

## UTILIZATION MANAGEMENT MEDICAL POLICY

**POLICY:** Oncology (Injectable – Programmed Death Receptor-1) – Tevimbra Utilization Management Medical Policy

- Tevimbra® (tislelizumab-jsgr intravenous infusion – BeiGene)

**REVIEW DATE:** 11/12/2025

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### OVERVIEW

Tevimbra, a programmed death receptor-1 (PD-1) blocking antibody, is indicated for the following in adults:<sup>1</sup>

- **Esophageal squamous cell carcinoma**, in adults:
  - For the treatment of unresectable or metastatic disease, after prior systemic chemotherapy that did not include a PD-1 or programmed death-ligand 1 (PD-L1) inhibitor, as a single agent.
  - For the treatment of unresectable or metastatic disease whose tumors express PD-L1 ( $\geq 1\%$ ), 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 ( $\geq 1\%$ ) in adults, 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

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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  $\geq 18$  years of age; AND
  - B) Patient has unresectable locally advanced, recurrent, or metastatic disease; AND
  - C) Patient meets ONE of the following (i or ii)
    - i. Patient has esophageal squamous cell carcinoma and meets ONE of the following (a or b)
      - a) Patient meets BOTH of the following [(1) and (2)]:

- (1) The tumor expression for programmed death-ligand 1 (PD-L1) has a combined positive score (CPS)  $\geq 1\%$ ; AND
- (2) 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.
- b) Medication is used as a single agent; OR
- ii. Patient has esophageal adenocarcinoma and meets BOTH of the following (a and b):
  - a) Patient has HER2 overexpression negative disease; AND
  - b) The tumor expression for PD-L1 has a CPS  $\geq 1\%$ ; AND
- D) 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) The medication is prescribed by or in consultation with an oncologist.

**Dosing:** Approve ONE of the following dosing regimens (A, B, or C):

- A) 150 mg administered by intravenous infusion no more frequently than once every 2 weeks; OR
- B) 200 mg administered by intravenous infusion no more frequently than once every 3 weeks; OR
- C) 300 mg administered by intravenous infusion no more frequently than once every 4 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, and E):

- A) Patient is  $\geq 18$  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 expression for programmed death-ligand 1 (PD-L1) has a combined positive score (CPS)  $\geq 1\%$ ; AND
- D) The 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.
- E) The medication is prescribed by or in consultation with an oncologist.

**Dosing:** Approve ONE of the following dosing regimens (A, B, or C):

- A) 150 mg administered by intravenous infusion no more frequently than once every 2 weeks; OR
- B) 200 mg administered by intravenous infusion no more frequently than once every 3 weeks; OR
- C) 300 mg administered by intravenous infusion no more frequently than once every 4 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  $\geq 18$  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) The medication is administered before proceeding to abdominoperineal resection; OR
  - ii. Patient meets BOTH of the following (a and b):
    - a) Patient has metastatic disease; AND

- b) The medication is used as subsequent therapy; AND
- 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, and D):
- A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has histologic Richter transformation; AND
  - C) The medication is used in combination with Brukinsa (zanubrutinib capsules); 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.

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5. **Classic Hodgkin Lymphoma:** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
- A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has refractory or relapsed disease; AND
  - C) The medication is used in combination with GEMOX; AND  
Note: GEMOX includes gemcitabine and oxaliplatin.
  - 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.

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6. **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  $\geq 18$  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. The disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden  $> 50$  mutations/megabase); AND
  - C) Patient has advanced or metastatic disease; 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.

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**7. Endometrial Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):

- A) Patient is  $\geq 18$  years of age; AND
- B) Patient has recurrent or metastatic disease; AND
- C) Patient has microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors; AND
- D) The medication will be used as a single agent; 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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**8. Hepatocellular Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):

- A) Patient is  $\geq 18$  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. The 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.

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**9. Nasopharyngeal Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A) Patient is  $\geq 18$  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. The medication is used for subsequent treatment; 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.

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**10. Small Bowel Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):

- A) Patient is  $\geq 18$  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 meets ONE of the following (i or ii):
  - i. Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease; OR
  - ii. The disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden > 50 mutations/megabase); AND
- D) The medication is used as a single agent; 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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**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**

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## HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/12/2024
Early Annual Revision	<p><b>Gastric or Gastroesophageal Junction Adenocarcinoma:</b> New condition of approval added.</p> <p><b>Anal Carcinoma:</b> New condition of approval added.</p> <p><b>Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma:</b> New condition of approval added.</p> <p><b>Hepatocellular Carcinoma:</b> New condition of approval added.</p> <p><b>Nasopharyngeal Carcinoma:</b> New condition of approval added.</p> <p><b>Small Bowel Adenocarcinoma:</b> New condition of approval added.</p>	01/22/2025
Early Annual Revision	<p><b>Esophageal Squamous Cell and Esophagogastric Junction Cancers:</b> 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) <math>\geq 1</math> 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 <math>\geq 1</math> 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.”</p> <p><b>Gastric or Gastroesophageal Junction Adenocarcinoma:</b> Added locally advanced, recurrent in “patient has unresectable locally advanced, recurrent, or metastatic human epidermal growth factor receptor 2 (HER2)-negative disease”.</p> <p><b>Colon, Rectal, or Appendiceal Cancer:</b> New condition of approval added.</p> <p><b>Hepatocellular Carcinoma:</b> The medication is being used for subsequent-line therapy was added as an option for approval.</p> <p><b>Small Bowel Adenocarcinoma:</b> Added “patient has advanced or metastatic disease” as an approval option.</p>	05/21/2025
Early Annual Revision	<p><b>Esophageal Squamous Cell and Esophagogastric Junction Cancers:</b> The approval option that the patient has esophageal squamous cell carcinoma that “the tumor expression for programmed death-ligand 1 (PD-L1) as determined by an approved test has a combined positive score (CPS) <math>\geq 1</math>” was modified to “the tumor expression for programmed death-ligand 1 (PD-L1) has a combined positive score (CPS) <math>\geq 1\%</math>”. The medication is used as first-line or induction therapy for tumor expression for PD-L1 has a CPS <math>\geq 1</math> in combination with chemotherapy was removed as an option for approval. Removed that the medication is used for subsequent therapy when the medication is used as a single agent as an option of approval. The approval option that the patient has esophageal adenocarcinoma that “the tumor expression for PD-L1 as determined by an approved test has a CPS <math>\geq 1</math>” was modified to “the tumor expression for PD-L1 has a CPS <math>\geq 1\%</math>”. Removed the approval option that the patient has NOT previously received a checkpoint inhibitor. The Note for examples of checkpoint inhibitors include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion) was removed. The dosing regimens of 150 mg administered by intravenous infusion no more frequently than once every 2 weeks and 300 mg administered by intravenous infusion no more frequently than once every 4 weeks were added as approval options.</p> <p><b>Gastric or Gastroesophageal Junction Adenocarcinoma:</b> The approval option that “the tumor expresses programmed death-ligand 1 (PD-L1) <math>\geq 1\%</math>” was modified to “the</p>	11/12/2025

11/12/2025

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	<p>tumor expression for programmed death-ligand 1 (PD-L1) has a combined positive score (CPS) <math>\geq 1\%</math>". The medication is used as first-line was removed as a requirement for approval. The dosing regimens of 150 mg administered by intravenous infusion no more frequently than once every 2 weeks and 300 mg administered by intravenous infusion no more frequently than once every 4 weeks were added as approval options.</p> <p><b>Anal Carcinoma:</b> The approval option that the patient has NOT received prior immunotherapy was removed. The Note for examples of immunotherapy include Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Libtayo (cemiplimab intravenous infusion), Jemperli (dostarlimab intravenous infusion) was removed.</p> <p><b>Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma:</b> The requirement that the "patient has histologic transformation to diffuse large B-cell lymphoma" was modified to the "patient has histologic Richter transformation". The requirement that the patient meets ONE of the following: tumor has del(17p)/TP53 mutation; disease is chemotherapy refractory; or the patient is unable to receive chemoimmunotherapy were removed. The Note for example of chemotherapy includes CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) was removed.</p> <p><b>Classic Hodgkin Lymphoma:</b> This was added as a new condition for approval.</p> <p><b>Colon, Rectal, or Appendiceal Cancer:</b> The approval option that the "patient has DNA polymerase epsilon/delta (POLE/POLD1) mutation" was modified to "the disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden &gt; 50 mutations/megabase)".</p> <p><b>Endometrial Carcinoma:</b> This was added as a new condition for approval.</p> <p><b>Nasopharyngeal Carcinoma:</b> The medication is used as a single agent or the medication is used in combination with cisplatin or gemcitabine were removed as options for approval.</p> <p><b>Small Bowel Adenocarcinoma:</b> The requirements that the patient has ultra hypermutated phenotype (along with the Note defining ultra hypermutated phenotype) and the patient has polymerase epsilon/delta (POLE/POLD1) mutation positive disease were combined to "the disease is polymerase epsilon/delta (POLE/POLD1) mutation positive with ultra-hypermutated phenotype (tumor mutation burden &gt; 50 mutations/megabase)."</p>	
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