

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

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

EFFECTIVE DATE: 06/12/2024

LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Tevimbra, a programmed death receptor-1 (PD-1) blocking antibody, is indicated for the treatment of unresectable or metastatic esophageal squamous cell carcinoma in adults after prior systemic chemotherapy that did not include a PD-1 or programmed death-ligand 1 (PD-L1) inhibitor.¹

Guidelines

The National Comprehensive Cancer Network (NCCN) **esophageal and esophagogastric junction cancers** (version 3.2024 – April 26, 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}

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 Indication

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 \geq 18 years of age:

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.

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; March 2024.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on June 5, 2024. Search term: tislelizumab.
3. The NCCN Esophageal and Esophagogastric Junction Cancers Clinical Practice Guidelines in Oncology (version 3.2024 – April 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 5, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/12/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024