Oscar Clinical Guideline: Tevimbra (tislelizumab) (PG210, Ver. 1)

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.

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 patients 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.

Tevimbra (tislelizumab) is a new treatment option for patients with advanced ESCC 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 for treating unresectable or metastatic esophageal squamous cell carcinoma (ESCC) in patients who have previously received systemic chemotherapy that did not include a PD-(L)1 inhibitor.

Definitions

"**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.

"**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.

"**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**" 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:

1. The medication is prescribed by or in consultation with a 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. Documentation indicating **BOTH** of the following:
    a. the member has documented disease progression on or after at least one prior line of systemic therapy for locally advanced or metastatic ESCC; ***and***

       Examples of qualifying prior systemic therapy:

       - *Fluoropyrimidine (5-FU or capecitabine) plus platinum (cisplatin or oxaliplatin) chemotherapy.*

- *Taxane chemotherapy such as paclitaxel or docetaxel.*
- *Irinotecan chemotherapy.*
- *Fluoropyrimidine (5-FU or capecitabine) plus irinotecan chemotherapy.*
- *Ramucirumab plus paclitaxel chemotherapy.*

b. Prior therapies did not contain a PD-1 or PD-L1 inhibitor; ***AND***

Examples of prior therapies that would disqualify a patient for Tevimbra (tislelizumab):

- *Bavencio (avelumab).*
- *Imfinzi (durvalumab).*
- *Jemperli (dostarlimab).*
- *Keytruda (pembrolizumab).*
- *Libtayo (cemiplimab).*
- *Loqtorzi (toripalimab).*
- *Opdivo (nivolumab).*
- *Opdualag (nivolumab; relatlimab).*
- *Tecentriq (atezolizumab).*
- *Zynyz (retifanlimab).*
- *Combination regimens containing any of the above immunotherapy agents.*

6. The member has Karnofsky performance score ≥60% or ECOG performance score ≤2; ***AND***
7. Tevimbra (tislelizumab) is being 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 6-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 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 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.
    - Use in other histological subtypes of esophageal cancer such as adenocarcinoma.
- Use in combination with other immunotherapy agents, chemotherapy, targeted therapy, or radiation therapy. The safety and efficacy of these combinations have not been established.
- Use as first-line treatment of advanced ESCC. The efficacy of Tevimbra (tislelizumab) in the first-line setting or in chemotherapy-naïve patients has not been proven.
- 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 patients with an ECOG performance status of >2, as they were excluded from the pivotal trial.

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)
C9399	Unclassified drugs or biologicals
J3590	Unclassified biologics
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
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

References

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Clinical Guideline Revision / History Information

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