UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Programmed Death Receptor-1) - Loqtorzi Utilization Management Medical Policy
- Loqtorzi™ (toripalimab intravenous infusion – Coherus BioSciences)

REVIEW DATE: 01/22/2025

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 recurrent unresectable or metastatic disease with disease progression on or after platinum-containing chemotherapy.

Guidelines

The National Comprehensive Cancer Network (NCCN) has addressed Loqtorzi in the following guidelines:

- **Anal Carcinoma** (version 1.2025 – December 4, 2024) clinical practice guidelines recommend Loqtorzi as a single agent for the subsequent treatment of metastatic disease if no prior immunotherapy received (category 2A).[2,5] Loqtorzi is also recommended as a single agent prior to proceeding to abdominoperineal resection for locally recurrent, progressive disease (category 2B).
- **Head and Neck Cancers** (version 1.2025 – November 26, 2024) 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).
- **Small Bowel Adenocarcinoma** (version 1.2025 – December 4, 2024) clinical practice guidelines recommend Loqtorzi as a single agent for the first-line or subsequent treatment of locally unresectable or medically inoperable disease with ultra-hypermutated phenotype (tumor mutational burden > 50 mutations/megabase) and either deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation positive (category 2A).[2,4]

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

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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 ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 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)** Patient meets ONE of the following [(1) or (2)]:
         - **(1)** Loqtorzi is used as a single agent; OR
         - **(2)** Loqtorzi is used in combination with cisplatin and gemcitabine; 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.

Other Uses with Supportive Evidence

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2. **Anal Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Patient meets BOTH of the following (a and b):
       - **a)** Patient has locally recurrent, progressive disease; AND
       - **b)** Medication is administered before proceeding to abdominoperineal resesction; OR
     - **ii.** Patient meets ALL of the following (a, b, and c):
       - **a)** Patient has metastatic disease; AND
       - **b)** Medication is used as subsequent therapy; AND
       - **c)** Patient has NOT received prior immunotherapy; AND
         Note: Examples of immunotherapy include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Libtayo (cemiplimab intravenous infusion), and Jemperli (dostarlimab intravenous infusion).
   - **C)** The medication is used as a single agent; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

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Dosing. Approve 3 mg/kg administered by intravenous infusion no more frequently than once every 2 weeks.

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3. Small Bowel Adenocarcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has locally unresectable or medically inoperable disease; AND
- **C)** Patient has ultra-hypermutated phenotype; AND
  Note: Ultra-hypermutated phenotype defined as tumor mutation burden > 50 mutations/megabase.
- **D)** Patient meets ONE of the following (i or ii):
  - **i.** Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease; OR
  - **ii.** Patient has polymerase epsilon/delta (POLE/POLD1) mutation positive disease; AND
- **E)** The medication is used as a single agent; AND
- **F)** The medication is prescribed by or in consultation with an oncologist.

Dosing. 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 2024.
2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 16, 2025. Search term: toripalimab.
3. The NCCN Head and Neck Cancers Clinical Practice Guidelines in Oncology (version 1.2025 – November 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 16, 2025.
4. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 1.2025 – December 4, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 16, 2025.
5. The NCCN Anal Carcinoma Clinical Practice Guidelines in Oncology (version 1.2025 – December 4, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 16, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/20/2023
Annual Revision	**Nasopharyngeal Carcinoma:** Added use in combination with cisplatin and gemcitabine as an option for subsequent therapy. **Anal Carcinoma:** Added new condition of approval. **Small Bowel Adenocarcinoma:** Added new condition of approval.	01/22/2025

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