

Specialty Guideline 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 Indications¹

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 are considered experimental/investigational and not medically necessary.

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.

Coverage Criteria

Cutaneous Squamous Cell Carcinoma (CSCC)^{1,2}

Authorization of 6 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

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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.