

# Medical Drug Clinical Criteria

**Subject:** Unloxcyt (cosibelimab-ipdl)

**Document #:** CC-0278

**Publish Date:** 03/18/2025

**Status:** New

**Last Review Date:** 02/21/2025

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## Overview

This document addresses the use of Unloxcyt (cosibelimab-ipdl). Unloxcyt is a programmed death ligand-1 (PD-L1) blocking antibody.

The FDA approved indications for Unloxcyt for adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

### Definitions and Measures

**Adenocarcinoma:** Cancer originating in cells that line specific internal organs and that have gland-like (secretory) properties.

**Carcinoid Tumors:** Rare, slow-growing tumors of the neuroendocrine cells (enterochromaffin or Kulchitsky cells) widely found in many organs of body, but usually originate in the digestive tract or lung; also called carcinoids or well-differentiated NETs.

**Chemotherapy:** Medical treatment of a disease, particularly cancer, with drugs or other chemicals.

**ECOG or Eastern Cooperative Oncology Group Performance Status:** A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:

- 0 = Fully active, able to carry on all pre-disease performance without restriction
- 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
- 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
- 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
- 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
- 5 = Dead

**Immune checkpoint inhibitor:** A type of drug that blocks certain proteins made by some types of immune system cells, such as T cells, and some cancer cells. When these proteins are blocked, the "brakes" on the immune system are released and T cells are able to kill cancer cells better. Examples of checkpoint proteins found on T cells or cancer cells include programmed death (PD)-1, PD-ligand 1 (PD-L1), and cytotoxic T-lymphocyte-associated antigen (CTLA)-4/B7-1/B7-2 (NCI, 2018).

**Line of Therapy:**

- **First-line therapy:** The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- **Second-line therapy:** Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- **Third-line therapy:** Treatment given when both initial (first-line therapy) and subsequent treatment (second-

line therapy) are not effective or there is disease progression.

Locally advanced cancer: Cancer that has spread only to nearby tissues or lymph nodes.

Melanoma: A type of cancer that begins in the melanocytes. Melanoma is also referred to as malignant melanoma and cutaneous melanoma.

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Unresectable: Unable to be removed with surgery.

## Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

### Unloxyct (cosibelimab-ipdl)

Requests for Unloxyct (cosibelimab-ipdl) may be approved if the following criteria are met:

- I. Individual has a diagnosis of cutaneous squamous cell carcinoma (CSCC) (Label); **AND**
- II. Individual is using in one of the following ways:
  - A. For the treatment of metastatic CSCC (mCSCC) (NCCN 2A); **OR**
  - B. For the treatment of locally advanced CSCC (laCSCC) and who are not candidates for curative surgery or radiation; **AND**
- III. Individual is using a single agent; **AND**
- IV. Individual has not received another anti-PD-1, anti-PD-L1 agent, or any other antibody or drug specifically targeting T-cell co-stimulation or immune checkpoint pathways; **AND**
- V. Individual has a current ECOG performance status of 0-1; **AND**
- VI. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Unloxyct (cosibelimab-ipdl) may not be approved for the following:

- I. Individual has uncontrolled or significant cardiovascular disease; **OR**
- II. Individual has an infection with HIV, hepatitis B or hepatitis C; **OR**
- III. When the above criteria are not met and for all other indications.

## Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

### HCPCS

C9399	Unclassified drugs or biologicals [when specified as Unloxyct (cosibelimab-ipdl)]
J9999	Not otherwise classified, antineoplastic drugs [when specified as Unloxyct (cosibelimab-ipdl)]

### ICD-10 Diagnosis

All diagnosis pend

## Document History

New: 02/21/2025

Document History:

- 02/21/2025 – Select Review: Add new clinical criteria document for Unloxcyt. Coding Reviewed: Added HCPCS NOC C9399, J9999, and all diagnosis pend for Unloxcyt.

## References

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4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 17, 2024.
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Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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