

Medical Policy:

Tevimbra (tislelizumab) intravenous infusion

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.416	May 6, 2025	November 5, 2024

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Tevimbra (tislelizumab-jsgr), as a single agent, is indicated for the treatment of adult patients with unresectable or metastatic esophageal squamous cell carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.

Length of Authorization

Coverage will be provided for 6 months and may be renewed

Dosing Limits [Medical Benefit]

Max Units (per dose and over time) [HCPCS Unit]:

200 billable units every 3 weeks

Guideline

I. INITIAL CRITERIA

1. **Esophageal Squamous Cell Carcinoma (ESCC) †**
 - A. Patient is ≥ 18 years of age; **AND**

- B. Patient is not a surgical candidate **OR** has unresectable locally advanced, recurrent, or metastatic disease; **AND**
- C. Patient meets **ONE** of the following, Tevimbra is being used as:
 - i. First-Line Treatment of Esophageal Squamous Cell Carcinoma- in combination with platinum-containing chemotherapy; **OR**
 - ii. As a single agent for previously Treated Esophageal Squamous Cell Carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor; **AND**
- D. Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., nivolumab, pembrolizumab, atezolizumab, avelumab, cemiplimab, dostarlimab, nivolumab/relatlimab, retifanlimab, toripalimab, durvalumab, etc.), unless otherwise specified; **AND**
- E. Medication is prescribed by or in consultation with an oncologist

2. **Gastric or Gastroesophageal Junction Adenocarcinoma.**

- 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) $\geq 1\%$; **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.

II. RENEWAL CRITERIA

Coverage may be renewed based upon the following criteria:

- 1. **Esophageal Squamous Cell Carcinoma (ESCC) or Gastric or Gastroesophageal Junction Adenocarcinoma.**
 - A. Patient continues to meet the universal and other indication-specific relevant criteria identified in Initial Criteria; **AND**
 - B. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
 - C. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe or life-threatening infusion-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash, etc.), complications of allogeneic hematopoietic stem cell transplantation (HCST), etc.

Applicable Procedure Codes

Code	Description
J9329	Injection, tislelizumab-jsgr, 1 mg; 1 billable unit = 1 mg

Applicable NDCs

Code	Description
72579-0121-01	Tevimbra 100 mg/10 mL single-dose vial

ICD-10 Diagnoses

Code	Description
C15.3	Malignant neoplasm of upper third of esophagus

C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant Neoplasm Of Esophagus, Unspecified
C16.0	Malignant Neoplasm Of Cardia
C16.1	Malignant Neoplasm Of Fundus Of Stomach
C16.2	Malignant Neoplasm Of Body Of Stomach
C16.3	Malignant Neoplasm Of Pyloric Antrum
C16.4	Malignant Neoplasm Of Pylorus
C16.5	Malignant Neoplasm Of Lesser Curvature Of Stomach, Unspecified
C16.6	Malignant Neoplasm Of Greater Curvature Of Stomach, Unspecified
C16.8	Malignant Neoplasm Of Overlapping Sites Of Stomach
C16.9	Malignant Neoplasm Of Stomach, Unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	05/06/2025	Update: Updated ICD-10 codes. Initial Criteria: Esophageal Squamous Cell Carcinoma (ESCC) † Removed: "Used as single-agent therapy; AND Used as second-line therapy after disease progression on initial chemotherapy; AND" Added: " Patient is ≥ 18 years of age; AND Patient meets one of the following, Tevimbra is being used as: First-Line Treatment of Esophageal Squamous Cell Carcinoma- in combination with platinum-containing chemotherapy; OR As a single agent for previously Treated Esophageal Squamous Cell Carcinoma after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor. "Medication is prescribed by or in consultation with an oncologist Added: "Gastric or Gastroesophageal Junction Adenocarcinoma. Patient is ≥ 18 years of age; AND Patient has unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative disease; AND The tumor expresses programmed death-ligand 1 (PD-L1) ≥ 1%; AND Medication is used first-line; AND Medication is used in combination with platinum and fluoropyrimidine-based chemotherapy; AND Note: <i>Examples of platinum medications include cisplatin and oxaliplatin. Examples of fluoropyrimidine medications include fluorouracil and capecitabine.</i> Medication is prescribed by or in consultation with an oncologist." RENEWAL CRITERIA- added: Gastric or Gastroesophageal Junction Adenocarcinoma._
EmblemHealth & ConnectiCare	11/05/2024	New Policy

References

1. Tevimbra[®] intravenous infusion [prescribing information]. San Mateo, CA: BeiGene; March 2024.