Instructions

This sample letter for informational purposes only. It provides an example of the type of information that may be required by a patient's health plan when responding to a request related to coverage.

Use of the sample letter provided below does not guarantee that the health plan will cover or reimburse TG Therapeutics medicines. It is not intended to substitute or influence the independent medical judgment of a healthcare provider. There is no requirement that any patient or healthcare provider use any TG Therapeutics product in exchange for this information.

Checklist

Patient Information:

- ☐ Full name
- ☐ Date of birth
- ☐ Insurance ID
- ☐ Insurance group number
- ☐ Case ID number (if applicable)

Clinical Rationale:

- ☐ Patient's diagnosis and the indication for the medicine being prescribed
- ☐ Severity of the patient's condition, including relevant test results and data to demonstrate current condition
- ☐ Summary of the patient's previous treatment(s) including: drug name(s), duration of treatment(s), treatment response(s), reason(s) for discontinuation (e.g., lack of response, tolerability), and recent symptom(s)/condition
- ☐ If a previous treatment resulted in additional care (e.g., hospitalization, side-effect management) and is a reason for discontinuation, include the details of the reasoning
- ☐ The clinical rationale for treatment, including trial data supporting the FDA approval, administration, and dosing information

Additional Enclosures:

- ☐ Prescribing information for the prescribed medication
- ☐ Relevant clinical documentation (e.g., history, medical physical, progress notes, and treatment history)
- ☐ Applicable coverage policies
- ☐ Medical literature, specialist recommendations, and guidelines regarding diagnosis and treatment selection

Sample Letter of Medical Necessity

[Date]
[Payer Name]
[Payer Street Address]
[City, State, ZIP Code]
[Payer Phone and Fax Number]
Patient Name: [Patient Name]
Patient Date of Birth: [Patient Date of Birth]
Member Identification Number: [Member Identification Number]
Group Number: [Number]

Dear [Authorization Reviewer]:

I am writing on behalf of my patient, [Patient Name], to document the medical necessity of [medication name] for the treatment of [Diagnosis and ICD-10-CM code]. This letter provides information about [his/her] medical history and diagnosis and a statement summarizing my treatment rationale.

[Provide a brief description of the patient's:
- Medical history and MS diagnosis;
- Disease progression (e.g., dates and symptoms, magnetic resonance imaging scans, pertinent laboratory values);
- Treatment history; and/or
- Current medical condition (e.g., severity and disability status).]

[Explain why [Drug Name] is the most clinically appropriate option for this patient, including:
- Efficacy, safety, and/or tolerability; and/or
- Dosage and/or route of administration.]

Considering [Patient Name]'s medical history, I believe that a treatment plan with [Drug Name] at this time is medically appropriate and necessary and should be a covered and reimbursed service. [This is substantiated by the enclosed:
- Prescribing information
- Medical guidelines (e.g., American Academy of Neurology, Consortium of Multiple Sclerosis Centers)
- Documentation from (insert specialist's name)]

To conclude, it is my professional opinion that [Drug Name] is medically necessary for [Patient Name]. I am confident that it represents the best viable option for [him/her], and I strongly recommend its approval. Please contact me if any additional information is required.

Thank you in advance for your immediate attention to this written request.

Sincerely,

[Physician's Name]
[Physician NPI Number]
[Physician's Practice Name]
[Physician's Practice Address]
[City, State, Zip Code]
[Physician's Phone and Fax Number]

Enc.