Clinical Policy: Tislelizumab-jsgr (Tevimbra)

Reference Number: CP.PHAR.687
Effective Date: 09.01.24
Last Review Date: 08.24
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

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

FDA Approved Indication(s)

Tevimbra is indicated:

- 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 programmed death receptor-ligand 1 (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 health plans affiliated with Centene Corporation® 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, or metastatic;
   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 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, or metastatic;
   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 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*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. NCCN Recommended Uses (off-label) (must meet all):
1. Tevimbra is prescribed in one of the following ways (a, b, or c):
   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;

      **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. Member has liver-confined, unresectable disease and is deemed ineligible for transplant;
   b. Member has extrahepatic, metastatic disease and is deemed ineligible for resection, transplant, or locoregional therapy;
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)**
   ** Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval duration: 6 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Tevimbra for a covered indication and has received this medication for at least 30 days;
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*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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

1. 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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CLL: chronic lymphocytic leukemia
dMMR: deficient mismatch repair
ESCC: esophageal squamous cell carcinoma
FDA: Food and Drug Administration
G/GEJ: gastric or gastroesophageal junction adenocarcinoma
HCC: hepatocellular carcinoma
HER2: human epidermal growth factor receptor 2
MSI-H: microsatellite instability-high
PD-1: programmed death receptor-1
PD-L1: programmed death-ligand 1
POLE/POLD1: polymerase epsilon/delta
SLL: small lymphocytic lymphoma

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 for all relevant lines of business 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.; March 2025. Available at: https://www.beigene.com/PDF/TEVIMBRAUSPI.pdf. Accessed March 17, 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	P&T Approval Date
Policy created	06.20.24	08.24
Added HCPCS code [J9329] and removed HCPCS codes [J3590, C9399]	08.07.24	
RT4: updated criteria to include new indication for G/GEJ.	01.08.25	
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,	03.17.25	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.