please note – the maximum number per supply is specified below. Pharmacy will adjust to individual patient needs).

For Reconstitution	QTY #	Refills #
☐ 3 mL syringe (22G x 1 in. needle)		
Water for reconstitution (select one):		
☐ BWFI 30 mL vials		
☐ SWFI 5 mL vials (for neonates and infants)		

For Administration	QTY #	Refills #
☐ Nurse Injection Training Requested		
☐ 1 mL tuberculin syringe		
☐ 31G 6mm 1 mL insulin syringe		
☐ 31G 6mm 3/10 mL insulin syringe		
☐ Other syringe size and needle gauge: _____		

The prescriber shall comply with his/her state specific prescription requirements such as e-prescribing, state specific prescription form, fax language, etc. Non-compliance with state specific requirements could result in pharmacy outreach to the prescriber.

I authorize Chiesi USA, and those working on its behalf (collectively, "Chiesi") to provide the Patient Support to transmit the above prescription to Accredo Health Group Inc., the specialty pharmacy, who services my patient.

SIGN HERE

Physician/Prescriber Signature **Product Selection Permitted**	Date
Physician/Prescriber Signature **Dispense As Written**	Date

License #	NPI #

Chiesi