CVS/caremark™

POLICY Document for UNLOXCYT

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall, clinically appropriate use. This document provides specific information to each of the three sections of the overall policy.

Section 1: Site of Care

- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria
Checkpoint Inhibitors

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Bavencio	avelumab	intravenous
Imfinzi	durvalumab	intravenous
Jemperli	dostarlimab-gxly	intravenous
Keytruda	pembrolizumab	intravenous
Libtayo	cemiplimab	intravenous
Loqtorzi	toripalimab-tpzi	intravenous
Opdivo	nivolumab	intravenous
Opdualag	nivolumab and relatlimab-rmbw	intravenous
Tecentriq	atezolizumab	intravenous
	penpulimab-kcqx	intravenous
Tevimbra	tislelizumab	intravenous
Unloxcyt	cosibelimab-ipdl	intravenous

Brand Name	Generic Name	Dosage Form
Yervoy	ipilimumab	intravenous
Zynyz	retifanlimab-dlwr	intravenous

Criteria For Approval For Administration In Outpatient Hospital Setting

This policy provides coverage for administration of a checkpoint inhibitor in an outpatient hospital setting for the initial 6 months approval and up to 45 days for renewal of therapy.

This policy provides coverage for administration of tocilizumab in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- The member has experienced an adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids, other pre-medications or slowing of infusion rate) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion or has experienced severe toxicity requiring continuous monitoring (e.g. Grade 2-4 bullous dermatitis, transaminitis, pneumonitis, Stevens-Johnson syndrome, acute pancreatitis, primary adrenal insufficiency aseptic meningitis, encephalitis, transverse myelitis, myocarditis, pericarditis, arrhythmias, impaired ventricular function, conduction abnormalities).
- The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
- The member has severe venous access issues that require the use of a special interventions only available in the outpatient hospital setting.
- The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
- The member is receiving provider administered combination chemotherapy.
- Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
- The member is less than 14 years of age.

For situations where administration of a checkpoint inhibitor does not meet the criteria for outpatient hospital infusion, coverage for a checkpoint inhibitor is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

Required Documentation

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion or a severe toxicity requiring continuous monitoring
- Medical records supporting the member is medically unstable
- Medical records supporting the member has severe venous access issues that require specialized interventions only available in the outpatient hospital setting
- Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- Medical records supporting the member is receiving provider administered combination therapy.
- Records supporting alternative infusion sites are greater than 30 miles from the member's home.
- Medical records supporting the member is new to therapy

Section 2: Clinical Criteria

Specialty Guideline Management
Unloxcyt

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over the counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Unloxcyt	cosibelimab-ipdl

Indication

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication

Cutaneous Squamous Cell Carcinoma (CSCC)

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.

All other indications are considered experimental/investigational and not medically necessary.

Exclusions

Coverage will not be provided for members who have experienced disease progression while on programmed death receptor-1 (PD-1) or programmed death ligand 1 (PD-L1) inhibitor therapy.

Coverage Criteria

Cutaneous Squamous Cell Carcinoma (CSCC)

Authorization of 6 months may be granted for treatment of metastatic or locally advanced CSCC when member is not a candadidate for curative surgery or radiation.

Continuation of Therapy

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

REFERENCES

SECTION 1

1. Opdivo [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; October 2024.
2. Bavencio [package insert]. Rockland, MA: EMD Serono, Inc; November 2024.
3. Imfinzi [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2025.
4. Jemperli [prescribing information]. Philadelphia, PA: GlaxoSmithKline LLC; August 2024.
5. Keytruda [prescribing information]. Rahway, NJ: Merck Sharp & Dome LLC; January 2025.
6. Libtayo [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; April 2024.
7. Tecentriq [package insert]. South San Francisco, CA: Genentech, Inc.; May 2023.
8. Yervoy [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; January 2025.
9. Opdualag [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; March 2024.
10. Zynyz [package insert]. Wilmington, DE: Incyte Corporation; April 2024.

11. Loqtorzi [prescribing information]. Redwood City, CA: Coherus BioSciences, Inc.; October 2024.
12. Tevimbra [prescribing information]. San Mateo, CA: BeiGene USA, Inc.; March 2025.
13. Unloxcyt [prescribing information]. Waltham, MA: Checkpoint Therapeutics, Inc; December 2024.

SECTION 2

1. Unloxcyt [package insert]. Waltham, MA: Checkpoint Therapeutics, Inc.; December 2024.