CARECONTINUUM™

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: 06/24/2026

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 use of Drug Name is recommended across multiple National Comprehensive Cancer Network (NCCN) guidelines and the NCCN Compendium.[2-6] Recommendations with a category of evidence of 2B or higher support the approval criteria outlined below.

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

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) The 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.

Other Uses with Supportive Evidence

2. Colon and Rectal Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, and C)
- **A)** The patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i or ii):
  - **i.** The disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); OR
  - **ii.** The disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype; AND
    Note: Ultra-hypermutated phenotype is defined as tumor mutational burden > 50 mutations/megabase.
- **C)** The 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.

3. Small Bowel Adenocarcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i or ii):
  - **i.** Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease; OR
  - **ii.** The disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype; AND
    Note: Ultra-hypermutated phenotype is defined as tumor mutational burden > 50 mutations/megabase.
- **C)** The 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; November 2025.

2. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 16, 2026. Search term: cosibelimab.
3. The NCCN Squamous Cell Skin Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – March 17, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2026.
4. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – April 7, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2026.
5. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 2.2026 – April 7, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2026.
6. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 2.2026 – April 7, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2026.

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
Annual Revision	No criteria changes.	12/10/2025
Early Annual Revision	**Colon and Rectal Cancer:** This was added as a new condition of approval to "Other Uses with Supportive Evidence". **Small Bowel Adenocarcinoma:** This was added as a new condition for approval to "Other Uses with Supportive Evidence".	06/24/2026