Medical Policy:

Loqtorzi (toripalimab) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.405	March 19, 2025	February 8, 2024

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Loqtorzi, a programmed death receptor-1 (PD-1) blocking antibody, is indicated in combination with cisplatin and gemcitabine for the first-line treatment of metastatic or recurrent locally advanced nasopharyngeal carcinoma in adult and as a single agent for the treatment of recurrent unresectable or metastatic nasopharyngeal carcinoma with disease progression on or after platinum-containing chemotherapy in adults. Binding of programmed death-ligand 1 (PD-L1) and programmed death-ligand 2 (PD-L2) to PD-1 on T-cells results in the inhibition of T-cell proliferation and cytokine production**.** Loqtorzi binds to PD-1, blocking its interaction with PD-L1 and PD-L2, thus releasing the inhibition of the immune response, including the immune response directed against tumors.

Length of Authorization

Initial: 12 months

Continuation: 12 months; for First line NPC- max of 24 months

Dosing Limits [Medical Benefit]

- First-line NPC – 240 mg every three weeks (until disease progression, unacceptable toxicity or up to 24 months)

- Recurrent NPC – 3mg/kg every two weeks (until disease progression or unacceptable toxicity)

Guideline

I. INITIAL CRITERIA

1. **Nasopharyngeal Carcinoma.** Approve if the patient meets the following:
   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. Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, nivolumab, atezolizumab, durvalumab, pembrolizumab, dostarlimab, retifanlimab, nivolumab/relatlimab, tislelizumab, etc.) [Δ]; **AND**
   E. The medication is prescribed by or in consultation with an oncologist.

II. RENEWAL CRITERIA

Coverage may be renewed based upon the following criteria [Δ]:

1. Patient continues to meet Initial criteria; **AND**

2. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

3. Absence of unacceptable toxicity from the drug. *Examples of unacceptable toxicity include: severe infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatotoxicity and hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash, etc.), complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.*; **AND**

4. Nasopharyngeal Carcinoma (combination therapy ONLY)

A. Patient has not exceeded a maximum of twenty-four (24) months of therapy

Δ Notes:

• Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration (i.e., receipt of 24 months of therapy) are eligible to re-initiate PD-directed therapy.

• Patients previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy beyond the 24-month limit without interruption or discontinuation.

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.

Applicable Procedure Codes

Code	Description

J3263	Injection, toripalimab-tpzi, 1 mg

Applicable NDCs

Code	Description
70114-0340-01	Loqtorzi 240mg/6ml (40mg/mL) single-dose vial

ICD-10 Diagnoses

Code	Description
C11	Malignant neoplasm of nasopharynx
C11.0	Malignant neoplasm of superior wall of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx
C11.9	Malignant neoplasm of nasopharynx, unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	03/19/2025	Annual Review: Initial Criteria: Removed: "Patient meets both of the following (a AND b): Loqtorzi is used for subsequent treatment; AND Loqtorzi is used as a single agent; AND" Replaced with: "Patient meets BOTH of the following (a and b): Loqtorzi is used for subsequent treatment; AND Patient meets ONE of the following [(1) or (2)]: Loqtorzi is used as a single agent; OR Loqtorzi is used in combination with cisplatin and gemcitabine; AND" Added: "Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, nivolumab, atezolizumab, durvalumab, pembrolizumab, dostarlimab, retifanlimab, nivolumab/relatlimab, tislelizumab, etc.) $^{\Delta}$; AND" Added RENEWAL CRITERIA: "Coverage may be renewed based upon the following criteria$^{\Delta}$: Patient continues to meet Initial criteria; AND Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; AND Absence of unacceptable toxicity from the drug. *Examples of unacceptable toxicity include: severe infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatotoxicity and hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash, etc.), complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.*; AND Nasopharyngeal Carcinoma (combination therapy ONLY) Patient has not exceeded a maximum of twenty-four (24) months of therapy *Δ Notes: Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration (i.e., receipt of 24 months of therapy) are eligible to re-initiate PD-directed therapy. Patients previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy beyond the 24-month limit without interruption or discontinuation."*
EmblemHealth & ConnectiCare	6/12/2024	Updated J codes- added J3263 effective 7/1/24, removed J9999 and C9399

EmblemHealth & ConnectiCare	02/08/2024	New Policy

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.