UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 01/22/2025

OVERVIEW

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

- **Esophageal squamous cell carcinoma**, unresectable or metastatic, after prior systemic chemotherapy that did not include a PD-1 or programed death-ligand 1 (PD-L1) inhibitor.
- **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.

Guidelines

The National Comprehensive Cancer Network (NCCN) has addressed Tevimbra in the following guidelines:

- **Anal Carcinoma** (version 1.2025 – December 4, 2024) clinical practice guidelines recommend Tevimbra as a single agent for the subsequent treatment of metastatic disease if no prior immunotherapy received (category 2A).[2,4] Loqtorzi is also recommended as a single agent prior to proceeding to abdominoperineal resection for locally recurrent, progressive disease (category 2B).
- **Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma** (version 1.2025 – October 1, 2024) clinical practice guidelines recommend Tevimbra in combination with Brukinsa® (zanubrutinib capsules) for histologic (Richter) transformation to diffuse large B-cell lymphoma in patients with del(17p)/TP53 mutation, or who are chemotherapy refractory or unable to receive chemoimmunotherapy.[2,5]
- E**sophageal and Esophagogastric Junction Cancers** (version 5.2024 – December 20, 2024) clinical practice guidelines recommend Tevimbra as a "Preferred Regimen" for the treatment of unresectable locally advanced, recurrent, or metastatic esophageal squamous cell carcinoma as a single agent, if checkpoint inhibitors were not previously used and local therapy is not indicated (category 1).[2,3]
- **Head and Neck Cancers** (version 1.2025 – November 26, 2024) clinical practice guidelines recommend Tevimbra in combination with cisplatin and gemcitabine as a "Other Recommended Regimen" for the first-line treatment of recurrent, unresectable, oligometastatic, or metastatic nasopharyngeal carcinoma without any surgical or radiation therapy options (category 2B).[2,6] Tevimbra is recommended as a single agent, as a "Other Recommended Regimen" for the subsequent treatment of nasopharyngeal carcinoma if disease progression on or after platinum-containing therapy (category 2B). It is also an "Other Recommended Regimen" for the subsequent treatment of nasopharyngeal carcinoma, in combination with cisplatin and gemcitabine if not previously used (category 2A).
- **Hepatocellular Carcinoma** (version 4.2024 – January 10, 2025) clinical practice guidelines recommend Tevimbra as a single agent for the first-line treatment of patients who have liver-confined, unresectable disease and are deemed ineligible for transplant; or have

extrahepatic/metastatic disease and are deemed ineligible for resection, transplant, or locoregional therapy.[2,7]

- **Small Bowel Adenocarcinoma** (version 1.2025 – December 4, 2024) clinical practice guidelines recommend Tevimbra as a single agent for the first-line or subsequent treatment of locally unresectable or medically inoperable disease with ultra-hypermutated phenotype (tumor mutational burden > 50 mutations/megabase) and either deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation positive (category 2A).[2,8]

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 Squamous Cell Carcinoma.** 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 unresectable locally advanced, recurrent, or metastatic disease; OR
     - **ii.** Patient is not a surgical candidate; AND
   - **C)** Medication is used as a single agent; AND
   - **D)** Medication is used for subsequent therapy; AND
   - **E)** Patient has NOT previously received a checkpoint inhibitor; AND
     Note: Examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion).
   - **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.

---

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 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

---

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), and 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.

---

4. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. 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 histologic transformation to diffuse large B-cell lymphoma; AND
C) Patient meets ONE of the following (i, ii, or iii):
i. Patient has del(17p)/TP53 mutation; OR
ii. Patient 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) and 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.

---

5. Hepatocellular 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 has liver-confined, unresectable disease and is deemed ineligible for transplant; OR
  - **ii.** Patient has extrahepatic/metastatic disease and are deemed ineligible for resection, transplant, or locoregional therapy; AND
- **C)** The medication is used first-line; 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.

---

6. 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.

---

7. 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 has locally unresectable or medically inoperable 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; December 2024.
2. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 16, 2025. Search term: tislelizumab.
3. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (version 5.2024 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 16, 2025.
4. The NCCN Anal Carcinoma Clinical Practice Guidelines in Oncology (version 1.2025 – December 4, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 16, 2025.
5. The NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Clinical Practice Guidelines in Oncology (version 1.2025 – October 1, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 16, 2025.
6. The NCCN Head and Neck Cancers Clinical Practice Guidelines in Oncology (version 1.2025 – November 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 16, 2025.
7. The NCCN Hepatocellular Carcinoma Clinical Practice Guidelines in Oncology (version 4.2024 – January 10, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 16, 2025.
8. The NCCN Small Bowel Adenocarcinoma Clinical Practice Guidelines in Oncology (version 1.2025 – December 4, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 16, 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.

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