Toripalimab-tpzi (Loqtorzi)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

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

- 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
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 ~~FOR INITIAL APPROVAL~~

Nasopharyngeal Carcinoma (NPC)

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

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

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

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)

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 ~~an indication listed in Section III~~ 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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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.

EFFECTIVE DATE

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