Loqtorzi (toripalimab-tpzi)
PAM – 084

Iowa Medicaid Program	Prior Authorization	**Effective Date**	07/01/2024
Revision Number	1	**Last Reviewed**	10/18/2024
Reviewed By	Medicaid Medical Director	**Next Review**	10/17/2025
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	10/18/2024

Overview

Medication: [1]	toripalimab-tpzi
Brand Name:	Loqtorzi®
Pharmacologic Category:	Antineoplastics; immune checkpoint inhibitor; PD-1 blocking antibody
FDA-Approved Indication(s):	1. In combination with cisplatin and gemcitabine: for the first-line treatment of adults with metastatic or with recurrent, locally advanced nasopharyngeal carcinoma (NPC). 2. As a single agent: for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing therapy.
How Supplied:	Single-dose vial: 240 mg/6 mL (40 mg/mL)
Dosage and Administration:	

Indication	Dosage (IV Infusion)	Duration of Treatment
First-line NPC	240 mg every 3 weeks	Until disease progression, unacceptable toxicity, or up to 24 months
Recurrent NPC	3 mg/kg every 2 weeks	Until disease progression or unacceptable toxicity

Benefit Category:	Medical

Descriptive Narrative

Nasopharyngeal carcinoma (NPC) is the predominant tumor type arising in the nasopharynx, the tubular passage behind the nasal cavity that connects to the oropharynx below. It differs from other head and neck squamous cell carcinomas in epidemiology, histology, natural history, and response to treatment.

Worldwide, there were over 133,000 new cases and 80,000 deaths due to NPC. NPC displays a distinct racial and geographic distribution, which is reflective of its multifactorial etiology. It is rare in the United States and Western Europe,

with an incidence of 0.5 to 2 cases per 100,000 (by contrast, NPC is endemic in Southern China, including Hong Kong, where the incidence may reach 25 cases per 100,000 per year).

The major etiologic risk factors for endemic NPC are genetic susceptibility, early age exposure to chemical carcinogens, and Epstein-Barr virus (EBV) infection. In the United States and Europe, NPC is more commonly associated with alcohol and tobacco use, which are classic risk factors for other head and neck tumors.

Histology

The World Health Organization classifies NPC into three histopathologic types:

1. **Keratinizing squamous cell carcinoma** – The sporadic form of nasopharyngeal carcinoma is most commonly the keratinizing subtype (previously WHO type I).
2. **Nonkeratinizing carcinoma** – This is subdivided into differentiated (previously WHO type II) and undifferentiated (previously WHO type III) forms. The endemic form of nasopharyngeal carcinoma is commonly the undifferentiated, nonkeratinizing subtype (previously WHO type III); this is strongly associated with Epstein-Barr virus (EBV) and has a more favorable prognosis than other types.
3. **Basaloid squamous cell carcinoma** – Basaloid squamous cell carcinoma was added to the WHO classification of head and neck tumors in 2005. There are few reported cases, but they are notable for an aggressive clinical course and poor survival.[2]

Guidelines

The National Comprehensive Cancer Network (NCCN) publishes guidelines for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines® are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. The guidelines are developed and updated by 61 individual panels, comprising over 1,700 clinicians and oncology researchers from the 33 NCCN Member Institutions.

Guidelines are reviewed and updated on a continual basis to ensure that the recommendations take into account the most current evidence. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.[3,4]

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):[5]

- Head and Neck Cancers (v.4.2024 – May 1, 2024)

NCCN Guidelines® Recommendation(s): systemic therapies for nasopharyngeal cancers [a]
Recurrent, unresectable, oligometastatic, or metastatic disease & no surgery or RT option a. First line [b] i. Cisplatin/gemcitabine + toripalimab-tpzi: Category 1, Preferred b. Subsequent line i. Toripalimab-tpzi (if disease progression on or after platinum-containing therapy): Category 2A, Preferred
[a] The recommendations are based on clinical trial data for those with Epstein-Barr virus (EBV)-associated nasopharynx cancer. [b] If not previously used, these regimens may be considered in subsequent-line therapy as other recommended regimens.

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Criteria

Prior authorization is required.

Loqtorzi® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of nasopharyngeal carcinoma (NPC) which meets one of the following (a or b):
   a. Recurrent locally advanced or metastatic, and Loqtorzi® is prescribed as first-line treatment in combination with cisplatin and gemcitabine; **OR**
   b. Recurrent unresectable or metastatic, with disease progression on or after a platinum-containing chemotherapy, and Loqtorzi® is prescribed as a single agent; **AND**
2. Member is 18 years of age or older; **AND**
3. Member has not received prior therapy with another anti-PD-1 (programmed death receptor-1 (PD-1)-blocking antibody) or anti-PD-L1 (programmed death-ligand 1 (PD-L1)-blocking antibody); **AND**

4. Prescribed by, or in consultation with, an oncologist; **AND**
5. Request meets one of the following (a, b, or c):
    a. In combination with cisplatin/gemcitabine and dose does not exceed 240 mg every 3 weeks; or
    b. As a single agent for disease that has progressed on or after platinum-containing chemotherapy and dose does not exceed 3 mg/kg every 2 weeks; or
    c. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Loqtorzi® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Prescribed by, or in consultation with, an oncologist; **AND**
4. Request meets one of the following (a, b, or c):
    a. In combination with cisplatin and gemcitabine and dose does not exceed 240 mg every 3 weeks until disease progression, unacceptable toxicity, or up to a total maximum of 24 months; or
    b. As a single agent for disease that has progressed on or after platinum-containing chemotherapy and dose does not exceed 3 mg/kg every 2 weeks until disease progression or unacceptable toxicity; or
    c. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

Indication	Quantity Limits	Approval Duration	
		Initial	Continuation
First-line NPC *	240 mg every 3 weeks	6 months	Up to 12 months per authorization; treat until disease progression, unacceptable toxicity, or up to 24 months total
Recurrent NPC	3 mg/kg every 2 weeks	6 months	12 months per authorization; treat until disease progression or unacceptable toxicity

* NPC = nasopharyngeal carcinoma

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J3263	Injection, toripalimab-tpzi, 1 mg

ICD-10	Description
C11	Malignant neoplasm of nasopharynx
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

NDC (and strength)	Labeler (and code)	Dosage	Pkg Size	Pkg Qty	Units/ Pkg
70114-0340-01 (240 mg/6 mL)	Coherus BioSciences, Inc. (70114)	1 mg	1	EA	240

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Loqtorzi® prescribing information (04/2024). Coherus BioSciences, Inc.: Redwood City, CA. Available online: loqtorzihcp.com. Accessed June 25, 2024.

[2] Hui EP, Chan AT. Epidemiology, etiology, and diagnosis of nasopharyngeal carcinoma. Yushak M, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed July 29, 2024.

[3] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[4] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[5] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

- Head and Neck Cancers (v.4.2024 – May 1, 2024)

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		[#]
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		[#]
Signature			

Change Date	Changed By	Description of Change	Version
10/18/2024	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee