# Medical Policy

**Healthcare Services Department**

| Policy Name | Policy Number | Scope |
|---|---|---|
| **Toripalimab-tpzi (Loqtorzi®)** | MP-RX-FP-147-24 | ☒ MMM MA ☒ MMM Multihealth |

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

## Service Description

This document addresses the use of *Toripalimab-tpzi (Loqtorzi®),* a programmed death receptor-1 (PD-1)-blocking antibody approved by the Food and Drug Administration (FDA) for the treatment of certain patients with nasopharyngeal carcinoma (NPC).

**Background Information**

Nasopharyngeal cancer (NPC) is a rare type of head and neck cancer that affects the upper part of the throat connecting the back of the nasal cavity to the back of the mouth (the nasopharynx). NPC most commonly starts in the squamous cells that line the nasopharynx. Histologically, squamous cell carcinoma is the most common (>90%) type of NPC. The treatment is the same for all types of NPC:

- Keratinizing squamous cell carcinoma is the most common type in places with low rates of NPC, like the United States.
- Non-keratinizing differentiated carcinoma is less common in areas with high rates of NPC and is often associated with the Epstein-Barr virus (EBV).
- Non-keratinizing undifferentiated carcinoma is the most common type in areas with high rates of NPC and is often associated with EBV. Basaloid squamous cell carcinoma is rare and very aggressive.

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the following uses:

- Head and Neck Cancers
  - Very advanced head and neck cancer (NCCN 1, 2A)
  - Cancer of the Nasopharynx (NCCN 1, 2A)
    - First-line systemic therapy in combination with cisplatin and gemcitabine (preferred) for T1-4, N0-3, M1
      - oligometastatic disease and PS 0-2
      - widely metastatic disease and good PS (0-2)
    - If not previously used, may be considered as subsequent-line systemic therapy in combination with cisplatin and gemcitabine for T1-4, N0-3, M1
      - oligometastatic disease and performance status (PS) 0-2

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- widely metastatic disease and good PS (0-2)

▪ Subsequent-line single agent systemic therapy (preferred) if disease progression on or after platinum-containing therapy for T1-4, N0-3, M1

- oligometastatic disease and performance status (PS) 0-2
- widely metastatic disease and good PS (0-2).

Definitions and Measures

- Adenocarcinoma: Cancer originating in cells that line specific internal organs and that have gland-like (secretory) properties.
- Chemotherapy: Medical treatment of a disease, particularly cancer, with drugs or other chemicals.
- Complete Response (CR): The disappearance of all signs of cancer as a result of treatment; also called complete remission; does not indicate the cancer has been cured.
- Disease Progression: Cancer that continues to grow or spread.
- ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:
  - 0 = Fully active, able to carry on all pre-disease performance without restriction
  - 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
  - 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
  - 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
  - 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
  - 5 = Dead
- Immune checkpoint inhibitor: A type of drug that blocks certain proteins made by some types of immune system cells, such as T cells, and some cancer cells. When these proteins are blocked, the "brakes" on the immune system are released and T cells are able to kill cancer cells better. Examples of checkpoint proteins found on T cells or cancer cells include programmed death (PD)-1, PD-ligand 1 (PD-L1), and cytotoxic T-lymphocyte–associated antigen (CTLA)-4/B7-1/B7-2 (NCI, 2018).
- Line of Therapy:
  - First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
  - Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.

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- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second- line therapy) are not effective or there is disease progression.

- Locally advanced cancer: Cancer that has spread only to nearby tissues or lymph nodes.
- Maintenance therapy: Designed to maintain a condition to prevent a relapse.
- Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.
- One line of therapy: Single line of therapy.
- Overall-survival (OS): The length of time from either date of diagnosis or the start of treatment for a disease, such as cancer, that individuals diagnosed with the disease remain alive.
- Primary treatment: The first treatment given for a disease. It is often part of a standard set of treatments, such as surgery followed by chemotherapy and radiation. Also called first-line therapy, induction therapy, and primary therapy.
- Progressive Disease (PD): Cancer that is growing, spreading, or getting worse.
- Refractory Disease: Illness or disease that does not respond to treatment.
- Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.
- Stable disease: Cancer that is not decreasing or increasing in extent or severity.
- Unresectable: Unable to be removed with surgery.

**Approved Indications**

A. First line treatment of metastatic or recurrent, locally advanced nasopharyngeal carcinoma in combination with cisplatin and gemcitabine.
B. As a single agent for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.

**Other Uses**

i. Head and Neck Cancers (see background information above).

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The

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inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| HCPCS | Description |
|---|---|
| J3263 | Injection, toripalimab-tpzi, 1 mg [Loqtorzi] |

| ICD-10 | Description |
|---|---|
| C11.0-C11.9 | Malignant neoplasm of superior wall of nasopharynx (posterior, lateral, and anterior wall of nasopharynx) |
| C14.0 | Malignant neoplasm of pharynx, unspecified |
| C14.2 | Malignant neoplasm of Waldeyer's ring |
| C30.0 | Malignant neoplasm of nasal cavity |
| C32.9 | Malignant neoplasm of the larynx, unspecified (used for head and neck cancers) |
| C76.0 | Malignant neoplasm of head, face, and neck, unspecified |
| D37.05 | Neoplasm of uncertain behavior of pharynx |

### Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

## *Toripalimab-tpzi (Loqtorzi®)*

**A. Criteria For Initial Approval** (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of nasopharyngeal carcinoma (NPC); **AND**
ii. Individual is using in one of the following ways:
   A. Individual has metastatic or recurrent, locally advanced NPC; **AND**
   B. Individual is using in combination with cisplatin and gemcitabine; **AND**
   C. Individual is using as first-line treatment; **AND**
   D. Individual will use until disease progression, unacceptable toxicity, or up to 24 months;
   **OR**
   E. Individual has recurrent, unresectable, or metastatic NPC with disease progression on or after platinum containing chemotherapy; **AND**
   F. Individual is using as a single agent;
   **OR**
   G. Individual has oligometastatic disease or widely metastatic disease; AND

H. Individual is using in combination with cisplatin and gemcitabine;

**AND**

iii. Individual has a current ECOG performance status of 0-2; **AND**

iv. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**

v. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

**B. Criteria For Continuation of Therapy**

i. MMM considers continuation of Toripalimab-tpzi (Loqtorzi®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen, and the maximum duration of treatment has not been exceeded. The following information should be submitted for reauthorization:

A. A current oncology note documenting the patient's response to treatment showing no progression of disease.

B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

ii. Maximum Duration of Therapy:

A. When used as first-line in patients with metastatic or recurrent, locally advanced NPC, in combination with cisplatin and gemcitabine: Up to 24 months of therapy

B. When used as a single agent in recurrent, unresectable, or metastatic NPC with disease progression on or after platinum containing chemotherapy: Until disease progression or unacceptable toxicity.

**C. Authorization Duration**

i. Initial Approval Duration: Up to 6 months

ii. Reauthorization Approval Duration: Up to 6 months (if a maximum duration of therapy is recommended, Loqtorzi® will be reauthorized until it has been reached).

**D. Conditions Not Covered**

*Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):*

i. Toripalimab-tpzi (Loqtorzi®) may not be approved when the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

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## Limits or Restrictions

A. Therapeutic Alternatives

*The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.*

i. N/A

B. Quantity Limitations

*Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.*

### Toripalimab-tpzi (Loqtorzi®) 240 mg/6 mL (40 mg/mL) SDV

| Indication | Recommended Dosing Schedule | Duration of treatment |
|---|---|---|
| First line NPC in combination with cisplatin and gemcitabine | 240 mg IV every three weeks | Until disease progression, unacceptable toxicity, or up to 24 months. |
| Recurrent NPC as a single agent | 3 mg/kg IV every two weeks | Until disease progression or unacceptable toxicity. |
| **Exceptions** | | |
| • Immune-mediated adverse reactions can occur. Liver enzymes, creatinine and thyroid function should be monitored at baseline and during treatment. | | |

## Reference Information

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: December 4, 2023
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on December 4, 2023.
    a. Head and Neck Cancers. V1.2024. Accessed January 29, 2023.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.



## Policy History

| Revision Type | Summary of Changes | P&T Approval Date | UM/CMPC Approval Date |
|---|---|---|---|
| Annual Review 12/26/2024 | Updated background information to add NCCN recommendations for Head and Neck Cancers. Added NCCN recommendations to clinical criteria for use in oligometastatic disease in combination with cisplatin and gemcitabine for subsequent-line systemic therapy. Updated ECOG score to 0-2. Updated quantity limit table to addd dosage forms and strenght, and immune adverse reactions warning per FDA label. Wording and formatting changes. Coding Reviewed: added HCPCS J3263; ICD10 C39.9 and 76.0. | 3/20/2025 | 4/2/2025 |
| Policy Inception 01/29/2024 | New Medical Policy creation | 4/18/2024 | 6/28/2024 |