Billing and Coding Guide

Step-by-step guide to coverage determination, claim submission, and reimbursement

TEPEZZA J-Code: J3241, 10 mg

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA®
teprotumumab-trbw

Welcome

TEPEZZA is indicated for the treatment of Thyroid Eye Disease regardless of Thyroid Eye Disease activity or duration.[1]

Horizon Therapeutics is committed to assisting patients throughout their access and treatment journeys. Horizon By Your Side is a patient support program with a wide array of patient-focused services, including education about the insurance process. We developed this guide to provide the information you may need to help with the coverage and reimbursement process for TEPEZZA.

HORIZON BY your side

Horizon By Your Side is a patient support program for patients prescribed TEPEZZA. The Horizon By Your Side team will provide information on patient support, logistical assistance, insurance benefits investigation, and financial assistance.

If your patient is interested in Horizon By Your Side, just call **1-833-5-TEPEZZA** or visit **TEPEZZAhcp.com** to initiate their enrollment. Your patient must complete the Patient Enrollment Form (PEF) to access these patient-focused services and resources.

Table of Contents

The information in this guide is intended for informational purposes only and does not represent legal or billing advice. For specific guidance in this area, consult your own legal/billing advisor and billing/coding specialist because it remains your responsibility to ensure the accuracy of the claims your site of care submits.

Responsibility for properly submitting claims lies with the healthcare provider. We make no representations about the eligibility or guarantee of coverage, coding, or reimbursement for any particular claim. It is the responsibility of the healthcare provider to choose the most appropriate code as documented in the patient's medical chart and submit the appropriate codes, charges, and modifiers for services or items rendered or applied. Your patient's enrollment in Horizon By Your Side will in no way guarantee reimbursement.

The content herein is based on information current as of August 2023, and may have changed. Any product, ancillary supplies, or services received free of charge cannot be billed to third-party payors because doing so could be a violation of federal and/or state laws and/or third-party payor requirements.

Physician office and office-based infusion center billing and coding

A medical group, or other entity entitled to bill and receive payment for physician services, uses the current ASC X12 professional claim billing format or Form CMS-1500 to submit claims to Medicare A/B MACs Part B and all other payors.[2]

This section provides general physician office coding information for TEPEZZA. The final coverage determination is not made until the payor receives and reviews the claim. Coding for TEPEZZA may vary by payor type (eg, Medicare, Medicaid, commercial payor) and plan type. Contact payors for specific coding requirements for billing TEPEZZA.

POS codes

POS codes identify the location where a service was performed. The following POS codes may be appropriate when TEPEZZA is administered in the physician office or office-based infusion center:

POS Code[3]	POS Name	Description
11	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis
49	Independent clinic	A location, not part of a hospital and not described by any other place of service code, that is organized and operated to provide preventive, diagnostic, therapeutic, rehabilitative, or palliative services to outpatients only

NDC

Payor requirements regarding the use of the 10- or 11-digit NDC may vary. Electronic data interchange (EDI) generally requires the use of the 11-digit NDC. Check payor requirements for appropriate reporting of the NDC. You may need to add the NDC for TEPEZZA to your EMR system if it is not already included.

TEPEZZA (teprotumumab-trbw) for injection is a sterile, preservative-free, white to off-white lyophilized powder available as follows[1]:

10-digit NDC[1]	11-digit NDC	Description
75987-130-15	75987-0130-15	Carton containing one 500-mg single-dose vial (lyophilized powder for intravenous infusion)

ICD-10-CM diagnosis codes

The following may be an appropriate ICD-10-CM diagnosis code for prescribing TEPEZZA:

ICD-10-CM Diagnosis Code[4]	Description
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm

Clinical Activity Score (CAS)-related ICD-10-CM diagnosis codes may be necessary to fully describe the patient's condition and associated manifestations. It is important to include CAS within your clinical documentation. Please click here for a listing of CAS-related ICD-10-CM diagnosis codes that you may want to include in a claim.

ASC X12, Accredited Standards Committee for X12; EMR, electronic medical records; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification; MAC, Medicare Administrative Contractor; NDC, National Drug Code; POS, place of service.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA® teprotumumab-trbw

HCPCS code

TEPEZZA has a permanent, product-specific HCPCS code: J3241.

HCPCS Drug Code[5]	Description
J3241	Injection, teprotumumab-trbw, 10 mg

When billing for TEPEZZA using J3241:

- One unit represents 10 mg of TEPEZZA. TEPEZZA should be billed based on units, not the number of milligrams

Modifiers

Modifiers are typically alphanumeric 2-character indicators that provide payors with additional information regarding the services rendered. If appropriate, more than 1 modifier may be used with a single procedure code.

Certain payors require the "JW" modifier to be used in order to obtain payment for a discarded amount of drug for single-dose or single-use packaging. For claims submitted with J3241, providers should use multiple lines to identify the amount administered and the amount wasted. One line of the claim should include J3241 and number of units administered. A separate line should include J3241 with the JW modifier and the number of units wasted.

Effective January 1, 2023, modifier "JZ" may be reported on claims to note zero discarded amounts from single-use vials or single-use packages. CMS requires the reporting of modifier JZ effective July 1, 2023. Claims processing edits will be implemented by the MACs effective October 1, 2023.[6]

Contact payors for specific coding requirements for billing wastage and modifiers.

Modifier	Description	Appropriate Use
JW	Drug amount discarded/not administered to any patient	Append to J3241 when there was discarded drug amount
JZ	Zero drug amount discarded/not administered to any patient	Append to J3241 when there was NO discarded drug amount

CPT® codes

When billing for TEPEZZA in the physician office, the following CPT® codes may be appropriate:

Chemotherapy Administration and Other Highly Complex Drug or Highly Complex Biologic Agent Administration

CPT® Code[7]	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug; each additional hour *List separately in addition to code for primary procedure*

CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; MAC, Medicare Administrative Contractor.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA® teprotumumab-trbw

Therapeutic, Prophylactic, and Diagnostic Injections and Infusions

CPT® Code[7]	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour; each additional hour *List separately in addition to code for primary procedure*

Other relevant testing considerations

Glucose testing codes

CPT® Code[7]	Description
82945	Glucose, body fluid, other than blood
82947	Glucose, quantitative, blood (except reagent strip)
82948	Glucose, blood, reagent strip
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use

Consult individual payors on any coding and documentation preferences

CPT®, Current Procedural Terminology; FDA, US Food and Drug Administration.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

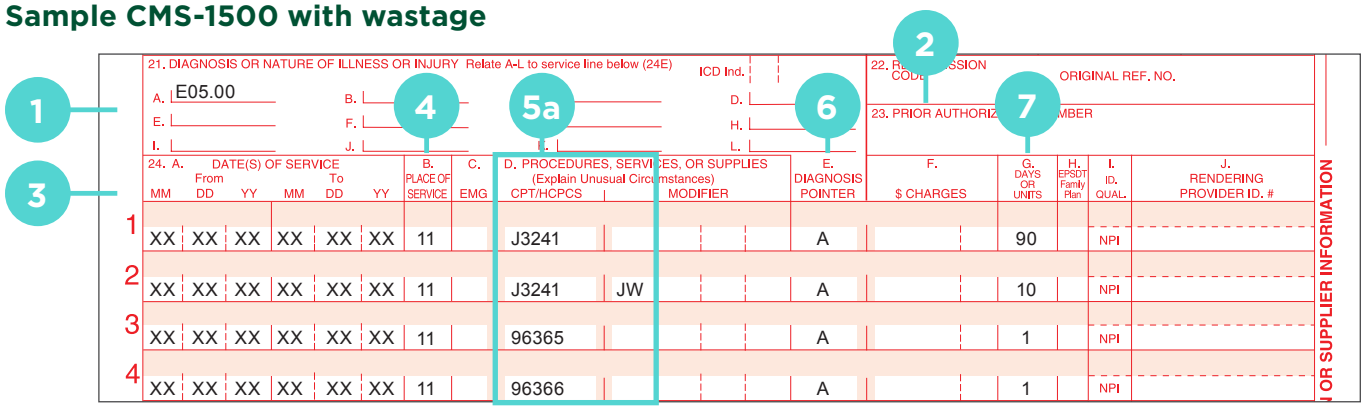
TEPEZZA® teprotumumab-trbw

Sample CMS-1500 claim form for use in physician offices

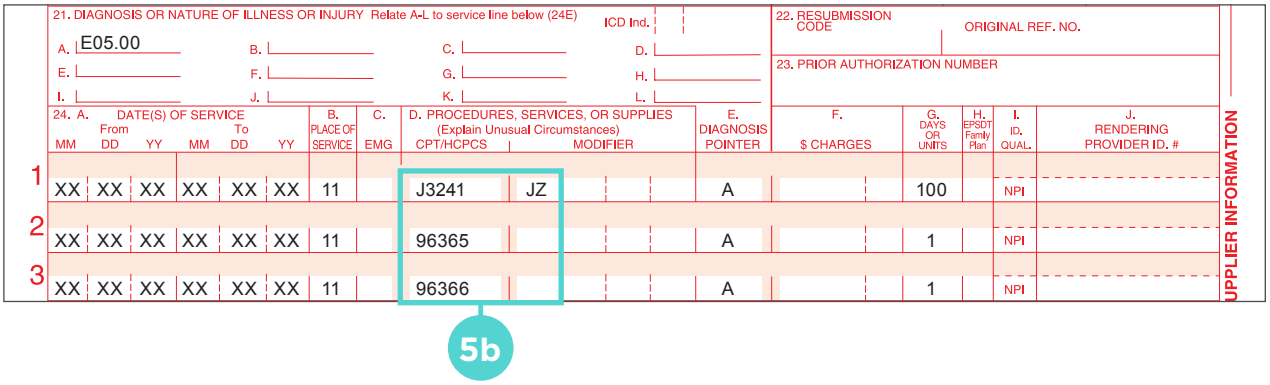
The following is an example of how to fill out the CMS-1500 paper form for a patient who received TEPEZZA (two 500-mg vials of teprotumumab-trbw) via intravenous infusion.[8]

In this example, the provider administered 900 mg via intravenous infusion and 100 mg was wasted. As shown below, Medicare providers report J3241 for TEPEZZA, 90 units for the amount administered, and J3241 with JW modifier, 10 units for the amount wasted, in Items 24A-24G. To report two 500-mg vials administered with no wastage, TEPEZZA would be reported on 1 line with J3241-JZ, 100 units.[6]

Sample CMS-1500 with wastage



Sample CMS-1500 with no drug wastage



Providers submitting claims for TEPEZZA via electronic software systems will need to translate claim information into compatible formats for input into their software systems. To view a crosswalk between **CMS-1500** and **X12N Health Care Claim: Professional (837)**, visit https://x12.org/codes

1 **Item 21:**

- Enter the appropriate ICD-10-CM diagnosis code(s)[3]
- The "ICD Ind." field identifies the ICD code set being reported. Enter "0" between the dotted vertical lines for ICD-10-CM codes[3]

2 **Item 23:** If required, report PA number.

3 **Item 24A:** Some payors may require NDC information. If required, enter information in the shaded field above the date of service, including[3]:

- Qualifier "N4" before the 11-digit NDC, followed by 3 spaces, the unit of measure (UN for units), and the quantity of drugs
  - Confirm with the payor how NDC numbers should be noted on the claim form

4 **Item 24B:** Enter 11 for physician offices.[3]

5 **Item 24D:** Enter the appropriate HCPCS (J3241) and CPT® codes. Include any additional modifiers required by the payor (eg, to indicate wastage). See page 5 of this guide for more information about using modifiers.

- **5a:** Use HCPCS code J3241 to report the drug and use JW to report waste (J3241-JW)
- **5b:** Use HCPCS code J3241 to report the drug and use JZ to indicate no drug waste (J3241-JZ)

6 **Item 24E:** Enter the letter that corresponds to the ICD-10-CM code recorded in Item 21. Only enter 1 diagnosis pointer per service line.[3]

7 **Item 24G:** Document the number of units used for each line item.[3]

- When billing for TEPEZZA with J3241, 1 unit represents 10 mg of TEPEZZA. TEPEZZA should be billed based on units, not the number of milligrams

CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification; NDC, National Drug Code; PA, prior authorization.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA® teprotumumab-trbw

Special billing circumstances in the physician office

Referring patients to alternative sites of care

Providers who wish to prescribe TEPEZZA but do not have in-office infusion capabilities to administer it to patients refer patients to sites of care to receive treatment (eg, provider-owned infusion suite, home infusion, or independently-owned infusion suite). When referring patients to alternate providers for TEPEZZA treatment, the prescribing or referring HCP should be prepared to supply a variety of information and documentation to the provider administering TEPEZZA to assist with fulfilling payor requirements. Necessary documentation may include:

- Prescription/infusion order
- Diagnosis and supporting documentation (eg, the 7-point Clinical Activity Score)
- Letter of medical necessity
- Chart notes

Please refer to the **Payor Access Guide** for more information on payor access concerns.

Referring HCPs should coordinate closely with the site of care to ensure all necessary documentation is accurate, thorough, and complete.

Specialty pharmacy use in the physician office

To bill for administering TEPEZZA procured through a specialty pharmacy, include the appropriate ICD-10-CM diagnosis code(s) and CPT® code for the drug administration on the CMS-1500 form or the electronic equivalent. Payor requirements vary. Confirm with the patient's insurer if they require information about TEPEZZA to be included on the claim with "0" (zero) units or a modifier to indicate that a specialty pharmacy supplied the drug.

Patients who have traditional FFS Medicare typically do not have access to specialty pharmacy benefits

CPT®, Current Procedural Terminology; FFS, fee-for-service; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification.

Physician office claims submission checklist

The following checklist provides an overview of requirements that may be necessary from payors when submitting claims for TEPEZZA. **Please check with individual payors for specific coding requirements.**

- **Use J3241 for TEPEZZA and include supporting information when necessary[5]**
- **Have the PA or predetermination approval on file[9]**
- **Confirm with the payor how NDC numbers should be noted on the claim form**
- **Include any documentation required by the payor**

NDC, National Drug Code; PA, prior authorization.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA® teprotumumab-trbw

Hospital outpatient department (HOPD) and hospital-based infusion center billing and coding

The products and services provided in the hospital outpatient department are billed using the CMS-1450/UB-04 claim form or its electronic claim equivalent.[10]

This section provides general hospital outpatient coding information for TEPEZZA. The final coverage determination is not made until the payor receives and reviews the claim. Coding for TEPEZZA may vary by payor type (eg, Medicare, Medicaid, commercial payor) and plan type. **Contact payors for specific coding requirements for billing TEPEZZA.**

POS codes

POS codes identify the location where a service was performed. The following POS codes may be appropriate when TEPEZZA is administered in the HOPD (on and off campus) and hospital-based infusion center:

POS Code[3]	POS Name	Description
22	On-campus outpatient hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization
19	Off-campus outpatient hospital	A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization

On-campus vs off-campus HOPD designation

The Medicare reimbursement policies vary for HOPDs that are on campus (POS 22) vs off campus (POS 19). To bill and be reimbursed appropriately, facilities must understand the nuances of what is considered on and off campus for outpatient hospital departments. Centers for Medicare & Medicaid Services (CMS) defines HOPD on-campus locations as the physical area immediately adjacent to the healthcare provider's main buildings, as well as other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings.[10] HOPD off-campus locations are paid under the Medicare Physician Fee Schedule (MPFS) rate, which is triggered when modifier "PN" is added to the claim form. HOPDs that are on campus are reimbursed at the facility rate.

NDC

Payor requirements regarding the use of the 10- or 11-digit NDC may vary. EDI generally requires the use of the 11-digit NDC. Check payor requirements for appropriate reporting of the NDC. You may need to add the NDC for TEPEZZA to your EMR system, if it is not already included.

10-digit NDC[1]	11-digit NDC	Description
75987-130-15	75987-0130-15	Carton containing one 500-mg single-dose vial) (lyophilized powder for intravenous infusion)

CMS, Centers for Medicare & Medicaid Services; EDI, electronic data interchange; EMR, electronic medical records; NDC, National Drug Code; POS, place of service.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

ICD-10-CM diagnosis code

The following may be an appropriate ICD-10-CM diagnosis code for TEPEZZA:

ICD-10-CM Diagnosis Code[4]	Description
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm

Clinical Activity Score (CAS)-related ICD-10-CM diagnosis codes may be necessary to fully describe the patient's condition and associated manifestations. It is important to include CAS within your clinical documentation. Please click here for a listing of CAS-related ICD-10-CM diagnosis codes that you may want to include in a claim.

HCPCS code

TEPEZZA has a permanent, product-specific HCPCS code: J3241.[5]

HCPCS Code[5]	Description
J3241	Injection, teprotumumab-trbw, 10 mg

When billing for TEPEZZA using J3241:

- One unit represents 10 mg of TEPEZZA. TEPEZZA should be billed based on units, not the number of milligrams

Revenue codes

Revenue codes are used on the CMS-1450 claim form to map a specific charge to a cost.[10] Examples of revenue codes that a hospital outpatient department may use to track costs for services associated with TEPEZZA include:

Revenue Code[11]	Description
0250	General pharmacy
0636	Drugs requiring detailed coding
0260	Intravenous therapy; general

CMS, Centers for Medicare & Medicaid Services; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification.

Modifiers

Modifiers are typically alphanumeric 2-character indicators that provide payors with additional information regarding the services rendered. If appropriate, more than one modifier may be used with a single procedure code.

Certain payors require the "JW" modifier to be used in order to obtain payment for a discarded amount of drug for single-dose or single-use packaging. For claims submitted with J3241, providers should use multiple lines to identify the amount administered and the amount wasted. One line of the claim should include J3241 and number of units administered. A separate line should include J3241 with the JW modifier and the number of units wasted.

Effective January 1, 2023, modifier "JZ" may be reported on claims to note zero discarded amounts from single-use vials or single-use packages. CMS requires the reporting of modifier JZ effective July 1, 2023. Claims processing edits will be implemented by the MACs effective October 1, 2023.[6]

Contact payors for specific coding requirements for billing wastage and modifiers.

Modifier	Description	Appropriate Use
JW	Drug amount discarded/not administered to any patient	Append to J3241 when there was discarded drug amount
JZ	Zero drug amount discarded/not administered to any patient	Append to J3241 when there was NO discarded drug amount

Modifier guidance on drugs acquired through 340B Drug Discount Program

To comply with certain requirements of the Inflation Reduction Act of 2022, CMS requires all 340B-covered entities, to include hospital-based and non–hospital-based entities, to utilize modifiers "JG" or "TB" on claim lines for separately payable Part B drugs and biologicals acquired through the 340B Drug Discount Program. All 340B-covered entities are required to utilize these modifiers no later than January 1, 2024.[12]

Modifiers PN and PO are used to report services provided at an off-campus, outpatient, provider-based department (PBD) of a hospital.

Modifier[12-14]	Description	Appropriate Use
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities	Critical access hospitals, Maryland All-Payor or Total Cost of Care Model hospitals, non-excepted off-campus PBDs, rural sole community hospitals, children's hospitals, PPS-exempt cancer hospitals
JG	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes	All other 340B-covered entities
PN	Non-excepted service provided at an off-campus, outpatient, provider-based department of a hospital	Services from non-excepted off-campus PBD of a hospital
PO	Excepted service provided at an off-campus, outpatient, provider-based department of a hospital	Services from excepted off-campus PBD of a hospital

CMS, Centers for Medicare & Medicaid Services; MAC, Medicare Administrative Contractor; PPS, prospective payment system.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA® teprotumumab-trbw

CPT® codes

When billing for TEPEZZA in the hospital outpatient department, the following CPT® codes may be appropriate:

Chemotherapy Administration and Other Highly Complex Drug or Highly Complex Biologic Agent Administration

CPT® Code[7]	Description
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug; each additional hour *List separately in addition to code for primary procedure*

Therapeutic, Prophylactic, and Diagnostic Injections and Infusions

CPT® Code[7]	Description
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour; each additional hour *List separately in addition to code for primary procedure*

Other relevant testing considerations

Glucose testing codes

CPT® Code[7]	Description
82945	Glucose, body fluid, other than blood
82947	Glucose, quantitative, blood (except reagent strip)
82948	Glucose, blood, reagent strip
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use

Consult individual payors on any coding and documentation preferences

CPT®, Current Procedural Terminology; FDA, US Food and Drug Administration.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA® teprotumumab-trbw

Sample CMS-1450 claim form for use in hospital outpatient departments

The following is an example of how to fill out the CMS-1450 paper form for a patient where the provider has used two 500-mg vials of TEPEZZA.[10] In this example, the provider administered 900 mg via intravenous infusion and 100 mg was wasted. As shown below, Medicare providers report J3241 for TEPEZZA, 90 units for the amount administered, and J3241 with JW modifier, 10 units for the amount wasted, in Boxes 42-47. To report two 500-mg vials administered with no wastage, TEPEZZA would be reported on 1 line with J3241-JZ, 100 units.[6]

Sample CMS-1450 with wastage

	1 42 REV. CD.	43 DESCRIPTION	2a 44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	3 46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49	
1	0636	Drugs requiring detailed coding (brand)	J3241	XX-XX-XX	90	XXX XX			1
2									2
3	0636	Drugs requiring detailed coding (brand)	J3241-JW	XX-XX-XX	10	XXX XX			3
4									4
5	0260	Intravenous infusion; initial, up to 1 hour	96365	XX-XX-XX	1	XXX XX			5
6									6
7	0260	Intravenous infusion; each additional hour	96366	XX-XX-XX	1	XXX XX			7

Sample CMS-1450 with no drug wastage

	42 REV. CD.	43 DESCRIPTION	2b 44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES
1	0636	Drugs requiring detailed coding (brand)	J3241-JZ	XX-XX-XX	100	XXXXX
2	0260	Intravenous infusion, initial, up to 1 hour	96365	XX-XX-XX	1	XXXXX
3	0260	Intravenous infusion, initial,	96366	XX-XX-XX	1	XXXXX

Providers submitting claims for TEPEZZA via electronic software systems will need to translate claim information into compatible formats for input into their software systems. To view a crosswalk between CMS-1450 and ASC X12 8371 v5010A2, visit https://www.cms.gov/files/document/837I-Form-CMS-1450-MLN006926.pdf

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

1 **Boxes 42-43:** Enter the appropriate revenue code and description corresponding to the HCPCS code listed in Box 44.

- Confirm with the payor how NDC numbers should be noted on the claim form

2 **Box 44:** Enter the appropriate HCPCS (J3241) and CPT® codes.[5] Include any additional modifiers (eg, to indicate wastage) required by the payor. See page 13 of this guide for more information about using modifiers.[6]

- **2a:** Use HCPCS code J3241 to report the drug and use JW to report waste (J3241-JW)
- **2b:** Use HCPCS code J3241 to report the drug and use JZ to indicate no drug waste (J3241-JZ)

3 **Box 46:** Document the number of units used for each line item.[15]

- When billing for TEPEZZA with J3241, 1 unit represents 10 mg of TEPEZZA. TEPEZZA should be billed based on units, not the number of milligrams

Hospital outpatient department claims submission checklist

The following checklist provides an overview of payor requirements that may be necessary when submitting claims for TEPEZZA. Please check with individual payors for specific coding requirements.

- **Use J3241 for TEPEZZA and include supporting information when necessary[5]**
- **Have the PA or predetermination approval on file[9]**
- **Confirm with the payor how NDC numbers should be noted on the claim form**
- **Include any documentation required by the payor**

CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code; PA, prior authorization.

Specialty pharmacy provider (SPP) infusion center billing and coding

Patients may receive TEPEZZA in an SPP infusion center. In this setting, commercial payors reimburse facilities for services and procedures. The products and services provided at the SPP infusion center are billed using the CMS-1500 claim form or its electronic claim equivalent.[8]

This section provides general SPP infusion center coding information for TEPEZZA. The final coverage determination is not made until the payor receives and reviews the claim. Coding for TEPEZZA may vary by commercial payor and plan type. Contact payors for specific coding requirements for billing TEPEZZA.

POS codes

POS codes identify the location where a service was performed. The following POS code may be appropriate when TEPEZZA is administered in an SPP infusion center:

POS Code[3]	POS Name	Description
49	Independent clinic	A location, not part of a hospital and not described by any other place of service code, that is organized and operated to provide preventive, diagnostic, therapeutic, rehabilitative, or palliative services to outpatients only
12	Home	Location, other than a hospital or other facility, where the patient receives care in a private residence

NDC

Payor requirements regarding the use of the 10- or 11-digit NDC may vary. EDI generally requires use of the 11-digit NDC as listed below. Some payors may require each NDC number on the claim. Check payor requirements for appropriate reporting of the NDC.

10-digit NDC[1]	11-digit NDC	Description
75987-130-15	75987-0130-15	Carton containing one 500-mg single-dose vial (lyophilized powder for intravenous infusion)

ICD-10-CM diagnosis codes

The following may be an appropriate ICD-10-CM diagnosis code for TEPEZZA:

ICD-10-CM Diagnosis Code[4]	Description
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm

Clinical Activity Score (CAS)-related ICD-10-CM diagnosis codes may be necessary to fully describe the patient's condition and associated manifestations. It is important to include CAS within your clinical documentation. Please click here for a listing of CAS-related ICD-10-CM diagnosis codes that you may want to include in a claim.

CMS, Centers for Medicare & Medicaid Services; EDI, electronic data interchange; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification; NDC, National Drug Code; POS, place of service.

HCPCS code

TEPEZZA has a permanent, product-specific HCPCS code: J3241.

HCPCS Drug Code[5]	Description
J3241	Injection, teprotumumab-trbw, 10 mg

When billing for TEPEZZA using J3241:

- One unit represents 10 mg of TEPEZZA. TEPEZZA should be billed based on units, not the number of milligrams

Modifiers

Modifiers are typically alphanumeric 2-character indicators that provide payors with additional information regarding the services rendered. If appropriate, more than one modifier may be used with a single procedure code.

Certain payors require the "JW" modifier to be used in order to obtain payment for a discarded amount of drug for single-dose or single-use packaging. For claims submitted with J3241, providers should use multiple lines to identify the amount administered and the amount wasted. One line of the claim should include J3241 and the number of units administered. A separate line should include J3241 with the JW modifier and the number of units wasted.

Effective January 1, 2023, modifier "JZ" may be reported on claims to note zero discarded amounts from single-use vials or single-use packages. CMS requires the reporting of modifier JZ effective July 1, 2023. Claims processing edits will be implemented by the MACs effective October 1, 2023.[6]

The "SS" modifier may also be used to identify the setting of the administration.

Contact payors for specific coding requirements for billing wastage and modifiers.

Modifier	Description	Appropriate Use
JW	Drug amount discarded/not administered to any patient	Append to J3241 when there was discarded drug amount
JZ	Zero drug amount discarded/not administered to any patient	Append to J3241 when there was NO discarded drug amount
SS	Home infusion services provided in the infusion suite of the intravenous therapy provider	Append to CPT/HCPCS code for drug administration when home infusion services are provided in the infusion suite of the intravenous therapy provider

CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; MAC, Medicare Administrative Contractor.

CPT® and HCPCS codes

When billing for TEPEZZA in the SPP facility, the following CPT® and HCPCS codes may be appropriate:

CPT®/HCPCS Code for Drug Administration[7,14]	Description
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)
99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (list separately in addition to code for primary procedure)
S9329	Home infusion therapy, chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem (do not use this code with S9330 or S9331)
S9379	Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9810	Home therapy; professional pharmacy services for provision of infusion, specialty drug administration, and/or disease state management, not otherwise classified, per hour (do not use this code with any per diem code)

Other relevant testing considerations

Glucose testing codes

CPT® Code[7]	Description
82945	Glucose, body fluid, other than blood
82947	Glucose; quantitative, blood (except reagent strip)
82948	Glucose, blood, reagent strip
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use

Consult individual payors on any coding and documentation preferences

CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; SPP, specialty pharmacy provider.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

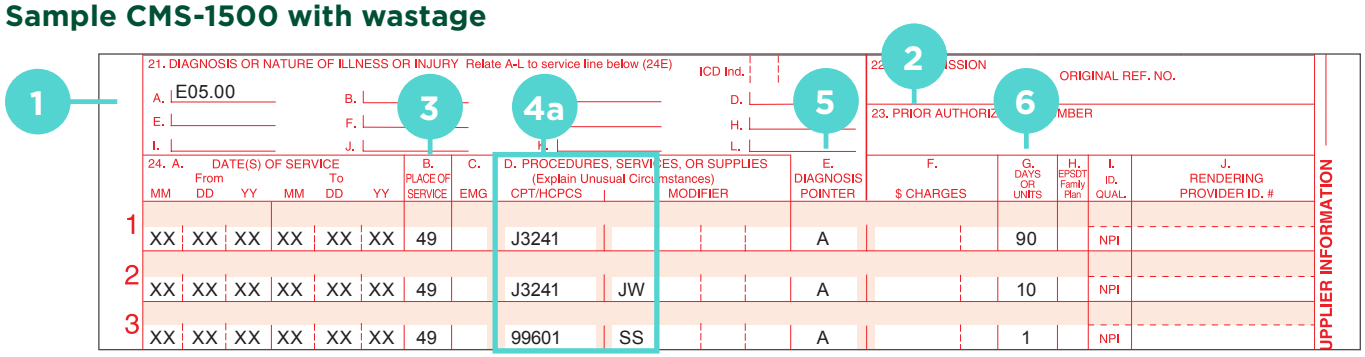
TEPEZZA® teprotumumab-trbw

Sample CMS-1500 claim form for use in SPP infusion centers

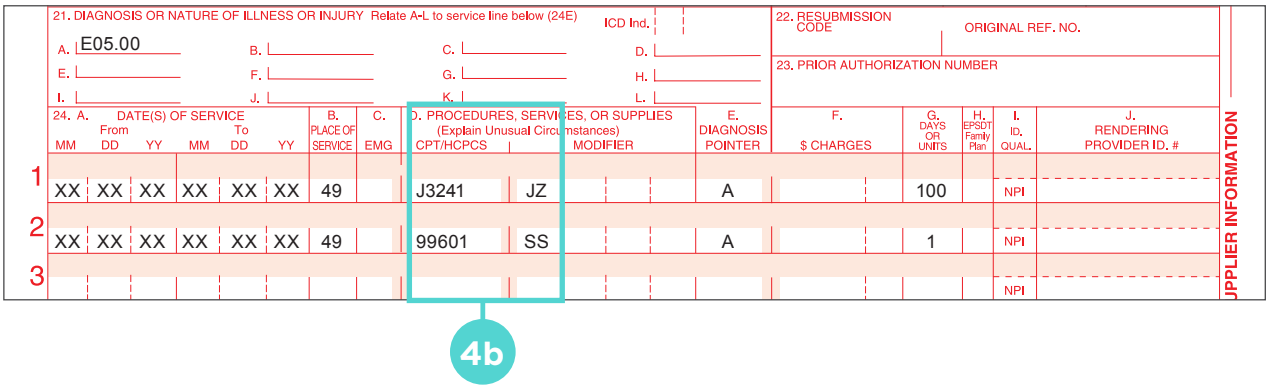
The following is an example of how to fill out the CMS-1500 paper form for a patient who received TEPEZZA (two 500-mg vials of teprotumumab-trbw) via intravenous infusion.[8]

In this example, the provider administered 900 mg via intravenous infusion and 100 mg was wasted. As shown below, providers report J3241 for TEPEZZA, 90 units for the amount administered, and J3241 with JW modifier, 10 units for the amount wasted, in Items 24A-24G. To report two 500-mg vials administered with no wastage, TEPEZZA would be reported on 1 line with J3241-JZ, 100 units.[6]

Sample CMS-1500 with wastage



Sample CMS-1500 with no drug wastage



Providers submitting claims for TEPEZZA via electronic software systems will need to translate claim information into compatible formats for input into their software systems. To view a crosswalk between **CMS-1500** and **X12N Health Care Claim: Professional (837)**, visit https://x12.org/codes

CMS, Centers for Medicare & Medicaid Services; SPP, specialty pharmacy provider.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA® teprotumumab-trbw

1. **Item 21:**
   - Enter the appropriate ICD-10-CM diagnosis code(s)[3]
   - The "ICD Ind." field identifies the ICD code set being reported. Enter "0" between the dotted vertical lines for ICD-10-CM codes[3]

2. **Item 23:** If required, report PA number.

3. **Item 24B:** Enter 49 for independent clinic.

4. **Item 24D:** Enter the appropriate HCPCS (J3241) and CPT® codes.[5] Include any additional modifiers (eg, to indicate wastage) required by the payor. See page 18 of this guide for more information about using modifiers.
   - **4a:** Use HCPCS code J3241 to report the drug and use JW to report waste (J3241-JW)
   - **4b:** Use HCPCS code J3241 to report the drug and use JZ to indicate no drug waste (J3241-JZ)
   - Confirm with the payor how NDC numbers should be noted on the claim form

5. **Item 24E:** Enter the letter that corresponds to the ICD-10-CM code recorded in Item 21. Only enter 1 diagnosis pointer per service line.

6. **Item 24G:** Document the number of units used for each line item.[3]
   - When billing for TEPEZZA with J3241, 1 unit represents 10 mg of TEPEZZA. TEPEZZA should be billed based on units, not the number of milligrams

SPP infusion center claims submission checklist

The following checklist provides an overview of requirements that may be necessary from payors when submitting claims for TEPEZZA:

- ☑ **Use J3241 for TEPEZZA and include supporting information when necessary[5]**
- ☑ **Have the PA or predetermination approval on file[9]**
- ☑ **Confirm with the payor how NDC numbers should be noted on the claim form**
- ☑ **Include any documentation required by the payor**

CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification; NDC, National Drug Code; PA, prior authorization; SPP, specialty pharmacy provider.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA® teprotumumab-trbw

Home infusion billing and coding

Patients may receive TEPEZZA in a home setting. In this setting, commercial payors reimburse providers separately for services and procedures. The products and services provided in the home setting are billed using the CMS-1500 claim form or its electronic claim equivalent.[16]

This section provides general home infusion coding information for TEPEZZA. The final coverage determination is not made until the payor receives and reviews the claim. Coding for TEPEZZA may vary by commercial payor type and plan type. Contact payors for specific coding requirements for billing TEPEZZA.

POS codes

POS codes identify the location where a service was performed. The following POS code may be appropriate when TEPEZZA is administered in the home:

POS Code[3]	POS Name	Description
12	Home	Location, other than hospital or other facility, where the patient receives care in a private residence

NDC

Payor requirements regarding use of the 10- or 11-digit NDC vary. EDI generally requires use of the 11-digit NDC as listed below. Note that some payors may require each NDC number to be listed on the claim. Check payor requirements for appropriate reporting of the NDC.

10-digit NDC[1]	11-digit NDC	Description
75987-130-15	75987-0130-15	Carton containing one 500-mg single-dose vial (lyophilized powder for intravenous infusion)

ICD-10-CM diagnosis codes

The following may be an appropriate ICD-10-CM diagnosis code for TEPEZZA:

ICD-10-CM Diagnosis Code[4]	Description
E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm

Clinical Activity Score (CAS)-related ICD-10-CM diagnosis codes may be necessary to fully describe the patient's condition and associated manifestations. It is important to include CAS within your clinical documentation. Please click here for a listing of CAS-related ICD-10-CM diagnosis codes that you may want to include in a claim.

HCPCS code

TEPEZZA has a permanent, product-specific HCPCS code: J3241.[5]

HCPCS Drug Code[5]	Description
J3241	Injection, teprotumumab-trbw, 10 mg

When billing for TEPEZZA using J3241:

- One unit represents 10 mg of TEPEZZA. TEPEZZA should be billed based on units, not the number of milligrams

CMS, Centers for Medicare & Medicaid Services; EDI, electronic data interchange; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification; NDC, National Drug Code; POS, place of service.

Modifiers

Modifiers are typically alphanumeric 2-character indicators that provide payors with additional information regarding the services rendered. If appropriate, more than one modifier may be used with a single procedure code.

Certain payors require the "JW" modifier to be used in order to obtain payment for a discarded amount of drug for single-dose or single-use packaging. For claims submitted with J3241, providers should use multiple lines to identify the amount administered and the amount wasted. One line of the claim should include J3241 and number of units administered. A separate line should include J3241 with the JW modifier and the number of units wasted.

Effective January 1, 2023, modifier "JZ" may be reported on claims to note zero discarded amounts from single-use vials or single-use packages. CMS requires the reporting of modifier JZ effective July 1, 2023. Claims processing edits will be implemented by the MACs effective October 1, 2023.[6]

Contact payors for specific coding requirements for billing wastage and modifiers.

Modifier	Description	Appropriate Use
JW	Drug amount discarded/not administered to any patient	Append to J3241 when there was discarded drug amount
JZ	Zero drug amount discarded/not administered to any patient	Append to J3241 when there was NO discarded drug amount

CPT® and HCPCS codes

When billing for TEPEZZA in the home, the following CPT® and HCPCS codes may be appropriate:

CPT®/HCPCS Code for Drug Administration[7,14]	Description
99601	Home infusion/specialty drug administration, per visit (up to 2 hours)
99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (list separately in addition to code for primary procedure)
S5035	Home infusion therapy, routine service of infusion device (eg, pump maintenance)
S5520	Home infusion therapy, all supplies (including catheter) necessary for a peripherally inserted central venous catheter (PICC) line insertion

CPT® and HCPCS codes continue on next page.

CMS, Centers for Medicare & Medicaid Services; CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; MAC, Medicare Administrative Contractor.

CPT® and HCPCS codes *(continued)*

CPT®/HCPCS Code for Drug Administration[14]	Description
S5523	Home infusion therapy, insertion of midline venous catheter, nursing services only (no supplies or catheter included)
S9329	Home infusion therapy, chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem (do not use this code with S9330 or S9331)
S9331	Home infusion therapy, intermittent (less than 24 hours) chemotherapy infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9379	Home infusion therapy, infusion therapy, not otherwise classified; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem
S9810	Home therapy; professional pharmacy services for provision of infusion, specialty drug administration, and/or disease state management, not otherwise classified, per hour (do not use this code with any per diem code)

Other relevant testing considerations

Glucose testing codes

CPT® Code[7]	Description
82945	Glucose, body fluid, other than blood
82947	Glucose; quantitative, blood (except reagent strip)
82948	Glucose, blood, reagent strip
82962	Glucose, blood by glucose monitoring device(s) cleared by the FDA specifically for home use

Consult individual payors on any coding and documentation preferences

CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

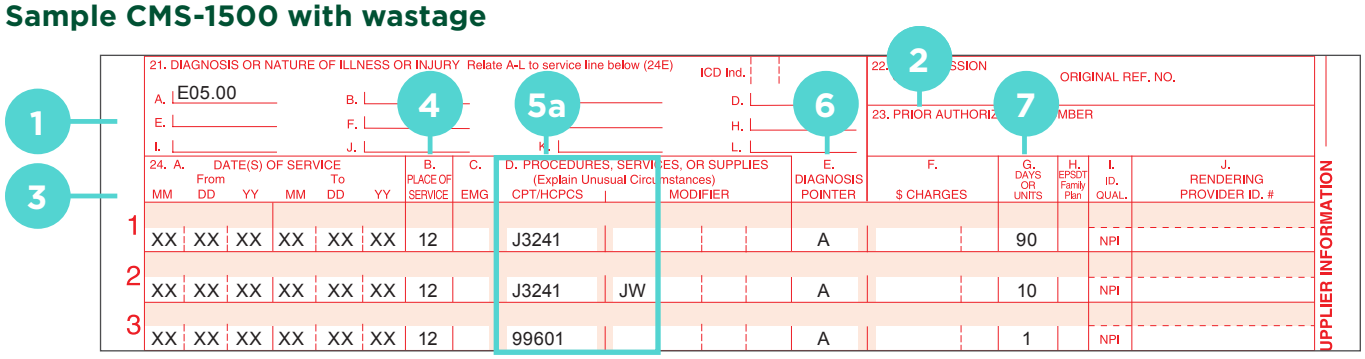
TEPEZZA® teprotumumab-trbw

Sample CMS-1500 claim form for use in the home infusion setting

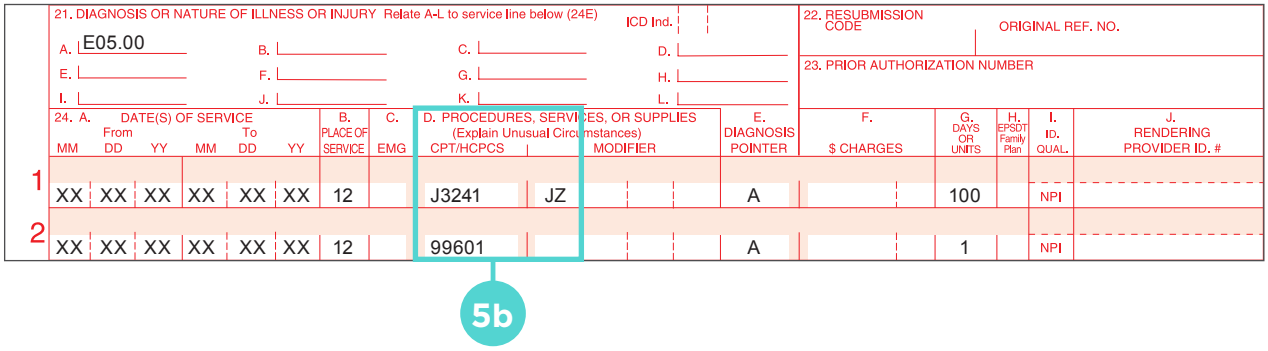
The following is an example of how to fill out the CMS-1500 paper form for a patient where the provider has used two 500-mg vials of TEPEZZA.[8]

In this example, the provider administered 900 mg via intravenous infusion and 100 mg was wasted. As shown below, providers report J3241 for TEPEZZA, 90 units for the amount administered, and J3241 with JW modifier, 10 units for the amount wasted, in Items 24A-24G. To report two 500-mg vials administered with no wastage, TEPEZZA would be reported on 1 line with J3241-JZ, 100 units.[6]

Sample CMS-1500 with wastage



Sample CMS-1500 with no drug wastage



Providers submitting claims for TEPEZZA via electronic software systems will need to translate claim information into compatible formats for input into their software systems. To view a crosswalk between CMS-1500 and X12N Health Care Claim: Professional (837), visit https://x12.org/codes

CMS, Centers for Medicare & Medicaid Services.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA® teprotumumab-trbw

1. **Item 21:**
   - Enter the appropriate ICD-10-CM diagnosis code(s)[3]
   - The "ICD Ind." field identifies the ICD code set being reported. Enter "0" between the dotted vertical lines for ICD-10-CM codes[3]

2. **Item 23:** If required, report PA number.

3. **Item 24A:** Some payors may require NDC information. If required, enter information in the shaded field above the date of service, including[3]:
   - Qualifier "N4" before the 11-digit NDC, followed by 3 spaces, the unit of measure (UN for units), and the quantity of drug
     - Confirm with the payor how NDC numbers should be noted on the claim form

4. **Item 24B:** Enter 12 for home.[3]

5. **Item 24D:** Enter the appropriate HCPCS (J3241) and CPT® codes.[5] Include any additional modifiers (eg, to indicate wastage) required by the payor. See page 23 of this guide for more information about using modifiers.
   - **5a:** Use HCPCS code J3241 to report the drug and use JW to report waste (J3241-JW)
   - **5b:** Use HCPCS code J3241 to report the drug and use JZ to indicate no drug waste (J3241-JZ)

6. **Item 24E:** Enter the letter that corresponds to the ICD-10-CM code recorded in Item 21. Only enter 1 diagnosis pointer per service line.

7. **Item 24G:** Document the number of units used for each line item.[3]
   - When billing for TEPEZZA with J3241, 1 unit represents 10 mg of TEPEZZA. TEPEZZA should be billed based on units, not the number of milligrams

Home infusion claims submission checklist

The following checklist provides an overview of payor requirements that may be necessary when submitting claims for TEPEZZA. Please check with individual payors for specific coding requirements:

- ☑ **Use J3241 for TEPEZZA and include supporting information when necessary[5]**
- ☑ **Have the PA or predetermination approval on file[9]**
- ☑ **Confirm with the payor how NDC numbers should be noted on the claim form**
- ☑ **Include any documentation required by the payor**

CPT®, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification; NDC, National Drug Code; PA, prior authorization.

Reimbursement considerations by payor type

Commercial health plans

For commercial payors, reimbursement for drugs and professional services depends significantly on the contracts negotiated between healthcare providers and the payor. The following list provides some important information you need to consider regarding your commercial payor contracts:

- **Identify your site of care's top payors**
- **Locate copies of your site of care's contracts with these payors**
- **Review the contracts to determine payment methodology for:**
  - Administration of infusion therapies with permanent billing codes
  - Other related services (eg, laboratory monitoring, pregnancy testing)
- **Determine how frequently the rates are updated**
  - If the rates are based on Medicare, are they updated annually, biannually, quarterly, or more frequently?
- **Review any product acquisition terms**
- **Determine the contract term, renewal date, and termination time frame**
- **Document contact information for the payor and your site of care's designated payor relations representative**
- **Store the contracts in a central location for easy access**

Medicare Fee for Service (FFS)

Hospital outpatient department

- TEPEZZA: J3241–Injection, teprotumumab-trbw, 10 mg[5]
  - TEPEZZA has status indicator "K" non–pass-through drugs and non-implantable biologicals, including therapeutic radiopharmaceuticals, paid under OPPS; separate APC payment, effective July 1, 2023
- Drugs and biologicals with status indicator K are reimbursed as separately payable under OPPS Addendum B and currently have a payment rate of 106% of ASP[17]
- For Medicare FFS, reimbursement methodology for TEPEZZA is ASP plus 6%[18]

For the drug and professional services associated with drug administration:

- Medicare Part B covers drugs that are administered by infusion or injection in healthcare provider (HCP) offices and HOPDs if they: (a) meet the statutory definition of a drug or a biological, (b) are usually not self-administered, (c) are incident to an HCP's service, (d) are reasonable and necessary for the diagnosis or treatment of an illness or injury, and (e) have not been determined by the US Food and Drug Administration to be less than effective[19]
  - Typically, HCPs are reimbursed 80% of the allowed amount of most covered Part B drugs like TEPEZZA and the associated administration[19]
  - A policy of Medicare FFS claims incurring a 2% reduction (sequestration) in HCP payments has been reimplemented beginning July 1, 2022[20]

APC, Ambulatory Payment Classification; ASP, average sales price; HCP, healthcare professional; HOPD, hospital outpatient department; OPPS, Outpatient Prospective Payment System.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA® teprotumumab-trbw

Medicaid

Reimbursement for TEPEZZA can vary based on whether a patient enrolls in a traditional FFS Medicaid plan or in a managed Medicaid plan. In many states, reimbursement for traditional Medicaid is based on a uniform, publicly available fee schedule. However, reimbursement methodologies for managed Medicaid plans will vary and may not be publicly accessible.

Drug reimbursement for traditional Medicaid and managed Medicaid may include:

- Percentage (±) of AWP
- Percentage (±) of WAC
- Percentage (±) of ASP
- Invoice price

Medicaid programs may also use a variety of methods to determine the reimbursement for drug administration associated with TEPEZZA, which include:

- Fee schedule-based reimbursement
- Percentage of the Medicare Physician Fee Schedule
- Usual, customary, and reasonable reimbursement
- Percentage of billed charges

It is particularly important to conduct patient-specific benefits investigations for Medicaid beneficiaries before each scheduled appointment, because in many states, enrollees have the option to switch their plans every month. Therefore, eligibility for these patients can change frequently. Verify benefits each month prior to infusion and check authorization at the start of each new plan year and for any patients turning 26 years of age

Dual-eligible beneficiaries who receive both Medicare and Medicaid benefits may require prior authorization for payment by their specific Medicaid plan

ASP, average sales price; AWP, average wholesale price; FFS, fee-for-service; WAC, wholesale acquisition cost.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA® teprotumumab-trbw

Considerations for appealing underpaid or denied claims

After checking your contract, if you still believe a claim for TEPEZZA has been improperly reimbursed or denied, you may consider submitting an appeal.

1. Review the EOB to determine what has been denied or underpaid (eg, drug, administration, both) and the reason for it.

- If the underpayment or denial was due to a technical billing error, verify/obtain specific directions from the payor and submit a corrected claim

2. If necessary to appeal, verify the appeals process with the payor:

- Is there a particular form that must be completed?
- Can the appeal be conducted over the phone or must it be in writing?
- To whom should the appeal be directed?
- What information must be included with the appeal (eg, copy of original claim, EOB, PA number, other supporting documentation)?
- How long does the appeals process usually take?
- How will the payor communicate the appeal decision?

3. Review the appeal request for accuracy, including the patient identification numbers, coding, and requested information.

4. File the appeal as soon as possible and within filing time limits.

5. Request that the payor have a specialist who is currently treating patients with TEPEZZA review the claim for medical necessity.

6. Reconcile claims appeal responses promptly and thoroughly to ensure appeal has been processed appropriately.

7. Record the appeal result (eg, payment amount or if further action is required).

If a claim is denied, some payors may use a process called "Same Specialist Review," which provides adjudication by a medical reviewer specializing in a particular disease. Contact your Provider Relations representative to request this review.

If the second claim submission is denied, consider contacting the payor's medical or claims director. A claim denial may be reversed upon a director's review of an accurate and complete denial appeal request

To download a sample Letter of Appeal, click here

To download a sample Letter of Medical Necessity, click here

EOB, explanation of benefits; PA, prior authorization.

Please see Important Safety Information on page 32 and accompanying Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA® teprotumumab-trbw

Appendix

Additional ICD-10-CM codes

Clinical Activity Score (CAS)-related ICD-10-CM diagnosis codes may be necessary to fully describe the patient's condition and associated manifestations. It is important to include CAS within your clinical documentation. The following list is not inclusive of all codes that are available or related to TED, but rather codes related to CAS. It is the responsibility of the healthcare provider to choose the most appropriate codes.

ICD-10-CM Codes[4]	Descriptor
H02.531-H02.539	Eyelid retraction
H02.841-H02.849	Edema of eyelid
H04.121-H04.129	Dry eye syndrome of lacrimal glands
H05.241-H05.249	Constant exophthalmos
H05.251-H05.259	Intermittent exophthalmos
H10.421-H10.429	Simple chronic conjunctivitis
H11.131-H11.139	Conjunctival pigmentations
H11.141-H11.149	Conjunctival xerosis
H11.411-H11.419	Vascular abnormalities of conjunctiva
H11.421-H11.429	Conjunctival edema
H11.431-H11.439	Conjunctival hyperemia
H16.211-H16.219	Exposure keratoconjunctivitis
H46.8	Other optic neuritis
H47.011-H47.019	Ischemic optic neuropathy
H47.091-H47.099	Other disorders of optic nerve
H50.21-H50.22	Vertical strabismus
H50.69	Other mechanical strabismus
H53.2	Diplopia
H53.451-H53.459	Other localized visual field defect
H57.10-H57.13	Ocular pain

ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification; TED, Thyroid Eye Disease.

INDICATION

TEPEZZA is indicated for the treatment of Thyroid Eye Disease regardless of Thyroid Eye Disease activity or duration.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Infusion Reactions: TEPEZZA may cause infusion reactions. Infusion reactions have been reported in approximately 4% of patients treated with TEPEZZA. Reported infusion reactions have usually been mild or moderate in severity. Signs and symptoms may include transient increases in blood pressure, feeling hot, tachycardia, dyspnea, headache, and muscular pain. Infusion reactions may occur during an infusion or within 1.5 hours after an infusion. In patients who experience an infusion reaction, consideration should be given to premedicating with an antihistamine, antipyretic, or corticosteroid and/or administering all subsequent infusions at a slower infusion rate.

Preexisting Inflammatory Bowel Disease: TEPEZZA may cause an exacerbation of preexisting inflammatory bowel disease (IBD). Monitor patients with IBD for flare of disease. If IBD exacerbation is suspected, consider discontinuation of TEPEZZA.

Hyperglycemia: Increased blood glucose or hyperglycemia may occur in patients treated with TEPEZZA. In clinical trials, 10% of patients (two-thirds of whom had preexisting diabetes or impaired glucose tolerance) experienced hyperglycemia. Hyperglycemic events should be controlled with medications for glycemic control, if necessary. Assess patients for elevated blood glucose and symptoms of hyperglycemia prior to infusion and continue to monitor while on treatment with TEPEZZA. Ensure patients with hyperglycemia or preexisting diabetes are under appropriate glycemic control before and while receiving TEPEZZA.

Hearing Impairment Including Hearing Loss: TEPEZZA may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Assess patients' hearing before, during, and after treatment with TEPEZZA and consider the benefit-risk of treatment with patients.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥5% and greater than placebo) are muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache, dry skin, weight decreased, nail disorders, and menstrual disorders.

Please see Full Prescribing Information or visit TEPEZZAhcp.com for more information.

References: 1. TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon. **2.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual Chapter 1 – General Billing Requirements. Revised August 25, 2022. Accessed August 8, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf **3.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual Chapter 26 – Completing and Processing Form CMS-1500 Data Set. Accessed August 8, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c26.pdf **4.** Centers for Disease Control and Prevention. ICD-10-CM Tabular List of Diseases and Injuries. Published April 1, 2022. Accessed August 8, 2023. https://www.cdc.gov/nchs/icd/icd10cm_browsertool.htm **5.** Centers for Medicare & Medicaid Services. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions. Accessed August 8, 2022. https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-2-2020-drugs-and-biologicals-updated-07312020.pdf **6.** Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program. Published November 18, 2022. Accessed August 8, 2023. https://www.federalregister.gov/documents/2022/11/18/2022-23873/medicare-and-medicaid-programs-cy-2023-payment-policies-under-the-physician-fee-schedule-and-other **7.** American Medical Association. *2023 CPT® Professional Edition.* Chicago, IL: American Medical Association; 2022. **8.** Centers for Medicare & Medicaid Services. CMS-1500 Health Insurance Claim Form. Revised February 1, 2012. Accessed August 8, 2023. https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf **9.** Centers for Medicare & Medicaid Services. Parts C & D Enrollee Grievances, Organization Coverage Determinations, and Appeals Guidance. Published August 3, 2022. Accessed August 8, 2023. https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf **10.** Centers for Disease Control. UB-04 CMS-1450. Revised April 18, 2014. Accessed August 8, 2023. https://www.cdc.gov/wtc/pdfs/policies/ub-40-P.pdf **11.** Centers for Medicare & Medicaid Services. CMS Manual System Pub. 100-04 Medicare Claims Processing Transmittal 167. Published April 30, 2004. Accessed August 8, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R167CP.pdf **12.** Medicare Learning Network Fact Sheet. Medicare Part B Inflation Rebate Guidance: Use of the 340B Modifier. Revised March 2023. Accessed August 30, 2023. https://www.cms.gov/files/document/mln4800856-medicare-part-b-inflation-rebate-guidance-use-340b-modifier.pdf **13.** Centers for Medicare & Medicaid Services. Billing 340B Modifiers under the Hospital Outpatient Prospective Payment System (OPPS). Published March 3, 2023. Accessed August 30, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/billing-340b-modifiers-under-hospital-opps.pdf **14.** Centers for Medicare & Medicaid Services. October 2023 Alpha Numeric HCPCS File. Published August 28, 2023. Accessed August 30, 2023. https://www.cms.gov/files/zip/october-2023-alpha-numeric-hcpcs-files.zip **15.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual Chapter 25 - Completing and Processing the Form CMS-1450 Data Set. Published November 3, 2006. Accessed August 8, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf **16.** Centers for Medicare & Medicaid Services. Professional Paper Claim Form (CMS-1500). Updated December 1, 2021. Accessed August 8, 2023. https://www.cms.gov/medicare/billing/electronicbillingeditrans/16_1500 **17.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual, Chapter 17 - Drugs and Biologicals. Revised August 25, 2022. Accessed August 8, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c17.pdf **18.** MedPAC. Part B Drugs Payment Systems. Revised October 2022. Accessed August 8, 2023. https://www.medpac.gov/wp-content/uploads/2021/11/MedPAC_Payment_Basics_22_PartB_FINAL_SEC.pdf **19.** Centers for Medicare and Medicaid Services. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services. Revised November 9, 2022. Accessed August 8, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf **20.** Centers for Medicare & Medicaid Services. 2021-12-16-MLNC. Published December 16, 2021. Accessed August 8, 2023. https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2021-12-16-mlnc#_Toc90391082

TEPEZZA®
teprotumumab-trbw