Sample Letter of Medical Necessity for MYALEPT® (metreleptin) for injection

This sample letter is intended as a general guide for submitting information to payers to substantiate medical necessity of MYALEPT. It is the prescriber's responsibility to verify and ensure the accuracy of the content included in the letter. All information 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 including Box Warning attached or 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]:

I am writing on behalf of [patient name] to document the medical necessity for MYALEPT® (metreleptin) for injection for the treatment of generalized lipodystrophy (GL). This letter provides the clinical history, treatment rationale, and other documents that support the use of MYALEPT for this patient with GL.

Clinical History
[Provide description of clinical history]

Prior Therapies
[Include other therapies used for the same diagnosis, dosages, and reason for discontinuation.]

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 lymphoma, 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.

Rationale for Initiating MYALEPT

[Highlight factors that led you to recommend the use of MYALEPT for this patient with GL.]

Please see full Prescribing information including Box Warning enclosed or available at MYALEPTpro.com.

In closing, I ask that you approve MYALEPT coverage for [Patient name] and that you update your formulary to include coverage for this medication for GL patients. Please contact me at [prescriber's telephone number] or [prescriber's email] if additional information is required for approval of this request. I look forward to receiving your response as soon as possible.

Sincerely,

[Prescriber name]

Enclosures
Enclosed is the full prescribing infomration for MYALEPT, including Box Warning.