

Myalept® Chiesi Total CareSM Patient Support Services Program Terms and Conditions

To enroll in Chiesi Total Care (the “Program”) and to assess eligibility for patient support services of the Program, patient must complete the Program Enrollment and Authorization Form and have a valid prescription for an eligible product of the Program. Additional documentation may be required. The patient must be a resident of the United States or one of its territories. If the patient is incapable of acting on their own behalf or if the patient is under 18 years old, enrollment into the Program may be completed by another person acting on their behalf (such as a caregiver).

A patient who receives healthcare benefits under any plan or program funded in whole or in part by federal or state governments including Medicare, Medicaid, TRICARE, Veterans Affairs (VA), State Prescription Assistance Plans (SPAPs) (other than health insurance for federal government employees), or any state healthcare program such as Medicaid, Children’s Health Insurance Program, programs funded under Maternal and Child Health Program, or programs funded under Social Services Block Grant (collectively, “Government-funded Plans”) are not eligible for the financial patient support services of the Program. A patient covered under a commercial health plan purchased through a health insurance marketplace or exchange is not a government-funded Plan beneficiary even if the costs of such coverage are subsidized by the federal government. If a change in prescription drug coverage should occur, the patient must notify the Program; such change may affect eligibility for the support services provided in the Program. Patients who have been prescribed a product for an indication that is not consistent with the US Food and Drug Administration-approved labeling will not be eligible for financial patient support services offered through the Program.

Patients residing in or receiving treatment in certain states may not be eligible for certain patient support services of the Program. Patients may not seek reimbursement for value received from the Program. The Program does not obligate the use of any specific medication or healthcare provider. Patients who receive treatment or reside in Massachusetts, Michigan, Minnesota, or Rhode Island are not eligible for co-pay assistance for infusion services or routine testing services.

Chiesi Total Care may recommend contacting an independent financial assistance foundation. Independent financial assistance foundations have their own rules for eligibility. Chiesi USA does not fund independent financial assistance foundations, nor does Chiesi Total Care have involvement or influence in independent foundation decision making or eligibility criteria and does not know if a foundation will be able to help you. Chiesi Total Care can only refer you to a foundation that supports your disease state. This information is provided as a resource for you. Chiesi Total Care does not endorse or show preference for any foundation. The foundations recommended to you may not be the only ones that might be able to help you.

Chiesi Patient Education Liaisons (“PELs”) may be available to assist you with disease education, provide relative educational or informational resources, and to answer questions you may have about your disease. Chiesi Field Reimbursement Managers (“FRMs”) may be available to assist you with your product prescription drug coverage, including prior authorization, appeals, and denials.

PELs and FRMs are employees of Chiesi USA, Inc. PELs and FRMs are not healthcare providers and are not part of your healthcare team. PELs or FRMs will not provide medical care or advice. All treatment decisions should be made by you and your treating healthcare professional. To assist you, PELs and FRMs may need your information. If you choose to opt out of services by PELs and FRMs, you may do so at any time. Please see Chiesi’s Privacy Policy at www.chiesiusa.com/privacy.

Program benefits may not be sold, purchased, traded, or offered for sale, purchase, or trade. The Chiesi Total Care patient support services are not valid where prohibited by law, taxed, or otherwise restricted. Offer subject to change or discontinuance without notice. Restrictions, including monthly maximums, may apply. This is not health insurance.

This is a voluntary program. Patients who choose not to enroll in the Program will be able to receive medication. Patients may participate in Chiesi Total Care without participating in a patient support services program of Chiesi Total Care. After enrolling in Chiesi Total Care, participants may opt out by contacting the Program, as outlined in the Chiesi Total Care Enrollment and Authorization Form. Patients must renew their eligibility by December 31 of each year to continue to receive support under the Program.

By participating in the Program, participants acknowledge that they understand and agree to comply with the Program Terms and Conditions.

Important Safety Information

What is Myalept?

Myalept® (metreleptin) is a leptin replacement therapy used with a doctor-recommended diet to treat problems caused by not having enough leptin (leptin deficiency) in people with generalized lipodystrophy.

- It is not known if Myalept is safe and effective when used to treat problems (complications) caused by partial lipodystrophy or to treat liver disease, including non-alcoholic steatohepatitis (NASH)
- Myalept should not be used to treat people with HIV-related lipodystrophy or people with metabolic disease, including diabetes mellitus and hypertriglyceridemia, without signs or symptoms of congenital or acquired generalized lipodystrophy.

Important Safety Information

Myalept is only available through a restricted program called the Myalept Risk Evaluation and Mitigation Strategy (REMS) Program. Your doctor must be enrolled and certified in the program in order to prescribe Myalept.

Myalept may cause serious side effects, including:

- **risk for developing certain proteins called neutralizing antibodies** that may reduce how well your own leptin or Myalept works. Side effects of these antibodies may include infection, problems with blood sugar (including diabetes), or an increase in triglycerides.
 - **increased risk of a type of blood cancer called lymphoma.**
- You should not take Myalept if you:**
- have general obesity not caused by a congenital leptin deficiency.
 - are allergic to metreleptin or any of the ingredients in Myalept. Symptoms of an allergic reaction include rash, itching (hives), swelling of face, lips, tongue, or throat, problems breathing or swallowing, fainting or dizziness, rapid heartbeat.

Before using Myalept, tell your doctor if you have any medical conditions including if you:

- have or have had problems with your blood cells, including low blood cell counts (especially your white blood cells), bone marrow, immune system, pancreas, swollen lymph nodes, lymphoma, high blood triglyceride levels, or use insulin or a sulfonylurea.
- are pregnant or plan to become pregnant as it is unknown if Myalept will harm your unborn baby. If you become pregnant while using Myalept, talk to your healthcare provider about registering with a program to collect information about the outcomes of moms and babies exposed to Myalept during pregnancy. You can enroll in the Myalept program by calling 1-855-669-2537.
- are nursing or plan to nurse. You should not nurse while you take Myalept.

Other possible side effects

The most common side effects of Myalept include headache, low blood sugar, decreased weight, and/or abdominal pain.

You may get low blood sugar (hypoglycemia) if you take Myalept with other medicines used to lower blood sugar, such as insulin or sulfonylurea. Your doses of these medications may need to be lowered while you use Myalept. Tell your doctor right away if you experience shakiness, sweating, headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, or a jittery feeling because these may be signs of low blood sugar (hypoglycemia).

For newborns and infants, mix Myalept with sterile water for injection (preservative-free) (WFI). Serious side effects including death have happened in newborns or infants who have received the preservative benzyl alcohol. Bacteriostatic water for injection contains benzyl alcohol and it should not be used to mix Myalept for newborns and infants.

Myalept may worsen symptoms caused by certain problems in your immune system (autoimmune disorder). Ask your doctor about what symptoms you should watch for that may require further testing.

Talk to your doctor about any side effect that bothers you or that does not go away. These are not all the possible side effects of Myalept. For more information, speak to your doctor or pharmacist. Tell your doctor about all the medications you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Take Myalept exactly as your doctor instructs you.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

This is the most important information about Myalept. For more detailed information, please see the patient Medication Guide and full Prescribing Information including Boxed Warning.



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By My Side

Chiesi
**TOTAL
care**

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