



Access and Coverage Navigation Guide

Sun Pharmaceutical Industries, Inc. cannot guarantee insurance coverage or reimbursement. Coverage or reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the healthcare provider to ensure the accuracy of all statements made in seeking coverage and reimbursement for an individual patient.

INDICATIONS AND USAGE

UNLOXCYT (cosibelimab-ipdl) 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.

It is not known if UNLOXCYT is safe and effective in children

The recommended dosage of UNLOXCYT is 1,200 mg as an intravenous infusion over 60 minutes every 3 weeks.

IMPORTANT SAFETY INFORMATION

WARNING AND PRECAUTIONS

Immune-mediated Adverse Reactions: Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue, including immune-mediated pneumonitis, colitis, hepatitis, endocrinopathies, dermatologic adverse reactions, nephritis and renal dysfunction, and solid organ transplant rejection. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously. While such adverse reactions usually manifest during treatment, they can also manifest after discontinuation of PD-1/PD-L1-blocking antibodies.

Monitor for early identification and management. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. Withhold or permanently discontinue UNLOXCYT based on the severity of reaction.

Please see additional Important Safety Information on page 19 and accompanying [Full Prescribing Information](#).

Welcome to the access and coverage guide for UNLOXCYT™ (cosibelimab-ipdl)

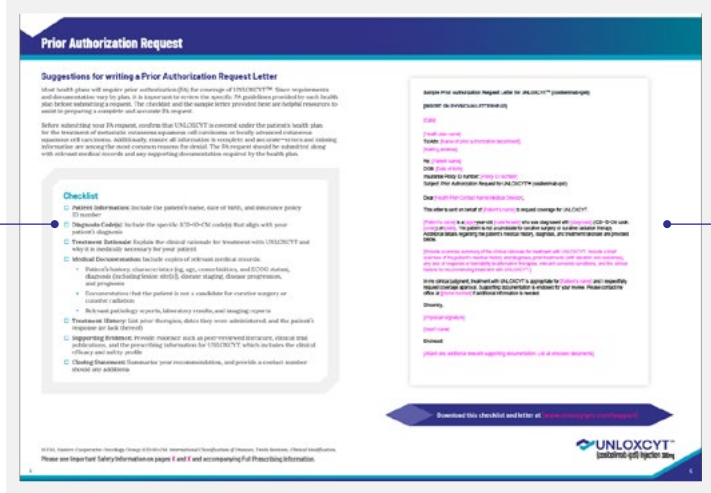
This resource kit provides practical tools and guidance to help you navigate the key steps in securing coverage and access for UNLOXCYT. The **Authorization and Appeals** section includes checklists and sample letters to support communication with health plans when requesting prior authorization or submitting an appeal. The **UNLOXCYT SUPPORT™** section highlights program services and resources that help healthcare professionals start patients on treatment and provide ongoing support throughout their journey with UNLOXCYT. This program is designed to streamline access and help ensure eligible patients can begin and continue treatment as prescribed. The **Product Access** section offers details on specialty distribution and J-code for your practice.

Checklist

Checklists that outline what information to include in your letter, as well as what other documents should accompany it.

Sample Letter/Template

Sample letters/templates with suggestions for information that will usually be required by plans. The **colored text** is for you to customize.



Please see Important Safety Information on page 19 and accompanying [Full Prescribing Information](#).

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Some plans ask for a Letter of Medical Necessity to be included with a PA or an appeal to explain why your chosen treatment is clinically appropriate or is preferable to formulary alternatives. It's also recommended that a Letter of Medical Necessity is included with any PA or medical exception request

Letter of Medical Exception 8-9

If UNLOXCYT isn't on a plan's formulary or has a National Drug Code (NDC) block, this type of letter can be helpful for securing coverage. While the patient's plan might offer a form on its website to request an exception, the suggestions and sample letter provided here illustrate the information typically required

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If a PA or medical exemption request is rejected, there can be multiple levels of appeal. Each of the appeal letters can be adapted for higher-level appeals. After a second-level appeal, additional adjudication may include review by an independent and noninsurance-affiliated external review board or hearing. Please refer to the plan's specific appeal guidelines, which are often available on their website. This section provides suggestions for writing a PA appeal letter

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Suggestions for writing a Prior Authorization Request Letter

Most health plans will require prior authorization (PA) for coverage of UNLOXCYT™. Since requirements and documentation vary by plan, it is important to review the specific PA guidelines provided by each health plan before submitting a request. The checklist and the sample letter provided here are helpful resources to assist in preparing a complete and accurate PA request.

Before submitting your PA request, confirm that UNLOXCYT is covered under the patient's health plan for the treatment of metastatic cutaneous squamous cell carcinoma or locally advanced cutaneous squamous cell carcinoma. Additionally, ensure all information is complete and accurate—errors and missing information are among the most common reasons for denial. The PA request should be submitted along with relevant medical records and any supporting documentation required by the health plan.

Checklist

- ☐ **Patient Information:** Include the patient's name, date of birth, and insurance policy ID number
- ☐ **Diagnosis Code(s):** Include the specific ICD-10-CM code(s) that align with your patient's diagnosis
- ☐ **Treatment Rationale:** Explain the clinical rationale for treatment with UNLOXCYT and why it is medically necessary for your patient
- ☐ **Medical Documentation:** Include copies of relevant medical records:
 - Patient's history, characteristics (eg, age, comorbidities, and ECOG status), diagnosis (including lesion site[s]), disease staging, disease progression, and prognosis
 - Documentation that the patient is not a candidate for curative surgery or curative radiation
 - Relevant pathology reports, laboratory results, and imaging reports
- ☐ **Treatment History:** List prior therapies, dates they were administered, and the patient's response (or lack thereof)
- ☐ **Supporting Evidence:** Provide evidence such as peer-reviewed literature, clinical trial publications, and the prescribing information for UNLOXCYT, which includes the clinical efficacy and safety profile
- ☐ **Closing Statement:** Summarize your recommendation, and provide a contact number should any additional information be required

Sample Prior Authorization Request Letter for UNLOXCYT™ (cosibelimab-ipdl)

[INSERT ON PHYSICIAN LETTERHEAD]

[Date]

[Health plan name]

To/Attn: [Name of prior authorization department]

[Mailing address]

Re: [Patient Name]

DOB: [Date of birth]

Insurance Policy ID number: [Policy ID Number]

Subject: Prior Authorization Request for UNLOXCYT™ (cosibelimab-ipdl)

Dear [Health Plan Contact Name/Medical Director],

This letter is sent on behalf of [Patient's name] to request coverage for UNLOXCYT.

[Patient's name] is a [age]-year-old [male/female] who was diagnosed with [diagnosis] (ICD-10-CM code: [code]) on [date]. The patient is not a candidate for curative surgery or curative radiation therapy. Additional details regarding the patient's medical history, diagnosis, and treatment rationale are provided below.

[Provide a concise summary of the clinical rationale for treatment with UNLOXCYT. Include a brief overview of the patient's medical history and diagnosis, prior treatments (with duration and outcomes), any lack of response or tolerability to alternative therapies, relevant comorbid conditions, and the clinical factors for recommending treatment with UNLOXCYT.]

In my clinical judgment, treatment with UNLOXCYT is appropriate for [Patient's name] and I respectfully request coverage approval. Supporting documentation is enclosed for your review. Please contact my office at [phone number] if additional information is needed.

Sincerely,

[Physician signature]

[Insert name]

Enclosed:

[Attach any additional relevant supporting documentation. List all enclosed documents]

Download this checklist and letter at www.unloxcytpro.com/support

Suggestions for writing a Letter of Medical Necessity

Some plans require that a Letter of Medical Necessity be submitted along with a prior authorization (PA) letter (see page 5) and medical exception request letter (see page 9) to support the choice of UNLOXCYT™ over other agents that are on formulary. You may find that this checklist and the sample letter are a helpful guide to preparing that letter. A Letter of Medical Necessity should also accompany a medical exception request letter.

Checklist

- ☐ **Patient Information:** Include the patient’s name, date of birth, insurance policy ID number, and if appropriate, PA denial reference number and date of denial
- ☐ **Diagnosis Code(s):** Include the specific ICD-10-CM code(s) that align with your patient’s diagnosis
- ☐ **Treatment Rationale:** Explain the clinical rationale for treatment with UNLOXCYT and why it is appropriate for your patient
- ☐ **Medical Documentation:** Include copies of relevant medical records:
 - Medical records documenting the patient’s history, characteristics (eg, age, comorbidities, and ECOG status), diagnosis (including lesion site[s]), disease progression, and prognosis
 - Documentation that the patient is not a candidate for curative surgery or curative radiation
 - Relevant pathology reports, laboratory results, and imaging reports
- ☐ **Treatment History:** List prior therapies, dates they were administered, and the patient’s response (or lack thereof)
- ☐ **Formulary Considerations:** Explain why formulary-preferred agents are not appropriate—eg, intolerance, contraindication, or lack of efficacy (if they are not already listed as previous therapies)
- ☐ **Supporting Evidence:** Provide evidence such as peer-reviewed literature, clinical trial publications, and the prescribing information for UNLOXCYT, which includes the clinical efficacy and safety profile
- ☐ **Closing Statement:** Summarize your recommendation, and provide a contact number should any additional information be required

Sample Letter of Medical Necessity for UNLOXCYT

[INSERT ON PHYSICIAN LETTERHEAD]

[Date]

[Health plan name]

To/Attn: [Name of prior authorization department]
[Mailing address]

Re: [Patient Name]

DOB: [Date of birth]

Insurance Policy ID number: [Policy ID Number]

Subject: Letter of Medical Necessity for UNLOXCYT™ (cosibelimab-ipdl)

Dear [Health Plan Contact Name/Medical Director],

I am writing to document the medical necessity of UNLOXCYT for [Patient’s name]. The following information summarizes the patient’s relevant medical history and clinical rationale for treatment with UNLOXCYT.

[Provide a concise summary of all clinically relevant information, including but not limited to a brief history, diagnosis, disease progression and prognosis, previous treatments (with duration and outcomes), lack of response or tolerability to other therapies, relevant comorbidities, and the clinical rationale for recommending UNLOXCYT. Include, if applicable, the anticipated duration of therapy.]

In my clinical judgment, treatment with UNLOXCYT is medically necessary for [Patient’s name]. I am requesting coverage approval for this therapy. Supporting documentation is enclosed for your review. Please contact my office at [phone number] if additional information is needed.

Sincerely,

[Physician signature]

[Insert name]

Enclosed:

[Attach any additional relevant supporting documentation. List all enclosed documents]

Download this checklist and letter at www.unloxcytpro.com/support

Suggestions for writing a Letter of Medical Exception

In cases where UNLOXCYT™ is not covered under the patient’s health plan or has a National Drug Code (NDC) block, a medical exception request letter may be submitted to request coverage. The letter should outline the clinical rationale for prescribing UNLOXCYT and explain why formulary alternatives are not appropriate for the patient. The checklist and sample letter provided here can help you prepare a complete and accurate medical exception request letter.

Checklist

- ☐ **Patient Information:** Include the patient’s name, date of birth, and insurance policy ID number
- ☐ **Diagnosis Code(s):** Include the specific ICD-10-CM code(s) that align with your patient’s diagnosis
- ☐ **Treatment Rationale:** Explain the clinical rationale for treatment with UNLOXCYT, including why in your clinical judgment it is medically necessary for your patient
- ☐ **Medical Documentation:** Include copies of relevant medical records:
 - Patient’s history, characteristics (eg, age, comorbidities, and ECOG status), diagnosis (including lesion site[s]), disease staging, disease progression, and prognosis
 - Documentation that the patient is not a candidate for curative surgery or curative radiation
 - Relevant pathology reports, laboratory results, and imaging reports
- ☐ **Treatment History:** List prior therapies, dates they were administered, and the patient’s response (or lack thereof)
- ☐ **Formulary Considerations:** Explain why formulary-preferred agents are not appropriate—eg, intolerance, contraindication, or lack of efficacy (if they are not already listed as previous therapies)
- ☐ **Letter of Medical Necessity:** Attach a Letter of Medical Necessity (see sample letter on page 7)
- ☐ **Supporting Evidence:** Provide evidence such as peer-reviewed literature, clinical trial publications, and the prescribing information for UNLOXCYT, which includes the clinical efficacy and safety profile
- ☐ **Closing Statement:** Summarize your recommendation, and provide a contact number should any additional information be required

Sample Letter of Medical Exception for UNLOXCYT™ (cosibelimab-ipdl)

[INSERT ON PHYSICIAN LETTERHEAD]

[Date]

[Health plan name]

To/Attn: [Name of prior authorization department]

[Mailing address]

Re: [Patient Name]

DOB: [Date of birth]

Insurance Policy ID number: [Policy ID Number]

Subject: Medical exception request for UNLOXCYT™ (cosibelimab-ipdl)

Dear [Health Plan Contact Name/Medical Director],

This letter is sent on behalf of [Patient’s name] to request a medical exception for UNLOXCYT.

[Patient’s name] is a [age]-year-old [male/female] who was diagnosed with [diagnosis] (ICD-10-CM code: [code]) on [date]. [He/she] is not a candidate for curative surgery or curative radiation therapy. The following information summarizes the clinical rationale for this request.

[Provide a concise summary of all clinically relevant information, including but not limited to a brief history, diagnosis, disease progression and prognosis, previous treatments (with duration and outcomes), lack of response or tolerability to other therapies, relevant comorbidities, and the clinical rationale for recommending UNLOXCYT. Include, if applicable, the anticipated duration of therapy.]

In my clinical judgment, treatment with UNLOXCYT is appropriate and medically necessary for [patient’s name]. I am requesting that it be covered by the health plan. Supporting documentation is enclosed for your review. Please contact my office at [phone number] if additional information is needed.

Sincerely,

[Physician signature]

[Insert name]

Enclosed:

[Attach any additional relevant supporting documentation. List all enclosed documents]

Download this checklist and letter at www.unloxcytpro.com/support

Suggestions for writing a Prior Authorization Appeal Letter

When a prior authorization (PA) request for UNLOXCYT™ has been denied, you may submit an appeal letter to support coverage for your patient. Many payers allow multiple levels of appeal for PA denials. Please refer to the plan’s specific appeal guidelines for timeframes and submission requirements.

Before preparing your appeal, confirm that UNLOXCYT is covered by the patient’s health plan for the appropriate diagnosis. Carefully review the initial PA request for completeness and accuracy—errors and missing information in the initial request are among the most common reasons for denial and can often be resolved by correcting these details in your appeal.

Submit your appeal letter along with a copy of the patient’s relevant medical records and a Letter of Medical Necessity (see sample letter on page 7).

Checklist

- ☐ **Patient Information:** Include the patient’s name, date of birth, insurance policy ID number, and, if appropriate, PA denial reference number and date of denial
- ☐ **Denial Acknowledgment:** Confirm that you are familiar with the payer’s policy, and state the reason for the denial—it is often included in the Explanation of Benefits letter
- ☐ **Diagnosis Code(s):** Include the specific ICD-10-CM code(s) that align with your patient’s diagnosis
- ☐ **Treatment Rationale:** Explain the clinical rationale for treatment with UNLOXCYT and why it is appropriate for your patient
- ☐ **Medical Documentation:** Include copies of relevant medical records:
 - Patient’s history, characteristics (eg, age, comorbidities, and ECOG status), diagnosis (including lesion site[s]), disease progression, and prognosis
 - Documentation that the patient is not a candidate for curative surgery or curative radiation
 - Relevant pathology reports, laboratory results, and imaging reports
- ☐ **Treatment History:** List prior therapies, dates they were administered, and the patient’s response (or lack thereof)
- ☐ **Formulary Considerations:** Explain why formulary-preferred agents are not appropriate—eg, intolerance, contraindication, or lack of efficacy (if they are not already listed as previous therapies)
- ☐ **Letter of Medical Necessity:** Attach a Letter of Medical Necessity (see sample letter on page 7)
- ☐ **Supporting Evidence:** Provide evidence such as peer-reviewed literature, clinical trial publications, and the prescribing information for UNLOXCYT, which includes the clinical efficacy and safety profile
- ☐ **Closing Statement:** Summarize your recommendation, and provide a contact number should any additional information be required

UNLOXCYT SUPPORT™
Program

Key Features



Enrollment

Begin your patient’s UNLOXCYT™ journey by enrolling them in UNLOXCYT SUPPORT™

How to enroll in UNLOXCYT SUPPORT:

- **Enroll online:** Visit <https://unloxcytsupport.com> to complete and submit an enrollment form
- A seamless e-enrollment period that does not require a log-in or password
- **Fax the form to 1-855-786-7458.** Patient consent can be obtained electronically from a mobile device

UNLOXCYT SUPPORT™ Patient Services Enrollment Form

Please complete all required fields (marked with an asterisk [*]) to prevent delays. For more information or assistance, please call UNLOXCYT SUPPORT at 1-855-865-9994 or visit www.unloxcytpro.com/support.

1 Patient Information (*REQUIRED)

*Patient Name: _____ *Date of Birth: ____/____/____ ☐ Male ☐ Female ☐ Other
*Address: _____ *City/State/ZIP: _____
*Mobile Phone: _____ Alternate Phone: _____ Email: _____
Caregiver Name: _____ Caregiver Phone: _____ Caregiver Email: _____

Messaging Consent (OPTIONAL):
☐ Opt in to receive recurring automated text messages from UNLOXCYT SUPPORT, including refill reminders and a digital savings card, at the mobile phone number provided. Consent to receiving text messages is not a condition of purchase of goods or services. Message and data rates may apply. Message frequency varies. Text HELP for help. Text STOP to opt out. Please visit SUN PHARMACEUTICAL INDUSTRIES, INC.'s privacy policy at <https://sunpharma.com/usa/privacy-policy/> and the mobile terms and conditions at www.unloxcytpro.com/support. Checkpoint Therapeutics Inc. is a subsidiary of Sun Pharmaceutical Industries, Inc.
☐ By checking this box, I am requesting Patient Access Liaison service for my patient. I understand that Patient Access Liaisons do not work under the direction of an HCP, nor do they offer medical advice. By requesting this service, I understand that a Patient Access Liaison may reach out to my patient on a regular basis to offer support throughout the UNLOXCYT™ treatment journey.

2 Insurance

Patient is: ☐ a US resident ☐ Uninsured ☐ Card(s) attached (if checked, proceed to step 3)

Primary Insurer	Secondary Insurer
Insurer Name	
Insurer Phone	
Policyholder Name	
Policy #	
Group #	
Medicare Beneficiary ID #	
Policyholder's Relationship to Patient	

3 Prescriber (*REQUIRED, where applicable)

*Prescriber Name: _____ *Practice/Facility Name: _____
*NPI #: _____ *State License #: _____ *GRP NPI #: _____
DEA #: _____ Tax ID #: _____ *Address: _____
Collaborating Physician Name (if Applicable): _____ *City/State/ZIP: _____
NPI #: _____ Office Contact: _____ Phone: _____ Fax: _____
Email: _____
Administration Site of Care (if different than Practice/Facility Name): _____
Name of facility: _____ Preferred Method of Contact: ☐ Phone ☐ Fax
Address: _____
City/State/ZIP: _____
☐ Physician Office ☐ Hospital Outpatient ☐ Ambulatory Surgical Center

4 Prescription and Authorization (*REQUIRED)

Please check the appropriate box:
☐ Patient is a new start: Expected start date: ____/____/____ Description: UNLOXCYT™ (cosibelimab-ipd) ☐ Dispense: 4 (four) Administer via intravenous infusion every 3 weeks. Refill: _____
☐ Patient is an existing patient: # of infusions: _____ *Allergies: ☐ No known allergies ☐ Yes (please list) _____
Last infusion date: ____/____/____

By signing below and submitting this form, I certify that: (a) the person named on this form is my patient (the "Patient"); the information provided, to the best of my knowledge, is complete and accurate; and therapy with UNLOXCYT is medically necessary for the Patient; (b) my office received the Patient's authorization to information above and other of the Patient's protected health information (as defined under the Health Insurance Portability and Accountability Act of 1996 (HIPAA)) PHARMACEUTICAL INDUSTRIES, INC., UNLOXCYT SUPPORT Patient Services, the contracted dispensing pharmacy, and other contractors of SUN PHARMACEUTICAL INDUSTRIES, INC. for the purpose of (i) requesting reimbursement support services such as benefits investigation, prior authorization, appeals, and co-pay assistance; (ii) enrolling the Patient in the Patient Assistance Program; and (iii) assisting in the Patient obtaining or continuing therapy; (c) product provided at no cost through UNLOXCYT SUPPORT Patient Services (if applicable) shall only be used for the Patient, and I will not attempt to resell, barter, transfer, trade, or return the product for credit, nor will I or my office seek reimbursement for free product provided to the Patient from any third-party payer (private or government, including but not limited to Medicare and Medicaid); (d) my office will maintain any free product separate and apart from other inventory; and (e) my office will not use the free product for any other purpose. I understand that if I or my office fail to comply with these terms, SUN PHARMACEUTICAL INDUSTRIES, INC. may suspend or terminate my office's access to UNLOXCYT SUPPORT Patient Services to transmit prescriptions. I agree to indemnify and hold SUN PHARMACEUTICAL INDUSTRIES, INC. harmless from any and all claims, damages, losses, and expenses, including reasonable attorneys' fees, that may be incurred by SUN PHARMACEUTICAL INDUSTRIES, INC. for doing so. Special Note: CA, MA, NC, and PR prescribers, please submit electronic prescription. The prescriber is to sign and submit the form electronically.

*Original Signature (Dispense as Written) Today's Date: _____

UNLOXCYT™ (cosibelimab-ipd) Injection 300mg

Fax: 1-855-786-7458 | Phone: 1-855-865-9994 | Please see full Prescribing Information at www.unloxcytpro.com and full Terms and Conditions for the participation in UNLOXCYT SUPPORT Patient Services Programs at www.unloxcytpro.com/support. See Privacy Policy at <https://sunpharma.com/privacy-policy-new/>.

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Verification

Streamlined results from the benefit investigation are delivered quickly with the benefit verification

- UNLOXCYT SUPPORT has a team of skilled Benefit Verification Specialists (BVS)
- Results are faxed to your office the same or next day*



Coordination

Patient Navigators help guide the UNLOXCYT treatment journey

- Initiate electronic prior authorization (PA) and provide appeals support
- Provide reimbursement claims support
- Offer support throughout the financial assistance process, such as the UNLOXCYT Copay Program or the Patient Assistance Program



Patient Access Liaison (PAL) support

Optional 1:1 patient support

- A dedicated PAL can help your patient throughout their journey
- Review benefits, coverage, and next steps through the authorization process
- Track authorization expirations on your behalf
- Nonprofit assistance navigation

UNLOXCYT SUPPORT is dedicated to supporting healthcare professionals with comprehensive resources for starting patients on UNLOXCYT

Learn more about UNLOXCYT SUPPORT

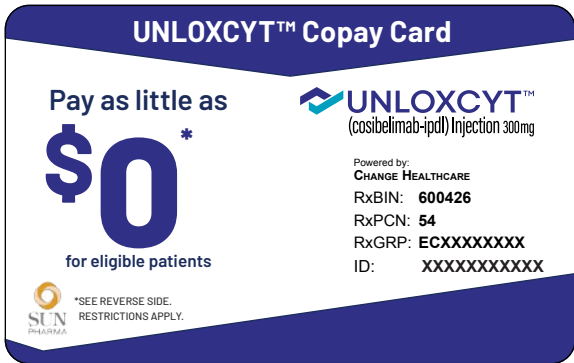
For additional resources visit www.unloxcytpro.com/support or call 1-855-865-9994

Please see Important Safety Information on page 19 and accompanying [Full Prescribing Information](#).

*Most completed enrollment forms received before 1:00 PM ET receive verification of benefits (VOB) the same day or the next day; most completed forms received after 1:00 PM ET receive VOB the next day.



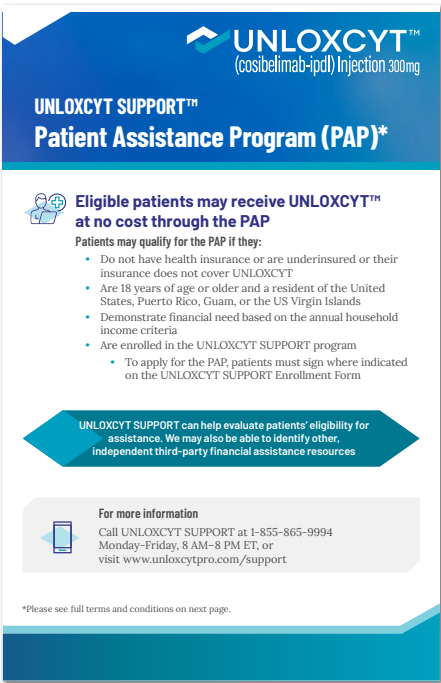
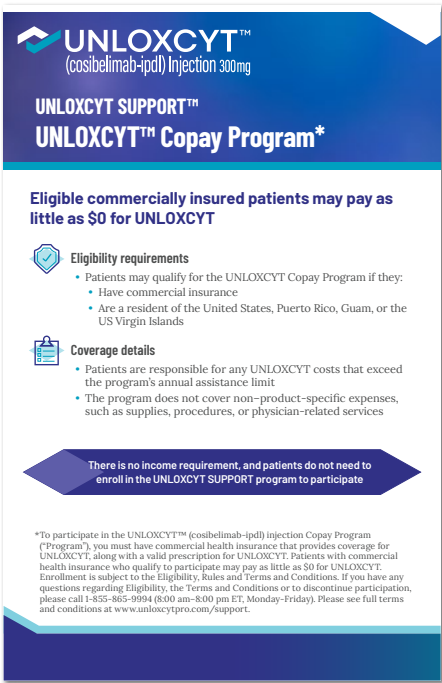
UNLOXCYT™ Copay Program*



- Patients with commercial insurance may pay as little as \$0 with the UNLOXCYT Copay Program
- Enrollment in UNLOXCYT SUPPORT™ is not required to obtain the UNLOXCYT Copay Card

Patient Assistance Program (PAP)†

- Patients who are underinsured or uninsured may be eligible to receive free medication



Product Access

Download UNLOXCYT financial support resources at
www.unloxcytpro.com/support

*See full Terms and Conditions of the UNLOXCYT Copay Program on page 17.
†See full Terms and Conditions of the UNLOXCYT PAP on page 18.
Please see Important Safety Information on page 19 and accompanying [Full Prescribing Information](#).

Authorized specialty distributors

Amerisource Bergen Specialty Distribution Phone: 1-800-746-6273 Web: asdhealthcare.com	Cardinal Health Specialty Distribution Phone: 1-877-453-3972 Web: specialtyonline.cardinalhealth.com
McKesson Specialty Health Phone: 1-800-482-6700 Web: oncology.mckessonspecialtyhealth.com	McKesson Plasma and Biologics Phone: 1-877-625-2566 Web: connect.mckesson.com
Oncology Supply Phone: 1-800-633-7555 Web: oncologysupply.com	CuraScript SD Phone: 1-877-599-7748 Web: curascriptsd.com/contact-us

Contracted specialty pharmacy

Onco360 Phone: 1-877-662-6633 Web: onco360.com

Sun Pharma does not recommend the use of any particular distributor or specialty pharmacy.

J-code for UNLOXCYT

The following permanent J-code can be used for billing and other administrative purposes:

J9275, injection, cosibelimab-ipdl, 2 mg

Coding requirements may vary by payer; please verify coding requirements before submitting claims.

Please see Important Safety Information on page 19 and accompanying [Full Prescribing Information](#).

To participate in the UNLOXCYT™ (cosibelimab-ipdl) injection Copay Program (“Program”), you must have commercial health insurance that provides coverage for UNLOXCYT, along with a valid prescription for UNLOXCYT. Patients with commercial health insurance who qualify to participate may pay as little as \$0 for UNLOXCYT. Enrollment is subject to the Eligibility Rules and Terms and Conditions stated below. If you have any questions regarding Eligibility, the Terms and Conditions or to discontinue participation, please call 1-855-865-9994 (8:00 am–8:00 pm ET, Monday-Friday).

Eligibility Rules

- To participate in this Program, you must have commercial health insurance and be a resident of the United States, Puerto Rico, Guam, or the Virgin Islands
- Patients who are members of health plans (often termed “maximizer” plans) that claim to reduce their patients' out-of-pocket costs may have a reduced maximum program benefit of \$10,000 per calendar year. Out-of-pocket costs may be copay, coinsurance, or deductible
- The following patients are *ineligible* for this Program:
 - Patients covered under Medicaid (including Medicaid patients enrolled in a Medicaid Managed Care Plan or a qualified health plan purchased through a health insurance exchange marketplace established by a state government or the federal government)
 - Patients covered by a Medicare or Medicare Part D or Medicare Advantage plan (regardless of whether a specific prescription is covered)
 - Patients covered by TRICARE, CHAMPUS, Puerto Rico Government Health Insurance Plan, or any other state or federal medical or pharmaceutical benefit program or pharmaceutical assistance program
 - Patients who are members of health plans that claim to eliminate their out-of-pocket costs are not eligible for cost support. If you are a member of one of these plans, please call 1-855-865-9994
 - Patients with no insurance

Terms and Conditions

- You agree not to seek any reimbursement for all or any part of the copay assistance received through the Program. By using this card, you are certifying that you understand the Eligibility Rules and Terms and Conditions, that you have responded truthfully to questions when activating the Card, and that you will disclose and report your receipt of any Program benefits to your insurer, health plan, or any third party that pays or reimburses you for the cost of medications, if required
- This offer may be rescinded, revoked, or cancelled at any time, without further notice, and the rules may be amended at any time, without further notice

Disclosures

- This Program is not insurance
- This Program is void where prohibited by law, taxed, or restricted. Any benefit provided is not transferable and cannot be combined with any other program, free trial, discount, prescription savings card, or other offer. No purchase, other than for an UNLOXCYT prescription, is required to participate
- Personal data that you provide to the Program may be collected, analyzed, and shared with the program sponsor for market research and other lawful purposes, but only in aggregated and de-identified form



Patient Assistance Program Terms and Conditions

The UNLOXCYT™ (cosibelimab-ipdl) injection Patient Assistance Program (PAP) (“Program”) is designed to support patients who are underinsured or uninsured. Patients may be eligible to receive free medication. To participate in the Patient Assistance Program, patients must be a resident of the United States, Puerto Rico, Guam, or the Virgin Islands. Eligibility ends each year on December 31st and requires annual enrollment. If you have any questions regarding Eligibility or the Terms and Conditions or to discontinue participation, please call 1-855-865-9994 (8:00 AM–8:00 PM ET, Monday-Friday).

This program is intended for:

- Patients who are noninsured, meaning who do not have insurance coverage due to coverage terminated
- Patients who have no insurance
- Patients who are functionally uninsured, meaning insurance does not cover UNLOXCYT
 - Patients who have no prescription coverage
 - Patients who have emergency-only coverage
 - Patients who have a discount card only
 - Patients who have exceeded the yearly cap, who have generic coverage only, whose insurance does not have product on formulary (no nonformulary exception available or nonformulary exception not approved)
- Patients who are functionally underinsured, in that the patient is unable to afford the medication after exhausting other options, not limited to UNLOXCYT Copay Program, alternate funding resources, or available state programs
- The provision of free product as part of the PAP is not contingent on any future purchase of UNLOXCYT

Eligibility criteria include:

- Requires the patient to provide, on the enrollment form, authorization to UNLOXCYT SUPPORT to obtain necessary information from consumer credit agencies for the sole purpose of determining the patient's financial qualification for PAP
- Income must be at or below 400% of the Federal Poverty Level, and cost of drug to the patient must exceed 10% of the patient's annual household income
- Noninsured or uninsured patients must present a letter of attestation from the prescriber that the patient is under their care and has been prescribed the medication
- This offer may be rescinded, revoked, or cancelled at any time, without further notice, and the rules may be amended at any time, without further notice

Further documentation may be required to determine eligibility, such as proof of income. Neither the prescriber nor the patient may seek reimbursement or credit from or submit a claim for UNLOXCYT provided through the PAP to any third-party insurer, health plan, or government program (such as Medicare and Medicaid); nor may the patient seek to have any part of the cost or value of any free UNLOXCYT provided by the PAP count toward any applicable out-of-pocket insurance spending calculations for drugs (e.g., deductible, out-of-pocket cap, or True Out of Pocket [“TrOOP”]).

The following patients are ineligible for this program:

- Patient is not at least 18 years of age
- Diagnosis is not an on-label ICD-10-CM code
- Patients are excluded if there is secondary coverage, including with the US Department of Veterans Affairs (VA), Department of Defense (DoD), Medicaid, or LIS

Important Safety Information

WARNINGS AND PRECAUTIONS

Immune-mediated Adverse Reactions: Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue, including immune-mediated pneumonitis, colitis, hepatitis, endocrinopathies, dermatologic adverse reactions, nephritis and renal dysfunction, and solid organ transplant rejection. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously. While such adverse reactions usually manifest during treatment, they can also manifest after discontinuation of PD-1/PD-L1-blocking antibodies.

Monitor for early identification and management. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. Withhold or permanently discontinue UNLOXCYT based on the severity of reaction.

Infusion-Related Reactions: Infusion-related reactions were reported in 11% (24/223) of patients, including Grade 2 in 5.8% (13/223) of patients receiving UNLOXCYT. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue UNLOXCYT based on severity of reaction. Consider premedication with an antipyretic and/or an antihistamine for patients who have had previous systemic reactions to infusions of therapeutic proteins.

Complications of Allogeneic HSCT: Fatal and other serious complications can occur in patients who receive allogeneic Hematopoietic Stem Cell Transplantation (HSCT) before or after being treated with a PD-1/PDL1 blocking antibody. Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1-blocking antibody prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity/Females and Males of Reproductive Potential: UNLOXCYT can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating UNLOXCYT. Females should use effective contraception during treatment with UNLOXCYT and for 4 months after the last dose. Advise female patients not to breastfeed during treatment with UNLOXCYT and for 4 months after the last dose.

ADVERSE REACTIONS

The most common adverse reactions (≥10%) were fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection, and urinary tract infection.

To report side effects of UNLOXCYT to FDA: visit www.fda.gov/medwatch or call 1-800-FDA-1088. Report SUSPECTED ADVERSE REACTIONS or any side effects or ADEs (adverse drug events) to our Drug Safety Department at 1-800-406-7984 or DrugSafety.USoperations@sunpharma.com (preferred) with as much information as available.



 UNLOXCYT™
(cosibelimab-ipdl) Injection 300mg

Authorization and Appeals

UNLOXCYT SUPPORT

Product Access

Important Safety Information



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HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use UNLOXCYT safely and effectively. See full prescribing information for UNLOXCYT.

UNLOXCYT (cosibelimab-ipdl) injection, for intravenous use
Initial U.S. Approval: 2024

INDICATIONS AND USAGE
UNLOXCYT is a programmed death ligand-1 (PD-L1) blocking antibody 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. (1.1)

DOSAGE AND ADMINISTRATION
The recommended dosage of UNLOXCYT is 1,200 mg as an intravenous infusion over 60 minutes every 3 weeks. (2.1)

DOSAGE FORMS AND STRENGTHS
Injection: 300 mg/5 mL (60 mg/mL) solution in a single-dose vial. (3)

CONTRAINDICATIONS
None. (4)

- WARNINGS AND PRECAUTIONS**
- Immune-Mediated Adverse Reactions (5.1)
 - Immune-mediated adverse reactions can occur in any organ system or tissue, including the following: immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated dermatologic adverse reactions, immune-mediated nephritis and renal dysfunction, and solid organ transplant rejection.
 - Monitor for early identification and management. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment.
 - Withhold or permanently discontinue UNLOXCYT based on the severity of reaction. (2.2)
 - Infusion-Related Reactions: Interrupt, slow the rate of infusion, or permanently discontinue based on severity of reaction. (2.2, 5.2)
 - Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT): Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1 blocking antibody. (5.3)
 - Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception. (5.4, 8.1, 8.3)

ADVERSE REACTIONS
The most common adverse reactions (≥10%) were fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection, and urinary tract infection. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. at 1-800-818-4555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS
Lactation: Advise not to breastfeed. (8.2)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised date: 11/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

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FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

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.

2. DOSAGE AND ADMINISTRATION

2.1. Recommended Dosage

The recommended dosage of UNLOXCYT is 1,200 mg administered as an intravenous infusion over 60 minutes every 3 weeks until disease progression or unacceptable toxicity.

2.2. Dose Modifications for Adverse Reactions

No dose reductions of UNLOXCYT are recommended. In general, withhold UNLOXCYT for severe (Grade 3) immune-mediated adverse reactions. Permanently discontinue UNLOXCYT for life-threatening (Grade 4) immune-mediated adverse reactions, recurrent severe (Grade 3) immune-mediated reactions that require systemic immunosuppressive treatment, or an inability to reduce corticosteroid dose to a prednisone equivalent of 10 mg or less per day within 12 weeks of initiating steroids.

Dosage modifications for UNLOXCYT for adverse reactions that require management different from these general guidelines are summarized in [Table 1](#).

Table 1: Recommended Dose Modifications for Adverse Reactions

Adverse Reaction	Severity ^a	UNLOXCYT Dosage Modifications
Immune-Mediated Adverse Reactions [<i>see Warnings and Precautions (5.1)</i>]		
Pneumonitis	Grade 2	Withhold ^b
	Grade 3 or 4	Permanently discontinue
Colitis	Grade 2 or 3	Withhold ^b
	Grade 4	Permanently discontinue
Hepatitis with no tumor involvement of the liver	AST or ALT increases to more than 3 and up to 8 times ULN or Total bilirubin increases to more than 1.5 and up to 3 times ULN	Withhold ^b
	AST or ALT increases to more than 8 times ULN or Total bilirubin increases to more than 3 times ULN	Permanently discontinue
Hepatitis with tumor involvement of the liver ^c	Baseline AST or ALT is more than 1 and up to 3 times ULN and increases to	Withhold ^b

Adverse Reaction	Severity ^a	UNLOXCYT Dosage Modifications
	more than 5 and up to 10 times ULN or Baseline AST or ALT is more than 3 and up to 5 times ULN and increases to more than 8 and up to 10 times ULN	
	AST or ALT increases to more than 10 times ULN or Total bilirubin increases to more than 3 times ULN	Permanently discontinue
Endocrinopathies ^d	Grade 3 or 4	Withhold until clinically stable or permanently discontinue, depending on severity ^b
Nephritis with renal dysfunction	Grade 2 or 3 increased blood creatinine	Withhold ^b
	Grade 4 increased blood creatinine	Permanently discontinue
Exfoliative dermatologic conditions	Suspected SJS, TEN, or DRESS	Withhold ^b
	Confirmed SJS, TEN, or DRESS	Permanently discontinue
Myocarditis	Grade 2, 3 or 4	Permanently discontinue
Neurological toxicities	Grade 2	Withhold ^b
	Grade 3 or 4	Permanently discontinue
Other Adverse Reactions		
Infusion-related reactions [see <i>Warnings and Precautions (5.2)</i>]	Grade 1 or 2	Interrupt or slow the rate of infusion
	Grade 3 or 4	Permanently discontinue

ALT = alanine aminotransferase; AST = aspartate aminotransferase; DRESS: drug rash with eosinophilia and systemic symptoms; SJS: Stevens-Johnson Syndrome; TEN: toxic epidermal necrolysis; ULN: upper limit of normal.

^a Based on National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), Version 5.

^b Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper. Permanently discontinue if no complete or partial resolution within 12 weeks of initiating steroids or inability to reduce corticosteroid to a prednisone equivalent of 10 mg/day or less within 12 weeks of initiating steroids.

^c If AST and ALT are less than or equal to ULN at baseline in patients with liver involvement, withhold or permanently discontinue UNLOXCYT based on recommendations for hepatitis with no tumor involvement of the liver.

^d Depending on clinical severity, consider withholding for Grade 2 endocrinopathy until symptom improvement with hormone replacement. Resume once acute symptoms have resolved.

2.3. Preparation and Administration

Visually inspect the vial for particulate matter and discoloration. UNLOXCYT is clear to opalescent, colorless to yellow or slightly brown. Discard the vial if visible particles are observed.

Do not shake the vial.

Preparation for Intravenous Infusion:

- Add 20 mL (1,200 mg) of UNLOXCYT to a 250 mL intravenous infusion bag containing 0.9% Sodium Chloride Injection. UNLOXCYT is compatible with an infusion bag made of polyolefin or polyvinyl chloride.
- Mix diluted solution by gentle inversion. **Do not shake.**
- Discard any unused portion left in the vial.

Storage of Infusion Solution:

The prepared infusion solution may be stored either:

- At room temperature up to 25°C (77°F) for no more than 24 hours from the time of preparation until the end of infusion.
- Under refrigeration at 2°C to 8°C (36°F to 46°F) for no more than 24 hours from time of preparation until end of infusion. If refrigerated, allow the diluted solution to come to room temperature prior to administration.
- Discard after 24 hours.
- Do not freeze.

Administration:

- Visually inspect the infusion bag for particulate matter and discoloration prior to administration. Discard if the solution is discolored or contains particulate matter.
- Administer by intravenous infusion over 60 minutes through an intravenous line containing a sterile, in-line or add-on of 0.2-micron to 0.22-micron filter.
- Do not administer UNLOXCYT as an intravenous push or bolus injection.
- Do not co-administer other drugs through the same infusion line.

3. DOSAGE FORMS AND STRENGTHS

Injection: 300 mg/5 mL (60 mg/mL), clear to opalescent, colorless to yellow or slightly brown solution in a single-dose vial.

4. CONTRAINDICATIONS

None.

5. WARNINGS AND PRECAUTIONS

5.1. Severe and Fatal Immune-Mediated Adverse Reactions

UNLOXCYT is a monoclonal antibody that belongs to a class of drugs that bind to either the programmed death receptor-1 (PD-1) or PD-ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions. Important immune-mediated adverse reactions listed in WARNINGS AND PRECAUTIONS may not include all possible severe and fatal immune-mediated reactions.

Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue. Immune-mediated adverse reactions can occur at any time after starting a PD-1/PD-L1–blocking antibody. While immune-mediated adverse reactions usually manifest during treatment with PD-1/PD-L1–blocking antibodies, they can also manifest after discontinuation of PD-1/PD-L1–blocking antibodies. Immune-mediated adverse reactions affecting more than one body system can occur simultaneously.

Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of PD-1/PD-L1–blocking antibodies. Monitor closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function tests at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Withhold or permanently discontinue UNLOXCYT depending on severity [*see Dosage and Administration (2.2)*]. In general, if UNLOXCYT requires interruption or discontinuation, administer systemic corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids.

Toxicity management guidelines for adverse reactions that do not necessarily require systemic steroids (e.g., endocrinopathies, dermatologic reactions) are discussed below.

Immune-Mediated Pneumonitis

UNLOXCYT can cause immune-mediated pneumonitis. In patients treated with other PD-1/PD-L1–blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation.

Immune-mediated pneumonitis occurred in 1% (3/223, Grade 2) of patients receiving UNLOXCYT. Pneumonitis led to withholding of UNLOXCYT in 0.4% (1/223) of patients. All 3 patients required systemic corticosteroids and pneumonitis did not resolve. One patient in whom UNLOXCYT was withheld for pneumonitis, had UNLOXCYT reinitiated after symptom improvement and had recurrence of pneumonitis.

Immune-Mediated Colitis

UNLOXCYT can cause immune-mediated colitis, which may present with diarrhea, abdominal pain, and lower gastrointestinal (GI) bleeding. Cytomegalovirus infection/reactivation has

occurred in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1–blocking antibodies. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

Immune-mediated colitis occurred in 0.4% (1/223, Grade 1) of patients receiving UNLOXCYT. Systemic corticosteroids were required in the patient experiencing colitis. The event of colitis did not resolve, and UNLOXCYT was not reinitiated.

Immune-Mediated Hepatitis

UNLOXCYT can cause immune-mediated hepatitis, defined as requiring the use of systemic corticosteroids and the absence of a clear alternate etiology.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

UNLOXCYT can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment per institutional guidelines, including hormone replacement as clinically indicated. Withhold or permanently discontinue UNLOXCYT depending on severity [see [Dosage and Administration \(2.2\)](#)].

Adrenal insufficiency occurred in 0.9% (2/223) of patients receiving UNLOXCYT, including Grade 2 in 0.4% (1/223) of patients. UNLOXCYT was withheld for adrenal insufficiency in one of these patients and was reinitiated after symptom improvement. Systemic corticosteroids were required in both patients with adrenal insufficiency.

Hypophysitis

UNLOXCYT can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field cuts. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue UNLOXCYT depending on severity [see [Dosage and Administration \(2.3\)](#)].

Thyroid Disorders

UNLOXCYT can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue UNLOXCYT depending on severity [see [Dosage and Administration \(2.2\)](#)].

Hypothyroidism: Hypothyroidism occurred in 10% (22/223) of patients receiving UNLOXCYT, including Grade 2 in 5% (10/223) of patients. Hypothyroidism resolved in 7 of the 22 patients.

Hyperthyroidism: Hyperthyroidism occurred in 5% (12/223) of patients receiving UNLOXCYT, including Grade 2 in 0.4% (1/223) of patients. Hyperthyroidism resolved in 10 of the 12 patients.

Type 1 Diabetes Mellitus, which can present with diabetic ketoacidosis

UNLOXCYT can cause type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue UNLOXCYT depending on severity [see [Dosage and Administration \(2.2\)](#)].

Immune-Mediated Nephritis with Renal Dysfunction

UNLOXCYT can cause immune-mediated nephritis, defined as the required use of systemic corticosteroids or other immunosuppressants and the absence of a clear alternate etiology.

Immune-Mediated Dermatologic Adverse Reactions

UNLOXCYT can cause immune-mediated rash or dermatitis. Bullous and exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS), have occurred with PD-1/PD-L1–blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-bullous/exfoliative rashes. Withhold or permanently discontinue UNLOXCYT depending on severity [see *Dosage and Administration (2.2)*].

Immune-mediated dermatologic adverse reactions occurred in 7% (15/223) of patients receiving UNLOXCYT, including Grade 3 in 0.9% (2/223) of patients and Grade 2 in 4% (9/223) of patients. Dermatologic adverse reactions led to permanent discontinuation of UNLOXCYT in 0.4% (1/223) of patients and withholding of UNLOXCYT in 0.9% (2/223) of patients. Systemic corticosteroids were required in 33% (5/15) of patients with dermatologic adverse reactions. Dermatologic adverse reactions resolved in 7 of the 15 patients. Of the 2 patients in whom UNLOXCYT was withheld for dermatologic adverse reactions, 1 patient reinitiated UNLOXCYT after symptom improvement and had recurrence of the dermatologic adverse reaction, which resolved after UNLOXCYT was withheld a second time.

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred in <1% of the 223 patients who received UNLOXCYT [see *Adverse Reactions (6.1)*] or were reported with the use of other PD-1/PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.

Cardiac/Vascular: Myocarditis, pericarditis, vasculitis.

Nervous System: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barre syndrome, nerve paresis, autoimmune neuropathy.

Ocular: Uveitis, iritis, other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.

Gastrointestinal: Pancreatitis, including increases in serum amylase and lipase levels, gastritis, duodenitis.

Musculoskeletal and Connective Tissue: Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica.

Endocrine: Hypoparathyroidism.

Other (Hematologic/Immune): Autoimmune hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing

lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection.

5.2. Infusion-Related Reactions

UNLOXCYT can cause severe or life-threatening infusion-related reactions. Infusion-related infusion reactions were reported in 11% (24/223) of patients, including Grade 2 in 5.8% (13/223) of patients receiving UNLOXCYT.

Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue UNLOXCYT based on severity of reaction [see [Dosage and Administration \(2.2\)](#)]. Consider premedication with an antipyretic and/or an antihistamine for patients who have had previous systemic reactions to infusions of therapeutic proteins.

5.3. Complications of Allogeneic HSCT

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1–blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT.

Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1–blocking antibody prior to or after an allogeneic HSCT.

5.4. Embryo-Fetal Toxicity

Based on its mechanism of action, UNLOXCYT can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus, resulting in fetal death. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with UNLOXCYT and for 4 months after the last dose [see [Use in Specific Populations \(8.1, 8.3\)](#)].

6. ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Severe and fatal immune-mediated adverse reactions [see [Warnings and Precautions \(5.1\)](#)]
- Infusion-related reactions [see [Warnings and Precautions \(5.2\)](#)]
- Complications of Allogeneic HSCT [see [Warnings and Precautions \(Error! Reference source not found.\)](#)]

6.1. Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The pooled safety population described in WARNINGS AND PRECAUTIONS reflects exposure to UNLOXCYT as a single agent in 223 patients in two open-label, single-arm, multicohort studies, including 141 patients with advanced CSCC and 82 patients with other solid tumors and hematologic malignancies. UNLOXCYT was administered intravenously at doses of 800 mg every 2 weeks (n=174), 1,200 mg every 3 weeks (n=35), or other doses (n=14). Among the 223 patients, 54% were exposed for ≥ 24 weeks and 17% were exposed for ≥ 72 weeks.

The safety of UNLOXCYT was evaluated in Study CK-301-101 in 141 patients with metastatic or locally advanced disease CSCC [see *Clinical Studies (14)*]. Patients received UNLOXCYT 800 mg every 2 weeks (n=115) or 1,200 mg every 3 weeks (n=26) as an intravenous infusion until disease progression or unacceptable toxicity. The median duration of exposure was 36 weeks (2 weeks to 3.7 years).

Serious adverse reactions occurred in 31% of advanced patients with CSCC who received UNLOXCYT. The most frequent serious adverse reactions ($\geq 2\%$ of patients) were sepsis (2.8%), pneumonia (2.8%) and pyrexia (2.1%).

Permanent discontinuation of UNLOXCYT due to an adverse reaction occurred in 8% of patients. Adverse reactions resulting in permanent discontinuation of UNLOXCYT were COVID-19, COVID-19 pneumonia, sepsis, ulcerative keratitis, tumor thrombosis, axillary pain, paresthesia, cholestasis, hepatic cytolysis, wound hemorrhage, neck pain, pemphigoid, and eye pain (1 patient each).

Dosage interruptions due to an adverse reaction occurred in 36% of patients who received UNLOXCYT. The adverse reaction that required dosage interruption in $\geq 2\%$ of patients who received UNLOXCYT was COVID-19 (2%).

The most common ($\geq 10\%$) adverse reactions were fatigue, musculoskeletal pain, rash, diarrhea, hypothyroidism, constipation, nausea, headache, pruritus, edema, localized infection, and urinary tract infection.

Table 2 and Table 3 summarize adverse reactions and laboratory abnormalities, respectively in CK-301-101.

Table 2: Adverse Reactions in $\geq 10\%$ of Patients with Metastatic or Locally Advanced CSCC Receiving UNLOXCYT in Study CK-301-101

	UNLOXCYT N = 141 %	
System Organ Class Preferred Term	All Grades %	Grade 3 or 4 %
General disorders and administrative site conditions		
Fatigue*	33	3
Edema*	11	0
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain*	25	3
Skin and subcutaneous tissue disorders		
Rash*	23	1
Pruritus*	12	0
Endocrine disorder		
Hypothyroidism*	14	0
Gastrointestinal disorders		
Diarrhea	14	0
Nausea	13	0
Constipation	13	0
Nervous system disorders		
Headache*	12	0
Infections and infestations		
Localized infection	10	0.7
Urinary tract infection*	10	0

Toxicity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) v.4.03 (or later version)

* Represents a composite of multiple related terms

Table 3: Laboratory Abnormalities that Worsened from Baseline to Grade 3 or 4 Occurring in $\geq 1\%$ of Patients with Metastatic or Locally Advanced CSCC Receiving UNLOXCYT in Study CK-301-101

Laboratory Abnormality	UNLOXCYT (N = 141)	
	All Grades % ^a	Grade 3 or 4 % ^a
Hematology		
Hemoglobin decreased	45	4
Lymphocytes decreased	41	6
Platelets decreased	14	1
Leukocytes decreased	10	1
Chemistry		
Sodium decreased	38	5
Alkaline phosphatase increased	26	1
Alanine transferase increased	25	4
Lipase increased	25	3
Aspartate transaminase increased	24	3
Potassium increased	23	3
Calcium increased	14	2

Toxicity graded per NCI CTCAE v5

^a The denominator used to calculate the rate varied from 122-140 based on the number of patients with a baseline value and at least one post-treatment value.

8. USE IN SPECIFIC POPULATIONS

8.1. Pregnancy

Risk Summary

Based on its mechanism of action, UNLOXCYT can cause fetal harm when administered to a pregnant woman [see [Clinical Pharmacology \(12.1\)](#)]. There are no available data on the use of UNLOXCYT in pregnant women. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death (see *Data*). Human IgG1 immunoglobulins (IgG1) are known to cross the placental barrier; therefore, cosibelimab-ipdl has the potential to be transmitted from the mother to the developing fetus. Advise women of the potential risk to a fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data: Animal reproduction studies have not been conducted with cosibelimab-ipdl to evaluate its effect on reproduction and fetal development. A central function of the PD-1/PD-L1 pathway is to preserve pregnancy by maintaining maternal immune tolerance to the fetus. In murine models of pregnancy, blockade of PD-L1 signaling has been shown to disrupt tolerance to the fetus and to result in an increase in fetal loss; therefore, potential risks of administering UNLOXCYT during pregnancy include increased rates of abortion or stillbirth. As reported in the

literature, there were no malformations related to the blockade of PD-1/PD-L1 signaling in the offspring of these animals; however, immune-mediated disorders occurred in PD-1 and PD-L1 knockout mice. Based on its mechanism of action, fetal exposure to UNLOXCYT may increase the risk of developing immune-mediated disorders or altering the normal immune response.

8.2. Lactation

Risk Summary

There is no information regarding the presence of cosibelimab-ipdl in human milk or its effects on the breastfed child or on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment and for 4 months after the last dose of UNLOXCYT.

8.3. Females and Males of Reproductive Potential

UNLOXCYT can cause fetal harm when administered to a pregnant woman [*see Use in Specific Populations (8.1)*].

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating UNLOXCYT [*see Use in Specific Populations (8.1)*].

Contraception

Females: Advise females of reproductive potential to use effective contraception during treatment with UNLOXCYT and for 4 months after the last dose.

8.4. Pediatric Use

The safety and effectiveness of UNLOXCYT have not been established in pediatric patients.

8.5. Geriatric Use

Of the 141 patients treated with UNLOXCYT as a single agent, 21% (29) were younger than 65 years, 31% (44) were aged 65 through 75 years, and 48% (68) were 75 years or older. No overall differences in safety or effectiveness were observed between these patients and younger patients.

11. DESCRIPTION

Cosibelimab-ipdl is a human programmed death ligand-1 (PD-L1) blocking antibody. Cosibelimab-ipdl is a human IgG1 lambda monoclonal antibody. Cosibelimab-ipdl is produced in Chinese hamster ovary (CHO) cells and has a calculated molecular weight of approximately 147 kDa.

UNLOXCYT (cosibelimab-ipdl) injection for intravenous use is a sterile, preservative-free, clear to opalescent, colorless to yellow or slightly brown solution. It is supplied in single-dose vials.

Each vial contains 300 mg of UNLOXCYT in 5 mL of solution with a pH of 5.3. Each mL of solution contains 60 mg of cosibelimab-ipdl, acetic acid (0.24 mg), mannitol (37.35 mg), polysorbate 80 (1.1 mg), sodium acetate (1.31 mg), sodium chloride (4.09 mg), and Water for Injection, USP.

12. CLINICAL PHARMACOLOGY

12.1. Mechanism of Action

PD-L1 may be expressed on tumor cells and tumor-infiltrating immune cells and can contribute to the inhibition of the anti-tumor immune response in the tumor microenvironment. Binding of PD-L1 to the PD-1 and B7.1 receptors found on T cells and antigen presenting cells suppresses cytotoxic T-cell activity, T-cell proliferation, and cytokine production. Cosibelimab-ipdl binds PD-L1 and blocks the interaction between PD-L1 and its receptors PD-1 and B7.1. This interaction releases the inhibitory effects of PD-L1 on the anti-tumor immune response. Cosibelimab-ipdl has also been shown to induce antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro.

12.2. Pharmacodynamics

Cosibelimab-ipdl exposure-response relationships and the time course of pharmacodynamic responses have not been fully characterized.

12.3. Pharmacokinetics

Cosibelimab-ipdl pharmacokinetic parameters are presented as geometric mean (coefficient of variation) unless otherwise stated. At the recommended dosage, the cosibelimab-ipdl steady-state maximum plasma concentration (C_{max}) is 492 $\mu\text{g/mL}$ (24.3%) and area under curve (AUC) is 112000 $\mu\text{g}\cdot\text{h/mL}$ (39.6%). Cosibelimab-ipdl C_{max} and AUC increased proportionally over the dose range of 800 mg to 1,200 mg following single dosing. Steady-state concentrations of cosibelimab-ipdl are reached by 12 weeks.

At 1,200 mg every 3 weeks, the mean cosibelimab-ipdl concentrations (coefficient of variation, CV%) at steady-state ranged between a minimum concentration of 120 $\mu\text{g/L}$ (46.3%) and a maximum concentration of 453 $\mu\text{g/L}$ (22.2%). Steady-state exposure was achieved after 84 days of treatment.

In patients with CSCC, cosibelimab-ipdl steady-state exposure at 1,200 mg every 3 weeks (the recommended dosage) was comparable to the exposure at 800 mg every 2 weeks.

Distribution

Cosibelimab-ipdl steady state volume of distribution is approximately 5.67 L (19.7%).

Elimination

Cosibelimab-ipdl steady state elimination half-life is 17.8 days (43.8%), and the clearance is 0.256 L/day (41%).

Specific Populations

No clinically significant differences in the pharmacokinetics of cosibelimab-ipdl were observed based on age (24.8 to 95.0 years), sex, race (79.6% White, 10.7% Asian, 0.5% African American, and 1.5% other), ethnicity (76.9% Not Hispanic/Latino and 4.9% Hispanic/Latino), ADA and nAb status, albumin (22 to 51 g/L), tumor type, tumor diameter, and renal impairment (CL_{cr} 15 mL/min and higher). The effect of severe hepatic impairment (bilirubin > 3 x ULN and any AST) on cosibelimab-ipdl pharmacokinetics is unknown.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies, including those of UNLOXCYT or of other cosibelimab products.

Anti-drug antibody (ADA) and neutralizing antibody (nAb) responses were monitored throughout the treatment period where the benefit to risk ratio was assessed. ADAs were detected in 65/133 (49%) of patients treated with UNLOXCYT and nAbs were detected in 2/65 (3.0%) of the patients. UNLOXCYT-treated patients who developed anti-cosibelimab antibodies had reduced UNLOXCYT concentrations (20% lower compared to UNLOXCYT-treated subjects who did not develop anti-cosibelimab-ipdl antibodies).

There was no clinically significant effect of anti-cosibelimab-ipdl antibodies on the efficacy or safety of cosibelimab-ipdl.

13. NONCLINICAL TOXICOLOGY

13.1. Carcinogenesis, Mutagenesis, Impairment of Fertility

No studies have been performed to assess the potential of cosibelimab-ipdl for carcinogenicity or genotoxicity.

Fertility studies have not been conducted with cosibelimab-ipdl in animals. In 1- and 3-month repeat-dose toxicology studies in monkeys, there were no notable effects in the male and female reproductive organs up to the highest dose tested of 100 mg/kg/dose; however, many animals in these studies were not sexually mature.

13.2. Animal Toxicology and/or Pharmacology

In animal models, inhibition of PD-L1/PD-1 signaling increased the severity of some infections and enhanced inflammatory responses. *Mycobacterium tuberculosis*-infected PD-1 knockout mice exhibit markedly decreased survival compared with wild-type controls, which correlated with increased bacterial proliferation and inflammatory responses in these animals. PD-L1 and PD-1 knockout mice and mice receiving PD-L1–blocking antibody have also shown decreased survival following infection with lymphocytic choriomeningitis virus.

14. CLINICAL STUDIES

14.1. Cutaneous Squamous Cell Carcinoma (CSCC)

The efficacy of UNLOXCYT was evaluated in Study CK-301-101 (NCT03212404), a multicenter, multicohort, open-label study in patients with metastatic CSCC (mCSCC) or locally advanced CSCC (laCSCC) who were not candidates for curative surgery or curative radiation. Patients were excluded if they had the following: active or suspected autoimmune disease, allogeneic transplant within 6 months prior to treatment, prior treatment with anti-PD-1/PD-L1 blocking antibodies or other immune checkpoint inhibitor therapy, uncontrolled or significant cardiovascular disease, ECOG PS ≥ 2 , or infection with HIV, hepatitis B or hepatitis C.

Patients received UNLOXCYT 800 mg every 2 weeks until disease progression or unacceptable toxicity. Tumor response assessments were performed every 8 weeks for the first 8 months and

every 12 weeks thereafter.

The major efficacy outcomes were objective response rate (ORR) and duration of response (DOR) as assessed by an independent central review committee (ICR) according to Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. For patients with laCSCC with externally visible target lesions not assessable by radiologic imaging, ORR was determined by ICR assessments of digital photography (WHO criteria).

The efficacy population consisted of 109 patients. The median age was 75 years (range 37-95); 78% were ≥ 65 years; 72% were male; 85% were White; 6% were Asian; 1% were Black or African American; 7% were race unknown or missing; 34% had ECOG performance status of 0, and 66% had ECOG performance score of 1. Seven percent of patients received at least one prior anti-cancer systemic therapy, 66% of patients had prior surgery, and 69% of patients had prior radiotherapy. Efficacy results are summarized in Table 4.

Table 4: Efficacy Results for Study CK-301-101

Efficacy Endpoints	mCSCC N = 78	laCSCC N = 31
Objective Response Rate (ORR)		
ORR, n (%) (95% CI)	39 (50) (38, 62)	17 (55) (36, 73)
Complete response, n (%)	10 (13)	8 (26)
Partial response, n (%)	29 (37)	9 (29)
Duration of Response (DOR)^a		
Number of responders	N=39	N=17
Median DOR in months ^b (Range)	NR (1.4+, 45.3+)	NR (8.3, 31.3+)
Responders with observed DOR ≥ 6 months, n (%) ^c	33 (85)	17 (100)
Responders with observed DOR ≥ 12 months, n (%) ^c	26 (67)	15 (88)

CI: confidence interval; NR: not reached; +: Denotes ongoing at last assessment.

^a Median follow up time: mCSCC: 29.3 months; laCSCC: 24.1 months.

^b Based on Kaplan-Meier estimate.

^c The numerator includes the number of patients whose observed DOR reached at least the specified times of 6 or 12 months. Patients who did not have the opportunity to reach the specified timepoint were included in the denominator only.

16. HOW SUPPLIED/STORAGE AND HANDLING

UNLOXCYT (cosibelimab-ipdl) injection is a clear to opalescent, colorless to yellow or slightly brown solution supplied in a carton containing one 300 mg/5 mL (60 mg/mL), single-dose vial (NDC 70095-130-01).

Store in a refrigerator at 2°C to 8°C (36°F to 46°F) in original carton to protect from light.

Do not freeze or shake.

17. PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Immune-Mediated Adverse Reactions

Advise patients that UNLOXCYT can cause immune-mediated adverse reactions that may require corticosteroid treatment and interruption or discontinuation of UNLOXCYT including the following [see *Warnings and Precautions (5.1)*]:

- Pneumonitis: Advise patients to contact their healthcare provider immediately for signs or symptoms of pneumonitis, including new or worsening symptoms of cough, chest pain, or shortness of breath.
- Colitis: Advise patients to contact their healthcare provider immediately for signs or symptoms of colitis, including diarrhea, blood or mucus in stools, or severe abdominal pain.
- Hepatitis: Advise patients to contact their healthcare provider immediately for signs or symptoms of hepatitis.
- Endocrinopathies: Advise patients to contact their healthcare provider immediately for signs or symptoms of hypothyroidism, hyperthyroidism, adrenal insufficiency, hypophysitis, or type 1 diabetes mellitus.
- Nephritis: Advise patients to contact their healthcare provider immediately for signs or symptoms of nephritis.
- Dermatologic Adverse Reactions: Advise patients to contact their healthcare provider immediately if they develop a new rash.
- Other Immune-Mediated Adverse Reactions:
 - Advise patients that immune-mediated adverse reactions can occur and may involve any organ system, and to contact their healthcare provider immediately for any new signs or symptoms [see *Warnings and Precautions (5.1)*].
 - Advise patients of the risk of solid organ transplant rejection and other transplant (including corneal graft) rejection. Advise patients to contact their healthcare provider immediately for signs or symptoms of organ transplant (including corneal graft) rejection [see *Warnings and Precautions (5.1)*].

Infusion-Related Reactions

Advise patients to contact their healthcare provider immediately for signs or symptoms of infusion-related reactions [see *Warnings and Precautions (5.2)*].

Complications of Allogeneic HSCT or Solid Organ Transplant Rejection

Advise patients to contact their healthcare provider immediately if they develop signs or symptoms of post-allogeneic HSCT complications or of solid organ transplant rejection [see *Warnings and Precautions (5.1, 5.3)*].

Embryo-Fetal Toxicity

- Advise females of reproductive potential that UNLOXCYT can cause harm to a fetus and to inform their healthcare provider of a known or suspected pregnancy [see *Warnings and Precautions (5.4)* and *Use in Specific Populations (8.1, 8.3)*].
- Advise females of reproductive potential to use effective contraception during treatment with UNLOXCYT and for 4 months after the last dose [see *Use in Specific Populations (8.3)*].

Lactation

- Advise female patients not to breastfeed during treatment with UNLOXCYT and for 4 months after the last dose [see *Use in Specific Populations (8.2)*].

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