

Medical Drug Clinical Criteria

Subject: Loqtorzi (toripalimab-tpzi)
Document #: CC-0255 **Publish Date:** [12/23/2024](#)[12/22/2025](#)
Status: Revised **Last Review Date:** [11/15/2024](#)[11/14/2025](#)

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Overview

This document addresses the use of Loqtorzi (toripalimab-tpzi). Loqtorzi is a programmed death receptor-1 (PD-1) blocking antibody. Loqtorzi (toripalimab-tpzi) is FDA approved for two distinct indications in nasopharyngeal carcinoma (NPC), regardless of patients' programmed death-ligand 1 (PD-L1) status:

- In combination with cisplatin and gemcitabine for the first-line treatment of adults with metastatic or recurrent, locally advanced NPC
- As a stand-alone treatment for adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy

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:

- Anal Carcinoma
 - Preferred second-line and subsequent therapy as a single agent for metastatic disease if no prior immunotherapy received.
- Appendiceal Carcinoma
 - Systemic therapy for advanced or metastatic disease (deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [eg, TMB >50 mut/Mb]) as a single agent if patient is a candidate for immunotherapy and no prior immunotherapy received.
- Colon Cancer
 - Therapy as a single agent (deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [eg, TMB >50 mut/Mb]) (candidate for immunotherapy and no prior immunotherapy received):
 - for locally unresectable or medically inoperable disease (preferred)
 - as primary treatment for synchronous abdominal/peritoneal metastases that are nonobstructing, or following local therapy for patients with existing or imminent obstruction
 - for synchronous unresectable metastases
 - as treatment for unresectable metachronous metastases

- Treatment as a single agent (deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [eg, TMB >50 mut/Mb]):
 - as neoadjuvant therapy in clinical T4b or bulky nodal disease (preferred)
 - as neoadjuvant therapy for resectable synchronous liver and/or lung metastases (if no previous treatment with a checkpoint inhibitor) (preferred)
 - as initial treatment for resectable metachronous metastases if no previous immunotherapy
- 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
 - 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)
 - Systemic therapy as a first-line or subsequent-line (if not previously used) option in patients with nasopharyngeal cancer and performance status (PS) 0-1 for: unresectable locoregional recurrence with prior radiation therapy (RT), unresectable second primary with prior RT, unresectable persistent disease with prior RT, or recurrent/persistent disease with distant metastases in combination with cisplatin and gemcitabine (preferred first-line).
- Rectal Cancer:
 - Therapy as a single agent in patients (deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [eg, TMB >50 mut/Mb]) if candidate for immunotherapy and no prior immunotherapy received:
 - as primary treatment for synchronous abdominal/peritoneal metastases that are nonobstructing, or following local therapy for patients with existing or imminent obstruction
 - as primary treatment for synchronous unresectable metastases
 - as primary treatment for potentially resectable or unresectable isolated pelvic/anastomotic recurrence
 - as primary treatment for unresectable metachronous metastases
 - Therapy as a single agent for patients (deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [eg, TMB >50 mut/Mb]):
 - as neoadjuvant treatment for resectable synchronous liver only and/or lung only metastases (no previous treatment with a checkpoint inhibitor)(preferred)
 - as initial treatment for resectable metachronous metastases and no previous immunotherapy
- Small Bowel Adenocarcinoma
 - Therapy as a single agent for advanced or metastatic disease (deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [eg, tumor mutational burden (TMB) > 50 mut/Mb]), if no previous treatment with a checkpoint inhibitor, for any line of therapy.
 - Therapy as a single agent as primary treatment for locally unresectable or medically inoperable disease (deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [eg, tumor mutational burden (TMB) > 50 mut/Mb]).

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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.
- **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.

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2. Individual is using for advanced or metastatic disease and had no prior treatment with a checkpoint inhibitor for any line of therapy;

AND

B. Individual has dMMR/MSI-H or POLE/POLD1 mutation with ultra-hypermuted phenotype [eg, TMB 50 mut/Mb]; **AND**

C. Using as a single agent;

OR

III.VIII. Individual has a diagnosis of nasopharyngeal carcinoma (NPC) (Label, NCCN 1, 2A); **AND**

III.X. Individual is using in one of the following ways:

A. Individual has recurrent, unresectable, or metastatic or recurrent, locally advanced NPC; **AND**

B. Individual does not have surgery or radiation therapy as an option; **AND**

B-C. Individual is using in combination with cisplatin and gemcitabine; **AND**

C-D. Individual is using as first-line treatment; **AND**

D-E. Individual will use until disease progression, unacceptable toxicity, or up to 24 months;

OR

F. Individual is using as subsequent-line therapy; **AND**

1. Using in combination with cisplatin or gemcitabine, if not previously used; **OR**

2. Using as single agent if disease progression on or after platinum-containing therapy;

OR

G. Individual is using as systemic therapy; **AND**

1. Using in combination with cisplatin or gemcitabine, if not previously used; **OR**

2. As an alternate single agent subsequent-line option if disease progression on or after platinum-containing therapy;

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

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

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

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J3263 Injection, toripalimab-tpzi, 1 mg [Lloqtorzi]

ICD-10 Diagnosis

C11.0-C11.9 Malignant neoplasm of the nasopharynx

C14.0 Malignant neoplasm of pharynx, unspecified

C17.0-C17.9 Malignant neoplasm of small intestine

C18.0-C18.9 Malignant neoplasm of colon

C19 Malignant neoplasm of rectosigmoid junction

C20 Malignant neoplasm of rectum

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C21.0-C21.8 Malignant neoplasm of anus and anal canal

C30.0 Malignant neoplasm of nasal cavity

Document History

Revised: 11/14/2024

Document History:

- 11/14/2025 – Annual Review: Add NCCN criteria for use in anal carcinoma, appendiceal carcinoma, colorectal cancer, and small bowel adenocarcinoma. Update existing NCCN criteria for use in nasopharynx cancer. Administrative update for age. Coding Reviewed: Added ICD-10-CM C14.0, C17.0-C17.9, C18.0-C18.9, C19, C20, C21.0-C21.8, C30.0.
- 11/15/2024 – Annual Review: Add NCCN criteria for use in oligometastatic disease in combination with cisplatin and gemcitabine for subsequent-line systemic therapy. Updated ECOG score to 0-2. Coding Reviewed: No changes.
- 12/11/2023 – Select Review: Add new criteria for Loqtorzi (toripalimab-tpzi). Coding Reviewed: Added J3490, J3590, C939. All diagnoses pend. Effective 7/1/2024 Added HCPCS J3263. Removed HCPCS J3490, J3590, C9399. Added ICD-10-CM C11.0-C11.9.

References

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 - a. Anal Carcinoma. V4.2025. Revised May 30, 2025. Accessed October 9, 2025.
 - b. Colon Cancer. V4.2025. Revised June 27, 2025. Accessed October 9, 2025.
 - c. Head and Neck Cancers. V5.2025. Revised August 12, 2025. Accessed October 9, 2025.
 - d. Rectal Cancer. V3.2025. Revised August 26, 2025. Accessed October 9, 2025.
 - e. Small Bowel Adenocarcinoma. V3.2025. Revised March 31, 2025. Accessed October 9, 2025.

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