# UNLOXCYT *(cosibelimab-ipdl)* injection, for IV use

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<tr><th>PA Criteria</th><th>Criteria Details</th></tr>
<tr><td>Description</td><td>UNLOXCYT is a programmed death ligand-1 (PD-L1) blocking antibody.</td></tr>
<tr><td>Covered Uses<br>(FDA approved indication)</td><td>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.</td></tr>
<tr><td>Dosing and Administration</td><td>
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<tr><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td>Cutaneous Squamous Cell Carcinoma (CSCC)</td><td>1200 mg IV infusion Q3 weeks.<br><br>Infusion time: 60 minutes<br><br>Continue until disease progression or unacceptable toxicity.</td><td>1200 mg</td></tr>
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<tr><td>Billing and Coding Information</td><td>
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<tr><th>10-digit NDC</th><th>11-digit NDC</th></tr>
<tr><td>70095-130-01</td><td>70095-0130-01</td></tr>
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<tr><th>HCPCS Code</th><th>Description</th></tr>
<tr><td>J9275</td><td>Injection, cosibelimab-ipdl, 2 mg</td></tr>
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<tr><th>CPT Procedural Codes</th><th>Description</th></tr>
<tr><td>96413</td><td>Chemotherapy infusion, up to one hour</td></tr>
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<tr><td>Product Availability</td><td>Single-dose vial: 300 mg/5 mL (60 mg/mL) solution</td></tr>
<tr><td>Contraindications</td><td>None.</td></tr>
<tr><td>Recommended Medical Monitoring</td><td>UNLOXCYT has been associated with:<br>a. Immune-mediated adverse reactions<br>b. Infusion-related reactions<br>c. Complications of Allogenic Hematopoietic Stem Cell Transplantation (HSCT)<br>d. Embryo-Fetal toxicity<br><br>Patients should be monitored for any of these reactions. UNLOXCYT dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions.<br><br>UNLOXCYT can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating treatment. Female patients of reproductive potential should be advised to use effective contraception during treatment with UNLOXCYT and for four months after the last dose.</td></tr>
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| **Approval Criteria**<br><br>**Cutaneous Squamous Cell Carcinoma (CSCC)** | a. Physician administered IV infusion; in-office or HOPD<br>i. Cannot be self-administered<br>b. Cutaneous Squamous Cell Carcinoma **(must meet all)**:<br>i. Diagnosis of metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced cutaneous squamous cell carcinoma (laCSCC)<br>ii. Patient is NOT a candidate for curative surgery or curative radiation<br>iii. Using as a single agent<br>iv. Prescribed by or in consultation with an oncologist<br>v. Patient age ≥ 18 years<br>vi. Individual has not received another anti-PD-1, anti-PD-L1 agent, or any other antibody or drug specifically targeting T-cell co-stimulation or immune checkpoint pathways<br>vii. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant<br>viii. Individual has ECOG performance status of 0-1 (see Appendix)<br>ix. Individual does NOT have uncontrolled or significant CVD<br>x. Individual does NOT have infection with HIV, Hepatitis B or Hepatitis C<br>xi. Dose does not exceed 1200 mg IV infusion Q3 weeks |
| **Age Restriction** | Adults ≥ 18 years old |
| **Coverage Duration** | **Initial**: six months. **Reauthorization**: 12 months.<br><br>Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice. |
| **Other Criteria (LCD, NCD, etc.)** | Must follow LCD L37205 – Chemotherapy Drugs and their Adjuncts |
| **Misc Info, Appendix Etc.** | **ECOG Performance Status** is a scale used in cancer care to measure patient's functional ability and overall well-being, indicating how well they are able to perform daily activities.<br>• 0 – fully active; can carry out all normal activities without restriction<br>• 1 – restricted in physically strenuous activity but can do light or sedentary work (e.g., light housework, office work)<br>• 2 – Ambulatory and capable of self-care but unable to work; up and about more than 50% of waking hours<br>• 3 – Capable of only limited self-care; confined to bed or chair more than 50% of waking hours<br>• 4 – Completely disabled; cannot carry out any self- care; totally confined to bed or chair<br>• 5 – Deceased |

| STATUS | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY | EFFECTIVE DATE |
|---|---|---|---|---|
| Created | 1/14/26 | 1/14/26 | Tamara Chinarian, PharmD, Clinical Pharmacist | N/A |
| Approved | N/A | 2/12/26 | Pharmacy & Therapeutics (P&T) Committee | 2/12/26 |
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