Reference number(s)
6423-A

Standard Medicare Part B Management Tevimbra

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tevimbra	tislelizumab-jsgr

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Esophageal Cancer

- Tevimbra, in combination with platinum-containing chemotherapy, is indicated for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1).
- Tevimbra as a single agent, is indicated for the treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.

Gastric Cancer

Tevimbra, 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).

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Compendial Uses[2]

- Esophageal cancer/esophagogastric junction cancer
- Hepatocellular carcinoma
- Histologic (Richter) transformation to diffuse large B-cell lymphoma
- Gastric cancer
- Small bowel adenocarcinoma
- Anal carcinoma
- Head and neck cancer
- Colon cancer
- Appendiceal cancer
- Rectal cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all submissions:

- Documentation of programmed death ligand 1 (PD-L1) tumor expression, where applicable.
- Documentation of laboratory report confirming MSI-H, mismatch repair deficient (dMMR) or polymerase epsilon/delta (POLE/POLD1) tumor status, where applicable.
- Documentation of human epidermal growth factor receptor 2 (HER2) status, where applicable.

Exclusions

Coverage will not be provided for members who have experienced progression while on PD-1 or PD-L1 therapy.

Coverage Criteria

Esophageal Cancer[1,2]

Authorization of 12 months may be granted for the treatment of esophageal and esophagogastric junction cancer in members who are not surgical candidates or have unresectable, recurrent, or metastatic disease when the requested medication will be used for any of the following:

- First-line therapy for members with PD-L1 ≥1 and squamous cell carcinoma or HER2-negative adenocarcima in combination with platinum-containing chemotherapy

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- Subsequent therapy for esophageal squamous cell carcinoma as a single agent

Authorization of 12 months may be granted for induction therapy for relieving dysphagia in combination with platinum-containing chemotherapy for members with PD-L1 ≥1 planned for esophagectomy.

Hepatocellular Carcinoma[2-4]

Authorization of 12 months may be granted as a single agent for the first line treatment of hepatocellular carcinoma when either of the following criteria are met:

- Member has unresectable disease and is ineligible for transplant.
- Member has extrahepatic/metastatic disease and is ineligible for resection, transplant, or locoregional therapy.

Authorization of 12 months may be granted as a single agent for the subsequent treatment of unresectable or extrahepatic/metastatic hepatocellular carcinoma.

Histologic (Richter) transformation to diffuse large B-cell lymphoma[2]

Authorization of 12 months may be granted for treatment of Histologic (Richter) transformation to diffuse large B-cell lymphoma in combination with zanubrutinib.

Gastric Cancer[1,2]

Authorization of 12 months may be granted for the treatment of HER2-negative gastric adenocarcinoma in members who are not surgical candidates or have unresectable, recurrent, or metastatic disease in combination with platinum and fluoropyrimidine-based chemotherapy for first-line treatment of tumors expressing PD-L1 (≥1).

Small Bowel Adenocarcinoma[2]

Authorization of 12 months may be granted as a single agent for treatment of unresectable, inoperable, advanced or metastatic small bowel adenocarcinoma for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

Anal Carcinoma[2]

Authorization of 12 months may be granted as a single agent for treatment of locally recurrent, progressive, or metastatic anal carcinoma.

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Head and Neck Cancer[2]

Authorization of 12 months may be granted in combination with cisplatin and gemcitabine or as a single agent for treatment of unresectable or metastatic nasopharyngeal cancer.

Colon Cancer[2]

Authorization of 12 months may be granted as a single agent for neoadjuvant therapy or treatment of unresectable, inoperable, or metastatic colon adenocarcinoma for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

Appendiceal Cancer[2]

Authorization of 12 months may be granted as a single agent for treatment of advanced or metastatic appendiceal adenocarcinoma for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

Rectal Cancer[2]

Authorization of 12 months may be granted as a single agent for neoadjuvant therapy or treatment of recurrent or metastatic rectal adenocarcinoma for microsatellite instability-high (MSI-H), or mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication
- The requested medication is being used to treat an indication listed in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen, and
    - No evidence of disease progression while on the current regimen

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Summary of Evidence

The contents of this document were created after examining the following resources:

- The prescribing information for Tevimbra.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Esophageal and esophagogastric junction cancer
- NCCN Guideline: Gastric cancer
- NCCN Guideline: Hepatocellular carcinoma
- NCCN Guideline: Chronic lymphocytic leukemia/Small lymphocytic lymphoma
- NCCN Guideline: Small bowel adenocarcinoma
- NCCN Guideline: Anal carcinoma
- NCCN Guideline: Head and neck cancers
- NCCN Guideline: Colon cancer
- NCCN Guideline: Rectal cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Tevimbra are covered in addition to the following:

- Hepatocellular carcinoma
- Histologic (Richter) transformation to diffuse large B-cell lymphoma
- Small bowel adenocarcinoma
- Anal carcinoma
- Head and neck cancer
- Colon cancer
- Appendiceal cancer
- Rectal cancer

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Tevimbra to treat the indications in coverage criteria section can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

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Support for using Imfinzi to treat unresectable hepatocellular carcinoma can be found in the Micromedex DrugDex database. Use of information in the DrugDex database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Tevimbra [package insert]. San Mateo, CA: BeiGene USA, Inc; June 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed July 10, 2025.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Hepatocellular Carcinoma. Version 1.2025. Accessed July 22, 2025. https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf.
4. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at https://www.micromedexsolutions.com Accessed July 22, 2025.

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