# Clinical Policy: Tislelizumab-jsgr (Tevimbra)

Reference Number: LA.PHAR.687
Effective Date: 12.18.24
Last Review Date: 03.11.25~~08.23.24~~
Line of Business: Medicaid

Coding Implications
Revision Log

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

****Please note: This policy is for medical benefit****

## Description

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

## FDA Approved Indication(s)

Tevimbra is indicated~~ for the treatment of adult patients~~:

- As a single agent in adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy ~~without~~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 Louisiana Healthcare Connections 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 ~~unresectable~~one of the following (a or b):
   ~~1.~~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, ~~both~~all of the following (a, b, and ~~b~~c):
   a. Member has had previous treatment 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.~~c. Tevimbra is used as a single-agent;
5. For G/GEJ, all of the following (a, b, c, and d):

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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*).

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

**Approval duration: 6 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 LA.PMN.255 ~~for Medicaid~~
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 LA.PMN.53 ~~for Medicaid~~.

**II. Continued Therapy**

**A. Gastric, Esophageal or Gastroesophageal Junction cancer** (must meet all)**:**

1. Currently receiving medication via Louisiana Healthcare Connections 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 LA.PMN.255 ~~for Medicaid~~
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 LA.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 policy~~ies~~ – refer to LA.PMN.53 ~~for Medicaid or evidence of coverage documents~~.

## 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:<br>• Fluoropyrimidine (e.g., fluorouracil or capecitabine) plus oxaliplatin or cisplatin<br>• | 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 |
|---|---|---|
| ~~Esophageal cancer~~ESCC, G/GEJ | 200 mg IV on Day 1 of every 3-week cycle | See regimen |

## VI. Product Availability

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

## VII. References

1. Tevimbra Prescribing Information. San Mateo, CA: BeiGene USA, Inc.; ~~March~~December 2024. Available at: https://www.beigene.com/PDF/TEVIMBRAUSPI.pdf. Accessed ~~June 20, 2024~~January 8, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at http://www.nccn.org. Accessed ~~June 20, 2024~~January 8, 2025.

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3. National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers, Version ~~3.2023~~5.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed ~~June 20, 2024.~~January 8, 2025.
~~3.~~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.
~~4.~~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 |
|---|---|
| ~~J3590~~J9329 | ~~Unclassified biologics~~Injection, tislelizumab-jsgr, 1 mg |
| ~~C9399~~ | ~~Unclassified drugs or biologicals~~ |

| Reviews, Revisions, and Approvals | Date | LDH Approval Date |
|---|---|---|
| Converted to Local Policy | 08.23.24 | 11.14.24 |
| Updated criteria to include new indication for G/GEJ; reviewed and updated references | 03.11.25 | |

**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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC .

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