CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – Programmed Death Receptor-1) – Tevimbra Utilization Management Medical Policy
- Tevimbra® (tislelizumab-jsgr intravenous infusion – BeiGene)

REVIEW DATE: 05/21/2025

OVERVIEW

Tevimbra, a programmed death receptor-1 (PD-1) blocking antibody, is indicated for the following in adults:[1]

- **Esophageal squamous cell carcinoma**
  - For the treatment of unresectable or metastatic disease, after prior systemic chemotherapy that did not include a PD-1 or programed death-ligand 1 (PD-L1) inhibitor, as a single agent.
  - For the treatment of unresectable or metastatic disease whose tumors express PD-L1 (≥1%), as first-line therapy in combination with platinum-containing chemotherapy.
- **Gastric or gastroesophageal junction adenocarcinoma**, unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative disease with tumors that express PD-L1 (≥ 1%), as first-line therapy in combination with platinum and fluoropyrimidine-based chemotherapy.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Tevimbra. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). Because of the specialized skills required for evaluation and diagnosis of patients treated with Tevimbra as well as the monitoring required for adverse events and long-term efficacy, approval requires Tevimbra to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tevimbra is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Esophageal and Esophagogastric Junction Cancers.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has unresectable locally advanced, recurrent, or metastatic disease; AND
   - **C)** Patient meets ONE of the following (i, ii, or iii)
     - **i.** Patient has esophageal squamous cell carcinoma and meets ALL of the following (a, b, and c)
       - **a)** Tumor expression for programmed death-ligand 1 (PD-L1) as determined by an approved test has a combined positive score (CPS) ≥ 1; AND

b) The medication is used as first-line or induction therapy; AND
c) The medication is used in combination with chemotherapy; OR
Note: Examples of chemotherapy include cisplatin plus fluorouracil or capecitabine; oxaliplatin plus fluorouracil or capecitabine; paclitaxel plus oxaliplatin or cisplatin.

ii. Patient has esophageal squamous cell carcinoma and meets BOTH of the following (a and b):
a) Medication is used for subsequent therapy; AND
b) Medication is used as a single agent; OR

iii. Patient has esophageal adenocarcinoma and meets BOTH of the following (a and b):
a) Patient has HER2 overexpression negative disease; AND
b) Tumor expression for PD-L1 as determined by an approved test has a CPS ≥ 1; AND

D) Patient meets ONE of the following (i or ii)
i. Patient has NOT previously received a checkpoint inhibitor; OR
Note: Examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion).
ii. Patient has NO tumor progression while on a checkpoint inhibitor; AND
Note: Examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion).

E) Medication is prescribed by or in consultation with an oncologist.

Dosing: Approve 200 mg administered by intravenous infusion no more frequently than once every 3 weeks.

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2. Gastric or Gastroesophageal Junction Adenocarcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
A) Patient is ≥ 18 years of age; AND
B) Patient has unresectable locally advanced, recurrent, or metastatic human epidermal growth factor receptor 2 (HER2)-negative disease; AND
C) The tumor expresses programmed death-ligand 1 (PD-L1) ≥ 1%; AND
D) Medication is used first-line; AND
E) Medication is used in combination with platinum and fluoropyrimidine-based chemotherapy; AND
Note: Examples of platinum medications include cisplatin and oxaliplatin. Examples of fluoropyrimidine medications include fluorouracil and capecitabine.
F) Medication is prescribed by or in consultation with an oncologist.

Dosing: Approve 200 mg administered by intravenous infusion no more frequently than once every 3 weeks.

Other Uses with Supportive Evidence

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3. Anal Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
i. Patient meets BOTH of the following (a and b):
a) Patient has locally recurrent, progressive disease; AND
b) Medication is administered before proceeding to abdominoperineal resection; OR
ii. Patient meets ALL of the following (a, b, and c):
a) Patient has metastatic disease; AND

b) Medication is used as subsequent therapy; AND
c) Patient has NOT received prior immunotherapy; AND
Note: Examples of immunotherapy include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Libtayo (cemiplimab intravenous infusion), Jemperli (dostarlimab intravenous infusion).

C) The medication is used as a single agent; AND
D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 3 mg/kg administered by intravenous infusion no more frequently than once every 2 weeks.

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4. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
A) Patient is ≥ 18 years of age; AND
B) Patient has histologic transformation to diffuse large B-cell lymphoma; AND
C) Patient meets ONE of the following (i, ii, or iii):
i. Tumor has del(17p)/TP53 mutation; OR
ii. Disease is chemotherapy refractory; OR
Note: An example of chemotherapy includes CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone).
iii. Patient is unable to receive chemoimmunotherapy; AND
Note: Examples of chemoimmunotherapy include RCHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone), OFAR (oxaliplatin, fludarabine, cytarabine, rituximab).
D) The medication is used in combination with Brukinsa (zanubrutinib capsules); AND
E) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 200 mg administered by intravenous infusion no more frequently than once every 3 weeks.

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5. Colon, Rectal, or Appendiceal Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
A) Patient is ≥ 18 years of age; AND
B) Patient meets ONE of the following (i or ii):
i. Patient has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) disease; OR
ii. Patient has DNA polymerase epsilon/delta (POLE/POLD1) mutation; AND
C) Patient has advanced or metastatic disease; AND
D) Medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 200 mg administered by intravenous infusion no more frequently than once every 3 weeks.

6. Hepatocellular Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i or ii):
  - **i.** Patient meets BOTH of the following (a and b):
    - **a)** Patient meets ONE of the following [(1) or (2)]:
      - **(1)** Patient has liver-confined, unresectable disease and is deemed ineligible for transplant; OR
      - **(2)** Patient has extrahepatic/metastatic disease and are deemed ineligible for resection, transplant, or locoregional therapy; AND
    - **b)** The medication is used first-line; OR
  - **ii.** Medication is being used for subsequent therapy; AND
- **C)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 200 mg administered by intravenous infusion no more frequently than once every 3 weeks.

7. Nasopharyngeal Carcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has recurrent, unresectable, oligometastatic, or metastatic disease; AND
- **C)** Patient meets ONE of the following (i or ii):
  - **i.** Patient meets BOTH of the following (a and b):
    - **a)** The medication is used for first-line treatment; AND
    - **b)** The medication is used in combination with cisplatin and gemcitabine; OR
  - **ii.** Patient meets BOTH of the following (a and b):
    - **a)** The medication is used for subsequent treatment; AND
    - **b)** Patient meets ONE of the following [(1) or (2)]:
      - **(1)** The medication is used as a single agent; OR
      - **(2)** The medication is used in combination with cisplatin and gemcitabine; AND
- **D)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 200 mg administered by intravenous infusion no more frequently than once every 3 weeks.

8. Small Bowel Adenocarcinoma. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, E, and F):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i or ii):
  - **i.** Patient has locally unresectable or medically inoperable disease; OR
  - **ii.** Patient has advanced or metastatic disease; AND
- **C)** Patient has ultra-hypermutated phenotype; AND
  Note: Ultra-hypermutated phenotype defined as tumor mutation burden > 50 mutations/megabase.
- **D)** Patient meets ONE of the following (i or ii):
  - **i.** Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease; OR
  - **ii.** Patient has polymerase epsilon/delta (POLE/POLD1) mutation positive disease; AND

E) The medication is used as a single agent; AND
F) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve 200 mg administered by intravenous infusion no more frequently than once every 3 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tevimbra is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tevimbra intravenous infusion [prescribing information]. San Mateo, CA: BeiGene; May 2025.
2. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on May 6, 2025, 2025. Search term: tislelizumab.
3. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (version 3.2025 – April 22, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025, 2025.
4. The NCCN Anal Carcinoma Clinical Practice Guidelines in Oncology (version 3.2025 – March 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025, 2025.
5. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 3.2025 – April 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025, 2025.
6. The NCCN Head and Neck Cancers Clinical Practice Guidelines in Oncology (version 2.2025 – January 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025, 2025.
7. The NCCN Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology (version 1.2025 – March 20, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025, 2025.
8. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 3.2025 – March 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025, 2025.
9. Yang Y, Pan J, Wang H, et al. Tislelizumab plus chemotherapy as first-line treatment for recurrent or metastatic nasopharyngeal cancer: a multicenter phase 3 trial (RATIONALE-309). *Cancer Cell*. 2023;41:1061-1072.
10. Al-Sawaf O, Ligtvoet R, Robrecht S, et al. Tislelizumab plus Zanubrutinib for Richter transformation: the phase 2 RT1 trial. *Nat Med*. 2024;30:240-248.
11. Qin S, Kudo M, Meyer T, et al. Tislelizumab vs sorafenib as first-line treatment for unresectable hepatocellular carcinoma: A Phase 3 randomized clinical trial. *JAMA Oncol*. 2023;9(12):1651-1659.
12. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – March 31, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025.
13. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – April 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025, 2025.
14. The NCCN Gastric Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – April 4, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 6, 2025, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/12/2024
Early Annual Revision	**Gastric or Gastroesophageal Junction Adenocarcinoma:** New condition of approval added. **Anal Carcinoma:** New condition of approval added. **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma:** New condition of approval added. **Hepatocellular Carcinoma:** New condition of approval added. **Nasopharyngeal Carcinoma:** New condition of approval added. **Small Bowel Adenocarcinoma:** New condition of approval added.	01/22/2025
Early Annual Revision	**Esophageal Squamous Cell and Esophagogastric Junction Cancers:** Previously referred to as "Esophageal Squamous Cell Carcinoma." Added esophageal adenocarcinoma in tumors that are human epidermal growth factor receptor 2 (HER2)-negative disease with tumor expression for programmed death-ligand 1 (PD-L1) as determined by an approved test has a combined positive score (CPS) ≥ 1 in combination with chemotherapy as a new option for approval. Added esophageal squamous cell carcinoma as first line or induction therapy for tumor expression for PD-L1 as determined by an approved test has a CPS ≥ 1 in combination with chemotherapy as a new option for approval. Revised "patient has NOT previously received a checkpoint inhibitor" to include "OR patient has NO tumor progression while on a checkpoint inhibitor." **Gastric or Gastroesophageal Junction Adenocarcinoma:** Added locally advanced, recurrent in "patient has unresectable locally advanced, recurrent, or metastatic human epidermal growth factor receptor 2 (HER2)-negative disease". **Colon, Rectal, or Appendiceal Cancer:** New condition of approval added. **Hepatocellular Carcinoma:** The medication is being used for subsequent-line therapy was added as an option for approval. **Small Bowel Adenocarcinoma:** Added "patient has advanced or metastatic disease" as an approval option.	05/21/2025