VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Programmed Death Ligand-1) – Unloxcyt Utilization Management Medical Policy
- Unloxcyt™ (cosibelimab-ipdl intravenous infusion – Checkpoint Therapeutics)

REVIEW DATE: 01/08/2025

OVERVIEW

Unloxcyt, a programmed death ligand-1 blocking antibody, is indicated for the treatment of metastatic cutaneous squamous cell carcinoma or locally advanced cutaneous squamous cell carcinoma in adults who are not candidates for curative surgery or curative radiation.[1]

Dosing Information

The recommended dose of Unloxcyt is 1,200 mg administered by intravenous infusion no more frequently than once every 3 weeks until disease progression or unacceptable adverse events.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) squamous cell skin cancer (version 1.2025 – January 17, 2025) clinical practice guidelines recommend Unloxcyt for the treatment of distant metastatic (category 2A) or locally advanced (category 2B) disease when curative surgery or curative radiation therapy are not feasible as an "Other Recommended Regimen".[2,3]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Unloxcyt. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Unloxcyt as well as the monitoring required for adverse events and long-term efficacy, approval requires Unloxcyt to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Unloxcyt is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. **Cutaneous Squamous Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has locally advanced or metastatic disease; AND
   - **C)** According to the prescriber, the patient is not a candidate for curative surgery or curative radiation therapy; AND

D) Medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 1,200 mg administered by intravenous infusion no more frequently than once every 3 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Unloxcyt is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Unloxcyt intravenous infusion [prescribing information]. Waltham, MA: Checkpoint Therapeutics; December 2024.
2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 21, 2025. Search term: cosibelimab.
3. The NCCN Squamous Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – Janaury 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 21, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/08/2025
Update	**01/21/2025:** Added National Comprehensive Cancer Network Squamous Cell Skin Cancer (version 1.2025 – January 17, 2025) clinical practice guideline recommendations to the policy.	NA