Reference number(s)
6765-A

Standard Medicare Part B Management Unloxcyt

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Unloxcyt	cosibelimab-ipdl

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Cutaneous Squamous Cell Carcinoma (CSCC)

Unloxcyt is indicated for the treatment of adults with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Exclusions

Coverage will not be provided for members who have experienced disease progression while on programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor therapy.

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Coverage Criteria

Cutaneous Squamous Cell Carcinoma (CSCC)[1,2]

Authorization of 12 months may be granted for treatment of metastatic or locally advanced CSCC when member is not a candidate for curative surgery or radiation.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested medication.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen AND
    - No evidence of disease progression while on the current regimen.

Summary of Evidence

The contents of this document were created after examining the following resources:

- The prescribing information for Unloxcyt.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Squamous cell skin cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Unloxcyt are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

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References

1. Unloxcyt [package insert]. Waltham, MA: Checkpoint Therapeutics, Inc.; December 2024.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed October 27, 2025.

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