Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
Tislelizumab-jsgr (Tevimbra®)	**MP-RX-FP-155-24**	☒ **MMM MA** ☒ **MMM MultiHealth**	**8/7/2024**	**5/6/2026**
			Last Review Date: **5/6/2026**	**Frequently Revision:** **Annual**

Service Category:

- ☐ Anesthesia
- ☐ Surgery
- ☐ Radiology Procedures
- ☐ Pathology and Laboratory Procedures
- ☐ Medicine Services and Procedures
- ☐ Evaluation and Management Services
- ☐ DME/Prosthetics or Supplies
- ☒ Other: Part B Drugs

Service Description:

This document addresses the use of Tislelizumab-jsgr (Tevimbra®), a programmed death receptor-1 (PD-1)–blocking antibody approved by the Food and Drug Administration (FDA) for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor. Also, for treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC), for the first-line treatment, in combination with platinum-containing chemotherapy whose tumors express PD-L1 (≥1). Tislelizumab-jsgr (Tevimbra®) is approved in Gastric Cancer for the treatment of adult patients for the first line treatment of unresectable or metastatic HER2 negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (≥1), in combination with platinum and fluoropyrimidine-based chemotherapy.

Background Information:

The FDA approved Tevimbra based on the results of the RATIONALE 302 trial, a multicenter, international, randomized, open-label, phase III study that included 512 patients. This study assessed the efficacy and safety of tislelizumab compared to the investigator's choice of chemotherapy as a **second-line treatment for unresectable, locally advanced, or metastatic esophageal squamous cell carcinoma.**

RATIONALE 302 demonstrated a statistically significant and clinically meaningful improvement in survival for patients treated with tislelizumab over those receiving chemotherapy. In the Intention to Treat population, the median overall survival for the tislelizumab group was 8.6 months (95% confidence interval [CI] = 7.5–10.4 months) compared to 6.3 months (95% CI = 5.3–7.0 months) for the chemotherapy group (P = .0001; hazard ratio = 0.70, 95% CI = 0.57–0.85).

Regarding safety, tislelizumab showed a more favorable profile than chemotherapy. The most common adverse events reported in the trial included increased glucose levels, decreased hemoglobin, decreased lymphocytes, decreased sodium, decreased albumin, increased alkaline phosphatase, anemia, fatigue, elevated AST, musculoskeletal pain, weight loss, increased ALT, and cough. Prescribing information for Tevimbra also includes warnings and precautions related to immune-mediated adverse reactions, infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation, and embryo-fetal toxicity.

Tevimbra has an approved indication for **first line treatment of adult patients with ESCC which expands first-line treatment** options for patients with this disease. The additional indication is based on results from BeiGene's RATIONALE-306, a randomized, placebo-controlled, double-blind, global Phase 3 study to evaluate the efficacy and safety of TEVIMBRA in combination with platinum-containing chemotherapy as a first-line treatment in adult patients (n=649) with unresectable, locally advanced recurrent or metastatic ESCC. The study met its primary endpoint and demonstrated a statistically significant improvement in overall survival (OS) for

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adult patients randomized to TEVIMBRA in combination with chemotherapy compared to placebo in combination with chemotherapy. Exploratory analyses indicated that the improvement in the intent-to-treat (ITT) population was primarily attributed to the results observed in the subgroup of patients with PD-L1 ≥1. Analysis of OS in the PD-L1 positive (≥1) population (n=481) showed a median OS of 16.8 months for patients treated with TEVIMBRA plus chemotherapy compared to 9.6 months for patients treated with placebo plus chemotherapy (HR: 0.66, [95% CI: 0.53, 0.82]), resulting in a 34% reduction in the risk of death. These results represent an unprecedented improvement in OS in first-line ESCC patients.

The safety of TEVIMBRA in combination with chemotherapy was evaluated in the same global clinical trial, RATIONALE-306. The most frequent serious adverse reactions (≥2%) were pneumonia, dysphagia, diarrhea, fatigue, and esophageal stenosis. The most common (≥20%) adverse reactions were anemia, fatigue, decreased appetite, nausea, constipation, decreased weight, diarrhea, peripheral sensory neuropathy, vomiting, and stomatitis.

The FDA also approved Tevimbra for the treatment **of gastric or gastroesophageal junction cancers in PD-L1** positive adult patients. The indication for first-line G/GEJ cancers is based on results from RATIONALE-305, a randomized, double-blind, placebo-controlled, global Phase 3 trial to evaluate the efficacy and safety of TEVIMBRA in combination with chemotherapy as a first-line treatment for adult patients with advanced unresectable or metastatic G/GEJ cancer. The study met its primary endpoint and demonstrated a statistically significant and clinically meaningful overall survival (OS) benefit with a median OS of 15.0 months for patients treated with TEVIMBRA in combination with the investigator's choice of chemotherapy compared to 12.9 months for patients treated with placebo plus chemotherapy (n=997; HR: 0.80 [95% CI: 0.70, 0.92]; P=0.0011), resulting in a 20% reduction in the risk of death.

The pooled safety data in the application included 1,972 patients who received TEVIMBRA monotherapy in two randomized open-label, active-controlled studies (RATIONALE-302, BGB-A317-303) and five open-label, single-arm studies (BGB-A317-208, BGB-A317-204, BGB-A317-203, BGB-A317-102, BGB A317_Study_001), which enrolled 307 patients with esophageal squamous cell carcinoma and 1,665 patients with advanced or recurrent tumors. The most common Grade 3 or 4 adverse reactions for TEVIMBRA given in combination with chemotherapy were neutropenia, thrombocytopenia, anemia, fatigue, hypokalemia, hyponatremia, pneumonia, decreased appetite, rash, lymphopenia, alanine aminotransferase increased, aspartate aminotransferase increased, diarrhea, pneumonitis, and hepatitis.

NCCN Compendial Uses: 1. Esophageal cancer/esophagogastric junction cancer 2. Hepatocellular carcinoma 3. Histologic (Richter) transformation to diffuse large B-cell lymphoma 4. Gastric cancer 5. Small bowel adenocarcinoma 6. Anal carcinoma 7. Head and neck cancer 8. Colon cancer 9. Colorectal cancer 10. Appendiceal cancer 11. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma 12. Uterine/endometrial cancer 13. Hodgkin Lymphoma.

Tevimbra is supplied as a 100mg/10mL solution in a single-dose vial and is administered via intravenous infusion once every three weeks. Dosage adjustments may be necessary to manage adverse reactions.

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Definitions and Measures

- ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:
  - 0 = Fully active, able to carry on all pre-disease performance without restriction
  - 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
  - 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
  - 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
  - 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
  - 5 = Dead
- Karnofsky Performance Status: A scale and criteria used by doctors and researchers to assess an individual's prognosis, measure changes in their function and abilities, and determine their ability to tolerate therapies. The lower the score (from 0-100), the worse the likelihood of survival.
  - 100 = Normal, no complaints
  - 90 = Able to carry on normal activities
  - 80 = Normal activity with effort
  - 70 = Care for self. Unable to carry on normal activity or to do active work
  - 60 = Requires occasional assistance, but able to care for most of his needs
  - 50 = Requires considerable assistance and frequent medical care
  - 40 = Disabled. Requires special care and assistance
  - 30 = Severely disabled. Hospitalization indicated though death nonimminent
  - 20 = Very sick. Hospitalization necessary. Active supportive treatment necessary
  - 10 = Moribund
  - 0 = Dead
- Line of Therapy:
  - First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.

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- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

- Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.
- Programmed death (PD)-1: PD-1 proteins are found on T-cells and attach to PD ligands (PD-L1) found on normal (and cancer) cells (see immune checkpoint inhibitor above). Normally, this process keeps T-cells from attacking other cells in the body. Examples of FDA approved PD-1 inhibitors include Keytruda (pembrolizumab), Opdivo (nivolumab), and Libtayo (cemiplimab).
- Programmed death ligand (PD-L)-1: The ligands found on normal (and cancer) cells to which the PD-1 proteins attach (see immune checkpoint inhibitor above). Cancer cells can have large amounts of PD-L1 on their surface, which helps them to avoid immune attacks. Examples of FDA approved PD-L1 inhibitors include Bavencio (avelumab), Tecentriq (atezolizumab), and Imfinzi (durvalumab).
- Unresectable: Unable to be removed with surgery.

Approved Indications

Tislelizumab-jsgr (Tevimbra®) is approved by the FDA for the treatment of:

A. Adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.

B. Adult patients with unresectable or metastatic esophageal squamous cell carcinoma (ESCC), for the first-line treatment, in combination with platinum-containing chemotherapy whose tumors express PD-L1 (≥1).

C. Adult patients for the first line treatment of unresectable or metastatic HER2 negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (≥1), in combination with platinum and fluoropyrimidine-based chemotherapy.

Other Uses

A. See Background section above.

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Medical Necessity Guidelines:

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Tislelizumab-jsgr (Tevimbra®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

Requests for Tislelizumab-jsgr (Tevimbra®) may be approved if the following criteria are met:

i. Individual has a diagnosis of unresectable or metastatic esophageal squamous cell carcinoma (ESCC); (Label, NCCN 1); **AND**
   - A. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-1; **AND**
   - B. Individual is using Tevimbra (tislelizumab-jsgr) in combination with platinum-containing chemotherapy as first line of therapy.

OR

ii. Individual has a diagnosis of unresectable locally advanced, recurrent or metastatic with esophageal or esophagogastric junction squamous cell carcinoma (ESCC); (NCCN 1, 2A); **AND**
   - A. Individual is using as palliative therapy for patients with PD-L1 CPS ≥ 1; **AND**
   - B. **AND**
   - C. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 or Karnofsky performance score ≥60%; **AND**
   - D. Individual is using Tevimbra (tislelizumab-jsgr) in combination with platinum-containing chemotherapy as first line of therapy.

OR

iii. Individual has a diagnosis of unresectable locally advanced, recurrent or metastatic with esophageal or esophagogastric junction Adenocarcinoma (ESCC); (NCCN 1, 2A); **AND**
   - A. Individual is using as palliative therapy for patients HER2 negative with PD-L1 CPS ≥ 1; **AND**
   - B. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 or Karnofsky performance score ≥60%; **AND**
   - C. Individual is using Tevimbra (tislelizumab-jsgr) in combination with platinum-containing chemotherapy as first line of therapy.

OR

iv. Individual has a diagnosis of unresectable, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC); (Label, NCCN 1); **AND**
   - A. Disease has progressed during or after first-line treatment; **AND**
   - B. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 or Karnofsky performance score ≥60%; **AND**
   - C. Individual is using as a single agent**.**

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v. Individual has a diagnosis of esophageal and esophagogastric junction cancer (NCCN 1); **AND**
   - A. Individual is using for induction systemic therapy for relieving dysphagia; **AND**
   - B. Individual has PD-L1 CPS ≥1; **AND**
   - C. Using in combination with chemotherapy;

OR

vi. Individual has a diagnosis of gastric cancer (gastric or gastroesophageal junction adenocarcinoma) (Label, NCCN 1, 2A); **AND**
   - A. Individual has either unresectable, recurrent or metastatic HER2-negative disease; **AND**
   - B. Individual has a tumor which expresses PD-L1 (≥1); **AND**
   - C. Individual is using as first-line therapy; **AND**
   - D. Individual has not received another anti-PD-1 or anti-PD-L1 agent or any other antibody or drug specifically targeting T-cell co-stimulation or checkpoint pathways; **AND**
   - E. Individual is using in combination with platinum and fluoropyrimidine-based chemotherapy**; AND**
   - F. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-2 or Karnofsky performance score ≥60%; **AND**

OR

vii. Individual is using for Chronic lymphocytic leukemia/Small lymphocytic leukemia (CLL/SLL) (NCCN 2A); **AND**
   - A. Individual is using Tevimbra (tislelizumab-jsgr) in combination with Brukinsa (zanubrutinib) for histologic (Richter) transformation.

OR

viii. Individual has a diagnosis of hepatocellular carcinoma (NCCN 1, 2A); **AND**
   - A. Individual is using as a single agent.

OR

ix. Individual has a diagnosis of colorectal cancer (NCCN 2A); **AND**
   - A. Individual has one of the following mutations:
     1. dMMR/MSI-H (deficient mismatch repair/microsatellite instability-high); **OR**
     2. POLE/POLD1 (polymerase epsilon/delta) with ultra-hypermutated phenotype (e.g. TMB > 50 mut/Mb); **AND**
   - B. Individual is using as a single agent;

OR

x. Individual has a diagnosis of Head and Neck (NCCN 2A); **AND**
   - A. Individual has nasopharyngeal cancer with histology of squamous cell carcinoma or mixed subtypes; **AND**
   - B. Individual is using as first line therapy or subsequent line in combination with cisplatin and gemcitabine; **AND**
   - C. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-1

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xi. Individual has a diagnosis of Classic Hodgkin Lymphoma with primary refractory disease or relapse (NCCN 2A); **AND**
   A. Individual is using as second-line therapy or subsequent systemic therapy; **AND**
   B. Individual is using in combination with GEMOX (gemcitabine, oxaliplatin)

OR

xii. Individual has a diagnosis of Endometrial Carcinoma/Uterine Neoplasm (NCCN 2A); **AND**
   A. Individual is using as Second-line or subsequent therapy; **AND**
   B. Individual is using as a single agent; **AND**
   C. Individual express biomarker microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors

OR

xiii. Individual has a diagnosis of metastatic anal squamous cell carcinoma (NCCN 2A); **AND**
   A. Individual is using as second-line and subsequent therapy; **AND**
   B. Individual is using as a single agent or in combination with paclitaxel and carboplatin; **AND**
   C. Individual has not received a prior anti-PD-1 or anti-PD-L1 agent;

OR

xiv. Individual has a diagnosis of appendiceal carcinoma (NCCN 2A); **AND**
   A. Individual has a diagnosis of advanced or metastatic disease; **AND**
   B. Individual has one of the following mutations:
      1. dMMR/MSI-H (deficient mismatch repair/microsatellite instability-high); **OR**
      2. POLE/POLD1 (polymerase epsilon/delta) with ultra-hypermutated phenotype (e.g. TMB > 50 mut/Mb); **AND**
   C. Individual is using as a single agent; **AND**
   D. Individual has not received a prior anti-PD-1 or anti-PD-L1 agent;

OR

xv. Individual has a diagnosis of small bowel adenocarcinoma (NCCN 2A); **AND**
   A. Individual has one of the following mutations:
      1. dMMR/MSI-H (deficient mismatch repair/microsatellite instability-high); **OR**
      2. POLE/POLD1 (polymerase epsilon/delta) with ultra-hypermutated phenotype (e.g. TMB > 50 mut/Mb); **AND**
   B. Individual is using as a single agent.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Tislelizumab-jsgr (Tevimbra®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:
   A. A current oncology note documenting the patient's response to treatment showing no progression of disease.

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B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Requests for tislelizumab-jsgr (TEVIMBRA) may not be approved when the above criteria are not met and for all other indications.
ii. Requests for tislelizumab-jsgr (TEVIMBRA) may not be approved when the requested use does not meet the applicable FDA-labeled indication or NCCN-supported use outlined in this policy, including but not limited to failure to meet required tumor type, biomarker, line of therapy, combination regimen, or performance status criteria.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing Schedule
Tislelizumab-jsgr (Tevimbra®) injection 100 mg/10mL (10mg/mL) solution in a single dose vial	Esophageal Cancer: • 150 mg every 2 weeks or 200 mg every 3 weeks or 300 mg every 4 weeks or 400 mg every 6 weeks in combination with platinum-containing chemotherapy for first-line treatment of unresectable or metastatic ESCC. • 150 mg every 2 weeks or 200 mg every 3 weeks or 300 mg every 4 weeks or 400 mg every 6 weeks as a single agent for treatment of unresectable or metastatic ESCC. Gastric Cancer: • 150 mg every 2 weeks or 200 mg every 3 weeks or 300 mg every 4 weeks or 400 mg every 6 weeks in combination with platinum and fluoropyrimidine-based chemotherapy.
Exceptions	
• Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment.	

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
C11.0-C11.9	Malignant neoplasm of nasopharynx
C14.0-C14.2	Malignant neoplasm of pharynx, unspecified
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0-C16.6	Malignant neoplasm of stomach
C16.8-C16.9	Malignant neoplasm of stomach
C17.0-C17.9	Malignant neoplasm of small intestine
C18.0-C18.9	Malignant neoplasm of colon
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0-C21.8	Malignant neoplasm of anus and anal canal
C22.0	Liver cell carcinoma
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C30.0	Malignant neoplasm of nasal cavity
C54.0-C54.3	Malignant neoplasm of corpus uteri (specific portions)
C54.8-C54.9	Malignant neoplasm of overlapping sites of corpus uteri
C55	Malignant neoplasm of uterus, part unspecified
C78.00-C78.02	Secondary malignant neoplasm of lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C79.89	Secondary malignant neoplasm of other specified sites
C81.10-81.99	Hodgkin lymphoma (various subtypes)
C83.00-C83.09	Small cell B-cell lymphoma
C83.30-83.39	Diffuse large B-cell lymphoma
C91.10-C91.12	Chronic lymphocytic leukemia of B-cell type
D37.05	Neoplasm of uncertain behavior of stomach
D37.1	Neoplasm of uncertain behavior of small intestine
D37.3	Neoplasm of uncertain behavior of appendix
D37.8	Neoplasm of uncertain behavior of other specified digestive organs

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D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
D38.5- D38.6	Neoplasm of uncertain behavior of other respiratory organs
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.028	Personal history of malignant neoplasm of other stomach
Z85.038	Personal history of malignant neoplasm of other large intestine
Z85.069	Personal history of malignant neoplasm of other digestive organs
Z85.42	Personal history of malignant neoplasm of uterus
Z85.71	Personal history of Hodgkin lymphoma
Z85.818	Personal history of malignant neoplasm of other sites

HCPCS Codes:

Codes	Description
J9329	Injection, tislelizumab-jsgr, 1mg [Tevimbra]

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Reference Information:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2026. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. U.S. Food and Drug Administration. Tevimbra (tislelizumab-jsgr) prescribing information.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2026; Updated periodically.
6. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Various tumor types listed above. Available at https://www.nccn.org. Accessed on February 18, 2026
    a. Esophageal and Esophagogastric Junction Cancers. V2.2026. Revised Feb 18, 2026.
    b. Gastric Cancer. V2.2026. Revised Feb 17, 2026.
    c. Hepatobiliary Cancers (Hepatocellular Carcinoma). V2.2025. Revised Feb 18, 2026
    d. Colon Cancer. V5.2025. Revised Feb 18, 2026
    e. Rectal Cancer. V4.2025. Revised Feb 17, 2026
    f. Anal Carcinoma. V1.2026. Revised Feb 18, 2026
    g. Small Bowel Adenocarcinoma. V1.2026. Revised Feb 18, 2026
    h. Appendiceal Neoplasms. V1.2026. Revised Feb 16, 2026
    i. Head and Neck Cancers (including Nasopharyngeal Cancer). V1.2026. Revised Feb 16, 2026
    j. B-Cell Lymphomas (Diffuse Large B-Cell Lymphoma). V1.2026. Revised Feb 18, 2026
    k. Hodgkin Lymphoma. V1.2026. Revised Feb 18, 2026
    l. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. V2.2026. Revised Feb 17, 2026.
    m. Uterine Neoplasms / Endometrial Carcinoma. V2.2026. Revised Feb 18, 2026.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	The policy was expanded to add several new medically necessary tumor-specific uses, primarily based on NCCN Category 2A recommendations, including hepatocellular carcinoma, biomarker-defined colorectal, appendiceal, and small bowel cancers, nasopharyngeal carcinoma, relapsed/refractory classic Hodgkin lymphoma, MSI-H/dMMR endometrial carcinoma, metastatic anal carcinoma, and Richter transformation to diffuse large B-cell lymphoma. ESCC criteria were broadened by updating disease terminology to unresectable, locally advanced, recurrent, or metastatic disease; adding new first-line and palliative use scenarios, including PD-L1 CPS ≥1 and HER2-negative/PD-L1-positive pathways; clarifying subsequent-line single-agent use after progression; and expanding performance status criteria from ECOG 0–1 to 0–2 or Karnofsky ≥60% for multiple indications. Gastric/GEJ criteria were also refined by maintaining HER2-negative and PD-L1 ≥1 requirements while broadening disease description and ECOG eligibility. In addition, the background and evidence sections were updated with newer trial data, NCCN references were refreshed to current versions, and the ICD-10 list was expanded to reflect the newly added indications. Dosing table was updated and an administrative update was completed to incorporate new policy template.	5/1/2026	5/6/2026
Annual Review	Coding changes: J3590 and J9999 removed. Indication for the first line therapy of ESCC in combination with platinum containing chemotherapy added. Indication for the first line treatment of unresectable or metastatic HER2- negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1, in combination with platinum and fluoropyrimidine-based chemotherapy. Use in combination with Brukinsa (zanubrutinib) for the treatmen of CLL/SLL with 17p deletion (CIT is not preferred), added to NCCN as a 2A recommendation.	7/17/2025	8/8/2025
Policy Inception	New Medical Policy creation	7/29/2024	8/7/2024