

Loqtorzi™ (toripalimab-tpzi) (Intravenous)

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I. Length of Authorization ^{Δ 1,4,5}

Coverage will be provided for 6 months and may be renewed. *(Note: Coverage can be authorized up to a maximum of 24 months (32 total doses) of therapy only when used as first-line therapy 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]:

- Combination therapy: 240 mg every 3 weeks
- Single-agent therapy: 480 mg 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 ¹⁻⁵

- 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, relatlimab, nivolumab/relatlimab, etc.); **AND**

Nasopharyngeal Carcinoma (NPC) † Φ ¹⁻⁵

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

- Used as single-agent therapy; **AND**
- Patient experienced disease progression on or after a platinum-containing chemotherapy regimen

† FDA Approved Indication(s); ‡ Compendia Approved Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ^{Δ 1,4,5}

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, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash), complications of allogeneic hematopoietic stem cell transplantation (HSCT), solid organ transplant rejection, etc.; **AND**
 - Used as first-line therapy; **AND**
 - Patient has not exceeded a maximum of twenty-four (24) months of therapy; **OR**
 - Used as subsequent 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}

Indication	Dose
Nasopharyngeal Carcinoma (NPC)	<u>First Line Therapy (Combination therapy)</u> Administer 240 mg intravenously every three weeks until disease progression or unacceptable toxicity, or up to 24 months.
	<u>Recurrent Therapy (Single-agent therapy)</u> Administer 3 mg/kg intravenously every two weeks until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J9999 – Not otherwise classified, antineoplastic drug
- C9399 – Unclassified drugs or biologicals (Hospital Outpatient Use Only)

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.; October 2023. Accessed November 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) toripalimab-tpzi. National Comprehensive Cancer Network, 2023. 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 November 2023.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Head and Neck Cancers. Version 1.2024. National Comprehensive Cancer Network, 2023. 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 November 2023.
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. Gupta S, Sonpavde G, Grivas P, et al. Defining “platinum-ineligible” patients with metastatic urothelial cancer (mUC). *J Clin Oncol*. 2019 Mar 1;37(7_suppl):451.
7. 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.
8. 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

9. Bach PB, Conti RM, Muller RJ, et al. Overspending driven by oversized single dose vials of cancer drugs. *BMJ*. 2016 Feb 29;352:i788.

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, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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