Billing and Coding Guide

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

Please see Important Safety Information on the back cover and accompanying Full Prescribing Information.
Welcome

TEPEZZA is the first U.S. Food and Drug Administration (FDA)–approved treatment indicated for Thyroid Eye Disease (TED) in adult patients.

Horizon Therapeutics is committed to providing detailed information to assist in obtaining reimbursement for TEPEZZA, drug administration, and related ancillary services. We have developed this guide to provide you with the information you need to help with the reimbursement process for TEPEZZA. Horizon Patient Services™ offers individualized support to help your patients throughout the treatment process.

SELECT IMPORTANT SAFETY INFORMATION

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.

Preexisting Inflammatory Bowel Disease (IBD) may be exacerbated by TEPEZZA. Monitor patients with IBD for flare of disease. If IBD exacerbation is suspected, consider discontinuation of TEPEZZA.

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. If necessary, these events should be managed with medications for glycemic control.

The most common adverse reactions (incidence ≥5% and greater than placebo) are muscle spasms, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache, and dry skin.
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. Using the assistance of Horizon Patient Services in no way guarantees reimbursement.

The content herein is based on information current as of January 2020, and may have changed. Any product, ancillary supplies, or services received free of charge cannot be billed to third-party payers because doing so could be a violation of federal and/or state laws and/or third-party payer requirements.
Conducting a benefits verification

Key considerations for a benefits verification

To identify possible coverage and reimbursement for a patient prescribed TEPEZZA, a benefits verification must be completed. Consider using the following as a guide:

**TEPEZZA coverage**
- Is TEPEZZA covered?
  - If so, is it covered under the medical benefit or pharmacy benefit?

**Prior authorization (PA)**
- Will PA be required for treatment with TEPEZZA?
  - What is the process for obtaining a PA?
  - What information will be required, and how long will the process take?
  - How long will the PA remain valid?

**Medical exception (ME)**
- If the payer does not have a policy in place for TEPEZZA or the patient does not meet payer coverage requirements, is there an ME or appeal process?
  - If so, what documentation is required to demonstrate medical necessity?

**Benefits coordination**
- Does the patient have any other supplemental insurance benefits that would require coordination?
  - Which benefit is primary? Which is secondary?

**Coding and claims submission**
- What are the specific coding and claims submission requirements for reporting TEPEZZA in this patient’s plan?
  - What codes should be noted on the claim form?
  - What type of documentation is required?

**Patient financial responsibility**
- What is the annual deductible amount the patient must meet?
  - Has this amount been met? What is the amount left?
- What is the patient’s copayment or coinsurance for TEPEZZA?
- Is there a maximum out-of-pocket amount the patient must meet?
  - Has this amount been met? What is the amount left?
- Does the patient’s plan contain an annual or lifetime maximum?
  - Has this amount been met? What is the amount left?

**Reimbursement for TEPEZZA**
- What is the reimbursement amount provided for TEPEZZA (drug and services)?
Requesting prior authorization or medical exception

PA and ME checklist

Documentation requirements vary among health plans. This process allows the payer to review the reason for the requested therapy and to determine medical appropriateness.

The following provides an outline of what you should keep in mind when submitting a PA or ME request for TEPEZZA:

- Obtain information from the payer about what is required to request initial authorization or ME for TEPEZZA. Such information may include, but is not limited to:
  - Payer-specific form(s)
  - Required method for submission (eg, email, fax, phone, or payer website)
- Determine the duration of authorization, if applicable
- Determine if a letter of medical necessity is required, and if the prescribing HCP, is willing to provide one with initial documentation
- Identify the information the payer requires for medical necessity documentation. Such information may include, but is not limited to:
  - Date of diagnosis
  - Laboratory tests required
  - Documentation of previous treatments
  - Documentation of disease activity and severity
- Provide the medical documentation required by the payer to maintain patients on continued treatment with TEPEZZA

Call 1-833-5-TEPEZZA to enroll in Horizon Patient Services™ and connect with your local Reimbursement Access Specialist

HCP, healthcare provider.
**Writing a letter of medical necessity**

A patient-specific letter of medical necessity explains the physician’s rationale and clinical decision-making in choosing TEPEZZA.

The following is a template letter of medical necessity for TEPEZZA that can be customized based on your patient’s medical history and demographic information. Some payers may have specific forms that must be completed in order to document medical necessity.

1. Provide relevant medical information and attach patient’s medical records and/or supporting documents for payers to review.

2. To download a copy of the full Prescribing Information, visit TEPEZZAhcp.com.

3. Check with the payer to identify specific documentation that may need to be submitted with the letter of medical necessity.

To download this sample letter of medical necessity, visit TEPEZZAhcp.com

To improve the efficiency of the prior authorization process, it can be beneficial to submit a letter of medical necessity even if it is not explicitly asked for. It can proactively answer questions the payer may have.
[Office letterhead]

[Date]

[Contact name of medical director or other payer representative]
[Contact title]
[Name of health insurance company]
[Address]

Re:
Letter of Medical Necessity for [HCPCS Code] [Drug name, billing unit]
Patient: [Patient Name]
Group/Policy Number: [Number]
Date(s) of Service: [Dates]
Diagnosis: [Code & description]

Dear [Insert contact name or department],

I am writing on behalf of my patient, [PATIENT NAME], to document medical necessity for treatment with TEPEZZA™ (teprotumumab-trbw). The patient will be treated with TEPEZZA for [DIAGNOSIS]. TEPEZZA is indicated for treatment of Thyroid Eye Disease. This letter serves to document that [PATIENT] needs TEPEZZA and that TEPEZZA is medically necessary for [HIM/HER] as administered. On behalf of the patient, I am requesting approval for use and subsequent payment for the treatments.

Medical History and Diagnosis

[ PATIENT NAME] is a [AGE]-year-old [MALE/ FEMALE] diagnosed with [DIAGNOSIS]. [ PATIENT NAME] has been in my care since [DATE]. As a result of [DIAGNOSIS], my patient [ENTER BRIEF DESCRIPTION OF PATIENT HISTORY]. Additionally, [PATIENT NAME] has tried [PREVIOUS TREATMENTS] and [OUTCOMES]. The attached medical records document [PATIENT NAME]’s clinical condition and the medical necessity for treatments with TEPEZZA.

Based on the above facts, I am confident that you will agree that TEPEZZA is indicated and medically necessary for this patient. The plan of treatment is to start the patient on TEPEZZA. Administration of TEPEZZA 10 mg/kg is planned on [DATE] and will be continued approximately every 3 weeks at 20 mg/kg for a total of 8 infusions.

Please consider coverage of TEPEZZA on [PATIENT NAME]’s behalf and approve use and subsequent payment for TEPEZZA as planned. Please refer to the enclosed Prescribing Information for TEPEZZA. If you have any further questions regarding this matter, please do not hesitate to call me at [PHYSICIAN TELEPHONE NUMBER]. Thank you for your prompt attention to this matter.

Sincerely,

[PHYSICIAN NAME], [DEGREE INITIALS] [PROVIDER IDENTIFICATION NUMBER]

Enclosures [attach as appropriate]
FDA approval letter (available at http:/ /www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)
Prescribing Information (PI)
Clinic notes & labs
CC: [Medical Director, patient, specialty society, insurance]
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 payer and submit a corrected claim

2. If necessary to appeal, verify the appeals process with the payer:
   - 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 payer 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 payer 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 payers 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 payer’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 this sample letter of appeal, visit TEPEZZAhcp.com

EOB, explanation of benefits; PA, prior authorization.
Sample letter of appeal

[Office letterhead]

[Date]

[Name of contact]
[Title]
[Name of health insurance company]
[Address]

Insured: [Patient Name]
Policy Number: [Policy number]
Group Number: [Group number]
Diagnosis: [Diagnosis and ICD-10-CM code]

Re: Claim denial

Dear [Insert contact name],

I have recently received a [DENIAL FOR PAYMENT/UNDERPAYMENT] for a claim for TEPEZZA™ (teprotumumab-trbw). You have indicated that TEPEZZA is not covered by [INSURANCE PLAN NAME] because [REASON FOR DENIAL]. This letter serves as a request for reconsideration of a claim for charges of TEPEZZA administered intravenously to [PATIENT NAME] on [DATE(s) OF SERVICE].

[PATIENT NAME] has been under my treatment for diagnosis of [DIAGNOSIS INFORMATION] since [DATE]. Due to the patient’s clinical problems, the plan of treatment was to start the patient on TEPEZZA. TEPEZZA was initially administered on [DATE OF TREATMENT] and continued approximately every [FREQUENCY]. The attached medical records document [PATIENT NAME]’s clinical condition and medical necessity for treatment with TEPEZZA.

TEPEZZA is indicated for treatment of Thyroid Eye Disease. TEPEZZA has been shown to reduce proptosis in clinical trials.

Because of [INSERT RELEVANT PATIENT INFORMATION SUCH AS HISTORY, DIAGNOSIS], I have administered TEPEZZA as a medically necessary part of this patient’s treatment, and we would appreciate your reconsideration of the [DATE(S) OF SERVICE] claim for [PATIENT NAME]. Please contact me at [PHYSICIAN PHONE NUMBER] if you require additional information or have any further questions.

Thank you in advance for your immediate attention to this request.

Sincerely,

[PHYSICIAN NAME], [DEGREE INITIALS] [PHYSICIAN’S PRACTICE NAME]

Enclosures [attach as appropriate]
[Original claim form]
[Denial/explanation of benefits]
[Additional supporting documents]
Reimbursement considerations by payer type

**Medicare**

Reimbursement for most Part B intravenous infusion drugs varies by site of care:

<table>
<thead>
<tr>
<th>Physician office/in-home infusion</th>
<th>Hospital outpatient department</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Prior to an ASP, reimbursement is 103% of WAC(^2,3)</td>
<td>• Prior to issuance of pass-through status, reimbursement is 95% of the AWP(^4)</td>
</tr>
<tr>
<td>• After ASP is established, the reimbursement is 106% of the ASP(^2)</td>
<td>• After pass-through status is approved, the reimbursement is 106% of the ASP or 103% of the WAC if ASP has not been established(^2,4)</td>
</tr>
</tbody>
</table>

For the drug and professional services associated with drug administration:
- Typically, physicians are reimbursed 80% of the allowed amount of most covered Part B drugs like TEPEZZA and the associated administration\(^5\)
  - However, as of April 1, 2013, Medicare fee-for-service claims incur a 2% reduction in physician payment as a result of federal budget sequestration cuts until further notice\(^6\)
- The Medicare beneficiary is then responsible for the remaining 20% in the form of coinsurance, as well as a separate annual deductible amount\(^5\)

**Medicaid**

Reimbursement for TEPEZZA can vary based on whether a patient enrolls in a traditional fee-for-service Medicaid plan or in a managed Medicaid plan. In many states, reimbursement for traditional Medicaid is based on a uniform, publicly available fee schedule, while 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 verifications for Medicaid beneficiaries before each scheduled appointment, because in many states, enrollees have the option to switch their plans every month. Therefore, eligibility can change frequently for these patients.

ASP, average sales price; AWP, average wholesale price; WAC, wholesale acquisition cost.
Commercial health plans
For commercial payers, reimbursement for drugs and professional services depends significantly on the contracts negotiated between healthcare providers and the payer. The following list provides some important information you need to consider regarding your commercial payer contracts:

- Identify your site of care’s top payers
- Locate copies of your site of care’s contracts with these payers
- Review the contracts to determine payment methodology for:
  - Administration of infusion therapies with and without permanent billing codes
  - Office visits
  - Other related services
- 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 payer and your site of care’s designated payer relations representative
- Store the contracts in a central location for easy access

If you have a question about payment on a claim for a commercial payer, Horizon Patient Services™ can review the claim to check for errors. If no errors are identified, you will need to contact your Provider Relations representative at the health plan to understand your payment terms.
Physician office billing and coding

Products and services provided in the physician office setting are billed using the CMS-1500 claim form or its electronic claim equivalent. This section provides general physician office coding information for TEPEZZA. The final coverage determination is not made until the payer receives and reviews the claim. Coding for TEPEZZA may vary by payer type (e.g., Medicare, Medicaid, commercial payer) and plan type. Contact payers for specific coding requirements for billing TEPEZZA or contact Horizon Patient Services™ for assistance in identifying payer coding requirements.

NDC

Payer requirements regarding the use of the 10- or 11-digit NDC may vary. Electronic data exchange generally requires the use of the 11-digit NDC. Check payer 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.

<table>
<thead>
<tr>
<th>10-digit NDC1</th>
<th>11-digit NDC</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>75987-130-15</td>
<td>75987-0130-15</td>
<td>500 mg teprotumumab-trbw in a vial (lyophilized powder for intravenous infusion)</td>
</tr>
</tbody>
</table>

ICD-10-CM diagnosis codes

There is no ICD-10 code specific to Thyroid Eye Disease (TED), but the following may be appropriate ICD-10-CM diagnosis codes for TEPEZZA:

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis Code8</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E05.00</td>
<td>Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm</td>
</tr>
</tbody>
</table>

Additional ICD-10-CM diagnosis codes may be used to fully describe the patient’s condition and associated manifestations.

HCPCS codes

TEPEZZA has not yet been assigned a permanent, product-specific HCPCS code. Meanwhile, an unclassified HCPCS code should be used on claims for TEPEZZA.

<table>
<thead>
<tr>
<th>HCPCS Drug Code9</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
</tr>
<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
</tr>
</tbody>
</table>

The “JW” modifier for reporting wastage is typically not used with unlisted/miscellaneous codes (e.g., J3590, C9399). Contact payers for specific coding requirements for billing wastage with unlisted/miscellaneous codes or contact Horizon Patient Services for assistance with identifying payer coding requirements.

**CPT® codes**

The following CPT codes may be appropriate for an intravenous injection of TEPEZZA in the physician office:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>96365</td>
<td>Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour</td>
</tr>
<tr>
<td>96366</td>
<td>Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour <em>List separately in addition to code for primary procedure</em></td>
</tr>
<tr>
<td>96413</td>
<td>Highly complex drugs, including biologic agents or chemotherapy, intravenous infusion technique; up to 1 hour, single or initial substance/drug</td>
</tr>
<tr>
<td>96415</td>
<td>Highly complex drugs, including biologic agents or chemotherapy, intravenous infusion technique; each additional hour <em>List separately in addition to code for primary procedure</em></td>
</tr>
</tbody>
</table>

*Consult individual payers on any coding and documentation preferences*
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 10-mL vials, each containing 500 mg of teprotumumab-trbw) via intravenous infusion.¹¹

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. MEDICARE</td>
<td></td>
</tr>
<tr>
<td>2. PATIENT’S NAME</td>
<td>Last Name, First Name, Middle Initial</td>
</tr>
<tr>
<td>3. PATIENT’S ADDRESS</td>
<td></td>
</tr>
<tr>
<td>4. INSURED’S NAME</td>
<td>Last Name, First Name, Middle Initial</td>
</tr>
<tr>
<td>5. TELEPHONE</td>
<td></td>
</tr>
<tr>
<td>6. RESERVED FOR NUCE USE</td>
<td></td>
</tr>
<tr>
<td>7. RESERVED FOR NUCE USE</td>
<td></td>
</tr>
<tr>
<td>8. INSURANCE PLAN NAME</td>
<td></td>
</tr>
<tr>
<td>9. COMPLETE FORM BEFORE SENDING</td>
<td></td>
</tr>
</tbody>
</table>

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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 [http://www.nucc.org](http://www.nucc.org)
Items 1-13: Enter the patient’s personal and insurance information.

Item 19: When completing a claim using an unclassified code, additional information is required. Enter TEPEZZA brand and generic names, NDC, and amount administered to patient.

Item 21:
- Enter the appropriate ICD-10-CM diagnosis code(s)
- The “ICD Ind.” field identifies the ICD code set being reported. Enter “0” between the dotted vertical lines for ICD-10-CM codes

Item 23: If required, report PA number.

Item 24A: For dual eligible patients (ie, patients eligible for both Medicare and Medicaid), specific information may be required here. If required, enter information in the shaded field above the date of service, including:
- Qualifier “N4” before the 11-digit NDC, followed by 3 spaces, the unit of measure (UN for units), and the quantity of drugs
  - Example: N475987013015___UN1000
- Strength

Item 24B: Enter 11 for physician offices.

Item 24D: Enter the appropriate HCPCS (for billing with an unclassified code, J3490 or J3590) and CPT codes. Include any additional modifiers required by the payer (eg, to indicate use of specialty pharmacy). See page 23 of this guide for more information about using modifiers.

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.

Item 24G: Document the number of units used for each line item.
- When billing for TEPEZZA with an unclassified HCPCS code (such as J3490 or J3590), enter 1 unit
  - Total dosage administered, based on patient weight, is part of the information entered in Item 19

Unit means the amount of the measurement used in the code description. As J3490, J3590, or C9399 have no HCPCS descriptor unit measurement, the number of units is always 1.

Call 1-833-5-TEPEZZA to enroll in Horizon Patient Services™ and connect with your local Reimbursement Access Specialist

Special billing circumstances in the physician office

Specialty pharmacy use in the physician office
To bill for administering TEPEZZA procured through 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. Payer 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.

Referring patients to alternative sites of care
Providers who wish to prescribe TEPEZZA but not administer it to patients may refer patients to alternative sites of care to receive treatment (eg, hospital outpatient department). When referring patients to alternate providers for TEPEZZA treatment, the prescribing or referring physician may need to supply a variety of information and documentation to the provider administering TEPEZZA to assist with fulfilling payer requirements. Necessary documentation may include:

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

Referring physicians should coordinate closely with the hospital outpatient department to ensure all necessary documentation is in place.

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

CPT, Current Procedures Terminology; FFS, fee-for-service; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification; NDC, National Drug Code; PA, prior authorization.
Physician office claims submission checklist

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

- Use J3490 or J3590 for TEPEZZA and include supporting information
- Have the PA or predetermination approval on file
- Confirm with the payer or Horizon Patient Services™ how NDC numbers should be noted on the claim form
- Include any documentation required by the payer

Call 1-833-5-TEPEZZA to enroll in Horizon Patient Services and connect with your local Reimbursement Access Specialist
Hospital outpatient department 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.15

This section provides general hospital outpatient coding information for TEPEZZA. The final coverage determination is not made until the payer receives and reviews the claim. Coding for TEPEZZA may vary by payer type (eg, Medicare, Medicaid, commercial payer) and plan type. Contact payers for specific coding requirements for billing TEPEZZA or contact Horizon Patient Services™ for assistance with identifying payer coding requirements.

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Additional ICD-10-CM diagnosis codes may be used to fully describe the patient’s condition and associated manifestations.

Revenue codes

Revenue codes are used on the CMS-1450 claim form to map a specific charge to a cost.15 Example of revenue codes that a hospital outpatient department may use to track costs for services associated with TEPEZZA include:

<table>
<thead>
<tr>
<th>Revenue Code16</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0250</td>
<td>General pharmacy or biologics</td>
</tr>
<tr>
<td>0636</td>
<td>Drugs requiring detailed coding</td>
</tr>
<tr>
<td>0260</td>
<td>Intravenous therapy; general</td>
</tr>
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</table>

HCPCS codes

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</tr>
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<td>Non-Medicare</td>
</tr>
<tr>
<td>C9399</td>
<td>Unclassified drugs or biologics</td>
<td>Medicare</td>
</tr>
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CPT® codes

CPT codes may vary depending on different factors (eg, injection vs infusion, length of infusion, complexity of the administered drug or biologic). When billing for TEPEZZA in the hospital outpatient department, the following CPT codes may be appropriate:

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</table>

Consult individual payers on any coding and documentation preferences.
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 who has received two 500-mg vials of TEPEZZA via intravenous infusion. In this example, Medicare requires providers to report using C9399 for TEPEZZA on one line in Boxes 42-47.

| 0636 | Drugs requiring detailed coding (brand) | C9399 | 04-15-20 | 1 | XXX XX |
| 0260 | Intravenous infusion; initial, up to 1 hour | 96365 | 04-15-20 | 1 | XXX XX |
| 0260 | Intravenous infusion; each additional hour | 96366 | 04-15-20 | 1 | XXX XX |

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 the Jurisdiction M Part A hub at https://www.palmettogba.com.

Please see Important Safety Information on the back cover and accompanying Full Prescribing Information.
Boxes 8-15 and 50-65: Enter the patient’s personal and insurance information.

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

Box 44: Enter the appropriate HCPCS (eg, C9399) and CPT® codes.

Box 46: Document the number of units used for each line item.15
- When billing for TEPEZZA with an unclassified HCPCS code (eg, J3490 or J3590), enter 1 unit
  - Total dosage administered, based on patient weight, is part of the information entered in Item 19

Unit means the amount of the measurement used in the code description. As J3490, J3590, or C9399 have no HCPCS descriptor unit measurement, the number of units is always 1.

Box 66: Enter the appropriate indicator for ICD-10-CM (ie, “0”).15

Box 67: Enter the appropriate ICD-10-CM diagnosis code(s).15

Box 80: In the “Remarks” section, enter the NDC, the quantity of drug administered (expressed in the unit of measure), and the date of drug administration.

Hospital outpatient department claims submission checklist
The following checklist provides an overview of payer requirements that may be necessary when submitting claims for TEPEZZA. Please check with individual payers for specific coding requirements.

- Use an appropriate HCPCS code (J3490, J3590, or C9399) for TEPEZZA13
- Have the PA approval or predetermination approval on file14
- Confirm with the payer or Horizon Patient Services™ how NDC numbers should be noted on the claim form
- Include any documentation required by the payer

Call 1-833-5-TEPEZZA to enroll in Horizon Patient Services and connect with your local Reimbursement Access Specialist

SPP infusion center billing and coding

Patients may receive TEPEZZA in a SPP infusion center. In this setting, commercial payers 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.20

This section provides general SPP infusion center coding information for TEPEZZA. The final coverage determination is not made until the payer receives and reviews the claim. Coding for TEPEZZA may vary by commercial payer and plan type. Contact payers for specific coding requirements for billing TEPEZZA or contact Horizon Patient Services™ for assistance with identifying payer coding requirements.

NDC

Payer requirements regarding the use of the 10- or 11-digit NDC may vary. Electronic data exchange generally requires use of the 11-digit NDC as listed below. Some payers may require each NDC number on the claim. Check payer requirements for appropriate reporting of the NDC.

<table>
<thead>
<tr>
<th>10-digit NDC</th>
<th>11-digit NDC</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>75987-130-15</td>
<td>75987-0130-15</td>
<td>500 mg teprotumumab-trbw in a vial (lyophilized powder for intravenous infusion)</td>
</tr>
</tbody>
</table>

ICD-10-CM diagnosis codes

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

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E05.00</td>
<td>Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm</td>
</tr>
</tbody>
</table>

Additional ICD-10-CM diagnosis codes may be used to fully describe the patient’s condition and associated manifestations.

HCPCS codes

TEPEZZA has not yet been assigned a permanent, product-specific HCPCS code. Meanwhile, an unclassified HCPCS code should be used on claims for TEPEZZA.

<table>
<thead>
<tr>
<th>HCPCS Drug Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
</tr>
<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
</tr>
</tbody>
</table>

The “JW” modifier for reporting wastage is typically not used with unlisted/miscellaneous codes (e.g., J3590, C9399). Contact payers for specific coding requirements for billing wastage with unlisted/miscellaneous codes or contact Horizon Patient Services for assistance with identifying payer coding requirements.

**CPT® and HCPCS codes**

SPP infusion centers may use CPT or HCPCS codes to report medical services provided in the facilities, including the administration of TEPEZZA. When billing for TEPEZZA in the SPP facility, the following CPT and HCPCS codes may be appropriate:

<table>
<thead>
<tr>
<th>CPT/HCPCS Code for Drug Administration*</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99601</td>
<td>Home infusion/specialty drug administration, per visit (up to 2 hours)</td>
</tr>
<tr>
<td>S9329</td>
<td>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)</td>
</tr>
<tr>
<td>S9379</td>
<td>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</td>
</tr>
<tr>
<td>S9810</td>
<td>Professional pharmacy services for provision of infusion, specialty drug administration, and/or disease state management, not otherwise classified, per hour</td>
</tr>
</tbody>
</table>

**Modifiers**

Modifiers are typically 2 alphanumeric character indicators that provide payers additional information regarding the services rendered.

If appropriate, more than one modifier may be used with a single procedure code. SPPs may use certain modifiers to indicate the service is performed in a facility but is considered a home place of service. The modifier “SS” should be used with both the HCPCS code for the drug and with the CPT or HCPCS code for the administration.

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SS</td>
<td>Home infusion services provided in the infusion suite of the Intravenous therapy provider</td>
</tr>
</tbody>
</table>

Call 1-833-5-TEPEZZA to enroll in Horizon Patient Services™ and connect with your local Reimbursement Access Specialist
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 10-mL vials each containing 500 mg of TEPEZZA) via intravenous infusion. In this example, the specific payer requires providers to report using J3590 for TEPEZZA on the line in Box 24D and include additional information about TEPEZZA in Box 19.

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 http://www.nucc.org

Please see Important Safety Information on the back cover and accompanying Full Prescribing Information.
Items 1-13: Enter the patient’s personal and insurance information.

Item 19: When completing a claim using an unclassified code, additional information is required. Enter TEPEZZA brand and generic names, NDC, and amount administered to patient.

Item 21:
- Enter the appropriate ICD-10-CM diagnosis code(s)12
- The “ICD Ind.” field identifies the ICD code set being reported. Enter “0” between the dotted vertical lines for ICD-10-CM codes12

Item 23: If required, report PA number.

Item 24D: Enter the appropriate HCPCS (eg, J3590) and CPT® codes. Include any modifiers required by the payer (eg, “SS” to indicate use of specialty pharmacy).

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.

Item 24G: Document the number of units used for each line item.12
- When billing for TEPEZZA with an unclassified HCPCS code (eg, J3490 or J3590), enter 1 unit
  - Total dosage administered, based on patient weight, is part of the information entered in Item 19

Unit means the amount of the measurement used in the code description. As J3490, J3590, or C9399 have no HCPCS descriptor unit measurement, the number of units is always 1.

SPP infusion center claims submission checklist
The following checklist provides an overview of requirements that may be necessary from payers when submitting claims for TEPEZZA:

- Use an HCPCS code (J3490, J3590) appropriate for TEPEZZA13
- Have the PA approval or predetermination approval on file
- Confirm with the payer or Horizon Patient Services™ how NDC numbers should be noted on the claim form
- Include any documentation required by the payer

Call 1-833-5-TEPEZZA to enroll in Horizon Patient Services and connect with your local Reimbursement Access Specialist

Simplify access to TEPEZZA with Horizon Patient Services™

Horizon Patient Services offers a wide array of services tailored to fit the needs of your patients and practice:

**Patient Support**
- Provide education about Thyroid Eye Disease (TED) and TEPEZZA so your patients feel more confident and prepared
- Support adherence by checking in with your patients prior to each infusion

**Financial Assistance**
- Educate your patients about their insurance benefits
- Help patients navigate their financial assistance options so they can pay the lowest amount possible

**Insurance Benefits Investigation**
- Assist in conducting insurance benefits investigations
- Provide guidance for prior authorization, medical exception, or the appeal process
- Review billing and coding requirements

**Infusion Logistics Assistance**
- Provide options for a site of care for infusion (eg, hospital outpatient department, physician office, independent infusion center, home)
- Help schedule infusion appointments

Your Regional Access Specialist has the local expertise to provide guidance and assistance by overseeing the completion of insurance approvals and can help resolve unique situations, such as denied claims.
We believe patients should pay the lowest amount possible

In today’s complex insurance landscape, it’s possible for patients to miss out on the most affordable option. Horizon Patient Services™ understands this challenge and is dedicated to helping patients prescribed TEPEZZA find their lowest possible treatment cost, regardless of coverage.

Financial assistance options are available, based on your patient’s insurance

Patients with commercial insurance may qualify for a $0 co-pay for both the cost of the medication and the IV infusion through our co-pay reduction program.*

Patients with government insurance, such as Medicare, may be eligible for independent foundation support.†

For uninsured patients, the Patient Assistance Program may provide support for eligible patients (TEPEZZA medication only).

Travel reimbursement assistance may be available through independent foundation support.

Simplify access for you and your patients, including financial assistance, through Horizon Patient Services. Just call 1-833-5-TEPEZZA or visit TEPEZZAhcp.com to enroll

IV, intravenous.

*Terms and Conditions: Offer cannot be combined with any other rebate or coupon, free trial, or similar offer for the specified prescription. Not valid for prescriptions reimbursed in whole or in part by Medicaid, Medicare, VA, DOD, TRICARE, or other federal or state programs (including state prescription drug programs). Offer good only in the United States at participating retail pharmacies. Offer not valid where otherwise prohibited by law, for example by applicable state law prohibiting co-pay cards. Horizon Therapeutics reserves the right to rescind, revoke, or amend offer without notice. The selling, purchasing, trading, or counterfeiting of this card is prohibited by law. This card is not insurance and is not intended to substitute for insurance. Participating patients and pharmacists understand and agree to comply with all Terms and Conditions of offer. Patients must be 18 or older.

†Please note that independent foundations establish, administer, and implement the funds, which are separate and apart from Horizon.
INDICATION
TEPEZZA is indicated for the treatment of Thyroid Eye Disease.

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 managed with medications for glycemic control, if necessary. Monitor patients for elevated blood glucose and symptoms of hyperglycemia while on treatment with TEPEZZA. Patients with preexisting diabetes should be under appropriate glycemic control before receiving TEPEZZA.

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, and dry skin.

For additional information on TEPEZZA, please see accompanying Full Prescribing Information.

References: