

## Loqtorzi® (toripalimab-tpzi) (Intravenous)

-E-

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### I. Length of Authorization <sup>Δ 1,4,5,9-13</sup>

- 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 <sup>1</sup>

Prior authorization validity is provided in the following conditions:

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

**Universal Criteria <sup>1,2</sup>**

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy <sup>Δ</sup>; **AND**

**Head and Neck Cancers † ‡ Φ <sup>1-5,9</sup>**

- 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 (M0) locally advanced T4b, N0-3, or newly diagnosed unresectable regional nodal disease, or those unfit for surgery, metastatic disease at initial presentation (M1); or recurrent or persistent disease with or without metastases.*

**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); Ⓢ Orphan Drug

#### IV. Renewal Criteria <sup>Δ 1,4,5,9</sup>

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.

##### <sup>Δ</sup> 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 <sup>Δ 1,9-13</sup>

| Indication            | Dose                                                                                                                      |
|-----------------------|---------------------------------------------------------------------------------------------------------------------------|
| Head and Neck Cancers | <u>Combination therapy</u>                                                                                                |
|                       | Administer 240 mg intravenously every three weeks until disease progression or unacceptable toxicity, or up to 24 months. |
|                       | <u>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:

- 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)

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3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Head and Neck Cancers. Version 5.2025. 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 October 2025.
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## Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime’s assessment led to for each.

| Factor                     | Conclusion            |
|----------------------------|-----------------------|
| Indication                 | Yes: Consider for PA  |
| Safety and efficacy        | No: PA not a priority |
| Potential for misuse/abuse | No: PA not a priority |

Cost of drug

Yes: Consider for PA

## 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                               |
| 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.                           |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions |                                                                                             |                                                   |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------|---------------------------------------------------|
| Jurisdiction                                                  | Applicable State/US Territory                                                               | Contractor                                        |
| 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                           |