

Clinical Policy: Toripalimab-tpzi (Loqtorzi)

Reference Number: PA.CP.PHAR.668

Effective Date: 02/2024

Last Review Date: 01/2026

Description

Toripalimab-tpzi (Loqtorzi[®]) is a programmed death receptor-1 (PD-1)-blocking antibody.

FDA Approved Indication(s)

Loqtorzi is indicated for the treatment of:

- In combination with cisplatin and gemcitabine, for first-line treatment of adults with metastatic or with recurrent locally advanced nasopharyngeal carcinoma (NPC)
- 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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness[®] that Loqtorzi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Advanced Nasopharyngeal Carcinoma (must meet all):

1. Diagnosis of NPC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is unresectable, recurrent, or metastatic;
5. Loqtorzi is prescribed in one of the following ways (a or b):
 - a. In combination with cisplatin and gemcitabine;
 - b. As a single agent for disease that has progressed on or after platinum-containing chemotherapy;
6. Member has not received prior treatment with an anti-PD-(L)1 antibody;
7. Request meets one of the following (a, b or c):
 - a. In combination with cisplatin and gemcitabine: 240 mg every three weeks;
 - b. As a single agent for disease that has progressed on or after platinum-containing chemotherapy: 3 mg/kg intravenously every two weeks;
 - c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration: 12 months

B. NCCN Recommended Uses (off-label) (must meet all):

1. Diagnosis of one of the following (a, b or c):
 - a. Anal carcinoma;
 - b. One of the following deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with

- ultra-hypermutated phenotype [eg, tumor mutational burden (TMB) > 50 mut/Mb]) cancers (i, ii, iii, or iv):
 - i. Small bowel adenocarcinoma;
 - ii. Appendiceal neoplasms and cancers;
 - iii. Colon cancer;
 - iv. Rectal cancer;
- c. Other NCCN recommendations listed as category 1, 2A, or 2B;
- 2. Prescribed by or in consultation with an oncologist or hematologist;
- 3. Age \geq 18 years;
- 4. Prescribed as a single agent;
- 5. For anal carcinoma, disease is metastatic, recurrent, or progressive and one of the following (i, ii or iii):
 - i. Prescribed before proceeding to abdominoperineal resection;
 - ii. Prescribed as second-line and subsequent therapy;
 - iii. Other NCCN recommendations listed as category 1, 2A, or 2B;
- 6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

C. Other diagnoses/indications

- 1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. All Indications in Section I (must meet all):

- 1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
- 2. Member is responding positively to therapy;
- 3. If request is for a dose increase, request meets one of the following (a, b or c):
 - a. In combination with cisplatin and gemcitabine: new dose does not exceed 240 mg every three weeks for up to total maximum of 24 months;
 - b. As a single agent: new dose does not exceed 3 mg/kg every two weeks;
 - c. New dose is with FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

- 1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

NCCN: National Comprehensive Cancer Network

NPC: Nasopharyngeal Carcinoma

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
First-line treatment for NPC	<u>In combination with cisplatin and gemcitabine:</u> 240 mg IV every three weeks up to 24 months	240 mg/3 weeks
Previously treated, unresectable or metastatic NPC	<u>As a single agent:</u> 3 mg/kg IV every two weeks	3 mg/kg every two weeks

VI. Product Availability

Solution, single-dose vial: 240mg/6mL

VII. References

1. Loqtorzi Prescribing Information. Redwood City, CA: Coherus BioSciences, Inc; April 2024. Available at: www.loqtorzi.com. Accessed November 25, 2025.
2. Toripalimab In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed November 19, 2025.
3. National Comprehensive Cancer Network. Head and Neck Cancers Version 5.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed November 7, 2024.
4. Rui-hua Xu, Hai-Qiang Mai, JUPITER-02: Randomized, double-blind, phase III study of toripalimab or placebo plus gemcitabine and cisplatin as first-line treatment for recurrent

or metastatic nasopharyngeal carcinoma (NPC). Journal of Clinical Oncology 2021. 39:18_suppl, LBA2.

5. Wang FH, Wei XL, Efficacy, Safety, and Correlative Biomarkers of Toripalimab in Previously Treated Recurrent or Metastatic Nasopharyngeal Carcinoma: A Phase II Clinical Trial. Journal of Clinical Oncology 2021. 39(7):704-712.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3263	Injection, toripalimab-tpzi, 1 mg

Reviews, Revisions, and Approvals	Date
Policy created	01/2024
1Q 2025 annual review: no significant changes; added HCPCS code [J3263] and removed HCPCS codes [J3590, C9399]; references reviewed and updated.	01/2025
1Q 2026 annual review: added NCCN recommended off-label indications for anal carcinoma, small bowel adenocarcinoma, appendiceal neoplasms and cancers, colon cancer and rectal cancer per NCCN; extended initial approval duration from 6 to 12 months for this maintenance medication for a chronic condition; references reviewed and updated	01/2026