

Clinical Policy: Tislelizumab-jsgr (Tevimbra)

Reference Number: LA.PHAR.687
 Effective Date: 12.18.24
 Last Review Date: ~~01.12.2603.11.25~~
 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:

- 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 ~~esophageal squamous cell carcinoma (ESCC)~~ ESCC after prior systemic chemotherapy that did not include a ~~programmed death receptor ligand 1 (PDPD-(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 one of the following (a)ESCC 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, ~~at~~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):
 - ~~4.a.~~ Prescribed as a single agent and ~~e);~~both of the following (i and ii):

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- ~~a.i.~~ Member has had previous treatment with a fluoropyrimidine-based (e.g., 5-fluorouracil, capecitabine) and platinum-based (e.g., ~~carboplatin~~, cisplatin, oxaliplatin) chemotherapy;
 - ~~b.ji.~~ Prior systemic chemotherapy did NOT include a PD-1 or PD-(L)1 inhibitor (e.g., nivolumab, ipilimumab, pembrolizumab);
 - ~~b.~~ Tevimbra Prescribed in combination with platinum (e.g., cisplatin, oxaliplatin)-containing chemotherapy and both of the following (i and ii):
 - ~~i.~~ Request is used as a single agent for first-line treatment or member is planned for esophagectomy;
 - ~~e.ii.~~ Tumor is PD-L1 positive;
- 5-6. For G/GEJ, all of the following (a, b, c, ~~d~~, and ~~e~~):
- ~~a.~~ Disease is unresectable, locally advanced, recurrent, or metastatic;
 - ~~a-b.~~ Disease is HER2-negative;
 - ~~b-c.~~ Tumor is PD-L1 positive;
 - ~~e-d.~~ Request is for first-line treatment;
 - ~~d-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;
- 6-7. 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 bowel 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):

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- 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;
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

B-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 LA.PMN.255
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.

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II. Continued Therapy

A. ~~Gastric, Esophageal or Gastroesophageal Junction cancer~~ All Indications in Section I (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
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.

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 – refer to LA.PMN.53.

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

POLE/POLD1: polymerase epsilon/delta

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

SLL: small lymphocytic lymphoma

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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: <ul style="list-style-type: none"> • <u>Fluoropyrimidine (e.g., fluorouracil or capecitabine) plusPLUS oxaliplatin or cisplatin AND nivolumab or pembrolizumab</u> • <u>Nivolumab and ipilimumab</u> • <u>Fluorouracil and irinotecan</u> • <u>Paclitaxel or docetaxel ± carboplatin or cisplatin</u> 	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

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1. Tevimbra Prescribing Information. San Mateo, CA: BeiGene USA, Inc.; ~~December 2024~~ April 2025. Available at: <https://www.beigene.com/PDF/TEVIMBRAUSPI.pdf>. Accessed ~~January 8~~ April 24, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at <http://www.nccn.org>. Accessed ~~January 8~~ May 16, 2025.
3. National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers, Version ~~5.2024~~ 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf. Accessed ~~January 8~~ May 16, 2025.
4. National Comprehensive Cancer Network. Gastric Cancer Version ~~5.2024~~ 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed ~~January 8~~ May 16, 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.

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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.

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

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	<u>05.19.25</u>
<u>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; for HCC, clarified criterion as first-line systemic therapy and added</u>	<u>01.12.26</u>	

Reviews, Revisions, and Approvals	Date	LDH Approval Date
<u>option to be prescribed as subsequent-line systemic therapy; updated Appendix B; references reviewed and updated.</u>		

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.

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