Suggestions for Writing a Letter of Medical Necessity

Some plans require that a Letter of Medical Necessity be submitted along with a prior authorization (PA) letter (available at www.unloxcytpro.com/support) to support the choice of UNLOXCYT™ (cosibelimab-ipdl) over other agents that are on formulary. You may find that this checklist and the corresponding sample letter are helpful resources for preparing that letter. A Letter of Medical Necessity should also accompany a medical exemption request letter (available at www.unloxcytpro.com/support).

Checklist

- ☐ **Patient Information**: Include the patient's name, date of birth, insurance policy ID number, and if appropriate, PA denial reference number and date of denial
- ☐ **Diagnosis Code(s):** Include specific ICD-10-CM code(s) that align with your patient's diagnosis
- ☐ **Treatment Rationale**: Explain the clinical rationale for treatment with UNLOXCYT and why it is appropriate for your patient
- ☐ **Medical Documentation**: Include copies of relevant medical records:
  - Medical records documenting the patient's history, characteristics eg, age, comorbidities, and ECOG status), diagnosis (including lesion site[s]), disease progression, and prognosis
  - Documentation that the patient is not a candidate for curative surgery or curative radiation
  - Relevant pathology reports, laboratory results, and imaging reports
- ☐ **Treatment History**: List prior therapies, dates they were administered, and the patient's response (or lack thereof)
- ☐ **Formulary Considerations**: Explain why formulary-preferred agents are not appropriate—eg, intolerance, contraindication, or lack of efficacy (if they are not already listed as previous therapies)
- ☐ **Supporting Evidence**: Provide evidence such as peer-reviewed literature, clinical trial publications, and the prescribing information for UNLOXCYT, which includes the clinical efficacy and safety profile
- ☐ **Closing Statement**: Summarize your recommendation, and provide a contact number should any additional information be required

ECOG, Eastern Cooperative Oncology Group; ICD-10-CM, *International Classification of Diseases, Tenth Revision, Clinical Modification*.

Sample Letter of Medical Necessity for UNLOXCYT

[INSERT ON PHYSICIAN LETTERHEAD]

[Date]

[Health plan name]
To/Attn: [Name of prior authorization department]
[Mailing address]

Re: [Patient Name]
DOB: [Date of birth]
Insurance Policy ID number: [Policy ID Number]
Subject: Letter of Medical Necessity for UNLOXCYT™ (cosibelimab-ipdl)

Dear [Health Plan Contact Name/Medical Director],

I am writing to document the medical necessity of UNLOXCYT for [Patient's name]. The following information summarizes the patient's relevant medical history and clinical rationale for treatment with UNLOXCYT.

[Provide a concise summary of all clinically relevant information, including but not limited to a brief history, diagnosis, disease progression and prognosis, previous treatments (with duration and outcomes), lack of response or tolerability to other therapies, relevant comorbidities, and the clinical rationale for recommending UNLOXCYT. Include, if applicable, the anticipated duration of therapy.]

In my clinical judgment, treatment with UNLOXCYT is medically necessary for [Patient's name]. I am requesting coverage approval for this therapy. Supporting documentation is enclosed for your review. Please contact my office at [phone number] if additional information is needed.

Sincerely,

[Physician signature]

[Insert name]

Enclosed:

[Attach any additional relevant supporting documentation. List all enclosed documents]