

POLICY: Oncology (Injectable – Programmed Death Receptor-1) - Loqtorzi Utilization Management Medical Policy

- Loqtorzi™ (toripalimab intravenous infusion – Coherus BioSciences)

EFFECTIVE DATE: 3/15/2024

LAST REVISION DATE: 12/20/2023

COVERAGE CRITERIA FOR: All Aspirus Medicare Plans

OVERVIEW

Loqtorzi, a programmed death receptor-1 blocking antibody, is indicated for the following uses:¹

- **Nasopharyngeal carcinoma**, in adults for the first-line treatment of metastatic or recurrent, locally advanced disease in combination with cisplatin and gemcitabine.
- **Nasopharyngeal carcinoma**, in adults as a single agent for the treatment of previously treated unresectable or metastatic disease.

Guidelines

The National Comprehensive Cancer Network (NCCN) head and neck cancers (version 2.2024 – December 8, 2023) clinical practice guidelines recommend Loqtorzi in combination with cisplatin and gemcitabine as a “Preferred Regimen” for the first-line treatment of recurrent, unresectable, oligometastatic, or metastatic nasopharyngeal carcinoma without any surgical or radiation therapy options (category 1).^{2,3} Loqtorzi is recommended as a single agent, as a “Preferred Regimen” for the subsequent treatment of nasopharyngeal carcinoma if disease progression on or after platinum-containing therapy (category 2A). It is also an “Other Recommended Regimen” for the subsequent treatment of nasopharyngeal carcinoma, in combination with cisplatin and gemcitabine if not previously used (category 2A).

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Loqtorzi. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Loqtorzi as well as the monitoring required for adverse events and long-term efficacy, approval requires Loqtorzi to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Loqtorzi is recommended in those who meet the following criteria:

FDA-Approved Indication

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1. **Nasopharyngeal Carcinoma.** Approve for 1 year if the patient meets the following (A, B, C, and D):
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- A) Patient is \geq 18 years of age; AND
- B) Patient has recurrent, unresectable, oligometastatic, or metastatic disease; AND
- C) Patient meets ONE of the following (i or ii):
 - i. Patient meets BOTH of the following (a and b):
 - a) Loqtorzi is used for first-line treatment; AND
 - b) Loqtorzi is used in combination with cisplatin and gemcitabine; OR
 - ii. Patient meets both of the following (a and b):
 - a) Loqtorzi is used for subsequent treatment; AND
 - b) Loqtorzi is used as a single agent; AND
- D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve ONE of the following dosing regimens (A or B):

- A) First-line treatment: Approve 240 mg administered by intravenous infusion no more frequently than once every 3 weeks; OR
- B) Subsequent treatment: Approve 3 mg/kg administered by intravenous infusion no more frequently than once every 2 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Loqtorzi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Loqtorzi™ intravenous infusion [prescribing information]. Redwood City, CA: Coherus BioSciences; October 2023.
2. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 11, 2023. Search term: toripalimab.
3. The NCCN Head and Neck Cancers Clinical Practice Guidelines in Oncology (version 2.2024 – December 8, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed December 11, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/20/2023