Reference number(s)
6238-A

Standard Medicare Part B 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)

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All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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.

Coverage Criteria

Nasopharyngeal Carcinoma (NPC)[1,2]

Authorization of 12 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 12 months may be granted as a single agent for subsequent treatment of metastatic anal carcinoma if the member has not received prior immunotherapy or as a single agent before resection for locally recurrent progressive anal carcinoma.

Small Bowel Adenocarcinoma[2]

Authorization of 12 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.

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Colorectal Cancer[2]

Authorization of 12 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 12 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

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months (for up to 24 months total when being used as first line therapy) may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat nasopharyngeal carcinoma
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, and
    - No evidence of disease progression while on the current regimen

Neoadjuvant NSCLC

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months (for up to 13 cycles) may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat NSCLC

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- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, and
    - No evidence of disease progression while on the current regimen

NSCLC

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months (for up to 24 months total) may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat NSCLC
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, and
    - No evidence of disease progression while on the current regimen

All Other Indications

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication in the coverage criteria
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, and
    - No evidence of disease progression while on the current regimen

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Loqtorzi.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Head and neck cancer
- NCCN Guideline: Anal carcinoma
- NCCN Guideline: Small bowel adenocarcinoma
- NCCN Guideline: Colon cancer
- NCCN Guideline: Rectal cancer

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After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Loqtorzi are covered in addition to the following:

- Anal carcinoma
- Small bowel adenocarcinoma
- Colorectal cancer
- Non-small cell lung cancer

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using the requested medication to treat the following indications can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

- Anal carcinoma
- Small bowel adenocarcinoma
- Colorectal cancer

Support for using Loqtorzi for NSCLC can be found in the Micromedex DrugDex database. Use of information in the DrugDex database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

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.

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