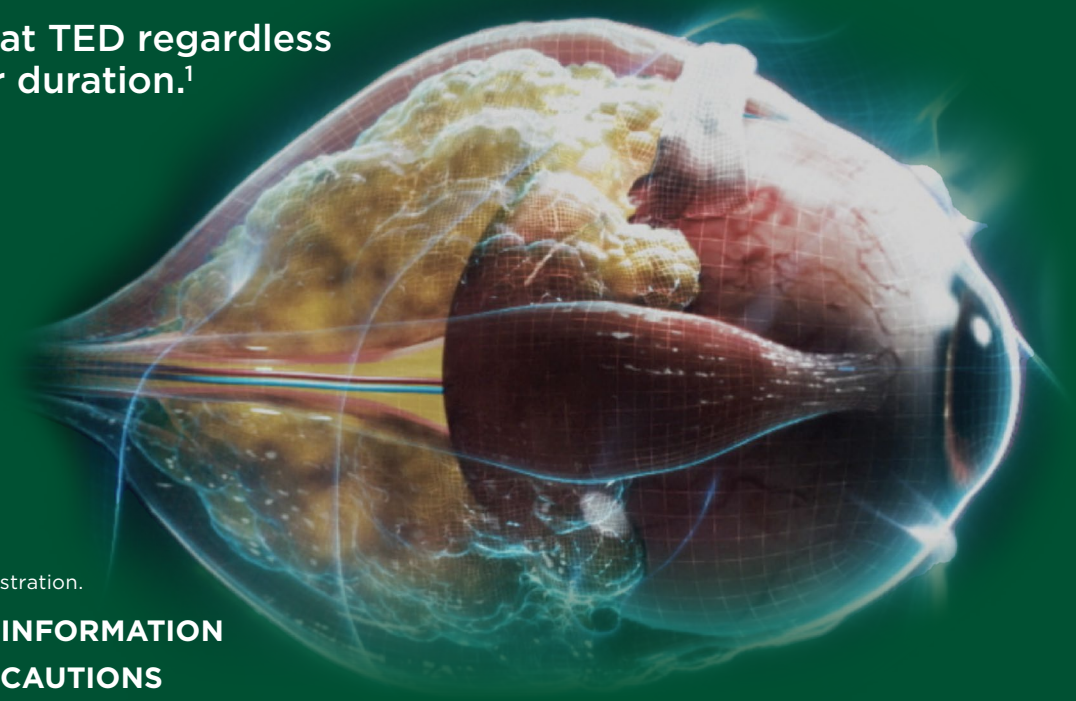
TEPEZZA at your practice

A guide to clinical, access, and reimbursement considerations

The first and only FDA-approved treatment for patients that treats a source of Thyroid Eye Disease (TED).

TEPEZZA can treat TED regardless of TED activity or duration.[1]



FDA, US Food and Drug Administration.

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.

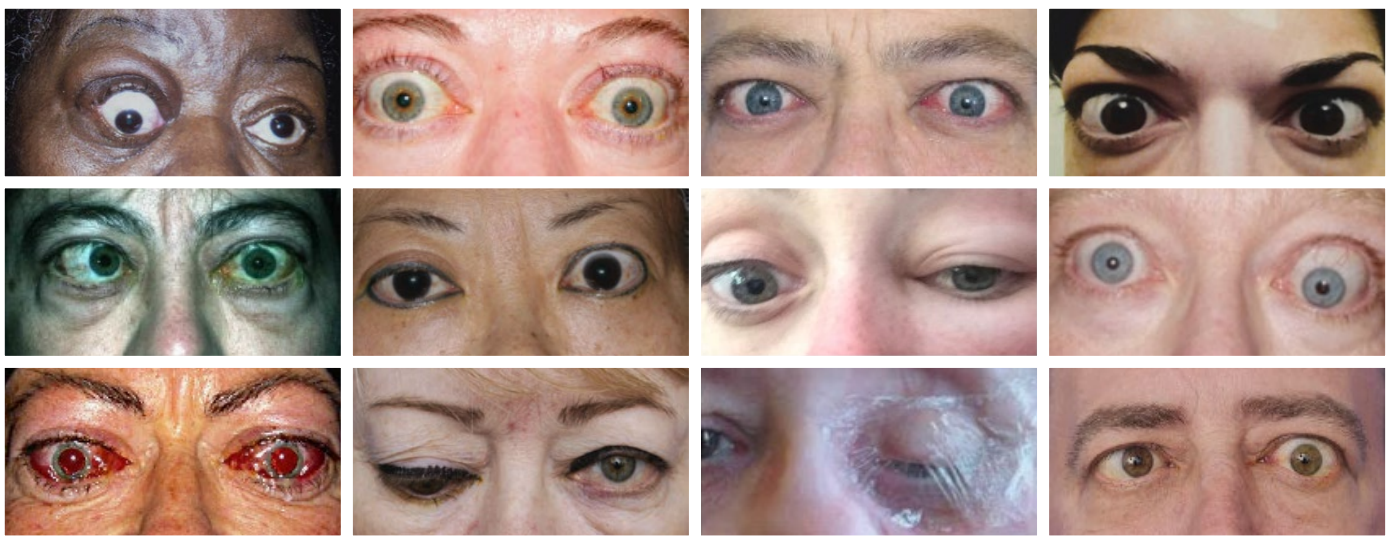
Please see additional Important Safety Information throughout and on page 33, and see Full Prescribing Information or visit TEPEZZAhcp.com.

TEPEZZA®
teprotumumab-trbw

A resource to help you confidently support your patients prescribed TEPEZZA

This resource aims to provide sites of care (SOCs) with detailed information about infusing TEPEZZA® (teprotumumab-trbw)

Topics include a TED overview, TEPEZZA efficacy, safety and dosing, patient support, care coordination, and access and reimbursement.



Patients with TED at varying degrees of activity. Images used with permission.

Your Amgen representative is available for further questions as you support and infuse your patients prescribed TEPEZZA

TED, Thyroid Eye Disease.

IMPORTANT SAFETY INFORMATION

Infusion Reactions (cont'd): 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.

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

Amgen By Your Side

Amgen By Your Side is a support program for patients prescribed TEPEZZA. Our dedicated team is your patient's partner, committed to providing nonmedical support to help patients as they start and continue on treatment as prescribed. Call **1-844-469-4297** or visit **AmgenByYourSide.com** to initiate enrollment for your patient by submitting the Patient Enrollment Form (PEF).

Patient Access Liaison (PAL)

The PAL provides dedicated, one-on-one support for your patient. They work directly with individual patients to answer non-medical, logistical questions and provide support upon enrollment. Additionally, the PAL educates about navigating insurance processes and accessing treatment on your patient's behalf. The PAL has the expertise and tools to support the patient by educating on patient benefits, prior authorization requirements, payer policies, and coding and claim submissions.

Area Lead (Site of Care)

The Area Lead (Site of Care) is your main Amgen point of contact who establishes business-to-business relationships with sites of care and expands the network of infusion center options. The team educates on coding, billing, and payer access and provides product in-servicing.

TEPEZZA® teprotumumab-trbw

Financial Support

Financial support programs may be available for your patients:

- Eligible patients with commercial insurance may pay as little as **$0 out-of-pocket*** for the cost of the medication and the infusion administration through the Amgen Commercial Co-Pay Program
- Patients with government insurance, such as Medicare, Medicaid, or TRICARE, are not eligible for co-pay assistance, but may be eligible for independent foundation support†
- Patients who are uninsured may be eligible for the patient assistance program

The Amgen Commercial Co-Pay Program offers multiple reimbursement methods in the form of credit cards, checks, and electronic funds transfer (EFT). Contact an Amgen representative for more information about registering for any of these reimbursement methods

*The Amgen Commercial Co-Pay Program may be available to patients who meet the following minimum criteria:

- Patient's prescription cannot be paid in part or in full by any government-funded program, including but not limited to Medicare, Medicare Part D, Medicaid, Medigap, VA, CHAMPUS, Department of Defense (DOD), TRICARE, or any state, patient foundation, or other pharmaceutical program
- Patient is prescribed a covered Amgen rare disease medication for an indication approved by the Food and Drug Administration; the indication for each product is shown in its prescribing information
- Patient is a resident of the United States
- Patient must be commercially insured and have financial responsibility for a portion of the drug and/or infusion cost if applicable

The assistance offered under this co-pay program is subject to additional terms and conditions, including but not limited to the following:

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 any government-funded program, including but not limited to Medicare, Medicare Part D, Medicaid, Medigap, VA, CHAMPUS, DOD, TRICARE, or any state, patient foundation, or other pharmaceutical program. Offer good only in the United States at participating specialty pharmacies or sites of care. Offer not valid where otherwise prohibited by law, for example by applicable state law prohibiting co-pay cards. Amgen reserves the right to rescind, revoke, or amend offer without notice. The selling, purchasing, trading, or counterfeiting of any co-pay card or benefits is prohibited by law. This co-pay program is not insurance and is not intended to substitute for insurance. Age for eligibility is dependent on product indication.

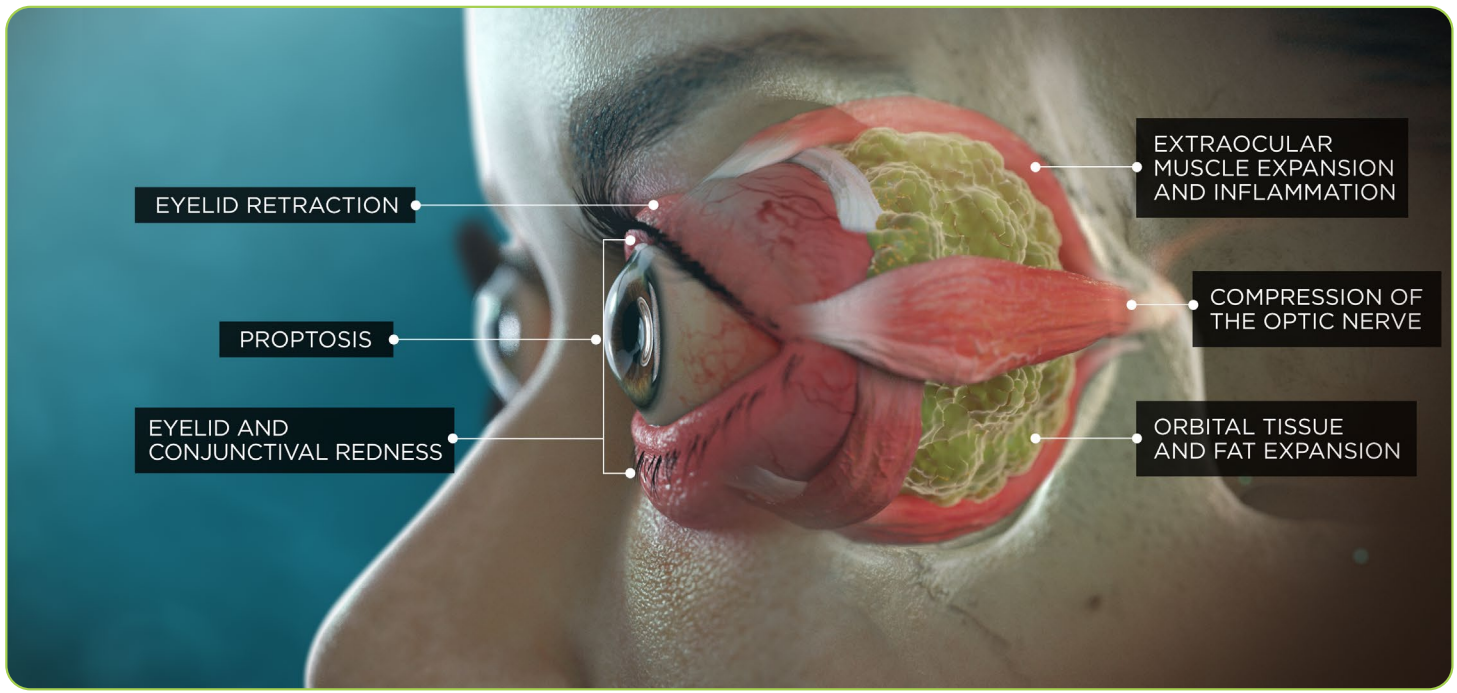
Participating Pharmacies or Healthcare Providers: By using this co-pay program, you acknowledge and confirm that the prescription will not be reimbursed in whole or in part by any government-funded program (such as, without limitation, Medicare, Medicaid, VA, DOD, or TRICARE) and the patient and prescription meet the eligibility criteria set forth in the terms and conditions. You are responsible for reporting the receipt of the co-pay program benefits as required by an insurer, payer, or applicable law or regulation.

Patients: By enrolling in this co-pay program, you acknowledge and confirm that you and the prescription meet the eligibility requirements set forth in the terms and conditions, including that the prescription will not be reimbursed in whole or in part by any government-funded program (such as, without limitation, Medicare, Medicaid, VA, DOD, or TRICARE). You may not seek any claims to government payers or other payers or insurers for this prescription. You may not seek reimbursement from any health savings, flexible savings, or other healthcare reimbursement account for any amounts received from the co-pay program. You are responsible for reporting the receipt of the co-pay program benefits as required by an insurer, payer, or applicable law or regulation.

†Please note that independent foundations establish, administer, and implement the funds, which are separate and apart from Amgen. While we cannot guarantee access or reimbursement for our medicines, we can educate you and your staff about gaining access to the medicine and various patient financial support programs.

TEPEZZA® teprotumumab-trbw

TED is identified by ongoing inflammation, tissue expansion, and remodeling around the eye[2,3]



The visible and nonvisible signs and symptoms of TED can have a debilitating impact on your patients' daily activities and self-confidence[4-6]

61% n=242/394
had trouble performing 1 or more daily activities[6]

45% n=177/394
had trouble reading[6]

Based on an online 62-question survey of 443 TED patients with a diagnosis that ranged from <1 to >10 years and 394 completed QOL questionnaire.[6]

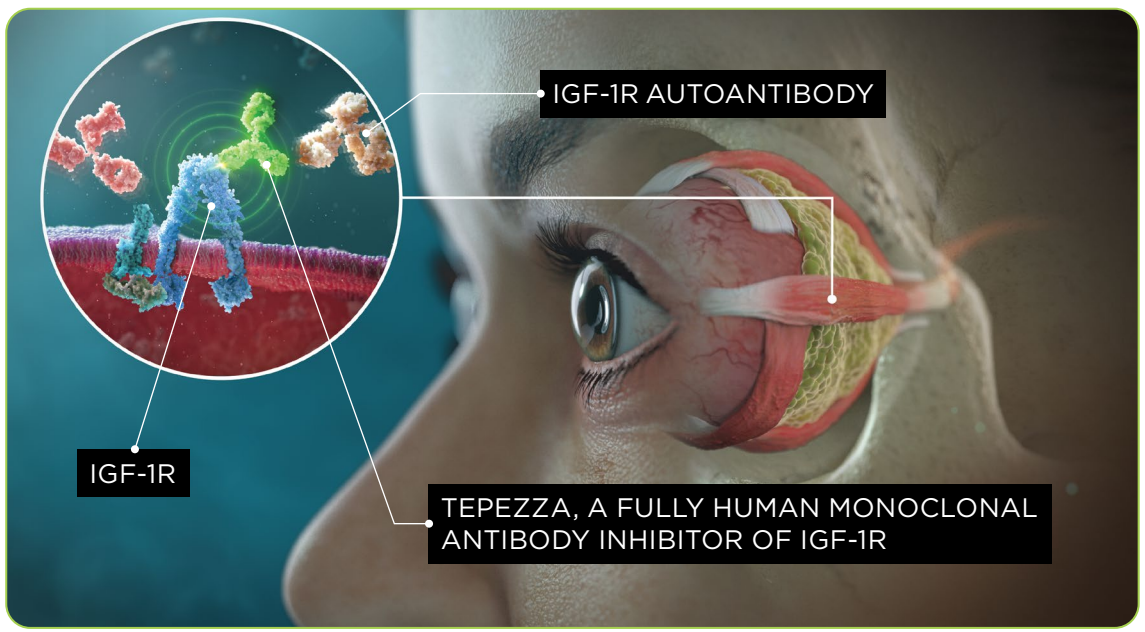
71% n=50/70
felt their self-confidence had been negatively affected[7]

Based on responses from 70 patients with TED with a duration of disease ranging from 12 to 18 months who answered 16 questions from the GO-QOL questionnaire.[7]

GO-QOL, Graves' Ophthalmopathy-Quality of Life; TED, Thyroid Eye Disease.

TEPEZZA is the first and only FDA-approved medicine that treats at a key source of TED

TEPEZZA is designed to block the insulin-like growth factor-1 receptor (IGF-1R), a key mediator of TED pathophysiology throughout the course of disease.[1,10-12]



TEPEZZA is designed to block the IGF-1R that triggers TED.[1]

TEPEZZA is a fully human monoclonal antibody inhibitor of IGF-1R and decreases proptosis by:[1,3,12,13]

- Preventing muscle and fat-tissue remodeling
- Reducing tissue expansion behind the eye

Teprotumumab-trbw's mechanism of action in patients with TED has not been fully characterized. Teprotumumab-trbw binds to IGF-1R and blocks its activation and signaling.[1]

For more information regarding the mechanism of action of TEPEZZA, visit TEPEZZAhcp.com

FDA, US Food and Drug Administration; TED, Thyroid Eye Disease.

IMPORTANT SAFETY INFORMATION

Inflammatory Bowel Disease: TEPEZZA may cause an exacerbation of inflammatory bowel disease (IBD). IBD has been reported in some patients without a prior diagnosis of IBD. Monitor patients for signs and symptoms of IBD. If IBD exacerbation is suspected, discontinue use of TEPEZZA.

Please see additional Important Safety Information throughout and on page 33.

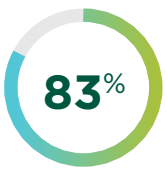
TEPEZZA® teprotumumab-trbw

Phase 2/3 studies demonstrated the efficacy of TEPEZZA for patients with TED

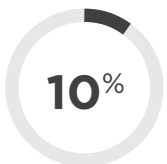
In patients with high disease activity and short duration TED, TEPEZZA has been shown to:

Reduce proptosis[1,10]

Percent of patients who were proptosis responders*



Phase 3 Primary endpoint
(*P*<0.001, Week 24)



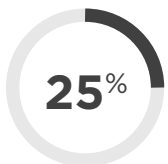
(TEPEZZA, n=34/41)

(Placebo, n=4/42)

Improve diplopia[1]

Percent of patients who were diplopia responders†

Pooled Analysis of Phase 2 and 3 Secondary endpoint
(*P*<0.01, Week 24)



(TEPEZZA, n=35/66)

(Placebo, n=15/59)

Phases 2 and 3 design: Two replicate 24-week, randomized, double-masked, placebo-controlled trials in moderate-to-severe TED patients.[1,6,10] In Phase 2, 42 patients received TEPEZZA, and 45 patients received placebo. In Phase 3, 41 patients received TEPEZZA and 42 patients received placebo. Infusions were administered once every 3 weeks for a total of 8 infusions. The primary endpoint of both studies was proptosis responder rate (percentage of patients with a ≥2-mm reduction in proptosis at Week 24).[1]

*Proptosis response was defined as a ≥2-mm reduction in proptosis in the study eye from baseline without deterioration (≥2-mm increase in proptosis) in the non-study eye.[1]

†Diplopia was evaluated on a 4-point Bahn-Gorman scale where scores ranged from 0 for no diplopia to 3 for constant diplopia. A diplopia responder was defined as a patient with baseline diplopia >0 and a score of 0 at Week 24.[1]

TED, Thyroid Eye Disease.

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

Phase 4 trial design

Patients with low disease activity and long-duration TED were studied in a 24-week, randomized, double-masked, placebo-controlled trial[15]

Select Inclusion Criteria	
Age ≥18 years	✓
TED duration ≥2 years but <10 years	✓
CAS ≤1 for ≥1 year OR no progression in proptosis or diplopia or new inflammatory symptoms for ≥1 year	✓
Euthyroid or mildly hypo/hyperthyroid*	✓
Select Exclusion Criteria	
Previous surgery in study eye	✗
Optic neuropathy	✗

2:1 Randomization	
TEPEZZA	Phase 4 trial (n=42) Once every 3 weeks for 8 infusions
Placebo	Phase 4 trial (n=20) Once every 3 weeks for 8 infusions

At baseline, mean TED duration was 5.1 to 5.4 years and proptosis was 24 to 24.6 mm

WEEK-24 EVALUATION	
Primary endpoint	Change in proptosis (mm) in the study eye from baseline†
Secondary endpoint	Proptosis responder rate (% of patients with ≥2-mm proptosis reduction)†

*Euthyroid or mildly hypo/hyperthyroid defined as free thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below the normal limits (every effort should be made to correct the mild hypo/hyperthyroidism promptly).

†Without deterioration in the non-study eye.

CAS, Clinical Activity Score; TED, Thyroid Eye Disease.

IMPORTANT SAFETY INFORMATION

Hyperglycemia (cont'd): 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.

Please see additional Important Safety Information throughout and on page 33.

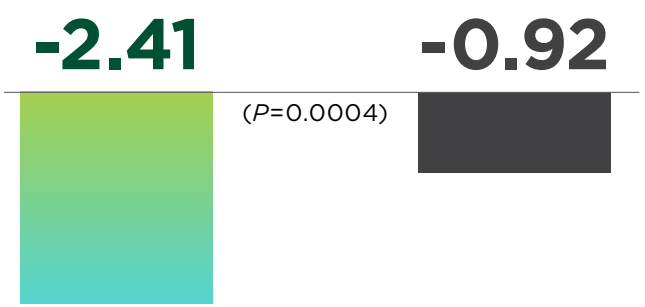
TEPEZZA® teprotumumab-trbw

Phase 4 clinical trial demonstrated the efficacy of TEPEZZA for patients with TED

In patients with low disease activity and long duration TED, TEPEZZA showed:

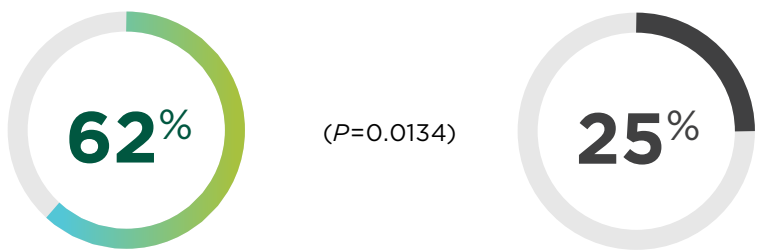
Significant reduction in proptosis[15]

Phase 4: Change in proptosis (mm) in the study eye from baseline at Week 24 (primary endpoint)



The majority of patients had a proptosis response[15]

Phase 4: Patients achieving ≥2-mm reduction in proptosis* at Week 24 (other endpoint)



Phase 4: Patients with low disease activity and long duration TED studied in a 24-week, randomized, double-masked, placebo-controlled trial.

In the Phase 4 trial, no differences between the teprotumumab and placebo groups were observed for diplopia endpoints. The trial was not powered to detect a treatment difference in diplopia due to the low incidence of diplopia at baseline among the study subjects.[15]

*Proptosis response was defined as ≥2-mm reduction in proptosis from baseline in the study eye without deterioration of ≥2-mm increase in proptosis in the fellow eye.

TED, Thyroid Eye Disease.

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

Phase 2/3 studies demonstrated TEPEZZA safety and tolerability profile[1,10,14]

89%
of patients completed full treatment course of TEPEZZA

- Most adverse events were mild or moderate, manageable, and resolved during or after treatment[16]

⊕ Hyperglycemia and hearing impairment details

Adverse reactions occurring in ≥5% of patients treated with TEPEZZA and with greater incidence than placebo[1]

Adverse Reactions	TEPEZZA (n=84), n (%)	Placebo (n=86), n (%)
Muscle spasms	21 (25%)	6 (7%)
Nausea	14 (17%)	8 (9%)
Alopecia	11 (13%)	7 (8%)
Diarrhea	10 (12%)	7 (8%)
Fatigue[a]	10 (12%)	6 (7%)
Hyperglycemia[b]	8 (10%)	1 (1%)
Hearing impairment[c]	8 (10%)	0
Dysgeusia (taste disturbance)	7 (8%)	0
Headache	7 (8%)	6 (7%)
Dry skin	7 (8%)	0
Weight decreased	5 (6%)	0
Nail disorder[d]	4 (5%)	0
Menstrual disorders[e]	5 (23%)	1 (4%)

[a]Fatigue includes asthenia.[1]
[b]Hyperglycemia includes blood glucose increase.[1]
[c]Hearing impairment (deafness, including sensorineural deafness, eustachian tube dysfunction, hyperacusis, hypoacusis, and autophony).[1]
[d]Nail disorder (includes nail discoloration, nail disorder, and onycholysis).[1]
[e]Menstrual disorders reported by menstruating patients included amenorrhea, metrorrhagia, and dysmenorrhea (TEPEZZA group, n=22, placebo, n=25).[1]

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

Hyperglycemia: Previous glycemic abnormalities in patients receiving TEPEZZA[16]

In the Phase 2 and 3 studies (N=84)[16]

10%

(n=8/84)

of patients experienced a hyperglycemic event[16]

63%

(n=5/8)

of patients who experienced a hyperglycemic event had preexisting diabetes[16]

The majority of hyperglycemic events resolved during or shortly after treatment[16]

- Of 8 total events, 6 resolved during treatment, 2 resolved after the last dose

[c]Hearing impairment (deafness, including sensorineural deafness, eustachian tube dysfunction, hyperacusis, hypoacusis, and autophony).[1]

[d]Nail disorder (includes nail discoloration, nail disorder, and onycholysis).[1]

[e]Menstrual disorders reported by menstruating patients included amenorrhea, metrorrhagia, and dysmenorrhea (TEPEZZA group, n=22, placebo,n=25).[1]

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

Most hearing impairment events were transient, mild or moderate, and resolved during or after treatment[16]

In the Phase 2 and 3 studies (N=84)[16]

10%

(n=8/84)

of patients experienced a hearing impairment event[16]

75%

(n=5/8)

of the cases of hearing impairment resolved, and 1 case improved during the 24-week double-masked period[16]

In an observational study, patients at greatest risk of hearing impairment events caused by TEPEZZA:[17,*]

- Are older age (>65)
- Have preexisting hearing loss and a high CAS

*Results from a prospective observational study of 52 TED patients who completed a full course of TEPEZZA treatment. Data are not derived from a controlled clinical study and no conclusions of statistical or clinical significance can be drawn.

[c]Hearing impairment (deafness, including sensorineural deafness, eustachian tube dysfunction, hyperacusis, hypoacusis, and autophony).[1]

[d]Nail disorder (includes nail discoloration, nail disorder, and onycholysis).[1]

[e]Menstrual disorders reported by menstruating patients included amenorrhea, metrorrhagia, and dysmenorrhea (TEPEZZA group, n=22, placebo,n=25).[1]

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

Demonstrated safety and tolerability profile in Phase 4 clinical trial[15]

>9 out of 10
completed treatment with TEPEZZA[15]

- Most adverse events were mild or moderate, manageable, and resolved during or after treatment[15]

Hyperglycemia and hearing impairment details

Adverse events of special interest and other AEs of importance[15]		
Adverse Reactions	**TEPEZZA (n=41), n (%)**	**Placebo (n=20[a]), n (%)**
Muscle spasms	17 (42%)	2 (10%)
Fatigue	9 (22%)	2 (10%)
Hearing impairment	9 (22%)	2 (10%)
Diarrhea	8 (20%)	4 (20%)
Headache	7 (17%)	2 (10%)
Hyperglycemia	6 (15%)	2 (10%)
Dry skin	5 (12%)	0
Dysgeusia	4 (10%)	1 (5%)
Infusion reaction	2 (5%)	3 (15%)
Nausea	2 (5%)	1 (5%)
Alopecia	2 (5%)	0 (0%)
Nail bed disorder	2 (5%)	0 (0%)
New onset/exacerbation of bowel disease	0 (0%)	0 (0%)

*Includes patient who received 1 dose of TEPEZZA in error.

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

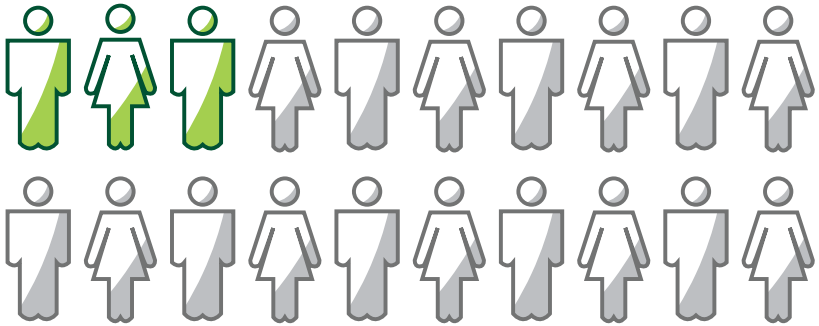
Hyperglycemia: Previous glycemic abnormalities in patients receiving TEPEZZA[15]

In the Phase 4 study (N=41)[15]

~15%

(n=6/41)

of patients experienced a hyperglycemic event[15]



83%

(n=5/6)

of patients who experienced a hyperglycemic event had preexisting diabetes or possibility of preexisting diabetes/impaired glucose tolerance[15,*]

The majority of hyperglycemic events were managed with adjustment of medication with none leading to discontinuation of treatment[15]

*One patient had a history of diabetes mellitus, and for 4 other patients, Day 1 HbA1c values (range, 5.7%-6.0%) suggest the possibility of preexisting prediabetes/impaired glucose tolerance (prediabetes: HbA1c 5.7%-6.4%, as defined by the American Diabetes Association, 2019).

*Includes patient who received 1 dose of TEPEZZA in error.

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

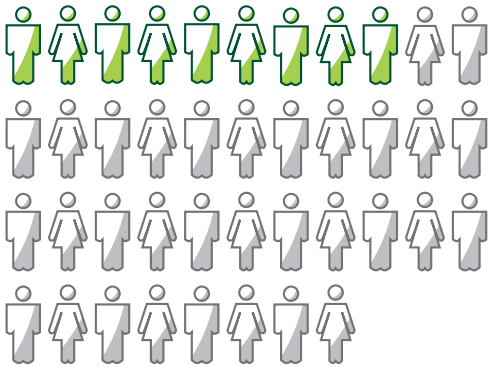
Hearing impairments were mostly mild or moderate[15]

In the Phase 4 study (N=41):[15]

22%

(n=9/41)

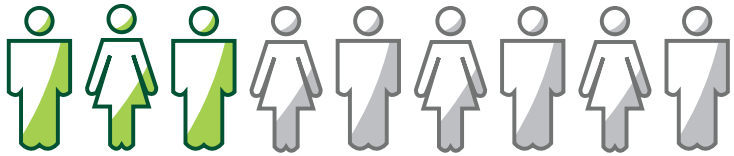
of patients who received TEPEZZA experienced a hearing impairment event[15]



33%

(n=3/9)

of cases of hearing impairment resolved/resolving at 30-day follow-up period[15]



Patients at greatest risk of hearing impairment events caused by TEPEZZA:[17,*]

- Are older age (>65)
- Have preexisting hearing loss and a high CAS

*Results from a prospective observational study of 52 TED patients who completed a full course of TEPEZZA treatment. Data are not derived from a controlled clinical study and no conclusions of statistical or clinical significance can be drawn.

*Includes patient who received 1 dose of TEPEZZA in error.

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

TEPEZZA storage instructions

Prior to reconstitution[1]

Store inside the carton

Protect from light

Refrigerate between 2 °C to 8 °C (36 °F to 46 °F)

Do not freeze

After reconstitution

the combined storage time of reconstituted solution in the vial and diluted solution in the infusion bag is a total of:[1]

Up to **4 hours** at room temperature

20 °C to 25 °C (68 °F to 77 °F)

Up to **48 hours** in refrigeration

2 °C to 8 °C (36 °F to 46 °F)

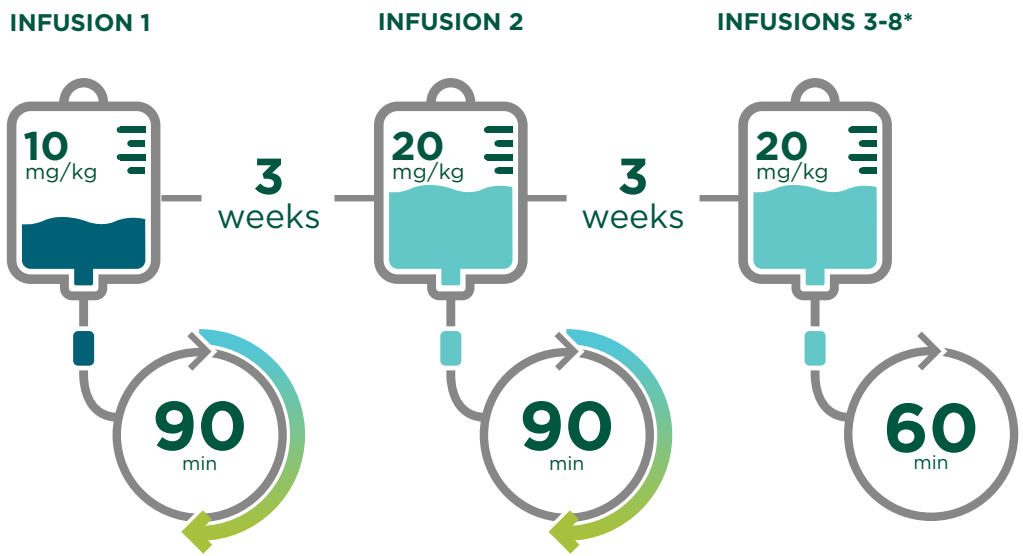
If not administered immediately, protect from light

If refrigerated, allow the diluted solution to reach room temperature prior to infusion

TEPEZZA® teprotumumab-trbw

Dosing information

Patients should complete the full treatment course of 8 IV infusions given every 3 weeks to get the full benefit[1]



- TEPEZZA is dosed according to the patient's actual weight[1]
  - The initial dose is 10 mg/kg. The dose for infusions 2 to 8 is 20 mg/kg[1]

* If well tolerated, the minimum infusion time for doses 3-8 can be reduced to 60 minutes. If not well tolerated, the minimum infusion duration should remain at 90 minutes for doses 3-8[1]

Patient weight may change throughout the infusion process. Ensure dosing is calculated based on the patient's actual weight at the time of infusion[1]

IV, intravenous.

IMPORTANT SAFETY INFORMATION

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, ear discomfort, weight decreased, nail disorders, and menstrual disorders.

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

Sample dosing calculations for a 75-kg patient[1]

	Infusion 1 (10 mg/kg)	**Infusions 2 to 8** (20 mg/kg)	**Notes**
1. Determine patient's actual weight	165 lb / 2.2 lb/kg = **75 kg**	165 lb / 2.2 lb/kg = **75 kg**	• Confirm patient weight prior to each infusion
2. Calculate weight-based dose	75 kg x 10 mg/kg = **750 mg**	75 kg x 20 mg/kg = **1500 mg**	• Multiply the patient weight (kg) by the dosage (mg/kg)
3. Determine number of vials required	750 mg / 500 mg = 1.5 → **2 vials**	1500 mg / 500 mg = 3 → **3 vials**	• Each vial delivers 500 mg of TEPEZZA • Always round up when determining the number of vials
4. Convert dose (mg) to volume of solution to withdraw (mL)	750 mg / 47.6 mg/mL = **15.8 mL**	1500 mg / 47.6 mg/mL = **31.5 mL**	• After reconstitution, each vial will contain 10.5 mL of reconstituted solution • The final concentration is 47.6 mg/mL
5. Select appropriate-sized saline bag	100 mL	100 mL	• If dose is <1800 mg, use a 100-mL bag • If dose is ≥1800 mg, use a 250-mL bag
6. Calculate wastage	2 vials required x 500 mg/vial = 1000 mg – 750 mg = **250 mg**	3 vials required x 500 mg/vial = 1500 mg – 1500 mg = **0 mg**	• Multiply the number of vials required by the 500 mg of TEPEZZA per vial, then subtract the dose given*

Access additional dosing information at TEPEZZAhcp.com

*Reference payer guidelines for wastage documentation requirements.

TEPEZZA® teprotumumab-trbw

Preparation and administration

Administration supplies

TEPEZZA vial(s)

IV infusion bag containing 0.9% Sodium Chloride Solution, USP (100 mL or 250 mL)*

Sterile syringe and needle

Infusion administration set (no special tubing required)

In-line filters with a 0.2-μm pore size (optional)

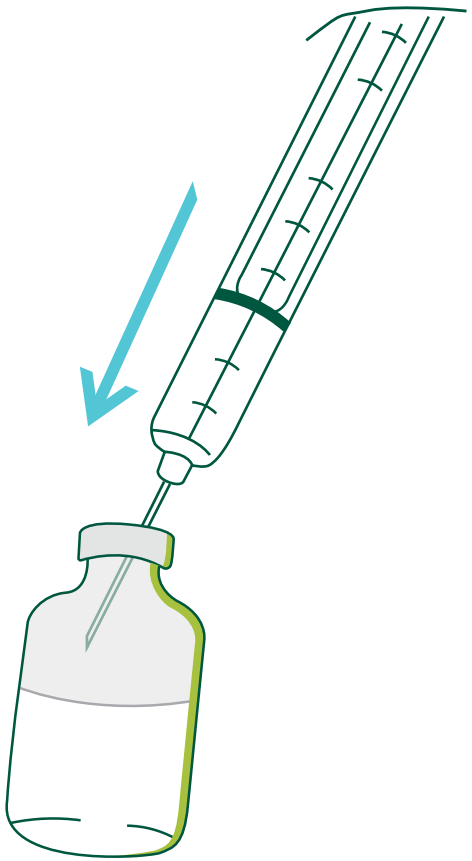
Routine infusion supplies (eg, alcohol swabs, gauze pads, bandages, and biohazard containers)

Sterile Water for Injection, USP

*Bag size dependent on dose.
IV, intravenous.

TEPEZZA® teprotumumab-trbw

Preparation and administration (cont'd)



> Reconstitute each vial with 10 mL of Sterile Water for Injection, USP.

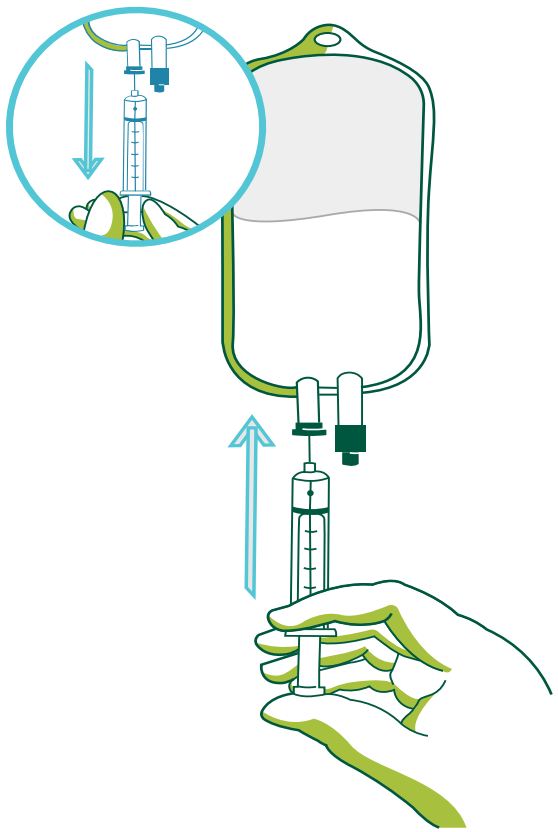
Reconstitute[1]

- Using appropriate aseptic technique, reconstitute each TEPEZZA vial with 10 mL of Sterile Water for Injection, USP
- Ensure that the stream of diluent is not directed onto the lyophilized powder, which has a cake-like appearance
- Gently swirl the solution by rotating the vial until the lyophilized powder is dissolved. Do not shake
  - Note: The reconstituted solution has a volume of 10.5 mL. The final concentration is 47.6 mg/mL
- Visually inspect the solution. It should be colorless or slightly brown, clear to opalescent. Discard the solution if any particulate matter or discoloration is observed

View a video demonstrating how to prepare TEPEZZA at TEPEZZAhcp.com

TEPEZZA® teprotumumab-trbw

Preparation and administration (cont'd)



> After removing the appropriate volume of saline, transfer the reconstituted TEPEZZA solution into the IV bag.

Dilute[1]

- The reconstituted TEPEZZA solution must be further diluted in 0.9% Sodium Chloride Injection, USP prior to infusion. Select the appropriate-sized saline bag based on the dose:

! For a dose **<1800 mg**, use a 100-mL bag

! For a dose **≥1800 mg**, use a 250-mL bag

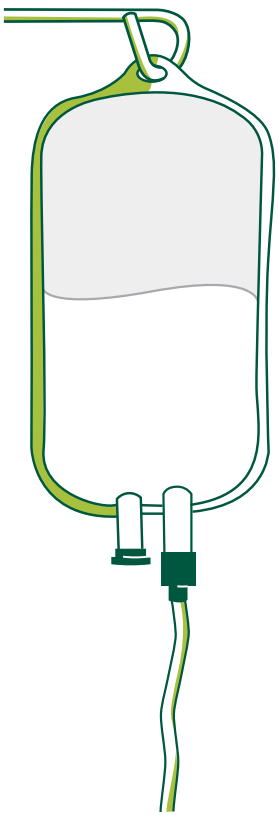
- To maintain a constant volume in the infusion bag, use a sterile syringe and needle to remove the volume of saline equal to the amount of reconstituted TEPEZZA solution to be placed into the bag. Discard the withdrawn saline
- Withdraw the required volume from the TEPEZZA vial(s) based on the dose and transfer into the infusion bag
- Mix diluted solution by gentle inversion. Do not shake
- The combined storage time of reconstituted TEPEZZA solution in the vial and the diluted solution in the infusion bag is a total of 4 hours at room temperature or up to 48 hours under refrigerated conditions while protected from light

View a video demonstrating how to prepare TEPEZZA at TEPEZZAhcp.com

IV, intravenous.

TEPEZZA® teprotumumab-trbw

Preparation and administration (cont'd)



> Infuse the diluted solution for the appropriate duration.

Infuse[1]

- If refrigerated prior to administration, allow the diluted solution to reach room temperature prior to infusion
- Infuse the diluted solution for the appropriate duration

! **Do not** administer as an intravenous push or bolus

! **Do not** infuse concomitantly with other agents

- Use your normal protocol to monitor for infusion reactions. If an infusion reaction occurs, interrupt or slow the rate of infusion and use appropriate medical management
- Discard vial(s) and all unused contents

View a video demonstrating how to prepare TEPEZZA at TEPEZZAhcp.com

TEPEZZA® teprotumumab-trbw

Infusion reactions

Infusion reactions were reported in ~4% of patients on TEPEZZA—most reactions were mild or moderate[1]

What to look for:[1]

- Signs and symptoms of an infusion reaction include:
  - **Transient increase in blood pressure**
  - **Dyspnea**
  - **Feeling hot**
  - **Headache**
  - **Tachycardia**
  - **Muscular pain**

Advise patients that TEPEZZA may cause infusion reactions that can occur at any time or within 1.5 hours after an infusion. Instruct patients to recognize the signs and symptoms of infusion reaction and to contact their healthcare provider immediately for signs or symptoms of potential infusion-related reactions[1]

If an infusion reaction occurs:[1]

- Interrupt or slow the rate of infusion and use appropriate medical management
- For subsequent infusions, consider premedicating with an antihistamine, antipyretic, or corticosteroid and/or slowing the rate of infusion

In clinical trials:

- Pretreatment medications were not routinely required[1]
- No antidrug antibodies were observed in patients treated with TEPEZZA[1]

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

Counseling and monitoring

Embryo-fetal toxicity

- Advise females of reproductive potential that TEPEZZA can cause harm to a fetus and to inform their healthcare provider of a known or suspected pregnancy[1]
- Educate and counsel females of reproductive potential about the need to use effective contraception prior to initiation, during treatment with TEPEZZA, and for 6 months after the last dose of TEPEZZA[1]
- Consider testing for pregnancy at each visit, as appropriate

Infusion-related reactions

- Reported in ~4% of patients on TEPEZZA–most reactions were mild or moderate
- Advise patients that TEPEZZA may cause infusion reactions that can occur at any time or within 1.5 hours after an infusion. Instruct patients to recognize the signs and symptoms of infusion reaction and to contact their healthcare provider immediately for signs or symptoms of potential infusion-related reactions

Inflammatory Bowel Disease (IBD)

- Monitor patients for signs and symptoms of IBD; if IBD exacerbation is suspected, discontinue use of TEPEZZA
- Advise patients on the risk of IBD, including patients with or without a prior diagnosis of IBD, and to seek medical advice immediately if they experience diarrhea, with or without blood or rectal bleeding, associated abdominal pain or cramping /colic, fecal urgency, tenesmus, or incontinence[1]

Most common adverse reactions

- Incidence ≥5% than placebo: muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache, dry skin, weight decreased, nail disorders, and menstrual disorders

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

Counseling and monitoring (cont'd)

Hyperglycemia

- Advise patients on the risk of hyperglycemia. Diabetic patients should discuss this with their healthcare provider to adjust glycemic control measures, including medications, as appropriate. Encourage compliance with glycemic control[1]
- In clinical trials, 10% of patients (two-thirds of whom had preexisting diabetes or impaired glucose tolerance) experienced hyperglycemia
- Assess patients for elevated blood glucose and hyperglycemia symptoms before and during treatment
- Ensure patients with hyperglycemia or preexisting diabetes are under appropriate glycemic control before and during treatment

Hearing impairment, including hearing loss

- TEPEZZA may cause severe hearing impairment, including hearing loss, which in some cases may be permanent[1]
- Assess patients' hearing before, during, and after treatment with TEPEZZA and consider the benefit-risk of treatment with patients[1]
- Instruct patients to contact their healthcare provider if they experience any signs or symptoms of hearing impairment or any changes in hearing[1]

Weight change

- Weigh patients at each infusion to ensure appropriate weight-based dosing[1]

Counsel patients about the importance of completing all 8 infusions

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

Answers to common patient questions

1 What should I know about the potential adverse reactions of TEPEZZA?

The most common adverse reactions of TEPEZZA include muscle cramps or spasms, nausea, hair loss, diarrhea, feeling tired, high blood sugar, hearing impairment, including hearing loss, taste changes, headache, dry skin, weight decreased, nail disorders, and menstrual disorders.[1]

2 Why can't I take TEPEZZA as a pill?

Some medicines need to be given in a particular way for them to work. TEPEZZA is given by a process known as intravenous (IV) infusion.[1]

3 This is my first time receiving an infusion–what should I expect?

We want you to be as comfortable as possible during your infusion. Our staff is trained on the proper way to give IV medicines, which are medicines that are given through a needle that is placed in your arm. You'll receive your TEPEZZA treatment in an infusion chair, which is a cushioned armchair similar to a recliner. There may be a TV to help you pass the time, or you can enjoy your own books, magazines, tablet, or phone. There may be other patients nearby receiving medicines for a variety of conditions, not just TED.

4 How often are the infusions given and how long will I be on treatment?

TEPEZZA is given once every 3 weeks for a total of 8 doses. So, completing your TEPEZZA treatment should take about 5 months. Make sure you complete your TEPEZZA treatment unless your doctor tells you to stop.[1]

5 Do I have to complete all 8 treatments?

Yes, people in clinical studies were given TEPEZZA once every 3 weeks—a total of 8 treatments over the course of about 5 months. So, it's important to complete all 8 treatments to see the best results.[1]

6 What if I become pregnant during treatment with TEPEZZA?

TEPEZZA can harm an unborn baby if given to a pregnant woman. You should use an effective form of birth control before treatment, during treatment, and for at least 6 months after your final infusion. Tell your doctor if you become pregnant or suspect you are pregnant during treatment with TEPEZZA.[1]

7 What happens if I miss an infusion?

Making time for your infusions can be challenging, but in order to see the best results with TEPEZZA, it's important to receive your infusion every 3 weeks. If you are going to miss an appointment, contact your infusion center as soon as possible to reschedule.

TED, Thyroid Eye Disease.

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

TED Team Peer-to-Peer Program

Patients prescribed TEPEZZA can speak with a patient who has completed treatment

TED TEAM

If your patient has questions about what to expect during TEPEZZA treatment, then the TED Team Peer-to-Peer Program may be helpful for them. In this program, the TED team, consisting of caregivers and patients who have completed their TEPEZZA treatment, can speak one-on-one with patients who have been prescribed TEPEZZA or have started their infusions. Once your patient is enrolled in Amgen By Your Side, their Patient Access Liaison can sign them up for the program.

What they can expect from the program:

- They can speak with another TED patient who will share what TEPEZZA treatment was like for them
- They can ask questions about topics that interest them in a one-on-one, private conversation
- Amgen program staff will take care of scheduling their call. And to ensure their privacy, they will dial into a secure, private line
- This does not have to be a long-term commitment. They can have just 1 call or several—whatever works best for them. After their call, if they want to schedule another, they just let the program staff know

TED, 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.

Please see additional Important Safety Information throughout and on page 33.

A variety of prescribers may refer patients with TED to your SOC

Endocrinologists

Comprehensive ophthalmologists

Oculoplastic surgeons

Neuro-ophthalmologists

Some prescribers may be unfamiliar with TEPEZZA and the prior authorization (PA) process. Clear communication with a prescriber regarding the PA process can help set expectations and streamline the patient's journey to infusion

SOC, site of care; TED, Thyroid Eye Disease.

IMPORTANT SAFETY INFORMATION

Infusion Reactions (cont'd): 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.

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

Care coordination checklist

Communication and coordination among the care team regarding laboratory testing and PA documentation is essential

Before first infusion

- ☑ Review insurance plan requirements
- ☑ Verify that all payer-required documentation has been provided by the referring provider
- ☑ Coordinate with the referring provider to submit the PA
- ☑ Confirm all necessary laboratory testing has been ordered (eg, blood glucose, thyroid, pregnancy)
- ☑ Provide patient education on:
  - The infusion process
  - Warnings, precautions, and potential side effects of TEPEZZA
  - The need for contraception for female patients of reproductive potential
- ☑ **Align with care team about who will be responsible for ongoing testing and monitoring**
  - Blood glucose
  - Pregnancy
  - Weight

Before subsequent infusion

- ☑ Verify any standing labs that must be performed prior to infusion (eg, blood glucose, pregnancy, weight)
  - Coordinate, if needed, with care management team to ensure these are completed
- ☑ Ensure consistent communication with the patient's care management team about the patient's progress, potential adverse events, and quality of life changes

After infusion

- ☑ Observe the patient post-infusion according to the infusion order
- ☑ Remind the patient of their next infusion appointment and to track any side effects they may be experiencing between infusions
  - If needed, schedule all subsequent patient infusions
- ☑ Share patient results with care management team and continue to coordinate ongoing patient testing and monitoring (eg, blood glucose, pregnancy, weight)

PA, prior authorization.

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

Payer policies have evolved favorably for patient access to TEPEZZA[18,19,*]

Clinical Activity Score (CAS)

[92%] of covered lives do not require a specific CAS score[†]

Diagnosis of moderate-to-severe TED

[81%] of covered lives have a moderate-to-severe diagnosis requirement[‡]

Step therapy

[91%] of covered lives do not have a mandatory steroid step when significant proptosis and/or diplopia are present[†]

Lifetime limits

[91%] of covered lives have lifetime limits for treatment[‡]

Prescriber type

[86%] of covered lives require that the patient is treated by a specific specialist (eg, ophthalmologist, endocrinologist)[‡]

As payer policies continue to evolve, access stays strong with [98%] coverage across all channels for TEPEZZA[20,§]

To help ensure a smooth PA process, it is important to work closely with referring prescribers and care team members to gather all relevant information and documentation for a complete PA request packet

Prior authorization criteria may include:

- Diagnosis of moderate-to-severe Thyroid Eye Disease
  - Best practice: providers should review payer criteria and include appropriate proptosis and diplopia documentation
- Thyroid disease that is controlled or actively being treated (defined by FT3, T3, FT4, T4, and/or TSH testing)
- Documentation of common inflammatory signs and symptoms that suggest Thyroid Eye Disease (TED), such as:
  - Moderate or severe soft tissue involvement, eye pain or pressure behind the eyes, swelling/retraction or redness of the eyelids, bulging or swelling of the eyes, double vision, persistent redness in or around the eyes, and excess dryness or irritation
- Prescribed by or in consultation with an ophthalmologist or endocrinologist
- Documentation of previous steroid use or contraindication to IV or oral steroids

78%

of patients prescribed TEPEZZA receive approval after their first PA[21,¶]

*As clinical data for TEPEZZA evolve to include a broader patient population, payer policies may change.
[†]Data were collected prior to and are effective as of September 2025.
[‡]Data updated as of May 2025.
[§]Individual patient access varies. Calculations are based on plans analyzed.
[¶]Data are from January 2024 through December 2024.
FT3, free triiodothyronine; FT4, free thyroxine; IV, intravenous; PA, prior authorization; TED, Thyroid Eye Disease; T3, triiodothyronine; T4, thyroxine; TSH, thyroid stimulating hormone.

IMPORTANT SAFETY INFORMATION

Inflammatory Bowel Disease: TEPEZZA may cause an exacerbation of inflammatory bowel disease (IBD). IBD has been reported in some patients without a prior diagnosis of IBD. Monitor patients for signs and symptoms of IBD. If IBD exacerbation is suspected, discontinue use of TEPEZZA.

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

Acquiring TEPEZZA from specialty distributors

TEPEZZA is available through 1 Amgen-authorized specialty pharmacy

Specialty pharmacy contact information		
Accredo® Ophthalmic TRC	**T:** 1-877-626-1511 **F:** 1-877-329-4605 *This is a dedicated phone line for ophthalmic products.*	www.accredo.com

TEPEZZA is available through multiple Amgen-authorized specialty distribution partners

Authorized Specialty Distributors for TEPEZZA			
Physician Channel (independent physicians and clinics)		**Acute Channel (hospitals and non-retail pharmacies)**	
BioCareSD®	**T:** 1-800-304-3064 www.biocaresd.com	**BioCareSD® Acute**	**T:** 1-800-304-3064 www.biocaresd.com
Cardinal Health™ PR 120, Inc.	**T:** 1-787-625-4100 www.cardinalhealth.pr	**Cardinal Health™ PR 120, Inc.**	**T:** 1-787-625-4100 www.cardinalhealth.pr
Cardinal Health™ Specialty Pharmaceutical Distribution	**T:** 1-877-453-3972 www.cardinalhealth.com	**Cardinal Health™ Specialty Pharmaceutical Distribution**	**T:** 1-877-453-3972 www.cardinalhealth.com
Cencora/Besse® Medical	**T:** 1-800-543-2111 www.besse.com	**Cencora/ASD Healthcare®**	**T:** 1-800-746-6273 www.asdhealthcare.com
Cencora/Oncology Supply®	**T:** 1-800-633-7555 www.oncologysupply.com	**CuraScript SD® Acute**	**T:** 1-877-599-7748 www.curascriptsd.com
CuraScript SD®	**T:** 1-877-599-7748 www.curascriptsd.com	**M&D® Specialty Distribution**	**T:** 1-800-710-6100 www.mdspecialtydist.com
M&D® Specialty Distribution	**T:** 1-800-710-6100 www.mdspecialtydist.com	**McKesson Plasma and Biologics**	**T:** 1-877-625-2566 www.mckesson.com/business-solutions/our-businesses/mckesson-plasma-biologics/
McKesson Specialty Health	**T:** 1-855-477-9800 www.mckessonspecialtyhealth.com		
Metro Medical Supply, Inc.	**T:** 1-800-768-2002 www.metromedical.com		

TEPEZZA® teprotumumab-trbw

TEPEZZA coding basics

Coding element	Information for TEPEZZA	Description
10-digit-NDC	75987-130-15	500 mg teprotumumab-trbw in a single-dose vial (lyophilized powder for injection for intravenous infusion)
11-digit-NDC	75987-0130-15	
ICD-10-CM Diagnosis Code	E05.00	Thyrotoxicosis with diffuse goiter without thyrotoxic crisis or storm
	H05.831	Thyroid orbitopathy, right orbit
	H05.832	Thyroid orbitopathy, left orbit
	H05.833	Thyroid orbitopathy, bilateral
	H05.839	Thyroid orbitopathy, unspecified orbit
HCPCS drug code	J3241	Injection, teprotumumab-trbw, 10 mg

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 above. Some payers may require both NDC numbers on the claim. Check payer requirements for appropriate reporting of the NDC.

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

HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information throughout and on page 33.

TEPEZZA® teprotumumab-trbw

TEPEZZA coding basics (cont'd)

Coding element	Information for TEPEZZA	Description
HCPCS Drug Administration Codes for Specialty Pharmacy Providers (SPP)	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)
CPT® Drug Administration Codes for Physician Offices and Hospital Outpatient Departments	96413	Highly complex drugs, including biologic agents or chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
	96415	Highly complex drugs, including biologic agents or chemotherapy administration, intravenous infusion technique; each additional hour (list separately in addition to code for primary procedure)
	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); each additional hour (list separately in addition to code for primary procedure)
CPT® Drug Administration Codes for SPP	99601	Home infusion/specialty drug administration, per visit (up to 2 hours)
Modifier*	JW	Drug amount discarded/not administered to any patient
	JZ	Zero drug amount discarded/not administered to any patient

Payer coding requirements may vary. Consult individual payer policies for specific coding and documentation requirements.

*As of July 1, 2023, CMS requires the "JZ" modifier to be reported on claims. Claims processing edits were implemented by the Medicare Administrative Contract in October 2023.

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

TEPEZZA® teprotumumab-trbw

TED glossary

Abduction: movement of the eye away from the midline or nose, also known as lateral movement.

Acuity or visual acuity: the clarity or sharpness of vision.

Adduction: movement of the eye toward the midline or nose, also known as medial movement.

Caruncle: small pink, globular spot at the inner corner of the eye. See Figure 1 A on next page

Chemosis: swelling of the tissue that lines the eyelids and surface of the eye (or conjunctiva).

Clinical Activity Score (CAS): one of several assessment scales designed to evaluate the signs and symptoms characteristic of Thyroid Eye Disease. Calculated by summing the signs and symptoms based on the 7- or 10-point CAS scale. CAS is commonly used in clinical trials and by payers.

Compressive optic neuropathy (CON): occurs when your optic (vision) nerve has been damaged from compression, such as tumors, or by orbital inflammatory conditions, such as Thyroid Eye Disease.

Conjunctiva: the mucous membrane that covers the front of the eye and lines the inside of the eyelids (surface of the eye).

Conjunctival redness: redness of the surface of the eye.

Cornea: clear dome over the iris.

Diplopia: double vision.

Edema: swelling.

Erythema: redness of the skin.

Esotropia: one eye deviates inward.

Exotropia: one eye deviates outward.

Eyelid erythema: redness of the eyelids.

Eyelid retraction: the upper or lower eyelid margins are drawn back from the normal position.

Free T3: “Free” refers to unbound triiodothyronine (T3) in the blood. A free T3 test is often ordered to help diagnose hyperthyroidism. (Some payers may have specific thyroid lab requirements.)

Free T4: “Free” refers to unbound thyroxine (T4) in the blood.

Gaze-evoked orbital pain: pain in, on, or around the eye, evoked by looking steadily or intently at something.

Iris: colored part of the eye.

Ischemic optic neuropathy (ION): a sudden loss of vision due to decreased or interrupted blood flow to the optic nerve.

Lagophthalmos: describes the incomplete or abnormal closure of the eyelids.

Letter of medical necessity (LOMN): formal argument made by a physician to a payer to cover a certain test or treatment. Explains the physician’s rationale and clinical decision-making.

TED glossary (cont'd)

Margin to reflex distance (MRD) measurement: the measurement in millimeters from the light reflex on the patient's cornea to the level of the center of the upper-eyelid margin, with the patient gazing in the primary position.

Oculus dexter (OD): right eye.

Oculus sinister (OS): left eye.

Oculus uterque (OU): both eyes.

Optic neuritis (ON): inflammation of the optic nerve.

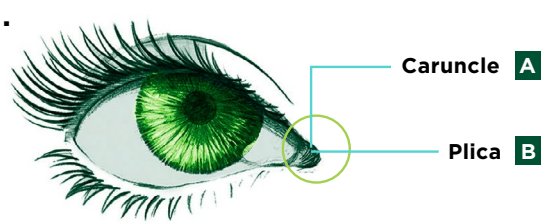
Orbit: bony cavity in the skull that houses the globe of the eye or eyeball, the muscles that move the eye (extraocular muscles), the lacrimal gland, and the blood vessels and nerves required to supply these structures.

Photophobia: extreme sensitivity to light.

Plica: vertical fold of conjunctiva that occupies the canthus (or either corner of the eye where the upper and lower eyelids meet) of the eye nearest the nose. See Figure 1, B.

Proptosis or exophthalmos: a medical term for bulging or protruding eyeballs.

Figure 1.



Sclera: white part of the eye.

Scleral show: an anatomical condition in which the sclera area is visibly exaggerated due to constitutional, evolutive, or endocrine etiology.

Spontaneous orbital pain: sudden pain in, on, or around the eye.

Strabismus or hypertropia: misalignment of the eyes.

Thyroid Eye Disease (TED): an autoimmune disease in which the eye muscles and fatty tissue behind the eye become inflamed. This inflammation can push the eyes forward ("staring" or "bulging") or cause the eyes and eyelids to become red and swollen.

Thyroid stimulating hormone (TSH): a hormone released by the pituitary gland that stimulates the thyroid to release thyroid hormones.

Thyroid stimulating immunoglobulin (TSI): thyroid stimulating immunoglobulins are antibodies that play a role in thyroid regulation.

T3 & T4: triiodothyronine & thyroxine are the two main hormones produced by the thyroid. They bind to proteins while circulating in the blood and help regulate various bodily functions.

Uniocular excursion: range of movement of one (uni-) eye (ocular).

Xerosis: dry skin or membranes.

Resource library

Visit TEPEZZAhcp.com or scan this QR code to find multiple tools to support caring for patients prescribed TEPEZZA at your SOC

A variety of patient-focused resources can be found at TEPEZZA.com or by scanning this QR code

Amgen representatives can provide many patient resources in other languages, as needed

TEPEZZA® teprotumumab-trbw

Indication and Important Safety Information

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.

Inflammatory Bowel Disease: TEPEZZA may cause an exacerbation of inflammatory bowel disease (IBD). IBD has been reported in some patients without a prior diagnosis of IBD. Monitor patients for signs and symptoms of IBD. If IBD exacerbation is suspected, discontinue use 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, ear discomfort, weight decreased, nail disorders, and menstrual disorders.

References: 1. TEPEZZA (teprotumumab-trbw) [prescribing information] Amgen. **2.** Bothun ED, et al. *Clin Ophthalmol*. 2009;3:543-551. **3.** Bahn RS. *N Engl J Med*. 2010;362(8):726-738. **4.** Kahaly GJ, et al. *Clin Endocrinol (Oxf)*. 2005;63(4):395-402. **5.** Estcourt S, et al. *Clin Endocrinol (Oxf)*. 2008;68(4):635-639. **6.** Smith TJ, et al. *Front Endocrinol (Lausanne)*. 2023;14:1283374. **7.** Terwee CB, et al. *Br J Ophthalmol*. 1998;82(7):773–779. **8.** Wang Y, et al. *Ophthalmol Ther*. 2021;10(1):75-87. **9.** Lee TC, et al. *Ophthalmic Plast Reconstr Surg*. 2023;39(3):281-287. **10.** Douglas RS, et al. *N Engl J Med*. 2020;382(4):341-352. **11.** Patel A, et al. *Am J Ophthalmol*. 2019;208:281-288. **12.** Douglas RS. *Eye (Lond)*. 2019;33(2):183-190. **13.** Dik WA, et al. *Exp Eye Res*. 2016;142:83-91. **14.** Smith TJ, et al. *N Engl J Med*. 2017;376(18):1748-1761. **15.** Douglas RS, et al. *J Clin Endocrinol Metab*. 2024;109(1):25-35. **16.** Kahaly GJ, et al. *Lancet Diabetes Endocrinol*. 2021;9(6):360-372. **17.** Douglas RS, et al. *Thyroid*. 2024;34(1):134-137. **18.** Data on File. Amgen, September 2025. **19.** Data on File. Amgen, May 2025. **20.** Data on File. Amgen, September 2025. **21.** Data on File. Amgen, August 2025.

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

AMGEN Rare Disease

TEPEZZA® teprotumumab-trbw