Loqtorzi® (toripalimab-tpzi)
(Intravenous)

-E-

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I. Length of Authorization Δ [1,4,5,9-13]

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter, unless otherwise specified.
  - Head and Neck Cancers in combination with chemotherapy: Prior authorization validity may be renewed up to a maximum of 24 months (35 total doses).

II. Dosing Limits

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

- 480 billable units every 2 weeks

III. Initial Approval Criteria [1]

Prior authorization validity 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 [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**

- 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**
        - Used as first-line therapy; **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.*

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications
Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity. Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

❖ *If confirmed using an FDA approved assay – http://www.fda.gov/CompanionDiagnostics*

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

IV. Renewal Criteria Δ 1,4,5,9

Prior authorization validity 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**
- Duration of authorization has not been exceeded *(refer to Section I)*; **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.

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.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration Δ 1,9-13

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:

- J3263 – Injection, toripalimab-tpzi, 1 mg; 1 billable unit = 1 mg

NDC:

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

VII. References (STANDARD)

1. Loqtorzi [package insert]. Redwood City, CA; Coherus BioSciences, Inc.; October 2024. Accessed August 2025.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) toripalimab-tpzi. National Comprehensive Cancer Network, 2025. 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 August 2025.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Head and Neck Cancers. Version 3.2025. National Comprehensive Cancer Network, 2025. 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 August 2025.
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 https://www.hoparx.org/documents/65/HOPA_Drug_Waste_Issue_Brief_-_Updated_01.19.22_FINAL.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.

10. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Small Bowel Adenocarcinoma. Version 3.2025. National Comprehensive Cancer Network, 2025. 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 August 2025.
11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Anal Carcinoma. Version 4.2025. National Comprehensive Cancer Network, 2025. 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 August 2025.
12. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Colon Cancer. Version 4.2025. National Comprehensive Cancer Network, 2025. 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 August 2025.
13. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Rectal Cancer. Version 2.2025. National Comprehensive Cancer Network, 2025. 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 August 2025.

VIII. References (ENHANCED)

1e. Jin Y, Cai XY, Shi YX, et al. Comparison of five cisplatin-based regimens frequently used as the first-line protocols in metastatic nasopharyngeal carcinoma. J Cancer Res Clin Oncol 2012;138:1717-1725.
2e. Hong S, Zhang Y, Yu G, et al. Gemcitabine plus cisplatin versus fluorouracil plus cisplatin as first-line therapy for recurrent or metastatic nasopharyngeal carcinoma: Final overall survival analysis of GEM20110714 phase III study. J Clin Oncol 2021;39:3273-3282.
3e. Mai HQ, Chen QY, Chen D, et al. Toripalimab plus chemotherapy for recurrent or metastatic nasopharyngeal carcinoma: the JUPITER-02 randomized clinical trial. JAMA 2023;330:1961-1970.
4e. Mai HQ, Chen QY, Chen D, 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). Journal of Clinical Oncology. 2023;41(16_suppl):6009. DOI.org/10.1200/JCO.2023.41.16_suppl.6009

5e. Xia F, Wang Y, Wang H, et al. Randomized Phase II Trial of Immunotherapy-Based Total Neoadjuvant Therapy for Proficient Mismatch Repair or Microsatellite Stable Locally Advanced Rectal Cancer (TORCH). J Clin Oncol. 2024 Oct;42(28):3308-3318. doi: 10.1200/JCO.23.02261.

6e. Overman MJ, McDermott R, Leach JL, et al. Nivolumab in patients with metastatic DNA mismatch repair-deficient or microsatellite instability-high colorectal cancer (CheckMate 142): an open-label, multicentre, phase 2 study. Lancet Oncol. 2017 Sep;18(9):1182-1191. doi: 10.1016/S1470-2045(17)30422-9. Epub 2017 Jul 19.

7e. Midgen MR, Khushalani, NI, Chang AL, et al. Cemiplimab in locally advanced cutaneous squamous cell carcinoma: results from an open-label, phase 2, single-arm trial. Lancet Oncol. 2020 Feb;21(2):294-305. doi: 10.1016/S1470-2045(19)30728-4

8e. Berton D, Banerjee SN, Curigliano G, et al. Antitumor activity of dostarlimab in patients with mismatch repair-deficient/microsatellite instability–high tumors: A combined analysis of two cohorts in the GARNET study.J Clin Oncol. 2021;39(15 suppl):abstr 2564.

9e. Berton, D, Pautier P, Lorusso, C, et al. Antitumor activity and safety of the PD-1 inhibitor retifanlimab in patients with recurrent microsatellite instability-high or deficient mismatch repair endometrial cancer: Final safety and efficacy results from cohort H of the POD1UM-101 phase I study. Gynecol Oncol. 2024 Jul:186:191-198. doi: 10.1016/j.ygyno.2024.05.025

10e. Li J, Xu Y, Zang, A et al. Tislelizumab in previously treated, locally advanced unresectable/metastatic microsatellite instability-high/mismatch repair-deficient solid tumors. Chin J Cancer Res. 2024 Jun 30;36(3):257-269. doi: 10.21147/j.issn.1000-9604.2024.03.03

11e. Morris VK, Salem ME, Nimeiri, H et al. Nivolumab for previously treated unresectable metastatic anal cancer (NCI9673): a multicentre, single-arm, phase 2 study. Lancet Oncol. 2017 Apr;18(4):446-453. doi: 10.1016/S1470-2045(17)30104-3.

12e. Ott PA, Piha-Paul SA, Munster P, et al. Safety and antitumor activity of the anti-PD-1 antibody pembrolizumab in patients with recurrent carcinoma of the anal canal. Ann Oncol. 2017 May 1;28(5):1036-1041. doi: 10.1093/annonc/mdx029.

13e. Rao S, Anandappa G, Capdevila, et al. A phase II study of retifanlimab (INCMGA00012) in patients with squamous carcinoma of the anal canal who have progressed following platinum-based chemotherapy (POD1UM-202). ESMO Open. 2022 Jul 8;7(4):100529. doi: 10.1016/j.esmoop.2022.100529.

14e. Lenz HJ, Lonardi S, Zagonel V et al. Nivolumab (NIVO) + low-dose ipilimumab (IPI) as first-line (1L) therapy in microsatellite instability-high/DNA mismatch repair deficient (MSI-H/dMMR) metastatic colorectal cancer (mCRC): Clinical update. J Clin Oncol. Vol 37, Num 15 supple. https://doi.org/10.1200/JCO.2019.37.15_suppl.35

15e. Andre T, Shiu KK, Kim TW, et al. Pembrolizumab versus chemotherapy for microsatellite instability-high/mismatch repair deficient metastatic colorectal cancer: The phase 3 KEYNOTE-177 Study. J Clin Oncol. Vol 38, Num 18 supple. https://doi.org/10.1200/JCO.2020.38.18_suppl.LBA

16e. Lakhani N, Cosman, Banerji, et al. A first-in-human phase I study of the PD-1 inhibitor, retifanlimab (INCMGA00012), in patients with advanced solid tumors (POD1UM-101). ESMO Open. 2024 Feb 21;9(4):102254. doi: 10.1016/j.esmoop.2024.102254

17e. Le DT, Kim TW, Van Cutsem E, et al. Phase II Open-Label Study of Pembrolizumab in Treatment-Refractory, Microsatellite Instability–High/Mismatch Repair–Deficient Metastatic Colorectal Cancer: KEYNOTE-164. J Clin Oncol. Vol 38, Num 1. https://doi.org/10.1200/JCO.19.0210

18e. Chalabi M, Verschoor YL, Tan PB, et al. Neoadjuvant Immunotherapy in Locally Advanced Mismatch Repair-Deficient Colon Cancer. N Engl J Med. 2024 Jun 6;390(21):1949-1958. doi: 10.1056/NEJMoa2400634.

19e. Zhang J, Cai J, Deng Y, et al. Complete response in patients with locally advanced rectal cancer after neoadjuvant treatment with nivolumab. Onc Imm. Vol 8, 2019. Issue 12. doi.org/10.1080/2162402X.2019.1663108

20e. Cercek A, Lumish M, Sinopoli J, et al. PD-1 Blockade in Mismatch Repair–Deficient, Locally Advanced Rectal Cancer. N Engl J Med 2022;386:2363-2376. DOI: 10.1056/NEJMoa2201445

21e. Le DT, Uram JN, Wang H, et al. PD-1 Blockade in Tumors with Mismatch-Repair Deficiency. New England Journal of Medicine. 2015;372(26):2509-2520. doi:https://doi.org/10.1056/nejmoa1500596

22e. Li J, Xu Y, Zang A, et al. Tislelizumab in previously treated, locally advanced unresectable/metastatic microsatellite instability-high/mismatch repair-deficient solid tumors. PubMed. 2024;36(3):257-269. doi:https://doi.org/10.21147/j.issn.1000-9604.2024.03.03

23e. Ludford K, Ho WJ, Thomas JV, et al. Neoadjuvant Pembrolizumab in Localized Microsatellite Instability High/Deficient Mismatch Repair Solid Tumors. Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology. Published online January 9, 2023:JCO2201351. doi:https://doi.org/10.1200/JCO.22.01351

24e. Prime Therapeutics Management. Loqtorzi Clinical Literature Review Analysis. Last updated August 2025. Accessed August 2025.

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
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum

ICD-10	ICD-10 Description
C79.89	Secondary malignant neoplasm of other specified sites
D37.05	Neoplasm of uncertain behavior of pharynx
D38.5	Neoplasm of uncertain behavior of other respiratory organs
D38.6	Neoplasm of uncertain behavior of respiratory organ, unspecified

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