Oscar Clinical Guideline: Tevimbra (tislelizumab) (PG210, Ver. 2)

Tevimbra (tislelizumab)

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 new 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 (≥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 (≥1).

Definitions

"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 1 in the Appendix).

"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.

"Karnofsy 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 2 in the Appendix).

"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.

"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.

Medical Necessity Criteria for Initial Authorization

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

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

1. The medication is prescribed by or in consultation with an oncologist; *AND*
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 has documented disease progression on or after at least ONE prior line of systemic therapy for locally advanced or metastatic ESCC; *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.*
6. 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.*
7. The member has Karnofsky performance score ≥60% or ECOG performance score ≤2; *AND*
8. 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.

First-line Treatment of Unresectable or Metastatic Esophageal Carcinoma (ESCC) in Patients Whose Tumors Express PD-L1 (≥1):

1. The medication is prescribed by or in consultation with an oncologist; *AND*

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 (≥1); *AND*
6. The member is being treated concomitantly with a platinum-containing chemotherapy (e.g., cisplatin, oxaliplatin, carboplatin); *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 ≥60% or ECOG performance score ≤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.

<u>Gastric Cancer:</u>

1. The medication is prescribed by or in consultation with an oncologist; *AND*
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 (≥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); *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 ≥60% or ECOG performance score ≤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.

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

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12 months will be granted if the member has recent (within the last 3 months) clinical chart documentation demonstrating ALL of the following:

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.

Experimental or Investigational / Not Medically Necessary

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

- Use in other types of cancers (e.g., use in other histological subtypes of esophageal cancer such as adenocarcinoma)
- Use in earlier stages of ESCC in the neoadjuvant, adjuvant or maintenance settings. The safety and efficacy have not been established in these contexts.
- Use in gastric cancer treatment as monotherapy, as Tevimbra has only been studied in combination with platinum and fluoropyrimidine-based chemotherapy.
- Use in members with an ECOG performance status of >2, as they were excluded from the pivotal trial.
- Use in pediatric members less than 18 years of age, as the safety and efficacy of Tevimbra (tislelizumab) has not yet been established.

Applicable Billing Codes (HCPCS/CPT Codes)

Service(s) name	
CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
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
ICD-10 codes considered medically necessary if criteria are met:	
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
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

Table 1: 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 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 2: 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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