TEVIMBRA®
(tislelizumab-jsgr)
Injection, for intravenous use 10 mg/mL

TEVIMBRA Billing and Coding Guide

INDICATIONS

TEVIMBRA is a programmed death receptor-1 (PD-1)-blocking antibody indicated for:

Esophageal Cancer

- in combination with platinum-containing chemotherapy for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1).
- as a single-agent, for the treatment of adults with unresectable or metastatic ESCC after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.

Gastric Cancer

- in combination with platinum and fluoropyrimidine-based chemotherapy for the first-line treatment of adults with unresectable or metastatic HER2-negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (≥1).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Severe and Fatal Immune-Mediated Adverse Reactions

TEVIMBRA is a monoclonal antibody that belongs to a class of drugs that bind to either the programmed death receptor-1 (PD-1) or PD-ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions.

Please see additional Important Safety Information on pages 17-21 and full **Prescribing Information**, including **Medication Guide**.

INTRODUCTION

BeOne Medicines has developed this resource to provide healthcare providers and their staff with general information about billing, coding, access, patient assistance, and more for TEVIMBRA.

Overview

Reimbursement information and support are just a call away. Call **1-833-234-4363**

Oncology Nurse Advocates are available Monday through Friday from 8 AM to 8 PM ET

DISCLAIMER

This billing and coding guide is intended for informational purposes only and is not a guarantee of coverage or reimbursement. This information is subject to change without notice and should be verified by the healthcare provider. Healthcare providers should exercise independent judgment when selecting codes and submitting claims to accurately reflect the services rendered.

PRODUCT HIGHLIGHTS[1]

DOSING AND ADMINISTRATION

Recommended intravenous (IV) infusion dosage

150 mg every two weeks, 200 mg every three weeks, **300 mg every four weeks**, or **400 mg every six weeks** until disease progression or unacceptable toxicity

Route of administration

- For **150 mg and 200 mg doses**, administer the initial infusion over **60 minutes**. If tolerated, all subsequent infusions may be administered over **30 minutes**
- For **300 mg doses**, administer the initial infusion over **90 minutes**. If tolerated, administer the second infusion over **60 minutes**. If the second infusion is tolerated, administer subsequent infusions over **30 minutes**
- For **400 mg doses**, administer the initial infusion over **120 minutes**. If tolerated, administer the second infusion over **60 minutes**. If the second infusion is tolerated, administer subsequent infusions over **30 minutes**

Dose reductions are not recommended.

- In general, withhold TEVIMBRA for severe (Grade 3) immune-mediated adverse reactions

Permanently discontinue for:

- Life-threatening (Grade 4) immune-mediated adverse reactions
- Recurrent severe (Grade 3) immune-mediated reactions that require systemic immunosuppressive treatment
- Inability to reduce corticosteroid dose to 10 mg or less of prednisone equivalent per day within 12 weeks of initiating steroids

HOW SUPPLIED

100 mg/10 mL

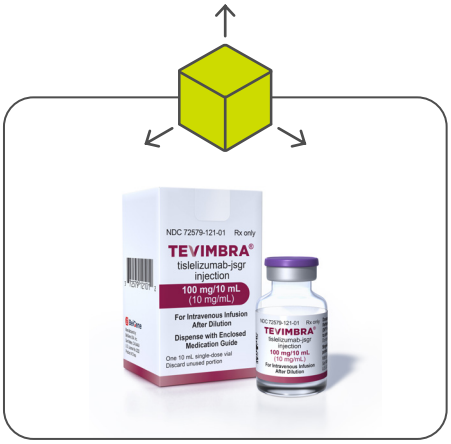
Carton containing one 100 mg/10 mL clear to slightly opalescent, colorless to slightly yellow solution in a **single-dose vial**

72579-0121-01

11-digit National Drug Code (NDC)

72579-0121-01

Note: Claim forms will require an 11-digit NDC. You may experience errors if you use a 10-digit NDC to complete a claim form.

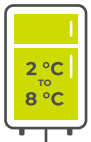


Please see Important Safety Information on pages 17-21 and full **Prescribing Information**, including **Medication Guide**.

TEVIMBRA® (tislelizumab-jsgr) Injection, for intravenous use 10 mg/mL

PRODUCT HIGHLIGHTS[1] (cont)

STORAGE AND HANDLING

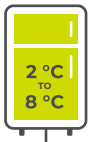


Storage of single-dose vial

- **Store** in a refrigerator at 2 °C to 8 °C (36 °F to 46 °F) in the original carton to keep out of light
- **Do not** freeze
- **Do not** shake

Preparation

- Withdraw the required volume from the vial(s)
- Transfer solution into an IV infusion bag with 0.9% sodium chloride injection. Final concentration should be between 2 mg/mL and 5 mg/mL
- Mix diluted solution by gentle inversion to avoid foaming or excessive shearing. Do not shake



Storage of diluted solution

- Store at **room temperature** for up to **four hours** from the time of dilution
- Store in a **refrigerator** at 2 °C to 8 °C (36 °F to 46 °F) for up to **10 days**. If refrigerated, allow the diluted solution to come to room temperature prior to administration
- **Do not** freeze

Discard vial:

- If solution is cloudy, discolored, or contains visible particles
- After use, including if any unused portion is left in the vial
- After four hours at room temperature or after 10 days under refrigeration

BILLING AND CODING

ICD-10-CM CODES

When appropriate, the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code set should be used, per the medical documentation, to report the patient-specific diagnosis. Payer-specific diagnosis code requirements should be confirmed.

Primary Diagnosis Codes[2]

ICD-10-CM code	Description
C15.3 - C15.9	Malignant neoplasm of esophagus
C16.0 - C16.9	Malignant neoplasm of stomach

Healthcare providers should exercise independent judgment when selecting codes and submitting claims to accurately reflect the services rendered.

It's important to review the payer's guidance to ensure appropriate codes are selected based on the patient's medical record

HCPCS CODES

Healthcare Common Procedure Coding System (HCPCS) codes (Level II) are used to identify medical products and services. The Centers for Medicare & Medicaid Services (CMS) have issued the following product-specific HCPCS code for TEVIMBRA.

HCPCS code[3]	Description[3]	Billable unit
J9329	Injection, tislelizumab-jsgr, 1 mg	1 mg = 1 unit

Based on the recommended dosage, providers should input 150 units, 200 units, or 300 units in Box 24G of the CMS-1500 Form (see page 9 for more information).

It's important to contact third-party payers for specific information on their coding, coverage, and payment policies

BILLING AND CODING (cont)

NATIONAL DRUG CODE (NDC)

Payers may require the NDC for TEVIMBRA on medical claims. Specific requirements for NDC reporting may vary; however, the 11-digit format is generally preferred for claim submissions.

10-digit NDC[1]	11-digit NDC[1]	Description[1]
72579-121-01	72579-0121-01	Tislelizumab-jsgr injection, for intravenous use

CURRENT PROCEDURAL TERMINOLOGY (CPT®) CODES

CPT codes define specific medical procedures performed by physicians. The following CPT code may be used to report the administration of TEVIMBRA.

CPT code[4]	Description[4]
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

MODIFIERS

Effective January 1, 2023, the JZ and JW modifiers will be applied to all drugs payable under Medicare Part B that are described in a "single-dose" container or "single-use" package. As of July 1, 2023, healthcare providers are required to report the JZ modifier when billing for drugs from single-dose containers, such as TEVIMBRA, when there are no discarded amounts. The JW modifier will still be required to report if any amount of the drug is discarded.[5]

All 340B covered entities must transition to the "TB" modifier by January 1, 2025. All 340B covered entities that previously reported the "JG" modifier on claim lines for separately payable Part B drugs acquired through the 340B program in 2024 should switch to reporting the "TB" on those same claim lines.[6]

Modifier[5,6]	Description[5,6]
JZ	Zero drug amount discarded/not administered to any patient[5]
JW	Drug amount discarded/not administered to any patient[5]
TB	Separately payable Part B drug acquired through 340B program[6]

BILLING AND CODING (cont)

REVENUE CODES

Revenue codes are standardized numerical codes used to identify specific services or procedures and are required on hospital outpatient and other facility claims.

The following list is not inclusive of all revenue codes that could be used. It is recommended to review individual payer guidance to determine the appropriate codes for TEVIMBRA.

Revenue code[7]	Description[7]
0636	Pharmacy, drugs requiring detailed coding
0260	IV therapy, general

SAMPLE CLAIM FORMS

Use the following section as an example of how to complete forms associated with health insurance claims for TEVIMBRA.

The sample claim forms in this section are provided for illustrative purposes only. It is the responsibility of the healthcare professional to determine the appropriate codes and submit true and correct claims for the products and services rendered. Contact the payer directly for specific information on their coding requirements, coverage policies, payment policies, and fee schedules, if needed.

CLAIMS FILING CHECKLIST

The following tips may help with filing successful claims for TEVIMBRA.

- ☐ **Use appropriate codes to report the patient's condition, the drugs the patient received, and the services provided**
  - ✓ ICD-10-CM code(s)
  - ✓ HCPCS code(s)
  - ✓ CPT code(s)
  - ✓ NDC
  - ✓ Dose administered
- ☐ **Attach additional information to the claim if necessary**
  - ✓ Letter of Medical Necessity
  - ✓ Prescribing information
  - ✓ Patient notes, including prior therapies received
- ☐ **Review claim for accuracy, including patient identification numbers, coding, and number of units**
- ☐ **File claim as soon as possible and within payer timely filing limits**
- ☐ **Reconcile claim reports promptly and thoroughly to ensure claims have been appropriately processed and paid**

SAMPLE CLAIM FORMS (cont)

CMS-1500 FORM

This form is the standard claim form used by healthcare professionals for the administration of TEVIMBRA in the office setting.[8]

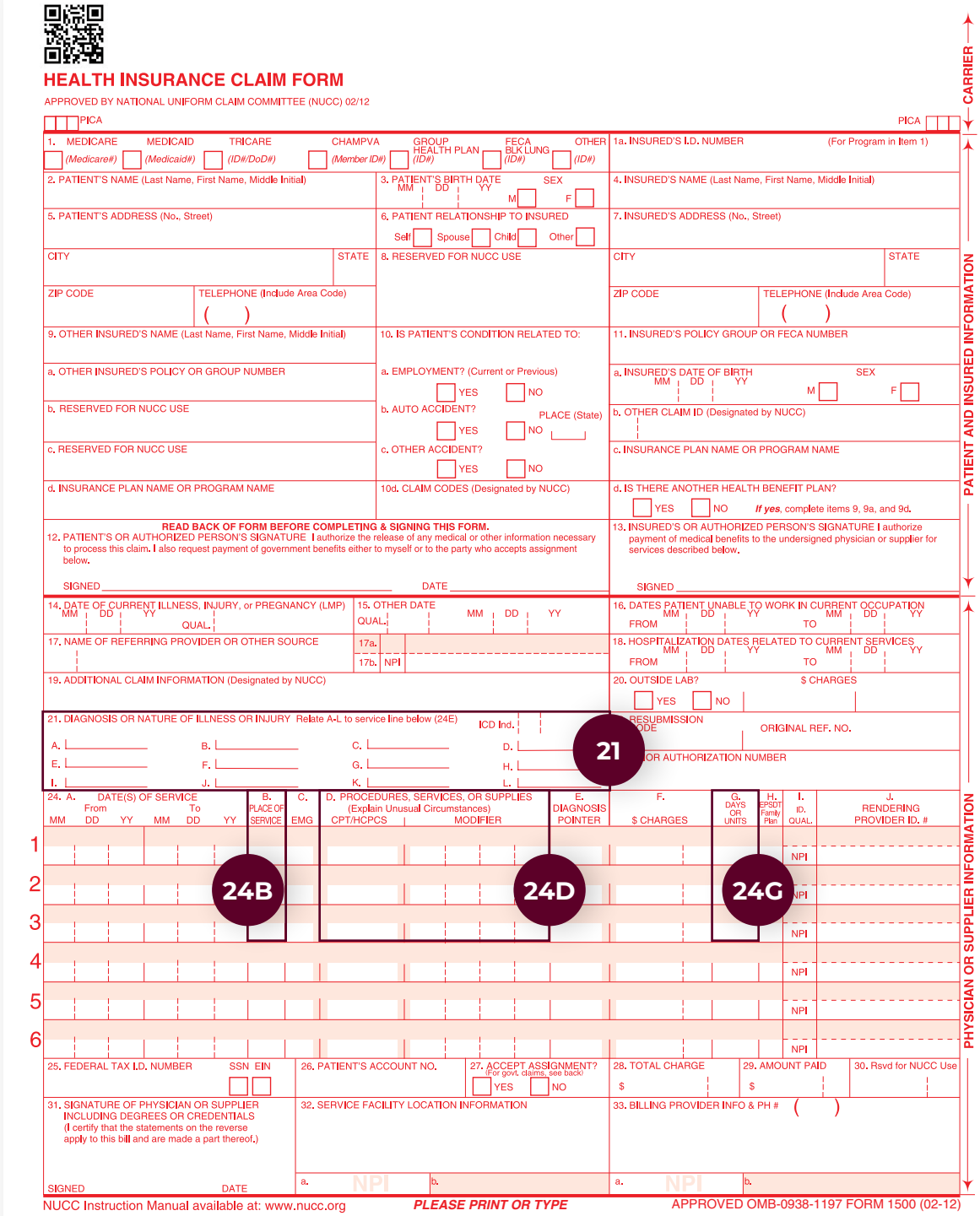
Find more information on submitting a **CMS-1500 Form**

Key components of this form are described below and are illustrated on the sample form on the following page

Section	
Box 21	Enter the appropriate diagnosis codes (eg, relevant ICD-10-CM codes)
Box 24B	Enter the appropriate code to indicate the setting where a service was provided
Box 24D	Enter the appropriate CPT, HCPCS, and modifier codes
Box 24G	Enter the appropriate number of units for TEVIMBRA

SAMPLE CLAIM FORMS (cont)

SAMPLE CMS-1500 FORM[9]



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code)

ZIP CODE TELEPHONE (Include Area Code)

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM MM DD YY TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM MM DD YY TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. B. C. D. E. F. G. H. I. J. K. L.

RESUBMISSION CODE ORIGINAL REF. NO.

OR AUTHORIZATION NUMBER

21

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY | B. PLACE OF SERVICE | C. EMG | D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS MODIFIER | E. DIAGNOSIS POINTER | F. $ CHARGES | G. DAYS OR UNITS | H. EPSDT Family Plan | I. ID. QUAL. | J. RENDERING PROVIDER ID. #

1 NPI

2 NPI

3 NPI

4 NPI

5 NPI

6 NPI

24B 24D 24G

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH #

a. NPI b.

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

BOX 21:

Diagnosis codes

BOX 24B:

Place of service

BOX 24D:

CPT, HCPCS, and modifier codes

BOX 24G:

Number of units

SAMPLE CLAIM FORMS (cont)

CMS-1450 (UB-04) FORM

This form, also known as the UB-04 Form, is a claim form used by institutions when TEVIMBRA is administered in the inpatient or outpatient setting.[10]

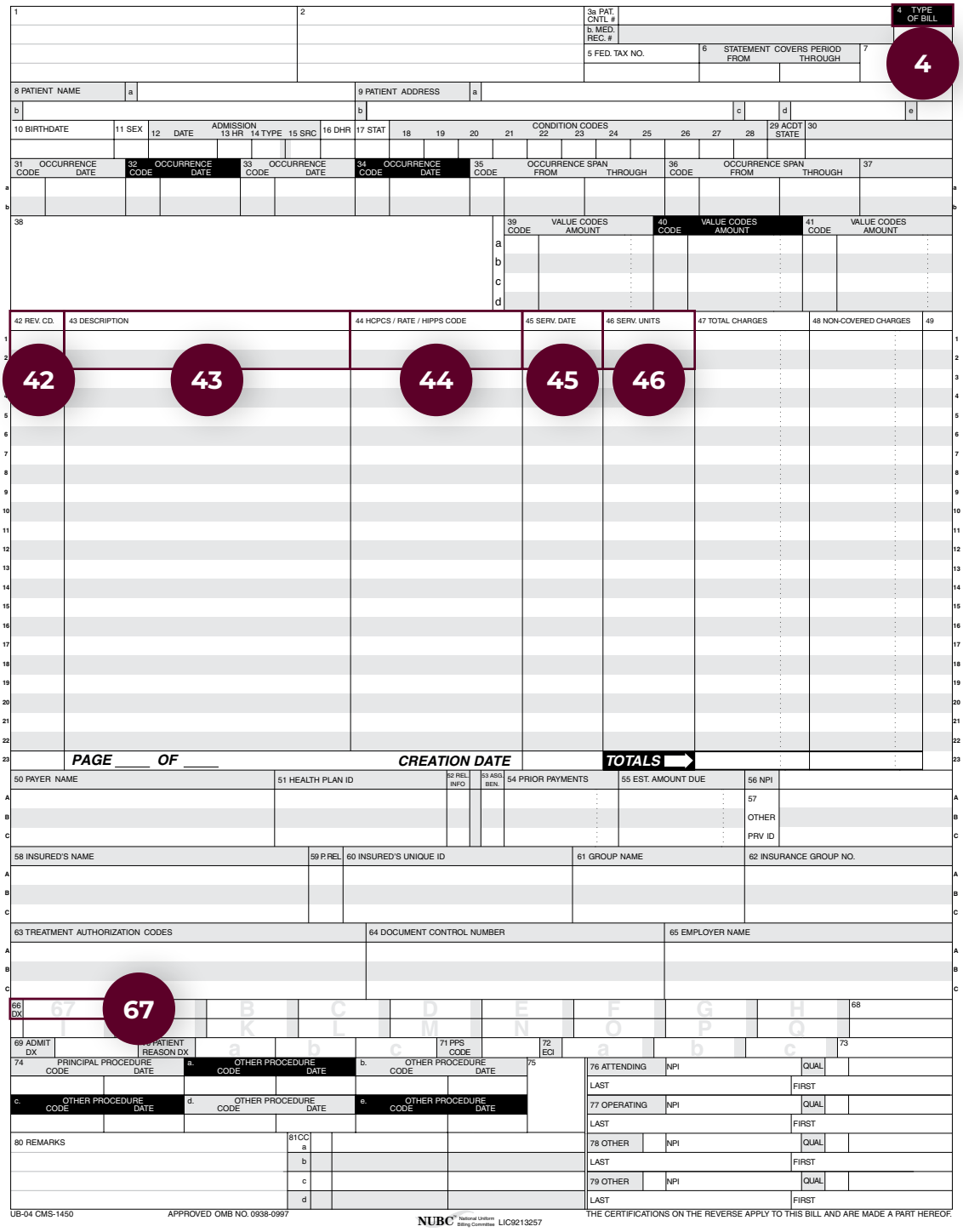
Find more information on submitting a **CMS-1450 Form**

Key components of this form are described below and are illustrated on the sample form on the following page

Section	
Box 4	Enter the appropriate code to indicate the setting where a service was provided
Box 42	Enter the appropriate revenue codes corresponding to the HCPCS codes in Box 44
Box 43	Enter the description corresponding to the revenue codes in Box 42
Box 44	Enter the appropriate CPT and HCPCS codes
Box 45	Enter the dates of service
Box 46	Enter the appropriate number of units for TEVIMBRA
Box 67	Enter the appropriate diagnosis codes (eg, relevant ICD-10-CM codes)

SAMPLE CLAIM FORMS (cont)

SAMPLE CMS-1450 (UB-04) FORM[11]



BOX 4:

Place of service

BOX 42:

Revenue codes

BOX 43:

Revenue code descriptions

BOX 44:

CPT and HCPCS codes

BOX 45:

Dates of service

BOX 46:

Number of units

BOX 67:

Diagnosis codes

COMPLETING PRIOR AUTHORIZATIONS

Prior authorizations (PAs) demonstrate to the payer that the health plan's specific requirements have been met or explain why TEVIMBRA is the most appropriate treatment for the patient. Use this section as a guide for completing and submitting a PA to the payer when required.

Review the payer's guidelines when completing a PA, as these requirements often differ between payers, health plans, prescribed medications, and more.

PA CHECKLIST

The following tips may help with completing comprehensive PAs for TEVIMBRA.

- ☐ **Include patient's name, date of birth, insurance ID number, insurance group number, and dates of service**
- ☐ **Include patient's diagnosis and corresponding ICD-10-CM code(s)**
- ☐ **List previous therapies**
- ☐ **Provide additional information at the request of the payer**
  - ✓ Physician information including name and tax ID number
  - ✓ Facility information including name and tax ID number
  - ✓ Setting of care
  - ✓ Date(s) of service
  - ✓ Patient clinical notes detailing relevant diagnosis
  - ✓ Supporting documentation for treatment decisions, including laboratory tests, imaging results, and pathology reports
  - ✓ Relevant codes, specifically CPT and HCPCS, for services/products to be performed or provided
  - ✓ TEVIMBRA prescribing information
- ☐ **Ensure information provided in the PA matches the billing claim**

Avoid further delays in treatment

Missing or incomplete information or documentation can lead to a PA being denied. Ensure all requested PA information is included, such as prior treatment history, testing history, and necessary code(s).

REASONS FOR DENIAL

If a payer chooses to deny coverage for TEVIMBRA, a letter will be sent to the healthcare professional explaining the rationale. These letters include claim adjustment reason codes (CARCs), which describe why a claim or service line was denied or paid differently than it was billed.[12] Typically, a payer denial for TEVIMBRA is related to the payer's coverage policy or a perceived lack of evidence of clinical appropriateness.

Common CARCs[12,13]

CARC	Explanation	Tips
#197 Precertification/ authorization/ notification absent	Almost all payers outside of traditional Medicare require a PA for branded drugs and biosimilars, and it is not enough to simply obtain a PA. The claim must reflect exactly what was approved.	• Record authorization numbers if issued • Ensure the following information in the claim matches what was approved in the PA: – Diagnosis code – Dose – Number of cycles – HCPCS code
#252 An attachment/other documentation is required to adjudicate this claim/service[a]	Most often, this code is used to request a medical record; other requested documents include: • Certificate of medical necessity • Progress notes • Patient treatment plans • Invoices (required by some Medicare contractors for new drugs) • Explanation of benefits (EOB) (secondary payer claims)	• Read the remark codes on the EOB to determine what documentation is being requested • Carefully track fulfillment of the request to avoid repeated denials
#16 Claim/service lacks information or has submission/billing error(s)	This is the most common denial code for all drugs. For programmed death receptor-1 (PD-1) inhibitors, this denial is most often issued for lack of or an incorrect NDC. Other reasons include wrong provider number, lack of units of service, wrong patient identification numbers, and other clerical omissions.	• Check each claim prior to submission to ensure all required information is included and no clerical errors are present • Double check NDCs, ensuring that they are in the proper 11-digit format or according to the payer requirement • Note that denials issued under this code can often be resolved via telephone

[a]At least one remark code must be provided.

REASONS FOR DENIAL (cont)

Common CARCs[12,13]

CARC	Explanation	Tips
#96 Non-covered charge[a]	This denial code does NOT mean that the drug is not covered by a specific payer, but instead that the claim has violated a contractual agreement with or a specified policy of the payer and is not covered. Most often, the claim does not match the product label in some way. Reasons specified in the remark codes include: • Incorrect diagnosis code • Violating the payer contract • Exceeding approved dosing • Reporting incorrect HCPCS units • Patient does not have a major medical benefit	• Read the remark codes carefully to determine the specific reason for the denial • If the violation is due to a clerical error, it may be corrected via telephone
#226 Information requested from the billing/ rendering provider was not provided or was insufficient/ incomplete[a]	Reasons for use of this denial code are often similar to those of #252—missing records, missing notes, missing EOB for secondary payers, etc. Additionally, this code may be used when the documentation does not match the request (eg, wrong patient information submitted, note not signed by the healthcare provider, or mismatched date of service).	• Double check any documentation submitted to ensure it matches all billing information • Read the remark codes carefully to determine the specific reason for the denial
#29 The time limit for filing has expired	This denial code means that the healthcare provider or the billing entity has failed to submit the claim within the specified timeframe allowed by the insurance company.	• Review the claim to verify: – Date of service – Reason for the delay

Search a full list of possible CARCs[12]

After receiving a denial letter, the healthcare professional can respond through a Letter of Appeal

[a]At least one remark code must be provided.

COMPLETING APPEALS

After receiving a claim denial for TEVIMBRA, healthcare professionals can respond to the payer with a Letter of Appeal. Use this section as a guide for completing and submitting a Letter of Appeal to the payer.

APPEAL CHECKLIST

The following tips may help with completing a Letter of Appeal for TEVIMBRA.

- ☐ **Include patient's name, date of birth, insurance ID number, insurance group number, and dates of service**
- ☐ **Include patient's diagnosis and corresponding ICD-10-CM code(s)**
- ☐ **Include responses to each specific reason for denial**
- ☐ **Attach copies of relevant medical records**
- ☐ **Attach clinical support for prescribing TEVIMBRA**
- ☐ **List previous therapies, including their duration and explanation of discontinuation**
- ☐ **Explain why the health plan's preferred treatment options are not appropriate for the patient**
- ☐ **Provide a Letter of Medical Necessity and the full Prescribing Information, including Medication Guide for TEVIMBRA**
- ☐ **Provide additional information at the request of the payer**
  - ✓ Reference number of existing claim decision, if applicable
  - ✓ Patient Authorization and Notice of Release of Information
  - ✓ Denial information, including the denial letter or EOB notification
  - ✓ Other supporting documents, such as chart notes, current medications, laboratory results, imaging results, or pathology reports

It is also important to review the EOB, which will indicate where the appeal should be filed, which form to use, and any specific deadlines.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Severe and Fatal Immune-Mediated Adverse Reactions

TEVIMBRA is a monoclonal antibody that belongs to a class of drugs that bind to either the programmed death receptor-1 (PD-1) or PD-ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions.

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. Immune-mediated adverse reactions can occur at any time after starting treatment with a PD-1/PD-L1 blocking antibody. While immune-mediated adverse reactions usually manifest during treatment with PD-1/PD-L1 blocking antibodies, immune-mediated adverse reactions can also manifest after discontinuation of PD-1/PD-L1 blocking antibodies. Important immune-mediated adverse reactions listed here may not include all possible severe and fatal immune-mediated reactions.

Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of PD-1/PD-L1 blocking antibodies. Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Withhold or permanently discontinue TEVIMBRA depending on severity. In general, if TEVIMBRA requires interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reactions are not controlled with corticosteroids.

Immune-Mediated Pneumonitis

TEVIMBRA can cause immune-mediated pneumonitis, which can be fatal. In patients treated with other PD-1/PD-L1 blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation.

Immune-mediated pneumonitis occurred in 4.7% (113/2390) of patients receiving TEVIMBRA, including fatal (0.1%), Grade 4 (0.3%), Grade 3 (1.4%), and Grade 2 (1.9%) adverse reactions. Pneumonitis led to permanent discontinuation of TEVIMBRA in 44 (1.8%) patients and withholding of TEVIMBRA in 40 (1.7%) patients.

Eighty-one (71.7%) of the 113 patients received systemic corticosteroids. Seventy-four (65.5%) of the 113 patients received high-dose systemic corticosteroids. Immune-mediated pneumonitis resolved in 48.7% of the 113 patients. Of the 40 patients in whom TEVIMBRA was withheld for pneumonitis, 26 (65%) reinitiated TEVIMBRA after symptom improvement; of these, 5 (19%) patients had recurrence of pneumonitis.

Immune-Mediated Colitis

TEVIMBRA can cause immune-mediated colitis, which can be fatal. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis treated with PD-1/PD-L1 blocking antibodies. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

Immune-mediated colitis occurred in 0.8% (19/2390) of patients receiving TEVIMBRA, including Grade 3 (0.3%) and Grade 2 (0.4%) adverse reactions. Colitis led to permanent discontinuation of TEVIMBRA in 5 (0.2%) patients and withholding of TEVIMBRA in 10 (0.4%) patients. Seventeen (89.5%) of the 19 patients received systemic corticosteroids. Twelve (63.2%) of the 19 patients received high-dose systemic corticosteroids. Two (10.5%) of the 19 patients received immunosuppressive treatment. Immune-mediated colitis resolved in 89.5% of the 19 patients. Of the 10 patients in whom TEVIMBRA was withheld for colitis, 9 (90%) reinitiated TEVIMBRA after symptom improvement; of these, 2 (22%) patients had recurrence of colitis.

WARNINGS AND PRECAUTIONS

Severe and Fatal Immune-Mediated Adverse Reactions (cont)

Immune-Mediated Hepatitis

TEVIMBRA can cause immune-mediated hepatitis, which can be fatal.

Immune-mediated hepatitis occurred in 1.3% (30/2390) of patients receiving TEVIMBRA, including Grade 4 (0.3%), Grade 3 (0.6%), and Grade 2 (0.3%) adverse reactions. Immune-mediated hepatitis led to permanent discontinuation in 6 (0.3%) patients and withholding of TEVIMBRA in 19 (0.8%) patients. Twenty-five (83.3%) of the 30 patients received systemic corticosteroids. Twenty-four (80%) of the 30 patients received high-dose systemic corticosteroids. Two (6.7%) of the 30 patients received immunosuppressive treatment. Immune-mediated hepatitis resolved in 66.7% of the 30 patients. Of the 19 patients in whom TEVIMBRA was withheld for hepatitis, 7 (37%) reinitiated TEVIMBRA after symptom improvement; of these, 1 (14%) patient had recurrence of hepatitis.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

TEVIMBRA can cause immune-mediated adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold TEVIMBRA depending on severity.

Immune-mediated adrenal insufficiency occurred in 0.5% (12/2390) of patients receiving TEVIMBRA, including Grade 4 (0.04%), Grade 3 (0.2%), and Grade 2 (0.3%) adverse reactions. Adrenal insufficiency did not lead to permanent discontinuation of TEVIMBRA. TEVIMBRA was withheld in 10 (0.4%) patients. All 12 patients received systemic corticosteroids. Three (25%) of the 12 patients received high-dose systemic corticosteroids. Adrenal insufficiency resolved in 25% of the 12 patients. Of the 10 patients in whom TEVIMBRA was withheld for adrenal insufficiency, 8 (80%) reinitiated TEVIMBRA after symptom improvement; of these, none of the patients had recurrence of adrenal insufficiency.

Hypophysitis

TEVIMBRA can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue TEVIMBRA depending on severity.

Hypophysitis/hypopituitarism occurred in 0.3% (6/2390) of patients receiving TEVIMBRA; all were Grade 2 (0.3%). Hypophysitis did not lead to permanent discontinuation of TEVIMBRA. TEVIMBRA was withheld in 1 (0.04%) patient. Five (83.3%) of the 6 patients received systemic corticosteroids. One (17%) of the 6 patients received high-dose systemic corticosteroids. Hypophysitis/hypopituitarism resolved in 17% of the 6 patients. For the 1 patient where TEVIMBRA was withheld for hypophysitis/hypopituitarism, there was no recurrence of hypophysitis/hypopituitarism.

Thyroid Disorders

TEVIMBRA can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue TEVIMBRA depending on severity.

Thyroiditis: Immune-mediated thyroiditis occurred in 1% (25/2390) of patients receiving TEVIMBRA, including Grade 2 (0.5%) adverse reactions. Thyroiditis did not lead to permanent discontinuation of TEVIMBRA. TEVIMBRA was withheld in 5 (0.2%) patients. Two (8%) of the 25 patients received systemic corticosteroids. Thyroiditis resolved in 36% of the 25 patients. All 5 patients in whom TEVIMBRA was withheld for thyroiditis reinitiated TEVIMBRA after symptom improvement; of these, 1 (20%) patient had recurrence of thyroiditis.

WARNINGS AND PRECAUTIONS

Severe and Fatal Immune-Mediated Adverse Reactions (cont)

Immune-Mediated Endocrinopathies (cont)

Thyroid Disorders (cont)

Hyperthyroidism: Immune-mediated hyperthyroidism occurred in 4.9% (118/2390) of patients receiving TEVIMBRA, including Grade 3 (0.04%) and Grade 2 (0.9%) adverse reactions. Hyperthyroidism led to the permanent discontinuation of TEVIMBRA in 1 (0.04%) patient and withholding of TEVIMBRA in 7 (0.3%) patients. Three (2.5%) of the 118 patients received systemic corticosteroids. Hyperthyroidism resolved in 76.3% of the 118 patients. Of the 7 patients in whom TEVIMBRA was withheld for hyperthyroidism, 5 (71.4%) reinitiated TEVIMBRA after symptom improvement; of these, none of the patients had recurrence of hyperthyroidism.

Hypothyroidism: Immune-mediated hypothyroidism occurred in 12.5% (299/2390) of patients receiving TEVIMBRA, including Grade 4 (0.04%), Grade 3 (0.04%), and Grade 2 (6.7%) adverse reactions. TEVIMBRA was permanently discontinued in 2 (0.1%) patients and treatment was withheld in 12 (0.5%) patients. Two (0.7%) of the 299 patients received systemic corticosteroids. One hundred ninety-five patients received hormone replacement therapy. Hypothyroidism resolved in 34.4% of the 299 patients. The majority (83.6%) of patients with hypothyroidism required long-term thyroid hormone replacement. Of the 12 patients in whom TEVIMBRA was withheld for hypothyroidism, 11 (91.7%) reinitiated TEVIMBRA after symptom improvement; of these, 2 (18.2%) patients had recurrence of hypothyroidism.

Type 1 Diabetes Mellitus, which can present with Diabetic Ketoacidosis

Diabetes mellitus has been reported with PD-1/PD-L1 blocking antibodies. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue TEVIMBRA depending on severity.

Diabetes mellitus occurred in 0.7% (16/2390) of patients receiving TEVIMBRA, including Grade 4 (0.1%), Grade 3 (0.3%), and Grade 2 (0.3%) adverse reactions. TEVIMBRA was permanently discontinued in 4 (0.2%) patients, and TEVIMBRA treatment was withheld in 4 (0.2%) patients. Fourteen of the 16 patients received insulin therapy for diabetes mellitus. Diabetes mellitus resolved in 12.5% of the 16 patients. Of the 4 patients in whom TEVIMBRA was withheld for diabetes mellitus, 1 (25%) patient reinitiated TEVIMBRA after symptom improvement.

Immune-Mediated Nephritis with Renal Dysfunction

TEVIMBRA can cause immune-mediated nephritis, which can be fatal.

Immune-mediated nephritis with renal dysfunction occurred in 0.2% (5/2390) of patients receiving TEVIMBRA, including Grade 3 (0.04%) and Grade 2 (0.1%) adverse reactions. TEVIMBRA was permanently discontinued in 1 (0.04%) patient and treatment was withheld in 3 (0.1%) patients. Three (60%) out of 5 patients received systemic corticosteroids. Three (60%) of the 5 patients received high-dose systemic corticosteroids. Nephritis with renal dysfunction resolved in 40% of the 5 patients. Of the 3 patients in whom TEVIMBRA was withheld for nephritis, 2 (66.7%) reinitiated TEVIMBRA after symptom improvement and no patients had recurrence of nephritis.

Immune-Mediated Dermatologic Adverse Reactions

TEVIMBRA can cause immune-mediated rash or dermatitis. Cases of severe cutaneous adverse reactions (SCARs), including exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), have been reported, some with fatal outcome. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-exfoliative rashes. Withhold or permanently discontinue TEVIMBRA depending on severity.

WARNINGS AND PRECAUTIONS

Severe and Fatal Immune-Mediated Adverse Reactions (cont)

Immune-Mediated Dermatologic Adverse Reactions (cont)

Immune-mediated dermatologic adverse reactions occurred in 13% (311/2390) of patients receiving TEVIMBRA, including Grade 4 (0.1%), Grade 3 (1.1%), and Grade 2 (3.4%) adverse reactions. Stevens-Johnson syndrome occurred in 1 (0.04%) patient. Dermatologic adverse reactions led to permanent discontinuation of TEVIMBRA in 3 (0.1%) patients and withholding of TEVIMBRA in 30 (1.3%) patients. Forty-four (14.1%) of the 311 patients received systemic corticosteroids. Nineteen (6.1%) of the 311 patients received high-dose systemic corticosteroids. Immune-mediated skin reactions resolved in 66.9% of the 311 patients. Of the 30 patients in whom TEVIMBRA was withheld for dermatologic adverse reactions, 26 (86.7%) reinitiated TEVIMBRA after symptom improvement; of these, 3 (12%) patients had recurrence of immune-mediated dermatologic adverse reactions.

Other Immune-Mediated Adverse Reactions

The following clinically significant immune-mediated adverse reactions occurred at an incidence of less than 1% in 2390 patients who received TEVIMBRA or were reported with the use of other PD-1/PD-L1 blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.

Cardiac/Vascular: Myocarditis, pericarditis, vasculitis.

Nervous System: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy.

Ocular: Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss.

Gastrointestinal: Pancreatitis including increases in serum amylase and lipase levels, gastritis, duodenitis, stomatitis.

Musculoskeletal and Connective Tissue: Myositis/polymyositis/dermatomyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica.

Endocrine: Hypoparathyroidism.

Other (Hematologic/Immune): Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Infusion-Related Reactions

TEVIMBRA can cause severe or life-threatening infusion-related reactions. Infusion-related reactions occurred in 5% (99/1972) of patients receiving TEVIMBRA, including Grade 3 or higher (0.2%) reactions. Monitor patients for signs and symptoms of infusion-related reactions.

Slow the rate of infusion for mild (Grade 1) and interrupt the infusion for moderate (Grade 2) infusion-related reactions. For severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions, stop infusion and permanently discontinue TEVIMBRA.

Complications of Allogeneic HSCT

Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with a PD-1/PD-L1 blocking antibody. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between PD-1/PD-L1 blockade and allogeneic HSCT.

Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with a PD-1/PD-L1 blocking antibody prior to or after an allogeneic HSCT.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity

Based on its mechanism of action, TEVIMBRA can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-1/PD-L1 pathway can lead to increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TEVIMBRA and for 4 months after the last dose.

ADVERSE REACTIONS

First-line Treatment of Unresectable Advanced or Metastatic Esophageal Carcinoma (ESCC)

Permanent discontinuation of TEVIMBRA due to adverse reactions occurred in 13% of patients. The adverse reaction which resulted in discontinuation in ≥2% of patients was pneumonitis (2.2%).

Dosage interruptions of TEVIMBRA due to adverse reactions occurred in 52% of patients. Adverse reactions which required dosage interruption in ≥2% of patients were neutrophil count decreased (7%), fatigue (6%), pneumonia (6%), anemia (4.3%), neutropenia (4.3%), white blood cell count decreased (4.3%), rash (3.7%), dysphagia (2.8%), platelet count decreased (2.8%), pyrexia (2.8%), and diarrhea (2.2%).

The most common (≥20%) adverse reactions, including laboratory abnormalities were decreased neutrophil count, decreased sodium, increased glucose, anemia, fatigue, decreased appetite, increased AST, decreased potassium, increased serum creatinine, decreased calcium, increased ALT, diarrhea, stomatitis, and vomiting.

Previously Treated Unresectable Advanced or Metastatic ESCC

Permanent discontinuation of TEVIMBRA due to an adverse reaction occurred in 19% of patients. Adverse reactions which resulted in permanent discontinuation in ≥1% of patients were hemorrhage, pneumonitis (including pneumonitis and immune-mediated pneumonitis), and pneumonia.

Dosage interruptions of TEVIMBRA due to an adverse reaction occurred in 23% of patients. Adverse reactions which required dosage interruptions in ≥2% of patients were pneumonia, pneumonitis, and fatigue.

The most common (≥20%) adverse reactions, including laboratory abnormalities, were increased glucose, decreased hemoglobin, decreased lymphocytes, decreased sodium, decreased albumin, increased alkaline phosphatase, anemia, fatigue, increased AST, musculoskeletal pain, decreased weight, increased ALT, and cough.

Treatment of Previously Untreated Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (G/GEJ)

Permanent discontinuation of TEVIMBRA due to an adverse drug reaction occurred in 16% of patients. Adverse drug reactions which resulted in permanent discontinuation in ≥1% of patients were death, fatigue, and pneumonitis.

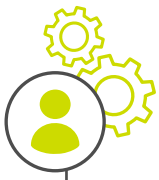
Dosage interruption of TEVIMBRA in the TEVIMBRA plus chemotherapy arm due to an adverse drug reaction occurred in 49% of patients. Adverse drug reactions which required dosage modifications in ≥2% of patients were, platelet count decreased (12%), neutrophil count decreased (10%), neutropenia (6%), white blood cell count decreased (6%), increased AST (4.8%), increased ALT (3.8%), increased blood bilirubin (3%), COVID-19 (3%), thrombocytopenia (2.8%), leukopenia (2.6%), pneumonitis (2.2%), and pneumonia (2%).

The most common (≥20%) adverse reactions, including laboratory abnormalities, for TEVIMBRA in combination with chemotherapy were nausea, fatigue, decreased appetite, anemia, peripheral sensory neuropathy, vomiting, decreased platelet count, decreased neutrophil count, increased aspartate aminotransferase, diarrhea, abdominal pain, increased alanine aminotransferase, decreased white blood cell count, decreased weight, and pyrexia.

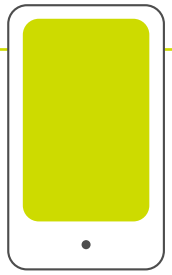
The myBeOneSupport program provides support for prescribed patients through personalized assistance from a dedicated Oncology Nurse Advocate, including:

Simplifying access through financial assistance

Educating patients and care partners



Providing personalized solutions



Reimbursement information and support are just a call away. Call **1-833-234-4363**

Oncology Nurse Advocates are available Monday through Friday from 8 AM to 8 PM ET

References: 1. TEVIMBRA. Package insert. BeOne Medicines USA, Inc.; 2025. **2.** ICD-10-CM diagnosis codes. National Center for Health Statistics – ICD-10-CM. Centers for Disease Control and Prevention. Accessed May 7, 2025. https://icd10cmtool.cdc.gov/?fy=FY2024 **3.** Second Quarter, 2024 HCPCS Coding Cycle. Centers for Medicare & Medicaid Services. July 2, 2024. Accessed May 7, 2025. https://www.cms.gov/files/document/2024-hcpcs-application-summary-quarter-2-2024-drugs-and-biologicals.pdf **4.** *CPT® 2024 Professional Edition*. 4th ed. American Medical Association; 2023. **5.** Medicare program: Discarded drugs and biologicals – JW modifier and JZ modifier policy frequently asked questions. Centers for Medicare & Medicaid Services. Accessed November 17, 2025. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **6.** Medicare part b inflation rebate guidance: Use of the 340B modifier. Centers for Medicare & Medicaid Services. November 2024. Accessed November 17, 2025. **7.** Medicare revenue codes. Noridian Healthcare Solutions. Accessed May 7, 2025. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **8.** *Medicare Claims Processing Manual*. Chapter 26 – Completing and Processing Form CMS-1500 Data Set. Rev. 12779. Centers for Medicare & Medicaid Services. Updated August 9, 2024. Accessed May 7, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf **9.** CMS-1500. Centers for Medicare & Medicaid Services. Accessed May 7, 2025. https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms1500.pdf **10.** *Medicare Claims Processing Manual*. Chapter 25 – Completing and Processing the Form CMS-1450 Data Set. Rev 12423. Centers for Medicare & Medicaid Services. Updated December 20, 2023. Accessed May 7, 2025. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c25.pdf **11.** CMS-1450. Centers for Medicare & Medicaid Services. June 6, 2023. Accessed May 7, 2025. https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing-items/cms-1450 **12.** X12. Claim adjustment reason codes. Updated March 1, 2025. Accessed May 7, 2025. https://x12.org/codes/claim-adjustment-reason-codes **13.** Denial code (CARC) list. MD Clarity. Accessed May 7, 2025. https://www.mdclarity.com/denial-code-carcs

Please see Important Safety Information on pages 17-21 and full **Prescribing Information**, including **Medication Guide**.

TEVIMBRA® (tislelizumab-jsgr) Injection, for intravenous use 10 mg/mL