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 (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) 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*.

Note: The maximum number of doses is dependent on the dosing frequency and duration of therapy. Refer to Section V for exact dosage.		
Dosing Frequency	**Maximum length of therapy**	**Maximum number of doses**
2 weeks	12 months	26 doses
3 weeks	24 months	35 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:

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

Universal Criteria [1,2]

- Member 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]

- Member has Cancer of the Nasopharynx; **AND**
  - Used as first-line therapy; **AND**
    - Member has metastatic OR recurrent, locally advanced disease; **AND**

        - Used in combination with cisplatin and gemcitabine; **OR**
    - Used as subsequent therapy; **AND**
        - Member has recurrent unresectable or metastatic disease; **AND**
        - Used as single-agent therapy; **AND**
        - Member experienced disease progression on or after a platinum-containing chemotherapy regimen; **OR**
- Member has Very Advanced Head and Neck Cancer*; **AND**
    - Member has nasopharyngeal cancer; **AND**
        - Used for one of the following:
            - Unresectable disease with prior radiation therapy (RT); **OR**
            - Recurrent/persistent disease with distant metastases; **AND**
        - Used as one of the following:
            - Single agent; **AND**
                - Used as an alternate subsequent-line option if member experienced disease progression on or after platinum-containing therapy; **OR**
            - In combination with cisplatin and gemcitabine; **AND**
                - Used as first-line therapy; **AND**
                - Member 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 distant metastases.*

Small Bowel Adenocarcinoma ‡ [2,10,25e-32e]

- Used as single agent treatment; **AND**
    - Member has microsatellite instability-high (MSI-H)/mismatch repair deficient (dMMR) disease as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test❖; **AND**
        - Used as neoadjuvant therapy; **AND**
        - Member has resectable disease that is T4 or has bulky primary; **AND**
        - Use of toripalimab will be restricted to members with a contraindication or intolerance to dostarlimab, pembrolizumab, or tislelizumab; **OR**
    - Member has polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) > 50 mut/Mb] as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test❖; **AND**
        - Member has advanced or metastatic disease; **AND**

- Used as subsequent therapy; **AND**

▪ Use of toripalimab will be restricted to members with a contraindication or intolerance to dostarlimab or nivolumab

Colon Cancer ‡ [2,12,25e-32e]

- Used as single agent treatment; **AND**
  - Member has MSI-H/dMMR disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
    - Used for neoadjuvant therapy; **AND**
    - Member does not have distant metastases; **AND**
    - Used for one of the following:
      - Resectable, non-obstructing disease (for T4 or bulky primary); **OR**
      - Clinical T4b or bulky nodal disease; **AND**

▪ Use of toripalimab will be restricted to members with a contraindication or intolerance to dostarlimab, pembrolizumab, or tislelizumab; **OR**

  - Member has POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
    - Used for locally unresectable, medically inoperable, advanced, or metastatic disease; **AND**
    - Used as subsequent therapy; **AND**

▪ Use of toripalimab will be restricted to members with a contraindication or intolerance to dostarlimab or nivolumab

Appendiceal Neoplasms and Cancers ‡ [2,14,25e-32e]

- Used as single agent treatment; **AND**
- Member has POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test❖**; AND**
- Used for recurrent, progressive, metastatic peritoneal-only, or extraperitoneal disease; **AND**
- Used as subsequent therapy; **AND**

• Use of toripalimab will be restricted to patients with a contraindication or intolerance to dostarlimab or nivolumab

Rectal Cancer ‡ [2,13,25e-32e]

- Used as single agent treatment; **AND**

- Member has MSI-H/dMMR disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
  - Used for neoadjuvant therapy; **AND**
  - Member has T3, N Any; T1-2, N1-2; T4, N Any; **AND**
  - Member does not have distant metastases; **AND**

▪ Use of toripalimab will be restricted to members with a contraindication or intolerance to dostarlimab, pembrolizumab, or tislelizumab; **OR**

- Member has POLE/POLD1 mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb) as determined by an FDA-approved or CLIA-compliant test❖; **AND**
  - Used for locally unresectable, medically inoperable, advanced, or metastatic disease; **AND**
  - Used as subsequent therapy; **AND**

▪ Use of toripalimab will be restricted to members with a contraindication or intolerance to dostarlimab or nivolumab

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:

- Member 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:

- Members 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.
- Members 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.
- Members who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Members 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.
All other indications	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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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
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure

ICD-10	ICD-10 Description
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C30.0	Malignant neoplasm of nasal cavity
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C79.89	Secondary malignant neoplasm of other specified sites
D37.05	Neoplasm of uncertain behavior of pharynx
D37.3	Neoplasm of uncertain behavior of appendix
D38.5	Neoplasm of uncertain behavior of other respiratory organs
D38.6	Neoplasm of uncertain behavior of respiratory organ, unspecified
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.818	Personal history of malignant neoplasm of other sites of lip, oral cavity, and 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		
Jurisdictio	**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