Medical Drug Clinical Criteria

Subject:	**Tevimbra (tislelizumab-jsgr)**		
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Overview

This document addresses the use of Tevimbra (tislelizumab-jsgr). Tevimbra is a programmed death receptor-1 (PD-1) blocking antibody. The FDA approved indication for Tevimbra includes use in 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. Tevimbra also is FDA indicated in combination with platinum and fluoropyrimidine-based chemotherapy, is indicated for the first-line treatment of adults with unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma (G/GEJ) whose tumors express PD-L1 (≥1).

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

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.

Clinical Criteria

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.

Tevimbra (tislelizumab-jsgr)

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

I. Individual has a diagnosis of unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma (ESCC); (Label, NCCN 1); **AND**
   ~~II.~~ A. Disease has progressed during or after first-line treatment for advanced unresectable/metastatic ESCC; **AND**

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~~III.~~B. Individual has a current Eastern Cooperative Oncology Group (ECOG) performance status of 0-1; **AND**
~~IV.~~C. Individual is using as a single agent.

OR

~~V.~~II. Individual has a diagnosis of unresectable locally advanced, recurrent, or metastatic gastric cancer (gastric or gastroesophageal junction adenocarcinoma) (Label, NCCN 1, 2A); **AND**
~~VI.~~A. Individual has either unresectable or metastatic HER2-negative disease; **AND**
~~VII.~~B. Individual has a tumor which expresses PD-L1 (≥1); **AND**
~~VIII.~~C. Individual is using as first-line therapy; **AND**
~~IX.~~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**
~~X.~~E. Individual is using in combination with platinum and fluoropyrimidine-based chemotherapy; **AND**
~~XI.~~F. Individual has a current ECOG performance status of 0-1;

OR

III. 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 platinum and fluoropyrimidine-based chemotherapy;

OR

~~I.~~IV. Individual ~~is using for~~has a diagnosis of Chronic lymphocytic leukemia/Small lymphocytic leukemia (CLL/SLL) with 17p deletion (NCCN 2A); **AND**
A. Individual is using Tevimbra (tislelizumab-jsgr) in combination with Brukinsa (zanubrutinib); **AND**
B. Individual is chemotherapy refractory or unable to receive chemoimmunotherapy;

OR

V. Individual has a diagnosis of metastatic anal carcinoma; **AND**
A. Individual is using as second-line and subsequent therapy; **AND**
B. Individual is using as a single agent; **AND**
C. Individual has not received a prior anti-PD-1 or anti-PD-L1 agent;

OR

VI. Individual has a diagnosis of colorectal cancer, including small bowel adenocarcinoma; **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

VII. Individual has a diagnosis of head and neck cancer of the nasopharynx (NCCN 2A); **AND**
A. Individual has squamous cell carcinoma and is using as systemic therapy; **AND**
B. Individual is using in combination for subsequent-line therapy with cisplatin and gemcitabine; **AND**
C. Individual has a current ECOG performance status of 0-2;

OR

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

~~II.~~

Requests for Tevimbra (tislelizumab-jsgr) may not be approved for the following:

I. When using for ESCC:
A. Individual has used two or more prior systemic treatments for advanced/metastatic unresectable ESCC; **OR**
B. Individual has uncontrollable pleural effusion, pericardial effusion, or ascites requiring frequent drainage; **OR**

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C. Individual received prior therapies targeting programmed death 1 (PD-1) or programmed death ligand 1 (PD-L1); **OR**
D. Individual has active brain or leptomeningeal metastasis; **OR**
E. Individual has active autoimmune disease or history of autoimmune disease at high risk for relapse; **OR**
F. Individual has known history of, or any evidence of interstitial lung disease, non-infectious pneumonitis, pulmonary fibrosis diagnosed based on imaging or clinical findings, or uncontrolled systemic diseases, including diabetes, hypertension, acute lung disease, etc; **OR**

II. When using for gastric cancer:
A. Individual has squamous cell or undifferentiated or other histological type gastric cancer; **OR**
B. Individual has active leptomeningeal disease or uncontrolled brain metastasis; **OR**
C. Individual has active autoimmune disease or history of autoimmune disease, or a medical condition requiring systemic corticosteroids or immunosuppressants; **OR**

III. When the above criteria are not met, and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

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

ICD-10 Diagnosis

C11.0-C11.9	Malignant neoplasm of nasopharynx
C15.3-C15.9	Malignant neoplasm of esophagus
C16.0-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
C83.00-C83.09	Small cell B-cell lymphoma
C83.30-C83.38	Diffuse large B-cell lymphoma
C83.398	Diffuse large B-cell lymphoma of other extranodal and solid organ sites
C91.10-C91.12	Chronic lymphocytic leukemia of B-cell type
Z85.01	Personal history of malignant neoplasm of esophagus

Document History

Revised: 05/16/2025
Document History:

- 05/16/2025 – Annual Review: Add the following NCCN recommendations: Esophageal squamous cell carcinoma, Gastric and GEJ cancers--Clarified existing criteria for use in for use in unresectable locally advanced, recurrent or metastatic cancer, Add category 1 recommendation for use in induction therapy for relieving dysphagia in combination with platinum and fluoropyrimidine-based chemotherapy;. CLL/SLL--Add clarification for use in those who are chemotherapy refractory or unable to receive chemoimmunotherapy; Anal Carcinoma--Add criteria for use in second-line and subsequent therapy as a single agent; Colorectal Cancer--Add criteria for use in mutation specific cancer (dMMR/MSI-H or POLE/POLD1); Head and neck

cancer of the nasopharynx--Add criteria for combination use in squamous cell carcinoma as systemic therapy with cisplatin and gemcitabine; Hepatocellular carcinoma--Add criteria for use as a single-agent. Coding Reviewed: Added ICD-10-CM C11.0-C11.9, C17.0-C21.8, C22.0, C22.8, C22.9, C30.0.

- 02/21/2025 – Select: Add new FDA indication for use in gastric cancer. Add NCCN recommendation for use in CLL/SLL with Brukinsa (zanubrutinib). Update may not be approved section. Coding Reviewed: Consolidated ICD-10-CM C15.3-C15.9 into one range and updated description. Added C16.0-C16.9, C83.00-C83.09, C83.30-C83.38, C83.398, C91.10-C91.12.
- 05/17/2024 – Select Review: New criteria document for Tevimbra PA. Coding Reviewed: Added HCPCS J3590, J9999. Added All diagnoses pend. CMS Update: Remove HCPCS J3590 and J9999 and replace with J9329 and add ICD-10-CM C15.3, C15.4, C15.5, C15.8, C15.9, Z85.01.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on April 9, 2025.
    a. Anal Carcinoma. V3.2025. Revised March 31, 2025.
    b. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. V1.2025. Revised October 1, 2024.
    c. Colon Cancer. V2.2025. Revised March 31, 2025.
    d. Esophageal and esophagogastric junction cancers. V2.2025. Revised March 25, 2025.
    e. Hepatocellular Carcinoma. V1.2025. Revised March 20, 2025.
    f. Rectal Cancer. V2.2025. Revised March 31, 2025.
    g. Small Bowel Adenocarcinoam. V3.2025. Revised March 31, 2025.

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.