# Evolent Clinical Guideline 3049 for Tevimbra™ (tislelizumab-jsgr)

| **Guideline Number:** Evolent_CG_3049 | **Applicable Codes** | |
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| **Original Date:** May 2024 | **Last Revised Date:** June 2026 | **Implementation Date:** June 2026 |

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# STATEMENT

## Purpose

To define and describe the accepted indications for Tevimbra (tislelizumab-jsgr) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

# INDICATIONS

**Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided**

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

## Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)

- Tevimbra (tislelizumab-jsgr) may be used in combination with Brukinsa (zanubrutinib) in adult members with CLL/SLL for the histologic (Richter) transformation to diffuse large B-cell lymphoma (clonally related or unknown clonal status). The members have the del(17p)/TP53 mutation, OR are chemotherapy refractory or unable to receive chemoimmunotherapy.

## Colorectal Cancer

- Tevimbra (tislelizumab-jsgr) may be used as a single agent as initial or subsequent therapy in adult members with locally advanced unresectable or metastatic colorectal cancer that is mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) or has polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., TMB >50 mut/Mb), AND the member has no previous treatment with a checkpoint inhibitor.

## Esophageal and Esophagogastric Junction Cancers

- Tevimbra (tislelizumab-jsgr) may be used as monotherapy in adult members with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include an immune checkpoint inhibitor (i.e. nivolumab, pembrolizumab, durvalumab) OR there was no tumor progression while on therapy with a checkpoint inhibitor.
- Tevimbra (tislelizumab-jsgr) may be used in combination with platinum-containing chemotherapy for the first-line treatment of adult members with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 CPS ≥1.
- Tevimbra (tislelizumab-jsgr) may be used in combination with platinum-containing chemotherapy for the first-line treatment of adult members with unresectable or metastatic HER2-negative esophageal adenocarcinoma whose tumors express PD-L1 CPS ≥1, AND if no prior checkpoint inhibitor therapy was used or no tumor progression while on therapy with a checkpoint inhibitor.

## Gastric Cancer

- Tevimbra (tislelizumab-jsgr) may be used in combination with platinum and fluoropyrimidine-based chemotherapy in adult members for the first line treatment of unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 CPS ≥1, AND if no prior checkpoint inhibitor therapy was used or no tumor progression while on therapy with a checkpoint inhibitor.

# CONTRAINDICATIONS/WARNINGS

- None

# EXCLUSION CRITERIA

- Disease progression while taking Tevimbra (tislelizumab-jsgr).
- Dosing exceeds single dose limit of 400 mg.
- Investigational use of Tevimbra (tislelizumab-jsgr) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
    - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published

evidence.

- Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of < 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
- Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
- That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
- That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
- That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

# CODING AND STANDARDS

## Codes

- J9329 - Injection, tislelizumab-jsgr, 1mg

## Applicable Lines of Business

| | |
|---|---|
| ☐ | CHIP (Children's Health Insurance Program) |
| ☒ | Commercial |
| ☒ | Exchange/Marketplace |
| ☒ | Medicaid |
| ☐ | Medicare Advantage |

# POLICY HISTORY

| Date | Summary |
|---|---|
| June 2026 | • Updated maximum dose to “400 mg” under exclusion criteria<br>• Updated references |
| March 2026 | • Added colorectal cancer to indication section<br>• Added gastric cancer to indication section<br>• Updated esophageal cancer indication section<br>• Updated exclusion criteria<br>• Updated references |
| March 2025 | • Converted to new Evolent guideline template<br>• This guideline replaces UM ONC_1499 Tevimbra (tislelizumab-jsgr)<br>• Added new indication<br>• Updated references |
| May 2024 | • New Drug Policy |

# LEGAL AND COMPLIANCE

## Guideline Approval

### *Committee*

**Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee**

## Disclaimer

*Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider*

*agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.*

# REFERENCES


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