Tevimbra® (tislelizumab-jsgr)
(Intravenous)

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I. Length of Authorization Δ

- Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- Esophageal and Esophagogastric Junction Cancers & Gastric and Gastroesophageal Junction Cancers: 1200 billable units every 84 days
- All Other Indications: 200 billable units every 21 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy, unless otherwise specified Δ; **AND**

Esophageal and Esophagogastric Junction Cancers † ‡ Φ [1-3]

- Patient is medically fit and planned for esophagectomy; **AND**
  - Used as induction systemic therapy for relieving dysphagia; **AND**
  - Patient has cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3 cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; **AND**
    - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test❖; **AND**
      - Used in combination with platinum- and fluoropyrimidine-based chemotherapy; **AND**
      - Patient has squamous cell carcinoma, **OR**
- Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; **AND**

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- Used as first-line therapy; **AND**
  - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test❖; **AND**
    - Patient has human epidermal growth factor receptor 2 (HER2)-negative adenocarcinoma; **AND**
      - Used in combination with platinum- and fluoropyrimidine-based chemotherapy, **OR**
    - Patient has squamous cell carcinoma; **AND**
      - Used in combination with platinum- and fluoropyrimidine-based chemotherapy, **OR**
- Used as subsequent therapy; **AND**
  - Used as a single agent; **AND**
  - Patient has esophageal squamous cell carcinoma (ESCC) †

Gastric and Gastroesophageal Junction Cancers † ‡ Φ [1]

- Used in combination with a fluoropyrimidine- and platinum-containing chemotherapy-based regimen; **AND**
- Patient is not a surgical candidate or has unresectable, locally advanced, recurrent, or metastatic disease; **AND**
- Used as first-line therapy; **AND**
- Patient has HER2-negative disease; **AND**
- Tumor expresses PD-L1 (CPS ≥1) as determined by an FDA-approved or CLIA-compliant test❖

Hepatocellular Carcinoma ‡ [3]

- Used as single-agent therapy; **AND**
- Used as first-line systemic therapy; **AND**
  - Patient has liver-confined, unresectable disease and are deemed ineligible for transplant, **OR**
  - Patient has extrahepatic/metastatic disease and are deemed ineligible for resection, transplant, or locoregional therapy

Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma ‡ [3,5]

- Used in combination with zanubrutinib for histologic (Richter) transformation to diffuse large B-cell lymphoma; **AND**
  - Patient has del(17p)/TP53 mutation, **OR**
  - Patient is chemotherapy refractory or unable to receive chemoimmunotherapy

Head and Neck Cancers ‡ [3,6]

- Patient has Cancer of the Nasopharynx; **AND**

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- Used as subsequent therapy; **AND**
- Used in combination with cisplatin and gemcitabine for oligometastatic or metastatic disease, **OR**

- Patient has Very Advanced Head and Neck Cancer*****; **AND**
  - Patient has nasopharyngeal cancer; **AND**
  - Patient has a performance status 0-1; **AND**
  - Used as subsequent therapy in combination with cisplatin and gemcitabine; **AND**
    - Used for one of the following:
      - Unresectable locoregional recurrence with prior radiation therapy (RT)
      - Unresectable second primary with prior RT
      - Unresectable persistent disease with prior RT
      - Recurrent/persistent disease with distant metastases

***** *Very Advanced Head and Neck Cancer includes Newly diagnosed locally advanced T4b (M0) disease; newly diagnosed unresectable regional nodal disease (typically N3); metastatic disease at initial presentation (M1); or recurrent or persistent disease.*

Small Bowel Adenocarcinoma ‡ [3,7]

- Used as single agent treatment; **AND**
- Patient has microsatellite instability-high (MSI-H)/deficient mismatch repair (dMMR) disease OR polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) > 50 mut/Mb] as determined by an FDA-approved or CLIA-compliant test❖; **AND**
  - Patient has advanced or metastatic disease, **OR**
  - Patient has locally unresectable or medically inoperable disease; **AND**
    - Used as primary treatment

Anal Carcinoma ‡ [3,8]

- Patient has metastatic squamous cell carcinoma; **AND**
- Used as a single agent as subsequent therapy

Colon Cancer ‡ [3,12]

- Used as single agent treatment; **AND**
- Patient has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype [e.g., TMB > 50 mut/Mb] as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used for locally unresectable, medically inoperable, advanced, or metastatic disease

Appendiceal Adenocarcinoma – Colon Cancer ‡ [3,12]

- Used as single agent treatment; **AND**

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- Patient has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype [e.g., TMB > 50 mut/Mb] as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Patient has advanced or metastatic disease

Rectal Cancer ‡ [3,13]

- Used as single agent treatment; **AND**
- Patient has MSI-H/dMMR disease OR POLE/POLD1 mutation with ultra-hypermutated phenotype [e.g., TMB > 50 mut/Mb] as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used for advanced or metastatic disease

❖ *If confirmed using an FDA approved assay – http://www.fda.gov/CompanionDiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria Δ [1,3]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe or life-threatening infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash, etc.), complications of allogeneic hematopoietic stem cell transplantation (HCST), etc.

Δ **Notes:**

- Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration are eligible to re-initiate PD-directed therapy.
- Patients previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy without interruption or discontinuation.
- Patients who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.

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V. Dosage/Administration Δ [1,4,7-10]

Indication	Dose
Esophageal and Esophagogastric Junction Cancers & Gastric and Gastroesophageal Junction Cancers	• Administer 150 mg intravenously once every 2 weeks, until disease progression or unacceptable toxicity: **OR** • Administer 200 mg intravenously once every 3 weeks, until disease progression or unacceptable toxicity: **OR** • Administer 300 mg intravenously once every 4 weeks, until disease progression or unacceptable toxicity
All Other Indications	Administer 200 mg intravenously once every 3 weeks, until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code:

- J9329 – Injection, tislelizumab-jsgr, 1 mg; 1 billable unit = 1 mg

NDC:

- Tevimbra 100 mg/10 mL single-dose vial: 72579-0121-xx

VII. References

1. Tevimbra [package insert]. San Mateo, CA; BeiGene USA, Inc.; April 2025. Accessed April 2025.
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5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma, Version 2.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National

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7. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Small Bowel Adenocarcinoma, Version 2.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed March 2025.
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13. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) Rectal Cancer, Version 1.2025. National Comprehensive Cancer Network, 2025. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed March 2025.

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C11.0	Malignant neoplasm of nasopharynx
C11.1	Malignant neoplasm of posterior wall of nasopharynx
C11.2	Malignant neoplasm of lateral wall of nasopharynx
C11.3	Malignant neoplasm of anterior wall of nasopharynx
C11.8	Malignant neoplasm of overlapping sites of nasopharynx
C11.9	Malignant neoplasm of nasopharynx, unspecified
C14.0	Malignant neoplasm of pharynx, unspecified
C14.2	Malignant neoplasm of Waldeyer's ring
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	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon

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ICD-10	ICD-10 Description
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, 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
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left 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
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face, and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C83.30	Diffuse large B-cell lymphoma, unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma, intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma, intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb

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ICD-10	ICD-10 Description
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma, intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma, lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma, extranodal and solid organ sites
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
D37.05	Neoplasm of uncertain behavior of pharynx
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
D38.5	Neoplasm of uncertain behavior of other respiratory organs
D38.6	Neoplasm of uncertain behavior of respiratory organ, unspecified
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 other malignant neoplasm of stomach
Z85.068	Personal history of other malignant neoplasm of small intestine

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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