Clinical Policy: Tislelizumab-jsgr (Tevimbra)

Reference Number: PA.CP.PHAR.687
Effective Date: 02/2025
Last Review Date: 04/2025

Description
Tislelizumab-jsgr (Tevimbra™) is a programmed death receptor-1 (PD-1) blocking antibody.

FDA Approved Indication(s)
- In combination with platinum-containing chemotherapy for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express (PD-L1) (≥1).
- As a single agent in adults with unresectable or metastatic ESCC after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.
- In combination with platinum and fluoropyrimidine-based chemotherapy in adults for the first line treatment of unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction adenocarcinoma (G/GEJ) whose tumors express PD-L1 (≥ 1).

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Tevimbra is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria
- **A. Gastric, Esophageal or Gastroesophageal Junction Cancer** (must meet all)**:**
  1. Diagnosis of ESCC or G/GEJ;
  2. Prescribed by or in consultation with an oncologist;
  3. Age ≥18 years;
  4. For ESCC, one of the following (a or b):
     a. Disease is unresectable, locally advanced, recurrent, metastatic or member is not a surgical canidate;
     b. Member is planned for esophagectomy;
  5. For ESCC, one of the following (a or b):
     a. Prescribed as a single agent and both of the following (i and ii):
        i. Member has had previous treatment or will be treated with a fluoropyrimidine-based (e.g., 5-fluorouracil, capecitabine) and platinum-based (e.g., cisplatin, oxaliplatin) chemotherapy;
        ii. Prior systemic chemotherapy did NOT include a PD-1 or PD-(L)1 inhibitor (e.g., nivolumab, ipilimumab, pembrolizumab);
     b. Prescribed in combination with platinum (e.g., cisplatin, oxaliplatin)-containing chemotherapy and both of the following (i and ii):
        i. Request is for first-line treatment or member is planned for esophagectomy;
        ii. Tumor is PD-L1 positive;

6. For G/GEJ, all of the following (a, b, c, d and e):
   a. Disease is unresectable, locally advanced, recurrent, metastatic or member is not a surgical candidate;
   b. Disease is HER2-negative;
   c. Tumor is PD-L1 positive;
   d. Request is for first-line treatment;
   e. Tevimbra is prescribed in combination with both of the following (i and ii):
      i. Fluoropyrimidine (e.g., capecitabine, fluorouracil)-containing chemotherapy;
      ii. Platinum (e.g., cisplatin, oxaliplatin)-containing chemotherapy;
7. Request meets one of the following (a or b):
   a. Dose does not exceed one of the following (i-iii):
      i. 150 mg IV every 2 weeks;\
      ii. 200 mg IV every 3 weeks;
      iii. 300 mg IV every 4 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. NCCN Recommended Uses (off-label) (must meet all):
1. Tevimbra is prescribed in one of the following ways (a-d):
   a. As a single agent for one of the following diagnoses (i, ii, iii, or iv):
      i. Locally recurrent, progressive, or metastatic anal carcinoma;
      ii. One of the following deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation positive diseases (1 or 2):
         1. Small bowl adenocarcinoma, and disease is locally unresectable, medically inoperable, advanced, or metastatic;
         2. Colorectal cancer;
      iii. Hepatocellular carcinoma (HCC);
      iv. Head and neck cancers, and prescribed as subsequent-line therapy;
   b. In combination with cisplatin and gemcitabine as first-line or subsequent therapy for head and neck cancers;
   c. In combination with zanubrutinib* for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) with histologic (Richter) transformation to diffuse B-cell lymphoma;
   d. Other category 1, 2A, and 2B NCCN-recommendation uses not listed
   **Prior authorization may be required for zanubrutinib*
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For HCC, one of the following (a or b):
   a. Prescribed as first-line systemic therapy for those with one of the following (i or ii):
      i. Member has liver-confined, unresectable disease and is deemed ineligible for transplant;

ii. Member has extrahepatic, metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy;
b. Prescribed as subsequent-line systemic therapy; df

5. For CLL or SLL with histologic (Richter) transformation to diffuse B-cell lymphoma, one of the following (a, b, or c):
   a. Member has presence of del(17p)/TP53 mutation;
   b. Member is chemotherapy refractory;
   c. Member is unable to receive chemoimmunotherapy;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence)*

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed one of the following (i - iii)
      i. 150 mg IV every 2 weeks;
      ii. 200 mg IV every 3 weeks;
      iii. 300 mg IV every 4 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ESCC: esophageal squamous cell carcinoma
FDA: Food and Drug Administration
G/GEJ: gastric or gastroesophageal junction adenocarcinoma
HER2: human epidermal growth factor receptor 2
PD-1: programmed death receptor-1
PD-L1: programmed death-ligand 1

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Maximum Dose
Examples of first-line chemotherapy used in ESCC multi-drug chemotherapy regimens include: • Fluoropyrimidine (e.g., fluorouracil or capecitabine) plus oxaliplatin or cisplatin • Nivolumab and ipilimumab • Fluorouracil and irinotecan • Paclitaxel or docetaxel ± carboplatin or cisplatin	Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ESCC, G/GEJ	200 mg IV on Day 1 of every 3-week cycle	See regimen

VI. Product Availability

Single-dose vial for injection: 100 mg/10 mL (10 mg/mL)

VII. References

1. Tevimbra Prescribing Information. San Mateo, CA: BeiGene USA, Inc.; April 2025. Available at: https://www.beigene.com/PDF/TEVIMBRAUSPI.pdf. Accessed July 10, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at http://www.nccn.org. Accessed March 17, 2025.

3. National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers, Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed March 17, 2025.
4. National Comprehensive Cancer Network. Gastric Cancer Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed March 17, 2025.
5. Shen L, Kato K, Kim SB, et al. Tislelizumab Versus Chemotherapy as Second-Line Treatment for Advanced or Metastatic Esophageal Squamous Cell Carcinoma. J Clin Oncol. 2022 September 10;40(26):3065-3076.
6. Qiu MZ, Oh DY, Kato K, et al. Tislelizumab plus chemotherapy versus placebo plus chemotherapy as first line treatment for advanced gastric or gastro-esophageal junction adenocarcinoma: RATIONALE-305 randomised, double blind, phase 3 trial. BMJ. 2024 May 28; 385: e078876. doi: 10.1136/bmj-2023-078876.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9329	Injection, tislelizumab-jsgr, 1 mg

Reviews, Revisions, and Approvals	Date
Policy created	01/2025
RT4: updated criteria to include new indication for first-line ESCC treatment in combination with platinum-containing chemotherapy whose tumors express PD-L1 (≥ 1) per updated PI; for ESCC, added bypass option for disease criteria of unresectable, locally advanced, recurrent, or metastatic if member is planned for esophagectomy; for G/GEJ, added option for locally advanced, recurrent disease; added criteria for off-label indications: anal carcinoma, CLL or SLL with histologic (Richter) transformation to diffuse B-cell lymphoma, head and cancers, HCC, small bowel adenocarcinoma, and colorectal cancer as supported by NCCN; references reviewed and updated.	04/2025