Medical Drug Clinical Criteria

Subject:	Loqtorzi (toripalimab-tpzi)		
Document #:	CC-0255	**Publish Date:**	01/03/2024
Status:	New	**Last Review Date:**	12/11/2023

Table of Contents

Overview
Coding
References
Clinical Criteria
Document History

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.

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.

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.

Clinical Criteria

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.

Loqtorzi (toripalimab-tpzi)

Requests for Loqtorzi (toripalimab-tpzi) may be approved if the following criteria are met:

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;

AND

III. Individual has a current ECOG performance status of 0-1; **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.

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 [Loqtorzi]

ICD-10 Diagnosis

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

Document History

New: 12/11/2023
Document History:

- 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

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 December 4, 2023.

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.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

© CPT Only – American Medical Association