

DRUG POLICY

Tevimbra® (tislelizumab-jsgr)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits 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 adults 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

1. Esophageal cancer/esophagogastric junction cancer
2. Hepatocellular carcinoma
3. Histologic (Richter) transformation to diffuse large B-cell lymphoma
4. Gastric cancer
5. Small bowel adenocarcinoma
6. Anal carcinoma
7. Head and neck cancer

8. Colon cancer
9. Appendiceal cancer
10. Rectal cancer

POLICY

Required Documentation

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

1. Documentation of programmed death ligand 1 (PD-L1) tumor expression, where applicable
2. Documentation of laboratory report confirming MSI-H, mismatch repair deficient (dMMR) or polymerase epsilon/delta (POLE/POLD1) tumor status, where applicable
3. 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.

Criteria for Initial Approval

Esophageal Cancer

1. 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:
 - A. First-line therapy for members with PD-L1 ≥ 1 and squamous cell carcinoma or HER2-negative adenocarcinoma in combination with platinum-containing chemotherapy
 - B. Subsequent therapy for esophageal squamous cell carcinoma as a single agent
2. 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

1. Authorization of 6 months may be granted as a single agent for the first line treatment of hepatocellular carcinoma when either of the following criteria are met:
 - A. Member has unresectable disease and is ineligible for transplant
 - B. Member has extrahepatic/metastatic disease and is ineligible for resection, transplant, or locoregional therapy
2. Authorization of 6 months may be granted as a single agent for the subsequent treatment of unresectable or extrahepatic/metastatic hepatocellular carcinoma.

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 mutation burden [TMB] > 50mut/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] > 50mut/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 mutation burden [TMB] > 50mut/Mb).

Continuation of Therapy

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

Other

Tevimbra (tisnelizumab-jsgr) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J9329 – Injection, tislelizumab-jsgr, 1mg

REFERENCES

- Tevimbra [package insert]. San Mateo, CA: BeiGene USA, Inc; June 2025.
- The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. <https://www.nccn.org>. Accessed June 10, 2025.
- NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Hepatocellular Carcinoma. Version 1.2025. Accessed July 22, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf

POLICY HISTORY

Policy #: 05.05.59

Original Effective Date: January 25, 2025

Reviewed: August 2026

Revised: January 2026

Current Effective Date: February 4, 2026