Tislelizumab-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 Indications

Esophageal Cancer

- Tevimbra, in combination with platinum-containing chemotherapy, is indicated for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1).
- 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.

Gastric Cancer
Tevimbra, in combination with platinum and fluoropyrimidine-based chemotherapy, is indicated for the first-line treatment of adults with unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma (G/GEJ) whose tumors express PD-L1 (≥1).

Compendial Uses

- Esophageal cancer / esophagogastric junction cancer
- Hepatocellular carcinoma
- Histologic (Richter) transformation to diffuse large B-cell lymphoma
- Gastric cancer
- Small bowel adenocarcinoma
- Anal carcinoma
- Head and neck cancer
- Colon cancer
- Appendiceal cancer
- Rectal cancer

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

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of programmed death ligand 1 (PD-L1) tumor expression, where applicable.
- Documentation of laboratory report confirming MSI-H, mismatch repair deficient (dMMR) or polymerase epsilon/delta (POLE/POLD1) tumor status, where applicable.
- Documentation of human epidermal growth factor receptor 2 (HER2) status, where applicable.

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 Cancer

Authorization of 6 months may be granted for the treatment of esophageal and esophagogastric junction cancer in members who are not surgical candidates or have unresectable, recurrent, or metastatic disease when the requested medication will be used for any of the following:

- First-line therapy for members with PD-L1 ≥1 and squamous cell carcinoma or HER2-negative adenocarcinoma in combination with platinum-containing chemotherapy
- Subsequent therapy for esophageal squamous cell carcinoma as a single agent

Authorization of 6 months may be granted for induction therapy for relieving dysphagia in combination with platinum-containing chemotherapy for members with PD-L1 ≥1 planned for esophagectomy.

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.

Gastric Cancer

Authorization of 6 months may be granted for the treatment of HER2-negative gastric adenocarcinoma in members who are not surgical candidates or have unresectable, recurrent, or metastatic disease in combination with platinum and fluoropyrimidine-based chemotherapy for first-line treatment of tumors expressing PD-L1 (≥1).

Small Bowel Adenocarcinoma

Authorization of 6 months may be granted as a single agent for treatment of unresectable, inoperable, advanced or metastatic small bowel adenocarcinoma for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

Anal Carcinoma

Authorization of 6 months may be granted as a single agent for subsequent treatment of metastatic anal carcinoma.

Head and Neck Cancer

Authorization of 6 months may be granted in combination with cisplatin and gemcitabine for subsequent treatment of metastatic nasopharyngeal cancer.

Colon Cancer

Authorization of 6 months may be granted as a single agent for neoadjuvant therapy or treatment of unresectable, inoperable, or metastatic colon adenocarcinoma for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

Appendiceal Cancer

Authorization of 6 months may be granted as a single agent for treatment of advanced or metastatic appendiceal adenocarcinoma for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

Rectal Cancer

Authorization of 6 months may be granted as a single agent for neoadjuvant therapy or treatment of recurrent or metastatic rectal adenocarcinoma for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

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 2025.

2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed March 7, 2025.

EFFECTIVE DATE 7/31/2025

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