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Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	November 10, 2023
Subject:	Loqtorzi	**Page:**	1 of 4

Last Review Date: September 6, 2024

Loqtorzi

Description

Loqtorzi (toripalimab-tpzi)

Background
Loqtorzi (toripalimab-tpzi) is a programmed death receptor-1 (PD-1) blocking antibody. Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T cells, inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. Loqtorzi binds to the PD-1 receptor and blocks interaction with its ligands PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response (1).

Regulatory Status
FDA-approved indication: Loqtorzi is a programmed death receptor-1 (PD-1) blocking antibody indicated (1):

- In combination with cisplatin and gemcitabine, for first-line treatment of adults with metastatic or 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.

Loqtorzi contains warnings for the following: immune-mediated adverse reactions, infusion-related reactions, and complications of allogenic hematopoietic stem cell transplantation (HSCT) (1).

Loqtorzi can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment with Loqtorzi and for 4 months after the last dose (1).

The safety and effectiveness of Loqtorzi in pediatric patients less than 18 years of age have not been established (1).

Related Policies
Keytruda, Opdivo, Zynyz

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Loqtorzi may be considered **medically necessary** if the conditions indicated below are met.

Loqtorzi may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Metastatic or recurrent locally advanced nasopharyngeal carcinoma (NPC)
    a. Used in combination with cisplatin and gemcitabine
    b. Used as first-line treatment
2. Recurrent unresectable or metastatic nasopharyngeal carcinoma (NPC)
    a. Used as a single agent
    b. Disease progression on or after a platinum-containing chemotherapy

AND ALL of the following:

a. Prescriber agrees to discontinue treatment for any immune-mediated adverse reaction (e.g., encephalitis, nephritis, rash, decreased renal function, and endocrinopathies) or disease progression

b. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Loqtorzi and for 4 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Metastatic or recurrent locally advanced nasopharyngeal carcinoma (NPC)
    a. Used in combination with cisplatin and gemcitabine
2. Recurrent unresectable or metastatic nasopharyngeal carcinoma (NPC)
    a. Used as a single agent

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to discontinue treatment for any immune-mediated adverse reaction (e.g., encephalitis, nephritis, rash, decreased renal function, and endocrinopathies) or disease progression
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Loqtorzi and for 4 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Loqtorzi is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of adult patients with nasopharyngeal carcinoma. Patients taking Loqtorzi should be monitored for immune-mediated adverse reactions. The safety and effectiveness of Loqtorzi in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Loqtorzi while maintaining optimal therapeutic outcomes.

References

1. Loqtorzi [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; April 2024.
2. NCCN Drugs & Biologics Compendium® Toripalimab-tpzi 2024. National Comprehensive Cancer Network, Inc. Accessed on July 22, 2024.

Policy History

Date	Action
November 2023	Addition to PA
March 2024	Annual review and reference update
September 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.