



# Infusion Guide

Guidance for administering  
TEPEZZA and preparing  
patients for their  
infusion experience

Please see Important Safety Information on page 30  
and [Full Prescribing Information](https://www.tepezza.com) at [TEPEZZAhcp.com](https://www.tepezza.com).

About TED

About TEPEZZA

Storage  
Instructions

Dosing

Preparation and  
Administration

Infusion Reactions  
and Adverse Reactions

Patient Support

# It's time for a breakthrough

As the **first and only FDA-approved treatment** for Thyroid Eye Disease (TED), TEPEZZA is a breakthrough treatment for patients with this potentially debilitating disease. By administering TEPEZZA infusions, you are part of a new era in TED treatment.<sup>1</sup>

This infusion guide, developed in collaboration with infusion nurses, contains step-by-step instructions to **help you feel confident and prepared** to infuse TEPEZZA.

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Look for this icon throughout the guide. This icon will indicate additional helpful information in each section

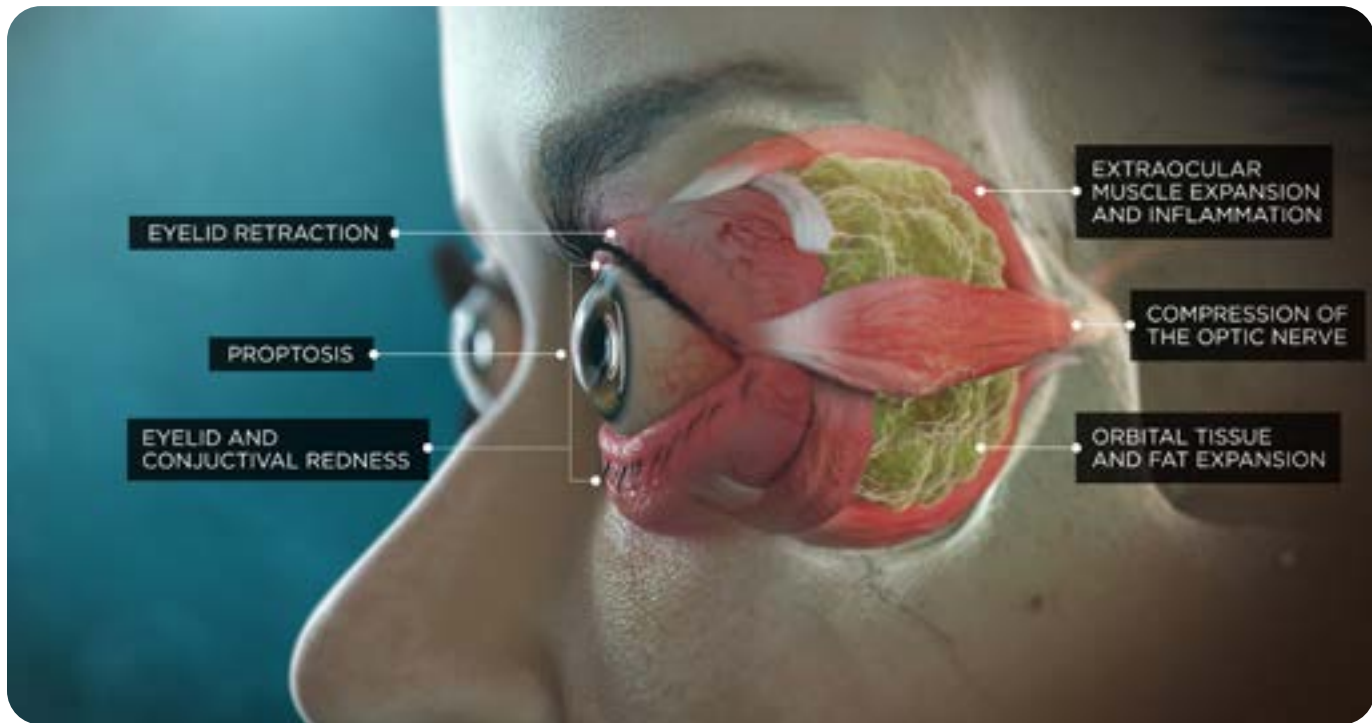
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# About Thyroid Eye Disease

TED, or Grave's orbitopathy, is a progressive autoimmune eye disease with potentially vision-threatening consequences.<sup>2,3</sup>

TED is identified by ongoing inflammation, tissue expansion, and remodeling around the eye.<sup>2,4</sup>



The effects of TED, such as proptosis, visual disturbances like diplopia, and pain, may limit a patient's functional ability and appearance.<sup>5</sup>



Impaired vision



Facial disfigurement and pain\*



Blurred vision

Some patients with TED are at an increased risk of limitations in day-to-day activities due to visual impairments<sup>6</sup>

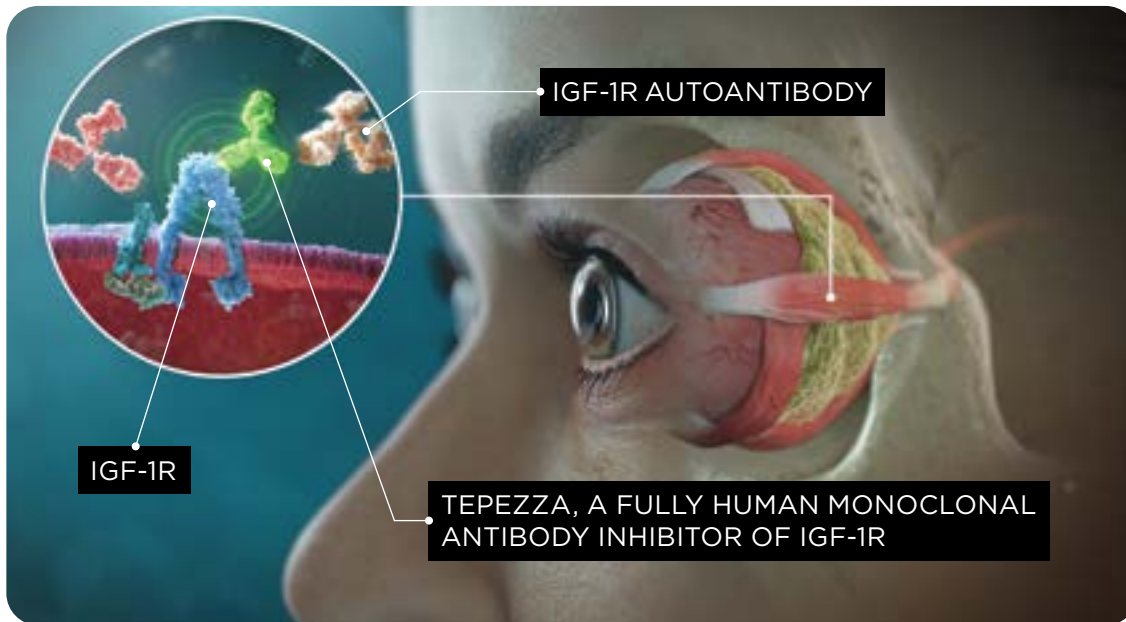
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# About TEPEZZA

TEPEZZA has a novel, breakthrough mechanism in TED designed to block the insulin-like growth factor-1 receptor (IGF-1R), a key mediator, and treat at the source of TED.<sup>1,3,7,8</sup>



TEPEZZA blocks the IGF-1R that triggers TED.<sup>1</sup>

- TEPEZZA is a fully human monoclonal antibody inhibitor of the IGF-1R<sup>1,9</sup>
- TEPEZZA decreases proptosis by<sup>1,4,8,10</sup>:
  - Reducing inflammation
  - Preventing muscle and fat-tissue remodeling
  - Preventing tissue expansion behind the eye
- Teprotumumab-trbw's mechanism of action in patients with TED has not been fully characterized<sup>1</sup>

For more information regarding the mechanism of action of TEPEZZA, visit [TEPEZZAhcp.com](https://TEPEZZAhcp.com)



## SELECT IMPORTANT SAFETY INFORMATION

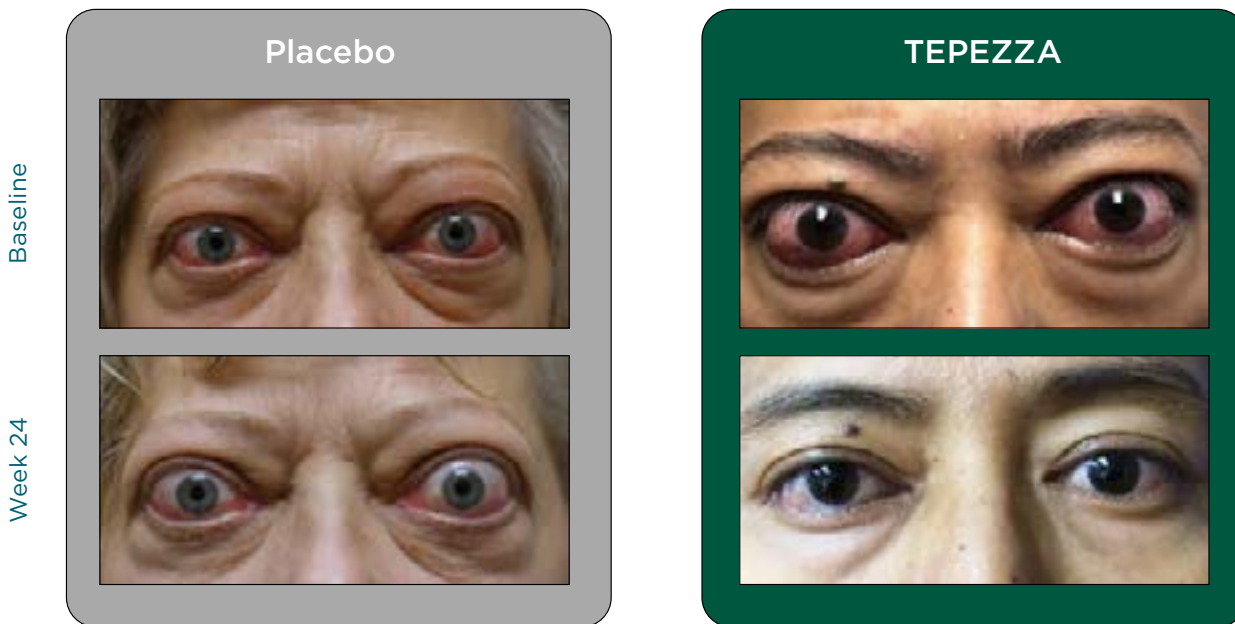
**Infusion Reactions** have been reported in approximately 4% of patients treated with TEPEZZA. Reported infusion reactions have usually been mild or moderate in severity. Signs and symptoms may include transient increases in blood pressure, feeling hot, tachycardia, dyspnea, headache, and muscular pain.

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# About TEPEZZA (cont'd)

See the TEPEZZA transformation<sup>3\*</sup>



Photos provided with permission from Raymond Douglas.  
\*Individual results may vary.

In clinical trials, TEPEZZA was proven to<sup>1,3,9</sup>:

- Decrease proptosis (bulging eyes)
- Improve diplopia (double vision)
- Reduce signs and symptoms (pain, redness, and swelling)

**56%** of patients who maintained a proptosis response in the clinical trials also maintained their response at 72 weeks<sup>1,11†</sup>

**TEPEZZA was generally well tolerated<sup>1,3,9</sup>**

- Most adverse events were mild or moderate, manageable, and resolved during or after treatment
- There was a low rate of discontinuation where 89% of patients completed treatment with TEPEZZA vs 93% with placebo

<sup>†</sup>Proptosis response was defined as a  $\geq 2$ -mm reduction in proptosis in the study eye without deterioration ( $\geq 2$ -mm increase in proptosis) in the fellow eye.<sup>1</sup>

## SELECT IMPORTANT SAFETY INFORMATION

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.

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# Storage Instructions

Prior to reconstitution:



**Store**  
inside the carton<sup>1</sup>



**Refrigerate**  
between 2°C to  
8°C (36°F to 46°F)<sup>1</sup>



**Protect**  
from light<sup>1</sup>



**Do not**  
freeze<sup>1</sup>



**TEPEZZA is supplied as a lyophilized powder for reconstitution. Each single-dose vial contains 500 mg of teprotumumab antibody.<sup>1</sup>**

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# Storage Instructions (cont'd)

## After reconstitution:

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



Up to **4 hours**  
at room temperature

20°C to 25°C (68°F to 77°F)<sup>1</sup>

**If not administered immediately,**  
protect from light<sup>1</sup>

OR



Up to **48 hours**  
in refrigeration

2°C to 8°C (36°F to 46°F)<sup>1</sup>

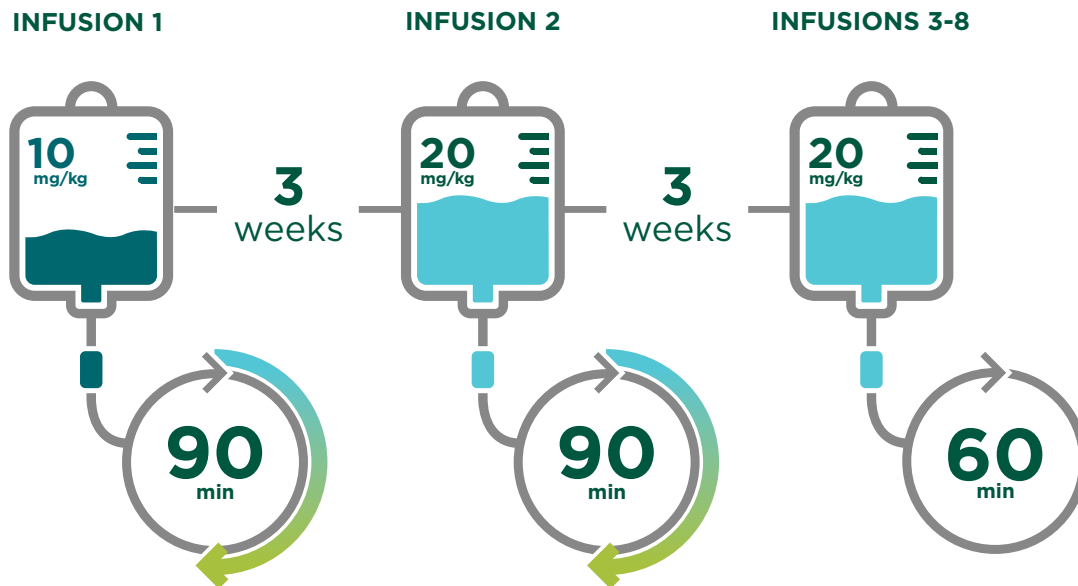
**If refrigerated,** allow the diluted solution to  
reach room temperature prior to infusion<sup>1</sup>

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# Dosing

TEPEZZA is given once every 3 weeks for a total of 8 infusions.<sup>1</sup>  
That means a full course of TEPEZZA treatment lasts about 5 months.



- TEPEZZA is dosed according to the patient's actual weight, **and there is no weight limit for TEPEZZA**<sup>1</sup>
- If not well tolerated, the minimum infusion duration should remain at 90 minutes<sup>1</sup>
- No special considerations or monitoring required for patients with mild or moderate renal impairment<sup>1</sup>



Patient weight may change throughout the infusion process. Ensure dosing is calculated based on the patient's actual weight at the time of infusion<sup>1</sup>

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# Dosing (cont'd)

## Sample dosing calculations for a 75-kg patient<sup>1</sup>

	Infusion 1 (10 mg/kg)	Infusions 2 to 8 (20 mg/kg)	Notes
<b>1. Determine patient's actual weight</b>	165 lb / 2.2 lb/kg = <b>75 kg</b>	165 lb / 2.2 lb/kg = <b>75 kg</b>	<ul style="list-style-type: none"> <li>Confirm patient weight prior to each infusion</li> </ul>
<b>2. Calculate weight-based dose</b>	75 kg x 10 mg/kg = <b>750 mg</b>	75 kg x 20 mg/kg = <b>1500 mg</b>	<ul style="list-style-type: none"> <li>Multiply the patient weight (kg) by the dosage (mg/kg)</li> </ul>
<b>3. Determine number of vials required</b>	750 mg / 500 mg = 1.5 → <b>2 vials</b>	1500 mg / 500 mg = 3 → <b>3 vials</b>	<ul style="list-style-type: none"> <li>Each vial delivers 500 mg of TEPEZZA</li> <li>Always round up when determining the number of vials</li> </ul>
<b>4. Convert dose (mg) to volume of solution to withdraw (mL)</b>	750 mg / 47.6 mg/mL = <b>15.8 mL</b>	1500 mg / 47.6 mg/mL = <b>31.5 mL</b>	<ul style="list-style-type: none"> <li>After reconstitution, each vial will contain 10.5 mL of reconstituted solution</li> <li>The final concentration is 47.6 mg/mL</li> </ul>
<b>5. Select appropriate-sized saline bag</b>	100 mL	100 mL	<ul style="list-style-type: none"> <li>If dose is &lt;1800 mg, use a 100-mL bag</li> <li>If dose is ≥1800 mg, use a 250-mL bag</li> </ul>
<b>6. Calculate wastage</b>	2 vials required x 500 mg/vial = 1000 mg - 750 mg = <b>250 mg</b>	3 vials required x 500 mg/vial = 1500 mg - 1500 mg = <b>0 mg</b>	<ul style="list-style-type: none"> <li>Multiply the number of vials required by the 500 mg of TEPEZZA per vial, then subtract the dose given*</li> </ul>

\*Reference payor guidelines for wastage documentation requirements.

For help calculating dosage, a digital  
Dosing Calculator is available on  
[TEPEZZAhcp.com](https://TEPEZZAhcp.com)










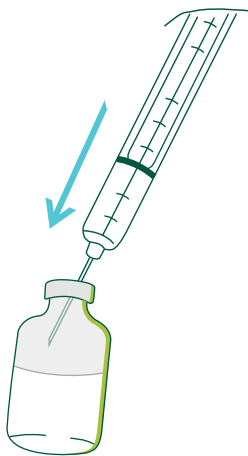
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# Preparation and Administration

## Administration Supplies

-  TEPEZZA vial(s)
-  Sterile syringe and needle
-  Sterile Water for Injection, USP
-  IV infusion bag containing 0.9% Sodium Chloride Solution, USP (100 mL or 250 mL)
-  Infusion administration set (no special tubing required)
-  Routine infusion supplies (eg, alcohol swabs, gauze pads, bandages, and biohazard containers)
-  In-line filters with a 0.2- $\mu$ m pore size (optional)



Reconstitute each vial with 10 mL of sterile water.

## Reconstitute<sup>1</sup>

- Using appropriate aseptic technique, reconstitute each TEPEZZA vial with 10 mL of Sterile Water for Injection, USP  
*Note: Reconstitution could take up to 30 minutes*
- 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



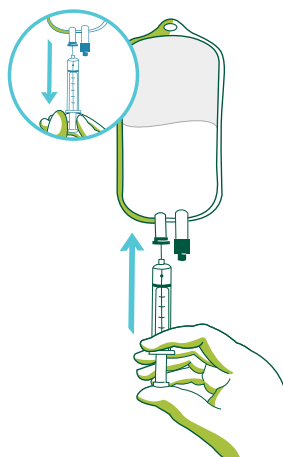
Be aware of the extra time needed for reconstitution, and communicate that with the patient in order to set expectations for the infusion process

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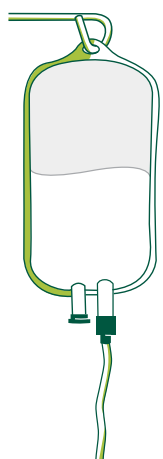
# Preparation and Administration (cont'd)



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

## Dilute<sup>1</sup>

- 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
- 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



Infuse the diluted solution for the appropriate duration.

## Infuse<sup>1</sup>

- 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

For more information regarding the administration of TEPEZZA, visit [TEPEZZAhcp.com](https://TEPEZZAhcp.com)



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# Infusion Reactions

4% rate of infusion reactions<sup>1</sup>



## What to look for<sup>1</sup>:

- Signs and symptoms of an infusion reaction include:
  - **Transient increase in blood pressure**
  - **Feeling hot**
  - **Tachycardia**
  - **Dyspnea**
  - **Headache**
  - **Muscular pain**
- Infusion reactions may occur during any of the infusions or within 1.5 hours after an infusion<sup>1</sup>
- Reported infusion reactions are usually mild or moderate in severity and can usually be successfully managed with corticosteroids and antihistamines<sup>1</sup>



## If an infusion reaction occurs<sup>1</sup>:

- 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<sup>12</sup>
- No antidrug antibodies were observed in patients treated with TEPEZZA<sup>1</sup>
- TEPEZZA may cause infusion reactions. Infusion reactions have been reported in approximately 4% of patients treated with TEPEZZA<sup>1</sup>














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# Adverse Reactions

In clinical studies, TEPEZZA was generally well tolerated.<sup>1-3</sup> Most adverse events were mild or moderate, manageable, and resolved during or after treatment.<sup>2,3</sup>

Consider discussing the adverse reactions listed below and their prevalence in clinical studies with your patients:

Adverse reaction	% of patients who experienced the adverse reactions in clinical studies	Adverse reaction	% of patients who experienced the adverse reactions in clinical studies
Muscle spasms 	<b>25%</b> of patients taking TEPEZZA	Hearing problems <sup>d</sup> 	<b>10%</b> of patients taking TEPEZZA
Nausea 	<b>17%</b> of patients taking TEPEZZA	Taste changes 	<b>8%</b> of patients taking TEPEZZA
Hair loss 	<b>13%</b> of patients taking TEPEZZA	Headache 	<b>8%</b> of patients taking TEPEZZA
Diarrhea 	<b>12%</b> of patients taking TEPEZZA	Dry skin 	<b>8%</b> of patients taking TEPEZZA
Feeling tired <sup>a</sup> 	<b>12%</b> of patients taking TEPEZZA	Menstrual disorders <sup>e</sup> 	<b>23%</b> of menstruating patients taking TEPEZZA
High blood sugar <sup>b</sup> 	<b>10%</b> of patients taking TEPEZZA	Weight decreased 	<b>6%</b> of patients taking TEPEZZA
Nail disorder <sup>c</sup> 	<b>5%</b> of patients taking TEPEZZA		

<sup>a</sup>Fatigue includes asthenia.

<sup>b</sup>Hyperglycemia includes blood glucose increase.

<sup>c</sup>Nail disorder includes nail discoloration, nail disorder and onychoclasia.

<sup>d</sup>Hearing impairment includes deafness, eustachian tube dysfunction, hyperacusis, hypoacusis and autophony.

<sup>e</sup>Menstrual disorders include amenorrhea, metrorrhagia, and dysmenorrhea.



Understanding the prevalence of each potential adverse reaction may help you anticipate patient needs during their treatment

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# Patient Support

This section provides you with information and resources to confidently support and educate your patients throughout their treatment.

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# Patient Counseling and Monitoring



## Risk during pregnancy

- 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<sup>1</sup>
- Educate and counsel these patients about the need to use effective contraception prior to initiation, during treatment, and for 6 months after the last dose<sup>1</sup>
- Consider testing for pregnancy at each visit, as appropriate



## Infusion reactions

- Advise patients that TEPEZZA may cause infusion reactions that can occur at any time<sup>1</sup>
- Instruct patients to recognize the signs and symptoms of an infusion reaction and to contact their healthcare provider immediately if they experience these signs or symptoms<sup>1</sup>
- One sign and symptom of an infusion-related reaction is transient blood pressure increases. Consider assessing patients' blood pressure before and during infusion<sup>1</sup>

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# Patient Counseling and Monitoring (cont'd)



## Worsening of IBD

- Advise patients that TEPEZZA may cause an exacerbation of preexisting inflammatory bowel disease (IBD)<sup>1</sup>
- Monitor patients with IBD for flare of disease. If IBD exacerbation is suspected, consider discontinuation of TEPEZZA.
- Instruct patients to seek medical advice immediately if they experience diarrhea (with or without blood or rectal bleeding) associated with abdominal pain or cramping/colic, urgency, tenesmus, or incontinence<sup>1</sup>



## Increased blood sugar

- 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<sup>1</sup>
- 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<sup>1</sup>



## Hearing Impairment

- Advise patient that TEPEZZA may cause severe hearing impairment including hearing loss, which in some cases may be permanent.
- Patients' hearing to be assessed before, during, and after treatment with TEPEZZA and consider the benefit-risk of treatment with patients.



## Changing weight

- Weigh patients at each infusion to ensure appropriate weight-based dosing<sup>1</sup>

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# Patient Considerations

Patients may be nervous about their treatment, especially if they are unfamiliar with the infusion process. Nurses who are involved in patient education and emotional support may be essential for alleviating patient anxiety throughout treatment.

## Help ease patient anxiety before the first infusion by setting expectations:



**TEPEZZA and the infusion process:** Prepare patients for their infusion experience by educating them about TEPEZZA and the infusion process prior to their first appointment. Encourage them to reach out with questions and direct them to [TEPEZZA.com](https://www.tepezza.com) for more information and to learn about other patients' experience with TEPEZZA.



**Time expectations:** Allow patients to schedule enough time for each of their treatments by informing them about the approximate length of each infusion, including any time needed for check-in before the infusion and observation after the infusion.



Remember to include the time needed for reconstitution (up to 30 minutes) in timing estimations, and be sure to inform patients that the first 2 infusions of TEPEZZA are administered over a longer period of time so that they can adequately prepare<sup>1</sup>

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## Patient Considerations (cont'd)



Help patients have a positive infusion experience by reminding them to eat a nutritious meal, stay hydrated, and wear comfortable clothing

### Help patients with TED feel more comfortable during their infusions:



**Dim the lights:** Painful light sensitivity is a common symptom of TED. When possible, dim the overhead lights or utilize window coverings. Patients may wear sunglasses or a hat during treatment.<sup>13,14</sup>



**Reduce air drafts:** Patients with TED often suffer from severely dry eyes. If possible, seat patients away from any air drafts created by fans, air conditioners, or blowing vents.<sup>13,15</sup>



**Provide assistance for vision impairment:** Patients with TED may have blurry vision, or difficulty seeing small type or driving at night. They may need assistance with reading and traveling to the infusion center.<sup>13,16,17</sup>



**Empathize with psychological and emotional challenges:** Patients with TED may struggle with the physical disfigurement associated with the disease. Help them feel welcome during their time at the infusion center.<sup>16</sup>



TED is commonly associated with a separate condition called Graves' disease, which causes an overproduction of thyroid hormones (hyperthyroidism)<sup>13,18</sup>

### Help accommodate TED patients with Graves' disease:



**Keep the temperature comfortable:** Patients with fluctuating thyroid levels can struggle with moderating body temperature. Have blankets and cold packs available to help patients stay warm or cool down during their infusion.<sup>19</sup>



**Allow for time to settle in:** Hyperthyroidism can cause high blood pressure, irregular heartbeat, hand tremors, anxiety, and irritability. With this in mind, give patients time to settle in and relax before their infusion.<sup>20-22</sup>

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# Patient Considerations (cont'd)

Continue supporting patients after each infusion by encouraging them to:



**Take pictures:** Patients may be able to see their TED symptoms improve throughout the infusion process. Help patients take photos of their eyes so they can track their progress. These photos may also be helpful for patients to send to and/or discuss with their healthcare providers.



**Record symptoms and adverse reactions:** Patients may experience adverse reactions during or after their infusions. Consider providing resources to the patient during each infusion to record any adverse reactions that they have been experiencing, so they can follow up with their healthcare providers for management. If you learn of a patient experiencing an adverse reaction, ensure you satisfy your adverse event reporting requirements.



As you encourage your patient to communicate with their healthcare providers, you should also assess and send pertinent information (ie, adverse reactions the patient is experiencing, if an infusion reaction occurred, updated labs, etc) to the physicians managing their care



When you sit with the patient at the beginning, it preps them for the treatment and helps them feel comfortable.

I like to give them a balanced and realistic outlook. Patients have different degrees of [results], but I haven't had any patient who didn't have some amount of improvement.

We schedule the patients' next appointment before they leave the infusion.

— Infusion center staff



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# Patient FAQs

Helpful answers to commonly asked questions from patients:

- 1 What are 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 problems, taste changes, headache, dry skin, weight decreased, nail disorders, and menstrual disorders.<sup>1</sup>
- 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.<sup>1</sup>
- 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 a lot like a recliner. There may be a TV to help you pass the time, or you can enjoy your own books, magazines, or your 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.<sup>1</sup>
- 5 Do I have to complete all 8 treatments?**

Yes, people in clinical studies were given TEPEZZA 1 time 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.<sup>1</sup>
- 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.<sup>1</sup>
- 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.

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# Horizon By Your Side, a Patient Support Program

Managing Thyroid Eye Disease (TED) can involve a lot of moving parts. Horizon By Your Side is a patient support program with dedicated team members who take a personalized approach to meeting your patient's unique treatment needs.



As treatment with TEPEZZA® (teprotumumab-trbw) begins, our Horizon By Your Side team is ready to support your patient and their caregivers. Once your patient is enrolled in the program, we'll partner with them to discuss support options and next steps. Our dedicated team provides ongoing non-medical, logistical assistance so there's support throughout your patient's treatment journey.

The Horizon By Your Side team is here to help, so your patient can focus on moving toward the future they deserve.

Together, we will:



## CONNECT

Your patient will be paired with a personal Patient Access Liaison who will support your patient throughout their treatment when they need it.



## COORDINATE

The Horizon By Your Side team will work with your patient and healthcare team to make sure non-medical, logistical efforts are coordinated properly.



## CHAMPION

The Patient Access Liaison will be the point of contact to work with your patient's unique needs and help them build confidence throughout their treatment.

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# Horizon By Your Side, a Patient Support Program (cont'd)

The Horizon By Your Side team provides support your patient can count on.



## 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, payor policies, and coding and claim submissions.



I've never had a relationship that is so well oiled and working for the benefit of the patient.

— Infusion center staff, on collaborating with PALs



## Specialty Account Manager (SAM)

The SAM is the primary Horizon contact for referring TEPEZZA prescribers. They provide clinical education and resources and introduce the full suite of Horizon team members to the prescriber, as appropriate.



## Associate/National Director, Site of Care Team (ADSOC/NDSOC)

The ADSOC/NDSOC establishes business-to-business relationships with sites of care and expands the network of infusion center options. The team educates on coding, billing, and payor access, and provides product in-servicing.

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# 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.

**Clinical Activity Score (CAS):** one of several assessment scales designed to evaluate the signs and symptoms characteristic of TED. 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 payors.

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

**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 payors 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.

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



Becoming familiar with the terms listed here may help providers as they support patients navigating their TED diagnosis and treatment journey

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# TED Glossary (cont'd)

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

**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.

**Sclera:** white part of the eye.

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

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

**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.

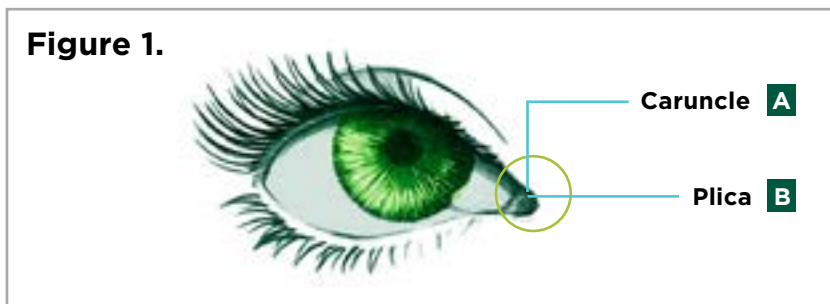
**Thyroid stimulating hormone (TSH):** a hormone released by the pituitary gland that stimulates the thyroid to release thyroid hormones.

**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.

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

**Xerosis:** dry skin or membranes.



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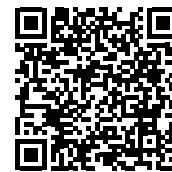
# Horizon Resources

Visit [TEPEZZAhcp.com](http://TEPEZZAhcp.com) or scan any of the QR codes below to find multiple tools to aid the infusion process.

## Provider resources:



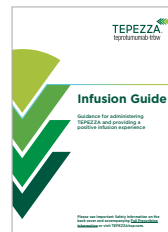
TEPEZZA product fact sheet



Dosing calculations flashcard



Infusion administration video flashcard



Infusion guide



Infusion checklist



Home infusion FAQs

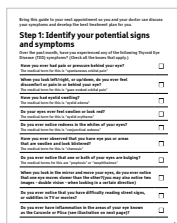
Please see **Important Safety Information** on page 30 and **Full Prescribing Information** at [TEPEZZAhcp.com](http://TEPEZZAhcp.com).

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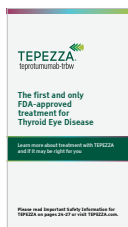
# Horizon Resources (cont'd)

A variety of patient-focused resources can be found at TEPEZZA.com or by scanning any of the QR codes list below.

## Patient resources:



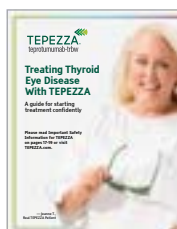
Doctor discussion guide



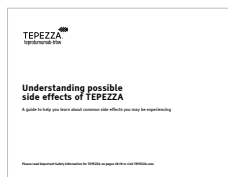
TEPEZZA education



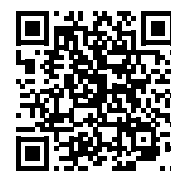
TEPEZZA insurance approval process guide



Getting started on TEPEZZA



Understanding possible side effects of TEPEZZA



Pre-infusion reminder list



Post-infusion reminder list



Treatment progress tracker



TEPEZZA home infusion guide



Home storage instructions



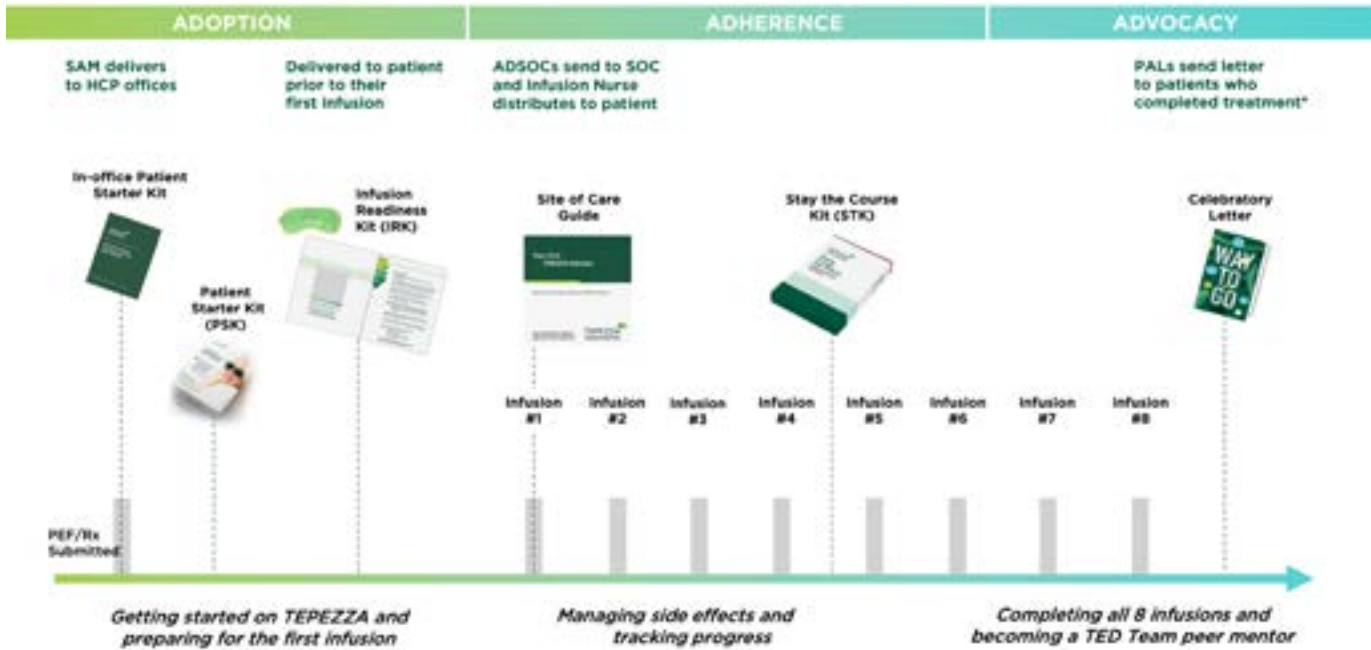
Many patient resources are also available in other languages and can be provided by a Horizon representative

Please see Important Safety Information on page 30 and Full Prescribing Information at [TEPEZZAhcp.com](http://TEPEZZAhcp.com).



# Printed Patient Resources

Patients may receive other printed educational materials from prescribers, through the mail, or from their PALs throughout their treatment. Below is a timeline outlining when patients may receive those resources, when appropriate.



\*If PALs feel that the patient had a suboptimal experience, this piece will not be sent.

Please see Important Safety Information on page 30 and Full Prescribing Information at [TEPEZZAhcp.com](http://TEPEZZAhcp.com).



# Horizon Co-Pay Program



## Your patients may be eligible for the Horizon Commercial Co-Pay Program\*

Savings may be available for your patients:

- Patients with commercial insurance may be eligible for a \$0 co-pay for both the cost of the medication and the infusion administration through our co-pay assistance program
- Travel reimbursement assistance may be available through independent foundation support<sup>†</sup>
- 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
- For uninsured patients, the patient assistance program may provide support for eligible patients



**PALs** can speak with patients prescribed TEPEZZA about the insurance approval process and help them understand coverage options.

\*The Horizon 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 Horizon 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. Horizon 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, 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, payor, 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, TRICARE). You may not seek any claims to government payors or other payors 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, payor, or applicable law or regulation.

<sup>†</sup>Please note that independent foundations establish, administer, and implement the funds, which are separate and apart from Horizon. 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.

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# TED Team Peer-to-Peer Program

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



If your patient has questions about what TEPEZZA treatment is like, then the TED Team Peer-to-Peer program is for them. This program allows them to connect via phone with patients or caregivers, also called “Teammates,” who have experience with TEPEZZA.

## 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
- Our 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 one call or multiple—whatever works best for them. After their call, if they want to schedule another, they just let the program staff know

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## INDICATION

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

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

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

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

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

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

### ADVERSE REACTIONS

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

Please see [Full Prescribing Information](#) or visit [TEPEZZAhcp.com](https://TEPEZZAhcp.com) for more information.



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