Utilization Review Policy 329

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: 06/25/2025

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

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 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) The medication is used for first-line treatment; AND
b) The medication is used in combination with cisplatin and gemcitabine; OR

ii. Patient meets BOTH of the following (a and b):
a) The medication is used for subsequent treatment; AND
b) Patient meets ONE of the following [(1) or (2)]:
(1) The medication is used as a single agent; OR
(2) The medication 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 resection; OR
ii. Patient meets ALL of the following (a, b, and c):
a) Patient has metastatic disease; AND
b) The medication is used as subsequent therapy; AND
c) Patient has NOT received prior checkpoint inhibitors; OR
Note: Examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Jimperli (dostarlimab-gxly intravenous infusion), Zynyx (retifanlimab-dlwr intravenous infusion), Loqtorzi (toripalimab-tpzi intravenous infusion), Libtayo (cemiplimab- rwlc intravenous infusion), Tevimbra (tislelizumab-jsgr intravenous infusion).
C) The medication is used as a single agent; AND
D) 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.

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3. Colon and Rectal Cancer. Approve for the duration noted if the patients meets ALL of the following A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
i. The disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); OR

ii. The disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden > 50 mutations/megabase); AND

C) Patient meets ONE of the following (i or ii):

i. Approve for 1 year of the patient meets BOTH of the following (a and b):

a) Patient has locally unresectable, advanced, recurrent, metastatic, or medically inoperable disease; AND

b) Patient has NOT received prior checkpoint inhibitors; OR

Note: Examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Jimperli (dostarlimab-gxly intravenous infusion), Zynyx (retifanlimab-dlwr intravenous infusion), Loqtorzi (toripalimab-tpzi intravenous infusion), Libtayo (cemiplimab- rwlc intravenous infusion), Tevimbra (tislelizumab-jsgr intravenous infusion).

ii. Approve for 6 months if the medication is used for neoadjuvant therapy; AND

D) The medication is used as single agent; AND

E) 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.

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4. Small Bowel Adenocarcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):

A) Patient is ≥ 18 years of age; AND

B) Patients meets ONE of the following (i or ii):

i. The disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); OR

ii. The disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden > 50 mutations/megabase); AND

C) Patients meets ONE of the following (i or ii):

i. Patient has locally unresectable, or medically inoperable disease; OR

ii. Patient has advanced or metastatic disease and has NOT received prior checkpoint inhibitors; AND

Note: Examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Jimperli (dostarlimab-gxly intravenous infusion), Zynyx (retifanlimab-dlwr intravenous infusion), Loqtorzi (toripalimab-tpzi intravenous infusion), Libtayo (cemiplimab- rwlc intravenous infusion), Tevimbra (tislelizumab-jsgr).

D) The medication is used as a single agent; AND

E) 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 June 16, 2025. Search term: toripalimab.
3. The NCCN Head and Neck Cancers Clinical Practice Guidelines in Oncology (version 3.2025 – June 11, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2025.
4. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 3.2025 – March 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2025.
5. The NCCN Anal Carcinoma Clinical Practice Guidelines in Oncology (version 4.2025 – May 30, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2025.
6. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – April 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2025.
7. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – March 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/20/2023
Aspirus P&T Review	Policy reviewed and approved by Aspirus P&T committee. Annual review process	09/16/2024
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
Early Annual Revision	**Anal Carcinoma:** The approval option "patient has not received prior immunotherapy" has been modified to "patient has not received prior checkpoint inhibitors." The note was modified to reflect this change. **Colon and Rectal Cancer:** Added new condition of approval. **Small Bowel Adenocarcinoma:** Moved "patient has ultra-hypermutated phenotype" to be included with "The disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden > 50 mutations/megabase)." Added "patient has advanced or metastatic disease and has NOT received prior checkpoint inhibitors" as an option for approval.	06/25/2025