When submitting a prior authorization (PA) request to a patient’s health insurance plan, including a Letter of Medical Necessity can help explain the rationale and clinical decision-making behind the choice of a specific therapy.

Tips for drafting a Letter of Medical Necessity

To help avoid denials when you submit the PA request to the payer, familiarize yourself with the plan’s specific guidelines (eg, obtain any necessary referrals, determine if treatment must be given in a particular setting).

Be sure to know and meet all deadlines for submitting the PA form and other required documents. Once you have received the PA, check with the payer to determine the length of the authorization, as this can vary.

Be detailed and thorough. Recommended information for a Letter of Medical Necessity includes:

1. Patient information:
   - Full name
   - Date of birth
   - Insurance ID number
   - Insurance group number
   - Case ID number (if available)

2. The patient’s diagnosis and the indication for the Genentech medicine being prescribed.

3. The severity of the patient’s condition.

4. A summary of the patient’s previous treatments, the duration of each and the rationale for discontinuation. Include coding information for prior treatments/services to help the health insurance plan conduct their research in a timely manner.

5. The clinical rationale for treatment, including trial data supporting the FDA approval, administration and dosing information.

6. A summary of your recommendation.

7. Additional enclosures, including:
   - Prescribing information
   - Clinical notes/medical records
   - Diagnostic test results
   - Scans for showing progressive disease
   - Pathology reports
   - Relevant peer-reviewed articles
   - FDA approval letter

Please remember to keep complete records, including a copy of the materials that you send and a log of telephone calls made to the patient’s health insurance plan.
SAMPLE LETTER of Medical Necessity

Below is a template you can use to draft your Letter of Medical Necessity. You may also find some of the information needed to help complete the letter on the Forms and Documents or Reimbursement pages of Genentech-Access.com.

[Template]

Use the physician’s letterhead to print the letter.

- PHYSICIAN’S LETTERHEAD

[Date]

[Contact Name/Medical Director]:

I am writing on behalf of my patient, [Patient First and Last Name], to [request prior authorization of/document medical necessity for] treatment with [DRUG NAME]. This letter provides information about the patient’s medical history and diagnosis, and a summary of the treatment plan.

Patient’s clinical history

[Patient Name] is [a/an] [age]-year-old [male/female] patient who has been diagnosed with [condition] as of [date]. [He/She] has been in my care since [date], having been referred to me by [Referring Physician Name] for [reason].

[Brief summary of rationale for treatment with [DRUG NAME]. This includes a brief description of the patient’s diagnosis, including the ICD-10-CM code, the severity of the patient’s condition, prior treatments, the duration of each, responses to those treatments, the rationale for discontinuation, as well as other factors (eg, underlying health issues, age) that have affected your treatment selection.]

Treatment plan

On [Date], the FDA approved [DRUG NAME] for the treatment of [Indication].

[Include plan of treatment (dosage, length of treatment) and clinical practice guidelines that support the use of [DRUG NAME]. Consider mentioning experts in the field who also support the treatment.]

Summary

Based on the above facts, I believe [DRUG NAME] is indicated and medically necessary for this patient. If you have any further questions about this matter, please contact me at [Physician Phone Number] or via email at [Physician Email]. Thank you for your time and consideration.

Sincerely,

[Physician Name and Credentials]

Enclosures

[List enclosures, which may include: prescribing information, clinical notes/medical records, diagnostic test results, relevant peer-reviewed articles, FDA approval letter, scans showing progressive disease, pathology reports.]


Download the full prescribing information in Forms and Documents under the Sample Letter of Medical Necessity.

Find a link to the FDA Approval Letter in Forms and Documents under the Sample Letter of Medical Necessity.

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.

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