

## Tevimbra (tislelizumab)

### Disclaimer

*Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.*

*Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.*

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## Summary

Esophageal squamous cell carcinoma (ESCC) is the most common type of esophageal cancer worldwide. Advanced ESCC is an aggressive cancer with a poor prognosis. For those with unresectable locally advanced, recurrent, or metastatic ESCC, systemic chemotherapy has been the standard treatment. However, the prognosis remains poor, with a median overall survival of less than 12 months.

Gastric cancer rates have been on the decline, however once diagnosed, individuals are typically symptomatic and have more advanced cases. If the cancer is located in an area of the body that is favorable for surgery - surgery, radiation and systemic medications can be administered. However, some cancers are not amenable to resection, or are metastatic, and may require systemic chemotherapy.

Tevimbra (tislelizumab) is a treatment option for those with advanced ESCC or gastric cancer, either as a first line therapy or in those who have progressed on prior chemotherapy. It is a monoclonal antibody that blocks the programmed death receptor-1 (PD-1) protein. It works by preventing PD-1 from interacting with its ligands, PD-L1 and PD-L2. Tislelizumab is indicated:

- 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
- In combination with platinum-containing chemotherapy, it is indicated for the first-line treatment of adults with unresectable or metastatic ESCC whose tumors express PD-L1 ( $\geq 1$ ).
- 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 whose tumors express PD-L1 ( $\geq 1$ ).

The National Comprehensive Cancer Network recommended Tevimbra (tislelizumab) for a number of other oncological conditions, including but not limited to: head and neck cancers, endometrial adenocarcinoma, Hodgkin Lymphoma, and appendiceal adenocarcinoma.

## Definitions

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Eastern Cooperative Oncology Group (ECOG) Performance Status" is a scale used to assess how a patient's disease is progressing and how the disease affects the daily living abilities of the patient. Scores range from 0 to 5, where lower numbers indicate higher functional status (see [Table 3](#) in the [Appendix A](#)).

"Esophageal squamous cell carcinoma (ESCC)" refers to a type of esophageal cancer arising from the squamous cells lining the esophagus. It is the predominant histology in esophageal cancers worldwide.

"HER-2" or "Human Epidermal Growth Factor Receptor-2" refers to a protein involved in normal cell growth. In some cancer cells, including bladder, breast, esophageal, ovarian, pancreatic, and stomach cancers, HER-2 can be over-expressed (made in larger than normal quantity), which may cause cancer cells to grow more quickly and spread to other areas of the body. During the diagnosis process, a cancer cell may be defined as being "HER-2 negative" or "HER-2 positive" referring to whether or not there are high levels of HER-2 protein in those cells.

"Karnofsky Performance Status Score" is a widely used tool to assess the functional status of a patient relative to their disease process. The score ranges from 0 to 100, where lower numbers indicate worse functional status (see [Table 4](#) in the [Appendix A](#)).

"Locally advanced" refers to cancer that has spread from where it started to nearby tissue or lymph nodes.

"Metastatic" refers to cancer that has spread to distant parts of the body.

"National Comprehensive Cancer Network (NCCN)" refers to an organization recognized as the gold standard for clinical policy guidelines in oncology.

"PD-1," or "Programmed death receptor-1," is a cell surface receptor that plays a critical role in downregulating the immune system and promoting self-tolerance by suppressing T cell activity. PD-1 blockade can enhance anti-tumor responses.

"PD-L1" is a protein expressed on tumor cells or tumor-infiltrating immune cells that binds to PD-1 and inhibits T cell activation. PD-L1 expression is a potential biomarker for response to PD-1/PD-L1 inhibitors.

"Unresectable" refers to a tumor that cannot be completely removed by surgery.

"[s]" indicates state mandates may apply.

## Clinical Indications

### Medical Necessity Criteria for Clinical Review

#### General Medical Necessity Criteria

The Plan considers Tevimbra (tislelizumab) medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with an oncologist; *AND*
2. Tevimbra (tislelizumab) is prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication; *AND*
3. The member meets ONE of the following:
  - a. Tevimbra (tislelizumab) is being used for treatment consistent with NCCN category 1, 2A, or 2B recommendation (see NCCN compendia) where [Initial Indication-Specific Criteria](#) is not covered below; *or*
  - b. The member meets the applicable [Medical Necessity Criteria for Initial Clinical Review](#) or [Subsequent Clinical Review](#) listed below.

If the above prior authorization criteria are met, the requested product will be authorized for up to 6-months.<sup>[s]</sup>

#### Medical Necessity Criteria for Initial Clinical Review

##### Initial Indication-Specific Criteria

##### Previously Treated Unresectable or Metastatic Esophageal Squamous Cell Carcinoma (ESCC)

The Plan considers Tevimbra (tislelizumab) medically necessary when ALL of the following criteria are met:

- 4.
5. The member is 18 years of age or older; *AND*
6. The member has a diagnosis of esophageal squamous cell carcinoma (ESCC); *AND*
7. The member has unresectable locally advanced, recurrent, or metastatic disease; *AND*
8. The member has documented disease progression on or after at least ONE (1) prior line of systemic therapy for locally advanced or metastatic ESCC<sup>[s]</sup>; *AND*
  - a. *Examples of qualifying prior systemic therapy:*
    - i. *Fluoropyrimidine (5-FU or capecitabine) plus platinum (cisplatin or oxaliplatin) chemotherapy.*
    - ii. *Taxane chemotherapy such as paclitaxel or docetaxel.*
    - iii. *Irinotecan chemotherapy.*
    - iv. *Fluoropyrimidine (5-FU or capecitabine) plus irinotecan chemotherapy.*
    - v. *Ramucirumab plus paclitaxel chemotherapy.*
9. Prior therapies did not contain a PD-1 or PD-L1 inhibitor; *AND*
  - a. *Examples of prior therapies that would disqualify a member for Tevimbra (tislelizumab):*
    - i. *Bavencio (avelumab).*
    - ii. *Imfinzi (durvalumab).*
    - iii. *Jemperli (dostarlimab).*
    - iv. *Keytruda (pembrolizumab).*

- v. *Libtayo (cemiplimab).*
- vi. *Loqtorzi (toripalimab).*
- vii. *Opdivo (nivolumab).*
- viii. *Opdualag (nivolumab; relatlimab).*
- ix. *Tecentriq (atezolizumab).*
- x. *Zynyz (retifanlimab).*
- xi. *Combination regimens containing any of the above immunotherapy agents.*

10. The member has Karnofsky performance score  $\geq 60\%$  or ECOG performance score  $\leq 2$ ; **AND**

11. Tevimbra (tislelizumab) is prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.

If the above prior authorization criteria are met, the requested product will be authorized for up to 6-months.<sup>[s]</sup>

First-line Treatment of Unresectable or Metastatic Esophageal Carcinoma (ESCC) in those Whose Tumors Express PD-L1 ( $\geq 1$ )

The Plan considers Tevimbra (tislelizumab) medically necessary when ALL of the following criteria are met:

- 1.
2. The member is 18 years of age or older; **AND**
3. The member has a diagnosis of esophageal squamous cell carcinoma (ESCC); **AND**
4. The member has unresectable locally advanced, recurrent, or metastatic disease; **AND**
5. The member's tumors express PD-L1 ( $\geq 1$ ); **AND**
6. The member is being treated concomitantly with a platinum-containing chemotherapy (e.g., cisplatin, oxaliplatin, carboplatin)<sup>[s]</sup>; **AND**
7. Prior therapies did not contain a PD-1 or PD-L1 inhibitor; **AND**
  - b. *Examples of prior therapies that would disqualify a member for Tevimbra (tislelizumab):*
    - i. *Bavencio (avelumab).*
    - ii. *Imfinzi (durvalumab).*
    - iii. *Jemperli (dostarlimab).*
    - iv. *Keytruda (pembrolizumab).*
    - v. *Libtayo (cemiplimab).*
    - vi. *Loqtorzi (toripalimab).*
    - vii. *Opdivo (nivolumab).*
    - viii. *Opdualag (nivolumab; relatlimab).*
    - ix. *Tecentriq (atezolizumab).*
    - x. *Zynyz (retifanlimab).*
    - xi. *Combination regimens containing any of the above immunotherapy agents.*
8. The member has Karnofsky performance score  $\geq 60\%$  or ECOG performance score  $\leq 2$ ; **AND**

9. Tevimbra (tislelizumab) is prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.

If the above prior authorization criteria are met, the requested product will be authorized for up to 6-months.<sup>[s]</sup>

### Gastric Cancer

The Plan considers Tevimbra (tislelizumab) medically necessary when ALL of the following criteria are met:

- 1.
2. The member is 18 years of age or older; *AND*
3. The member has a diagnosis of gastric or gastroesophageal junction adenocarcinoma; *AND*
4. The member has unresectable locally advanced, recurrent, or metastatic disease; *AND*
5. The member's tumors express PD-L1 ( $\geq 1$ ); *AND*
6. The member disease is diagnosed as HER-2 negative; *AND*
7. The member is being treated concomitantly with a platinum-containing chemotherapy (e.g., cisplatin, oxaliplatin, carboplatin) and a fluoropyrimidine-based chemotherapy (e.g., fluorouracil, capecitabine)<sup>[s]</sup>; *AND*
8. Prior therapies did not contain a PD-1 or PD-L1 inhibitor; *AND*
  - a. *Examples of prior therapies that would disqualify a member for Tevimbra (tislelizumab):*
    - i. *Bavencio (avelumab).*
    - ii. *Imfinzi (durvalumab).*
    - iii. *Jemperli (dostarlimab).*
    - iv. *Keytruda (pembrolizumab).*
    - v. *Libtayo (cemiplimab).*
    - vi. *Loqtorzi (toripalimab).*
    - vii. *Opdivo (nivolumab).*
    - viii. *Opdualag (nivolumab; relatlimab).*
    - ix. *Tecentriq (atezolizumab).*
    - x. *Zynyz (retifanlimab).*
    - xi. *Combination regimens containing any of the above immunotherapy agents.*
9. The member has Karnofsky performance score  $\geq 60\%$  or ECOG performance score  $\leq 2$ ; *AND*
10. Tevimbra (tislelizumab) is prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.

If the above prior authorization criteria are met, the requested product will be authorized for up to 6-months.<sup>[s]</sup>

*Continued Care*

**Medical Necessity Criteria for Subsequent Clinical Review**

**Subsequent Medical Necessity Criteria**

The Plan considers Tevimbra (tislelizumab) medically necessary when ALL of the following criteria are met:

1. The member continues to meet applicable **Initial Authorization** criteria; *AND*
2. Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; *AND*
3. There is no recorded evidence of disease progression, unacceptable toxicity or adverse reactions.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.<sup>[s]</sup>

**Experimental or Investigational or Unproven / Not Medically Necessary**<sup>[s]</sup>

Tevimbra (tislelizumab) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, unproven, or not medically necessary. Non-covered indications include, but are not limited to, the following:

- Use in other types of cancers without NCCN category 1, 2A or 2B recommendations.
- Use in gastric cancer treatment as monotherapy, as Tevimbra has only been studied in combination with platinum and fluoropyrimidine-based chemotherapy.

**Applicable Billing Codes**

Table 1	
CPT/HCPCS Codes for oncological indications considered medically necessary if criteria are met:	
<i>Code</i>	<i>Description</i>
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)
J9329	Injection, tislelizumab-jsgr, 1mg

Table 2	
ICD-10 diagnosis codes considered medically necessary for oncological indications with Table 1 (CPT/HCPCS) codes if criteria are met:	
<i>Code</i>	<i>Description</i>
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
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus

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## Appendix A

**Table 3: Eastern Cooperative Oncology Group (ECOG) Performance Status Scale**

ECOG Grade	ECOG Status
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work

ECOG Grade	ECOG Status
	activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

Table 4: Karnofsky Performance Status Scale

Karnofsky Grade	Karnofsky Status
100	Normal, no complaints; no evidence of disease
90	Able to carry on normal activity; minor signs or symptoms of disease
80	Normal activity with effort, some signs or symptoms of disease
70	Cares for self but unable to carry on normal activity or to do active work
60	Requires occasional assistance but is able to care for most of personal needs
50	Requires considerable assistance and frequent medical care
40	Disabled; requires special care and assistance
30	Severely disabled; hospitalization is indicated although death not imminent
20	Very ill; hospitalization and active supportive care necessary
10	Moribund
0	Dead

[Clinical Guideline Revision / History Information](#)

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