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POLICY Document for LOQTORZI (toripalimab-tpzi)

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
Loqtorzi

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
Loqtorzi	toripalimab-tpzi

Indications

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 Indications[1]

- Loqtorzi is indicated, in combination with cisplatin and gemcitabine, for first-line treatment of adults with metastatic or with recurrent locally advanced nasopharyngeal carcinoma (NPC).

- Loqtorzi is indicated, as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.

Compendial Uses[2,3]

Nasopharyngeal Carcinoma (NPC)

Anal Carcinoma

Small Bowel Adenocarcinoma

Colorectal Cancer

Non-small Cell Lung Cancer (NSCLC)

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of laboratory report confirming microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR) or polymerase epsilon/delta (POLE/POLD1) tumor status, where applicable.
- Documentation of the absence of epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) mutations, where applicable.

Exclusions

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy.

Coverage Criteria

Nasopharyngeal Carcinoma (NPC)[1,2]

Authorization of 6 months may be granted when either of the following criteria are met:

- The requested medication will be used in combination with cisplatin and gemcitabine for the treatment of unresectable, metastatic or recurrent locally advanced NPC.
- The requested medication will be used as a single agent for treatment of recurrent, unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.

Anal Carcinoma[2]

Authorization of 6 months may be granted as a single agent for subsequent treatment of metastatic anal carcinoma if the member has not received prior immunotherapy.

Small Bowel Adenocarcinoma[2]

Authorization of 6 months may be granted as a single agent for treatment of locally unresectable, medically inoperable, advanced or metastatic small bowel adenocarcinoma for microsatellite instability-high (MSI-H), or deficient mismatch repair (dMMR), or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype tumors.

Colorectal Cancer[2]

Authorization of 6 months may be granted as a single agent for the treatment of unresectable, medically inoperable, advanced, or metastatic colorectal cancer, including appendiceal adenocarcinoma, for microsatellite instability-high (MSI-H), or deficient mismatch repair (dMMR), or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype tumors.

Non-small Cell Lung Cancer (NSCLC)[3]

Authorization of 6 months may be granted:

- For treatment of advanced NSCLC when there are no EGFR or ALK mutations (unless testing is not feasible due to insufficient tissue) and the requested medication will be used as a first-line treatment in combination with platinum-doublet chemotherapy and then continued as single agent maintenance therapy.
- As neoadjuvant treatment if there are no EGFR or ALK mutations (unless testing is not feasible due to insufficient tissue) when used in combination with platinum-doublet chemotherapy and then continued as single agent adjuvant therapy after surgery.

Continuation of Therapy

Nasopharyngeal Carcinoma

Authorization of 6 months (for up to 24 months total when being used as first line therapy) may be granted for continued treatment in members requesting reauthorization for nasopharyngeal carcinoma when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Neoadjuvant NSCLC

Authorization of 6 months may be granted (up to 13 cycles total) for continued treatment in members requesting reauthorization for neoadjuvant treatment of NSCLC who have not experienced disease progression or an unacceptable toxicity.

NSCLC

Authorization of 6 months (for up to 24 months total) may be granted for continued treatment in members requesting reauthorization for NSCLC when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

All Other Indications

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed 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. Loqtorzi [package insert]. Redwood City, CA: Coherus BioSciences, Inc; October 2024.
2. The NCCN Drugs & Biologics Compendium 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 4, 2025.
3. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at https://www.micromedexsolutions.com Accessed March 6, 2025.