



**Unloxcyt**  
**Unloxcyt (Cosibelimab-ipdl) J9275**  
**Prior Authorization Request**  
**Medicare Part B Form**

Instructions: \* Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	<b>Standard Request– (72 Hours)</b>	<input type="checkbox"/>	<b>Urgent Request</b> (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

**MEMBER INFORMATION**

\*Name: \_\_\_\_\_ \*ID#: \_\_\_\_\_ \*DOB: \_\_\_\_\_

**PRESCRIBER INFORMATION**

\*Name: \_\_\_\_\_  MD  FNP  DO  NP  PA \*Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ \*Fax: \_\_\_\_\_

**DISPENSING PROVIDER / ADMINISTRATION INFORMATION**

\*Name: \_\_\_\_\_ Phone: \_\_\_\_\_

\*Address: \_\_\_\_\_ Fax: \_\_\_\_\_

**PROCEDURE / PRODUCT INFORMATION**

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____ )	Frequency	End Date if known

Self-administered       Provider-administered       Home Infusion

Chart notes attached. **Other important information:** \_\_\_\_\_

**Diagnosis: ICD10:** \_\_\_\_\_ **Description:** \_\_\_\_\_

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

**CLINICAL INFORMATION**

**New Start or Initial Request: (Clinical documentation required for all requests)**

**Cutaneous Squamous Cell Carcinoma (CSCC) – Metastatic or Locally Advanced**

- Patient is 18 years or older
- Confirmed diagnosis of cutaneous squamous cell carcinoma
- Disease is either:
  - Metastatic CSCC (mCSCC) OR
  - Locally advanced CSCC (laCSCC)
- Patient is not a candidate for curative surgery or curative radiation
- No prior disease progression while on PD-1 or PD-L1 inhibitor therapy
- ECOG performance status 0-1
- Prescribed by or in consultation with oncologist
- No active autoimmune disease requiring systemic immunosuppression
- No active hepatitis B, hepatitis C, or HIV infection (unless well-controlled and cleared by specialist)
- Tuberculosis screening negative prior to initiation (if indicated)

If not, please provide **clinical rationale** for formulary exception: \_\_\_\_\_  
\_\_\_\_\_

**Continuation Requests: (Clinical documentation required for all requests)**

- Patient continues to meet initial approval criteria
- No evidence of disease progression (per RECIST or clinical assessment)
- No unacceptable toxicity requiring discontinuation (e.g., severe immune-mediated adverse reactions)
- Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: \_\_\_\_\_  
\_\_\_\_\_

**ACKNOWLEDGEMENT**

**Request By (Signature Required):** \_\_\_\_\_ **Date:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

## Prior Authorization Group – Unloxcyt Prior Authorization

### Drug Name(s):

UNLOXCYT

COSIBELIMAB-IPDL

### Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per CMS recognized compendia, authoritative medical literature, evidence based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
  - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
  - Quantity limits and tiering will be determined by the Plan, in accordance with the Label.

### Exclusion Criteria:

N/A

### Prescriber Restrictions:

Oncologist or other related specialist

### Coverage Duration:

Approval will be for 6 months

### FDA Indications:

Unloxcyt

- Squamous cell carcinoma of skin, Locally advanced or metastatic, in patients who are not candidates for curative surgery or radiation

### Off-Label Uses:

N/A

### Age Restrictions:

- Safety and efficacy not established in pediatric patients [\[1\]](#)

### Other Clinical Consideration:

N/A

### Resources:

<https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Unloxcyt&SearchFilter=filterNone#>