Clinical Policy: Toripalimab-tpzi (Loqtorzi)

Reference Number: PA.CP.PHAR.668
Effective Date: 02/2024
Last Review Date: 01/2024

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: 6 months

B. 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. Advanced Nasopharyngeal Carcinoma (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.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. Request meets one of the following (a, b or c):
   a. In combination with cisplatin and gemcitabine: 240 mg every three weeks for up to total maximum of 24 months;
   b. As a single agent: 3 mg/kg 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. 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.LTSS.PHAR.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	In combination with cisplasin and gemcitabine: 240 mg IV every three weeks up to 24 months	240 mg/3 weeks

Indication	Dosing Regimen	Maximum Dose
Previously treated, unresectable or metastatic NPC	As a single agent: 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; October 2023. Available at: www.loqtorzi.com. Accessed November 16, 2023.
2. Toripalimab In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed November 16, 2023.
3. 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.
4. 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
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date
Policy created	01/2024