Ttislelizumab-jsgr (TEVIMBRA™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

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 Indication

Tevimbra as a single agent, is indicated for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.

Compendial Uses

- Esophageal squamous cell carcinoma
- Hepatocellular carcinoma
- Histologic (Richter) transformation to diffuse large B-cell lymphoma

All other indications are considered experimental/investigational and not medically necessary.

EXCLUSIONS

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy.

COVERAGE CRITERIA

Esophageal Squamous Cell Carcinoma

Authorization of 6 months may be granted for the treatment of esophageal squamous cell carcinoma in members who are not surgical candidates or have unresectable, recurrent, or metastatic disease when the following criteria are met:

- The member has tried prior systemic chemotherapy not including a PD-L1 inhibitor
- The requested medication will be used as a single agent

Hepatocellular Carcinoma

Authorization of 6 months may be granted as a single agent for the first line treatment of hepatocellular carcinoma when the member is deemed ineligible for resection, transplant, or locoregional therapy.

Histologic (Richter) Transformation to Diffuse Large B-cell Lymphoma

Authorization of 6 months may be granted for treatment of Histologic (Richter) transformation to diffuse large B-cell lymphoma in combination with zanubrutinib.

CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Tevimbra [package insert]. San Mateo, CA: BeiGene USA, Inc; March 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc.

EFFECTIVE DATE 4/30/2025

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