

## Clinical Policy: Cosibelimab-ipdl (Unloxcyt)

Reference Number: PA.CP.PHAR.711

Effective Date: 02/2025

Last Review Date: 01/2026

### Description

Cosibelimab-ipdl (Unloxcyt™) is a programmed death ligand-1 (PD-L1) blocking antibody.

### FDA Approved Indication(s)

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.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness® that Unloxcyt is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Cutaneous Squamous Cell Carcinoma (must meet all):

1. Diagnosis of CSCC;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Disease is locally advanced, satellitosis/in-transit metastasis or metastatic;
5. Member is not a candidate for curative surgery or radiation;
6. Request meets one of the following (a or b):
  - a. Dose does not exceed 1,200 mg (4 vials) every 3 weeks;
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 12 months**

##### B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

#### II. Continued Therapy

##### A. Cutaneous Squamous Cell Carcinoma (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
  - a. New dose does not exceed 1,200 mg (4 vials) every 3 weeks;

- b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

- 1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

**Approval duration: Duration of request or 12 months (whichever is less); or**

- 2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policies – PA.CP.PMN.53

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

CSCC: cutaneous squamous cell carcinoma

FDA: Food and Drug Administration

la: locally advanced

m: metastatic

PD-L1: programmed death ligand-1

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

None reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
CSCC	1,200 mg IV every 3 weeks until disease progression or unacceptable toxicity	1,200 mg every 3 weeks

**VI. Product Availability**

Single-dose vial for injection: 300 mg/5 mL

**VII. References**

- 1. Unloxyt Prescribing Information. Waltham, MA: Checkpoint Therapeutics, Inc.; December 2024. Available at: <https://checkpointtx.com/wp-content/uploads/2024/12/uspi-unloxyt.pdf>. Assessed November 6, 2025.
- 2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [www.nccn.org](http://www.nccn.org). Accessed December 1, 2025.

- National Comprehensive Cancer Network. Squamous Cell Skin Cancer, Version 1.2026. Available at [https://www.nccn.org/professionals/physician\\_gls/pdf/squamous.pdf](https://www.nccn.org/professionals/physician_gls/pdf/squamous.pdf). Accessed Novemeber 19, 2025.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9275	Injection, cosibelimab-ipdl, 2 mg

Reviews, Revisions, and Approvals	Date
Policy created	01/2025
1Q 2026 annual review: added option for satellitosis/in-transit metastasis per NCCN; added criterion, prescribed as a single agent per NCCN; extended initial approval duration from 6 to 12 months for this maintenance medication for a chronic condition; HCPCS code added [J9275] and removed codes [J3590, C9399]; references reviewed and updated.	01/2026