Sample Letter of Appeal for MYALEPT® (metreleptin) for injection

This sample letter is intended as a general guide for requesting reconsideration for denied claims of MYALEPT. It is the prescriber's responsibility to verify and ensure the accuracy of the content included in the letter. All information that is provided to payers must be truthful and accurate. *Use of the information in this letter does not guarantee that the payer will provide coverage for MYALEPT and is not intended to be a substitute for, or an influence on, the independent medical judgment of the prescriber.*

For additional information, please contact ByMySide at 1-855-6MYALEPT (1-855-669-2537) Monday through Friday from 8AM - 8PM ET. Visit MYALEPTpro.com to download a copy. Please see full Prescribing Information and Box Warning available at MYALEPTpro.com and http://myaleptpro.com/sites/default/files/myalept_pi_sept2015_final.pdf.

[Date]
ATTN: Medical Review
[Contact name]
[Insurance company]
[Insurance street address]
[Insurance city, state, ZIP]

Re:
[Patient name]
[Date of birth]
[Policy #]
[Group #]

Dear [Contact name]:

This letter is sent to request reconsideration of a claim for MYALEPT® (metreleptin) for injection for my patient, [patient name], with generalized lipodystrophy (GL). In a letter dated [date of denial letter], [Insurance company name] denied this claim because [reason for denial]. I continue to recommend MYALEPT as my treatment of choice for this patient based on my experience in treating GL.

[Patient name] is a [age]-year-old [female/male] who was initially diagnosed with GL on [date] and has been in my care since [date]. During this time, [he/she] has been treated with other therapies including [discuss previous therapies and patient's response to therapy].

The decision to use MYALEPT for [patient name] is based on [provide rationale for the use of MYALEPT in this clinical case]. Enclosed is additional information, including [list relevant documentation], that supports this treatment decision. I trust this information, along with my medical recommendations, will establish the medical necessity for payment of this claim.

Product Description
MYALEPT is an FDA-approved 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.

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), has not been established.

MYALEPT is not indicated for use in patients with HIV-related lipodystrophy or in patients with metabolic disease, including diabetes mellitus and hypertriglyceridemia without concurrent evidence of 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 Lymphonma, MYALEPT is available only through a restricted program called the MYALEPT REMS Program.

I've completed the necessary training for the appropriate selection and monitoring of patients for safe use with MYALEPT and I am a certified prescriber under the MYALEPT REMS Program. I have also completed the FDA required MYALEPT REMS Program Prescription Authorization Form.

Enclosed is the full prescribing information for MYALEPT including Box Warning.

Please contact me at [prescriber telephone number] if you require additional information. Thank you for your immediate attention to this very important matter.

Sincerely,

[Prescriber name]

Enclosures
Full prescribing information for MYALEPT including Box Warning

[list enclosures]