Reference number(s)
6238-A

STANDARD MEDICARE PART B MANAGEMENT

LOQTORZI (toripalimab-tpzi)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Loqtorzi is indicated, in combination with cisplatin and gemcitabine, for first-line treatment of adults with metastatic or with recurrent locally advanced nasopharyngeal carcinoma (NPC).
B. Loqtorzi is indicated, 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.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Nasopharyngeal carcinoma (NPC)
Authorization of 12 months may be granted when either of the following criteria are met:

A. The requested medication will be used in combination with cisplatin and gemcitabine for the first-line treatment of metastatic or recurrent locally advanced NPC.
B. The requested medication will be used as a single agent for treatment of recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months (for up to 24 months total when being used as first line therapy) may be granted when all of the following criteria are met:

A. The member is currently receiving therapy with the requested medication
B. The requested medication is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy. Benefit is defined as:
    1. No evidence of unacceptable toxicity while on the current regimen, and
    2. No evidence of disease progression while on the current regimen

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Loqtorzi.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Head and neck cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Loqtorzi are covered.

V. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

VI. REFERENCES

1. Loqtorzi [package insert]. Redwood City, CA: Coherus BioSciences, Inc; October 2023.