Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2025**
Policy Number: PA.CP.PHAR.687	**Effective Date: 02/2025** **Revision Date: 01/2025**
Policy Name: Tislelizumab-jsgr (Tevimbra)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Name of Authorized Individual (Please type or print): **Craig A. Butler, MD MBA**	**Signature of Authorized Individual:**

Clinical Policy: Tislelizumab-jsgr (Tevimbra)

Reference Number: PA.CP.PHAR.687
Effective Date: 02/2025
Last Review Date: 01/2025

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 esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a programmed death receptor-ligand 1 (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 one of the following (a or b):
   a. Unresectable, locally advanced, recurrent, or metastatic ESCC;
   b. Unresectable or metastatic G/GEJ;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥18 years;
4. For ESCC, all of the following (a, b, and c):
   a. Member has had previous treatment or will be treated with a fluoropyrimidine-based (e.g., 5-fluorouracil, capecitabine) and platinum-based (e.g., carboplatin, cisplatin, oxaliplatin) chemotherapy;
   b. Prior systemic chemotherapy did NOT include a PD-1 or PD-(L)1 inhibitor (e.g., nivolumab, ipilimumab, pembrolizumab);
5. For G/GEJ, all of the following (a, b, c, and d):
   a. Disease is HER2-negative;
   b. Tumor is PD-L1 positive;
   c. Request is for first-line treatment;
   d. 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., oxaliplatin)-containing chemotherapy;

6. Request meets one of the following (a or b):
   a. Dose does not exceed 200 mg IV every 3 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. 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. Gastric, Esophageal or Gastroesophageal Junction Cancer (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 200 mg IV every 3 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	Dose Limit/ 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	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.; December 2024. Available at: https://www.beigene.com/PDF/TEVIMBRAUSPI.pdf. Accessed January 8, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at http://www.nccn.org. Accessed January 8, 2025.
3. National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers, Version 5.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed January 8, 2025.
4. National Comprehensive Cancer Network. Gastric Cancer Version 5.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed January 8, 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