Suggestions for Writing a Letter of Medical Exception for UNLOXCYT™ (cosibelimab-ipdl)

In cases where UNLOXCYT is not covered under the patient's health plan or has a National Drug Code (NDC) block, a medical exception request letter may be submitted to request coverage. The letter should outline the clinical rationale for prescribing UNLOXCYT and explain why formulary alternatives are not appropriate for the patient. The checklist and sample letter provided here can help you prepare a complete and accurate medical exception request letter.

Checklist

- ☐ **Patient Information**: Include the patient's name, date of birth, and insurance policy ID number
- ☐ **Diagnosis Code(s):** Include the specific ICD-10-CM code(s) that align with your patient's diagnosis
- ☐ **Treatment Rationale**: Explain the clinical rationale for treatment with UNLOXCYT, including why, in your clinical judgment it is medically necessary for your patient
- ☐ **Medical Documentation**: Include copies of relevant medical records:
  - Patient's history, characteristics (eg, age, comorbidities, and ECOG status), diagnosis (including lesion site[s]), disease staging, 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)
- ☐ **Letter of Medical Necessity**: Attach a letter of Medical Necessity (sample available at www.unloxcytpro.com/support)
- ☐ **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 Exception for UNLOXCYT™ (cosibelimab-ipdl)

[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: Medical exception request for UNLOXCYT™ (cosibelimab-ipdl)

Dear[Health Plan Contact Name/Medical Director],

This letter is sent on behalf of [Patient's name] to request a medical exception for UNLOXCYT.

[Patient's name]is a [age]-year-old [male/female] who was diagnosed with [diagnosis] (ICD-10-CM code: [code]) on [date]. [He/she] is not a candidate for curative surgery or curative radiation therapy. The following information summarizes the clinical rationale for this request.

[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 appropriate and medically necessary for [patient's name]. I am requesting that it be covered by the health plan. 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]