

Prior
Authorization
and Access
Guide



Raeya, MYALEPT patient

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

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 non-alcoholic 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.

Please see additional Important Safety Information throughout and accompanying full Prescribing 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 of these neutralizing antibodies are not well characterized but could include inhibition of endogenous leptin action and/or loss of MYALEPT efficacy. Severe infection and/or worsening metabolic control have been reported.

Test for anti-metreleptin antibodies with neutralizing activity in patients who develop severe infections or show signs suspicious for loss of MYALEPT efficacy during treatment. Contact Amryt Pharmaceuticals DAC at 1-866-216-1526 for neutralizing antibody testing of clinical samples.

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 treatment with MYALEPT in patients with significant hematologic abnormalities and/or acquired generalized lipodystrophy.

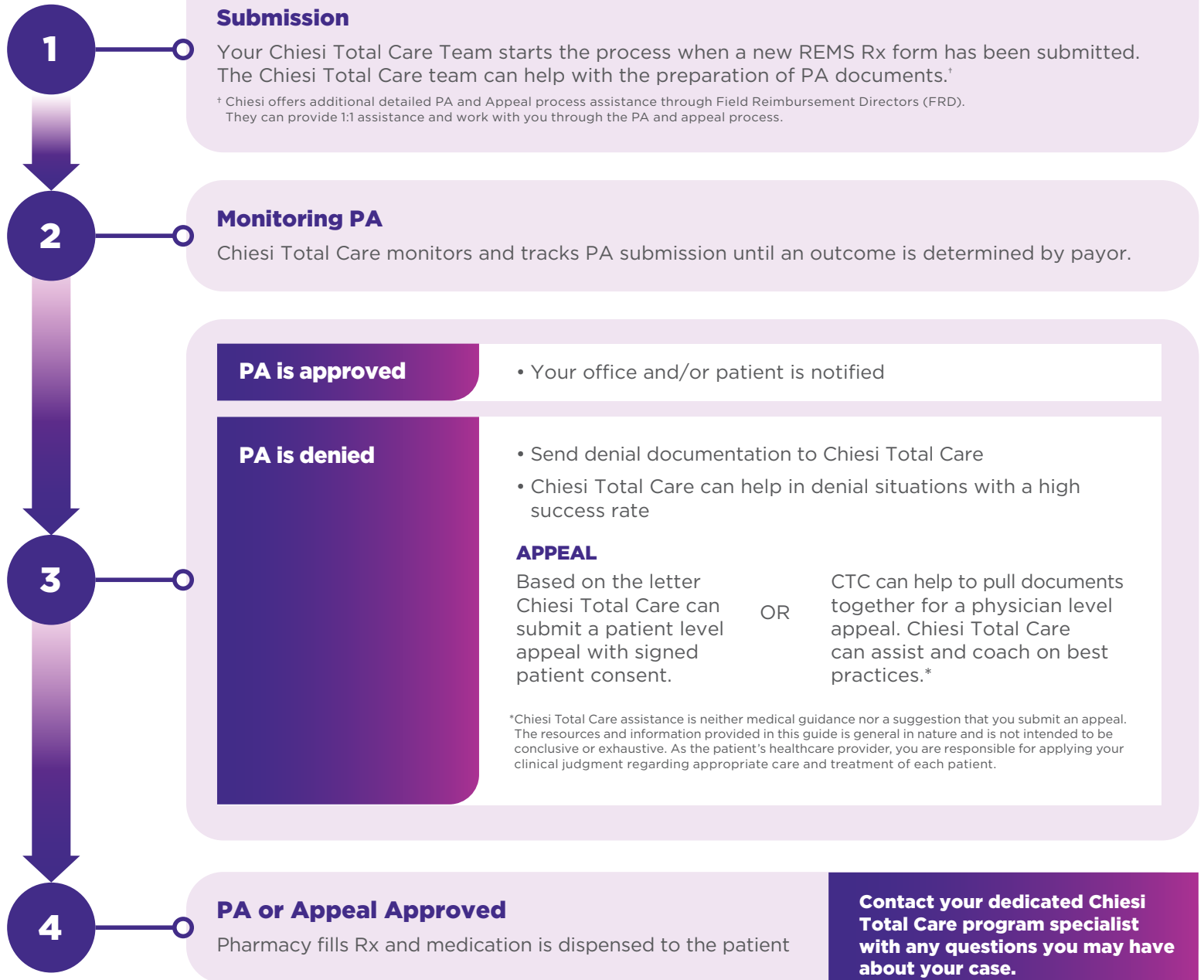
Because of these risks associated with the development of anti-metreleptin antibodies that neutralize endogenous leptin and/or MYALEPT and the risk for lymphoma, MYALEPT is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the MYALEPT REMS PROGRAM.

Visit chiesitotalcare.com
or call 1-855-669-2537.
We're ready to help!



Chiesi Total CareSM (CTC) will submit for insurance reimbursement and help you navigate prior authorization (PA).

Here's a step-by-step look at the process



PA denied? Chiesi Total Care is here to help.

It's not uncommon for the first PA submission to be denied. With a long track record of success in gaining PA and appeal approvals, Chiesi Total Care is here to provide assistance with the appeal process. Chiesi Total Care will assist in providing additional resources and/or publications depending on the reasons for denial. To request a copy of an additional resource or publication, please reach out directly to us.medical@chiesi.com.

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We provide updates on your patient's therapy and alert the office should there be any concerns. We also support patients by helping them cope with side effects and answering questions.



We can help by:

- Alerting when to refill or when refills are being missed
- Counseling patients on managing side effects
- Providing 24/7 pharmacist access
- Enrolling patients in the Myalept Copay Program – patients may pay as little as \$0 if eligible[†]

[†] Please refer to the full Terms and Conditions in the back pocket for additional eligibility requirements.

Here is a checklist of best practices for Prior Authorization submission:

- Include pertinent clinical notes, dates, and laboratory findings
- Include medical rationale for why the patient cannot use preferred formulary drugs
- Include prescribing practitioner NPI number and contact information
- Include therapeutic alternatives that were tried in the past, include documentation as to why it was inadequate

IMPORTANT SAFETY INFORMATION

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.

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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 ($\geq 10\%$) in clinical trials were headache, hypoglycemia, decreased weight, and abdominal pain.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information including Boxed Warning.