Loqtorzi® (toripalimab-tpzi)
(Intravenous)

Document Number: EOCCO-0735

Last Review Date: 07/02/2024
Date of Origin: 12/07/2023
Dates Reviewed: 12/2023, 03/2024, 07/2024

I. Length of Authorization Δ [1,4,5,9]

Coverage will be provided for 6 months and may be renewed (unless otherwise specified).

- Coverage can be authorized up to a maximum of 24 months (32 total doses) of therapy when used in combination with chemotherapy.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Loqtorzi 240 mg/6 mL single-dose vial: 2 vials every 2 weeks

B. Max Units (per dose and over time) [HCPCS Unit]:

- 480 billable units every 2 weeks

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1,2]

- 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**

Head and Neck Cancers † ‡ Φ [1-5,9]

- Patient has Cancer of the Nasopharynx; **AND**
  - Used as first-line therapy; **AND**
    - Patient has metastatic OR recurrent, locally advanced disease; **AND**
    - Used in combination with cisplatin and gemcitabine; **OR**
  - Used as subsequent therapy; **AND**
    - Patient has recurrent unresectable or metastatic disease; **AND**

- Used as single-agent therapy; **AND**
  - Patient experienced disease progression on or after a platinum-containing chemotherapy regimen; **OR**
- Used in combination with cisplatin and gemcitabine *(Note: Only applies to metastatic disease)*; **OR**

- Patient has Very Advanced Head and Neck Cancer*****; **AND**
  - Patient has nasopharyngeal cancer; **AND**
  - Used for one of the following:
    - Unresectable locoregional recurrence with prior radiation therapy (RT)
    - Unresectable second primary with prior RT
    - Unresectable persistent disease with prior RT
    - Recurrent/persistent disease with distant metastases; **AND**
  - Used as one of the following:
    - Single agent; **AND**
      - Used as an alternate subsequent-line option if patient experienced disease progression on or after platinum-containing therapy; **OR**
    - In combination with cisplatin and gemcitabine; **AND**
      - Patient has a performance status 0-1

****** *Very Advanced Head and Neck Cancer includes: Newly diagnosed locally advanced T4b (M0) disease; newly diagnosed unresectable regional nodal disease (typically N3); metastatic disease at initial presentation (M1); or recurrent or persistent disease.*

† FDA Approved Indication(s); **‡** Compendia Recommended Indication(s); **Φ** Orphan Drug

IV. Renewal Criteria Δ [1,4,5,9]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **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**

Head and Neck Cancers (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.

V. Dosage/Administration [Δ 1,9]

Indication	Dose
Head and Neck Cancers	Combination therapy Administer 240 mg intravenously every three weeks until disease progression or unacceptable toxicity, or up to 24 months. Single-agent therapy Administer 3 mg/kg intravenously every two weeks until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code(s):

- J3263 – Injection, toripalimab-tpzi, 1 mg; 1 billable unit = 1 mg (Effective 07/01/2024)
- J9999 – Not otherwise classified, antineoplastic drugs (Discontinue use on 07/01/2024)
- C9399 – Unclassified drugs or biologicals *(Hospital Outpatient Use Only) (Discontinue use on 07/01/2024)*

NDC:

- Loqtorzi 240 mg/6 mL solution in a single-dose vial: 70114-0340-xx

VII. References

1. Loqtorzi [package insert]. Redwood City, CA; Coherus BioSciences, Inc.; April 2024. Accessed May 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) toripalimab-tpzi. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2024.

3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Head and Neck Cancers. Version 4.2024. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed May 2024.
4. Mai HQ, Chen QY, Chen D, et al. Toripalimab or placebo plus chemotherapy as first-line treatment in advanced nasopharyngeal carcinoma: a multicenter randomized phase 3 trial [published correction appears in Nat Med. 2022 Jan;28(1):214]. *Nat Med*. 2021;27(9):1536-1543. doi:10.1038/s41591-021-01444-0
5. Wang FH, Wei XL, Feng J, et al. Efficacy, Safety, and Correlative Biomarkers of Toripalimab in Previously Treated Recurrent or Metastatic Nasopharyngeal Carcinoma: A Phase II Clinical Trial (POLARIS-02). *J Clin Oncol*. 2021;39(7):704-712. doi:10.1200/JCO.20.02712
6. Fahrenbruch R, Kintzel P, Bott AM, et al. Dose Rounding of Biologic and Cytotoxic Anticancer Agents: A Position Statement of the Hematology/Oncology Pharmacy Association. J Oncol Pract. 2018 Mar;14(3):e130-e136.
7. Hematology/Oncology Pharmacy Association (2019). Intravenous Cancer Drug Waste Issue Brief. Retrieved from http://www.hoparx.org/images/hopa/advocacy/Issue-Briefs/Drug_Waste_2019.pdf
8. Bach PB, Conti RM, Muller RJ, et al. Overspending driven by oversized single dose vials of cancer drugs. BMJ. 2016 Feb 29;352:i788.
9. Hai-Qiang Mai et al., Final overall survival analysis of JUPITER-02: A phase 3 study of toripalimab versus placebo in combination with gemcitabine and cisplatin as first-line treatment for recurrent or metastatic nasopharyngeal carcinoma (NPC). JCO 41, 6009-6009(2023). DOI:10.1200/JCO.2023.41.16_suppl.6009.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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
C14.0	Malignant neoplasm of pharynx, unspecified
C14.2	Malignant neoplasm of Waldeyer's ring
C30.0	Malignant neoplasm of nasal cavity
D37.05	Neoplasm of uncertain behavior of pharynx

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC