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Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	April 12, 2024
Subject:	Tevimbra	**Page:**	1 of 5

Last Review Date: March 7, 2025

Tevimbra

Description

Tevimbra (tislelizumab-jsgr)

Background
Tevimbra (tislelizumab-jsgr) is a programmed death receptor-1 (PD-1)-blocking antibody. Binding of the PD-1 ligands PD-L1 and PD-L2, to the PD-1 receptor found on T-cells, inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occur in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. Tevimbra binds to PD-1 and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway mediated inhibition of the immune response, including the anti-tumor immune response (1).

Regulatory Status
FDA-approved indications: Tevimbra is a programmed death receptor-1 (PD-1) blocking antibody indicated for: (1)

- Esophageal Cancer
  - as a single agent in adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.
- Gastric Cancer
  - in combination with platinum and fluoropyrimidine-based chemotherapy in adults for the first-line treatment of unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma (G/GEJ) whose tumors express PD-L1 (≥1).

Tevimbra carries warnings for immune-mediated adverse reactions, infusion-related reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), and embryo-fetal toxicity. Clinically significant immune-mediated adverse reactions may occur with Tevimbra therapy including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions, and solid organ transplant rejection. Patients should be monitored for signs and symptoms of adverse reactions and based on the severity, Tevimbra should be withheld or discontinued, and corticosteroids administered. Tevimbra may cause fetal harm when administered to a pregnant woman. Female patients of reproductive potential should be advised of the potential hazard to a fetus (1).

The safety and effectiveness of Tevimbra in pediatric patients less than 18 years of age have not been established (1).

Related Policies
Keytruda, Opdivo

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tevimbra may be considered **medically necessary** if the conditions indicated below are met.

Tevimbra may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Unresectable or metastatic esophageal squamous cell carcinoma (ESCC)
    a. Prior treatment with systemic chemotherapy that did not include a PD-L1
2. Unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma (G/GEJ)

a. Presence of PD-L1 in tumor specimens
b. Used as first-line treatment in combination with platinum and fluoropyrimidine-based chemotherapy

AND ALL the following:

a. Prescriber agrees to discontinue treatment for any immune mediated adverse reaction (encephalitis, nephritis, rash, decreased renal function and endocrinopathies) or disease progression
b. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Tevimbra and for 4 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Unresectable or metastatic esophageal squamous cell carcinoma (ESCC)
2. Unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma (G/GEJ)

AND ALL the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to discontinue treatment for any immune mediated adverse reaction (encephalitis, nephritis, rash, decreased renal function and endocrinopathies) or disease progression
c. Female patients of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Tevimbra and for 4 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Tevimbra (tislelizumab-jsgr) is a programmed death receptor-1 (PD1) blocking antibody. Tevimbra binds to PD-1 preventing its interaction with PD-L1 and PD-L2. This interaction releases the inhibitory effects of PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response, resulting in decreased tumor growth. Tevimbra carries warnings for immune-mediated adverse reactions, infusion-related reactions, complications of allogeneic HSCT and embryo-fetal toxicity. The safety and effectiveness of Tevimbra have not been established in pediatric patients age less than 18 years of age (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Tevimbra while maintaining optimal therapeutic outcomes.

References

1. Tevimbra [package insert]. San Mateo, CA: BeiGene, Ltd.; December 2024.
2. NCCN Drugs & Biologics Compendium® Tislelizumab-jsgr 2025. National Comprehensive Cancer Network, Inc. Accessed on January 27, 2025.

Policy History

Date	Action
April 2024	Addition to PA
June 2024	Annual review and reference update
December 2024	Annual review and reference update
January 2025	Per PI update, added indication of unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.