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Addressing Thyroid Eye Disease Burden: Early Diagnosis and Treatment With TEPEZZA® (teprotumumab-trbw)

INDICATION

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

Please see Important Safety Information throughout the presentation and on slides 23-24 and Full Prescribing Information at TEPEZZAhcp.com.

AMGEN Rare Disease

Disclaimer Information

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- This program is sponsored by Amgen
- I am presenting on behalf of Amgen and I am being compensated by them for my services

Key Highlights

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1. TED Overview and Disease Burden
2. Clinical Studies of TEPEZZA
3. Real-world Patient Case

TED, Thyroid Eye Disease.

Please see Important Safety Information throughout the presentation and on slides 23-24 and Full Prescribing Information at TEPEZZAhcp.com.

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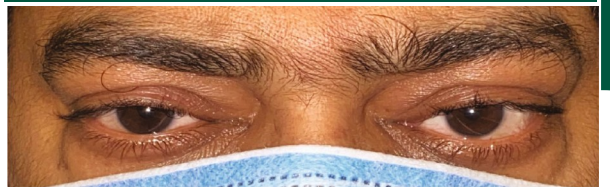
TED Overview and Disease Burden

TED Is a Serious, Progressive Autoimmune Disease that Can Lead to Long-term Repercussions[1,2]

Heterogeneity of TED



From Otero-Marquez O, et al. *Case Rep Ophthalmol Med.* 2022;2022:5275309.[12]

Image used with patient permission.

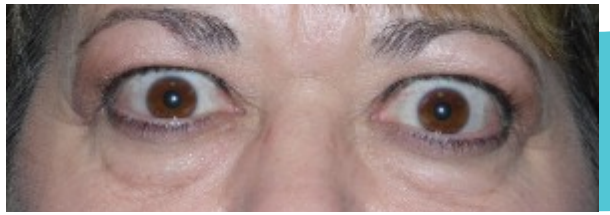


Image used with patient permission.

- TED is a lifelong and progressive autoimmune disorder that can potentially threaten vision and reactivate or flare over time[1-4]
- TED presents with highly variable signs and symptoms that differ from patient to patient[2,5,6]
- Risk factors for TED include smoking, radioactive iodine treatment, female sex, and increasing age[7-10]
- Disfigurement and vision-threatening complications of TED may lead to psychosocial and functional burdens for patients[11]

1. Bahn RS. *N Engl J Med*. 2010;362(8);726-738. 2. Patel A, et al. *Am J Ophthalmol*. 2019;208:281-288. 3. Douglas RS, et al. *Ophthalmology*. 2022;129(4):438-449. 4. Patel P, et al. *Ophthal Plast Reconstr Surg.* 2015;31:445-448. 5. Bothun ED, et al. *Clin Ophthalmol*. 2009;3:543-551. 6. Ponto KA, et al. *J Clin Endocrinol Metab.* 2013;98(1):145-152. 7. Prummel MF, et al. *JAMA.* 1993;269(4):479-482. 8. Perros P, et al. *Clin Endocrinol (Oxf).* 1993;38(4):367-372. 9. Bartley GB. *Trans Am Ophthalmol Soc.* 1994;92:477-588. 10. Khong JJ, et al. *J Clin Endocrinol Metab.* 2016;101(7):2711-2720. 11. Estcourt S, et al. *Clin Endocrinol (Oxf).* 2008;68(4):635-639. 12. Otero-Marquez O, et al. *Case Rep Ophthalmol Med*. 2022;2022:5275309.

Thyroid Eye Disease Is Distinct from Graves' Disease and Patients Often Present With Dry Eye Disease[1,2]

Graves' Disease

- Most common cause of hyperthyroidism[3]
- Systemic symptoms (eg, weight loss, fatigue, heat intolerance, tremors, and palpitations) due to hyperthyroidism[3]
- The ATA/ETA recommends screening all patients with Graves' disease for TED[4]

Thyroid Eye Disease

- **Often associated with hyperthyroidism but is separate and distinct from Graves' disease[1]**
- Ocular signs and symptoms (eg, proptosis, diplopia) due to inflammation/tissue enlargement of the orbit[5]

As an endocrinologist, screen your patients with Graves' disease for possible TED

Dry Eye Disease

- Commonly occurring heterogeneous disease due to abnormalities of the eyelid or ocular surface[2]
- **Present in 65.2% (30/46) of patients with TED in a study[2]**

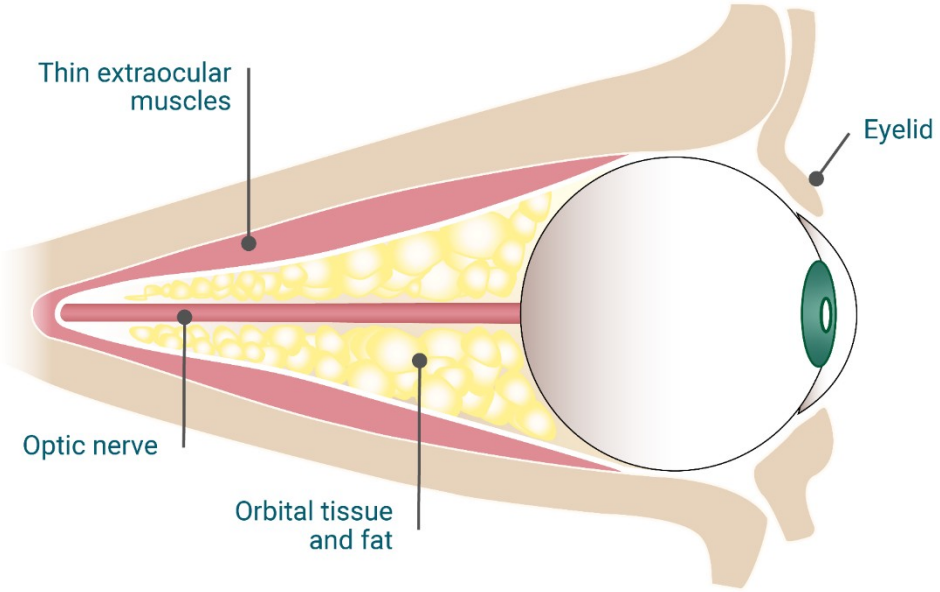
As an eye care specialist, consider the possibility of TED in patients with thyroid conditions and symptoms of dry eye disease

ATA, American Thyroid Association; ETA, European Thyroid Association.

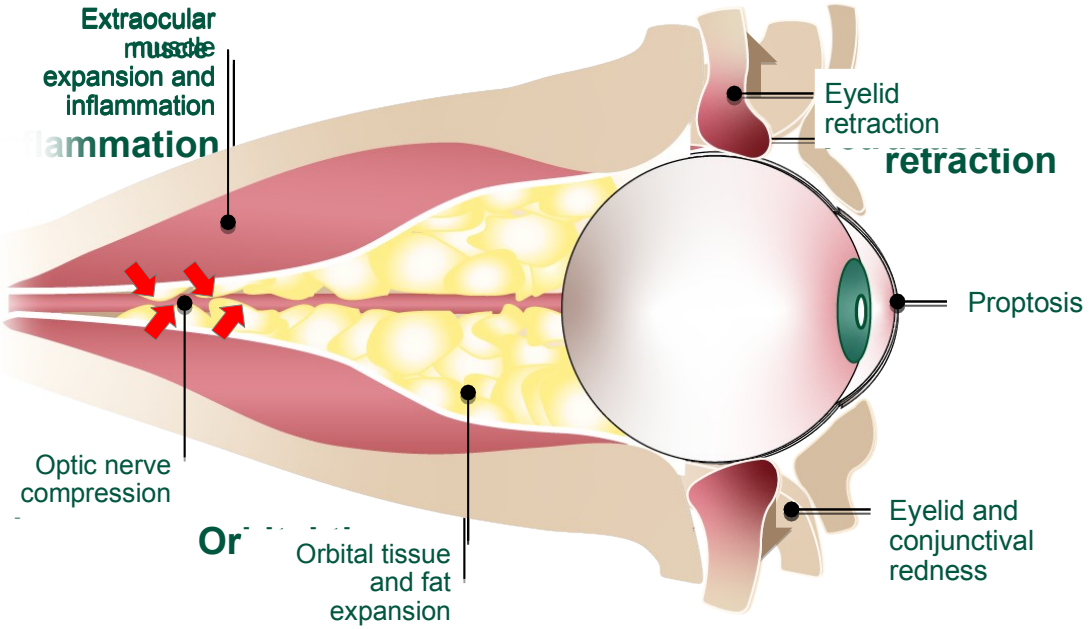
1. Lazarus JH. *Best Pract Res Clin Endocrinol Metab.* 2012;26(3):273-279. 2. Ismailova DS, et al. *Orbit*. 2013;32(2):87-90. 3. Smith TJ, et al. *N Engl J Med*. 2016;375(16):1552-1565. 4. Burch HB, et al. *Thyroid*. 2022;32(12):1439-1470. 5. Barrio-Barrio J, et al. *J Ophthalmol*. 2015;2015:249125.

TED Is Identified by Ongoing Inflammation, Tissue Expansion, and Remodeling Around the Eye[1,2]

Healthy Eye and Orbital Tissue



TED



Images are not exact representations of eye structures and are for illustration purposes only.

Targeting IGF-1R may help reduce inflammation and prevent muscle and fat tissue remodeling and expansion behind the eye[3]

1. Patel A, et al. *Am J Ophthalmol*. 2019;208:281-288. 2. Perros P, Krassas GE. *Nat Rev Endocrinol*. 2009;5(6):312-318. 3. Douglas RS, et al. *N Engl J Med*. 2020;382(4):341-352.

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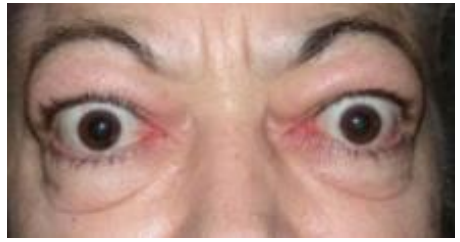
Know the Heterogeneous Presentation of TED So You Can Identify Early and Treat Proactively

Early intervention can help improve long-term outcomes and avoid potentially permanent damage[1,2]

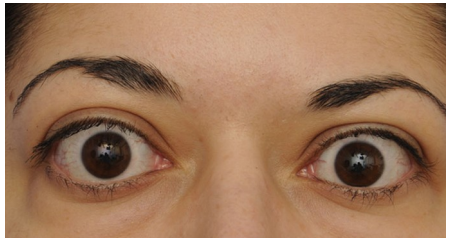
Eyelid[1,3,4]



From Chapter 18 of the Thyroid section of Endotext, a free online endocrine textbook (Endotext.org). Reprinted with permission.[7]

- Eyelid retraction **(91% affected)**
- Eyelid edema
- Lagophthalmos
- Redness and swelling

Proptosis[1,3-5]



From Novaes P, et al. *Clin Diabetes Endocrinol.* 2016;2:19. Reprinted with permission.[8]

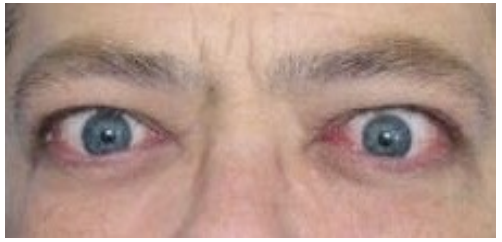
- Proptosis **(62% affected)**
- Disfigurement
- Pressure and/or pain behind eyes

Extraocular Muscle[1,3,5,6]

Stock image used with permission.

- Diplopia **(51% affected)**
- Strabismus with double vision
- Pressure and/or pain behind eyes
- Optic neuropathy

Conjunctiva and Cornea[1,3,5]



From Novaes P, et al. *Clin Diabetes Endocrinol.* 2016;2:19. Reprinted with permission.[8]

- Conjunctival chemosis
- Conjunctival injection/redness
- Exposure keratopathy
- Dry eye and grittiness
- Excessive tearing
- Photophobia
- Blurry vision

1. Wang Y, et al. *Ther Clin Risk Manag*. 2019;15:1305-1318. 2. Barrio-Barrio J, et al. *J Ophthalmol*. 2015;2015:2491253. 3. Bahn RS. *N Engl J Med.* 2010;362(8):726-738. 4. Bartley GB, et al. *Am J Ophthalmol.* 1996;121(3):284-290. 5. Patel A, et al. *Am J Ophthalmol*. 2019;208:281-288. 6. Terwee C, et al. *Eur J Endocrinol.* 2002;146(6):751-757. 7. Bartalena L. Graves' Disease: Complications. https://www.ncbi.nlm.nih.gov/books/NBK285551/?report=classic. Accessed June 26, 2023. 8. Novaes P, et al. *Clin Diabetes Endocrinol.* 2016;2:19.

Patients With TED Reported an Impact on Psychosocial Health and Decline in Well-being

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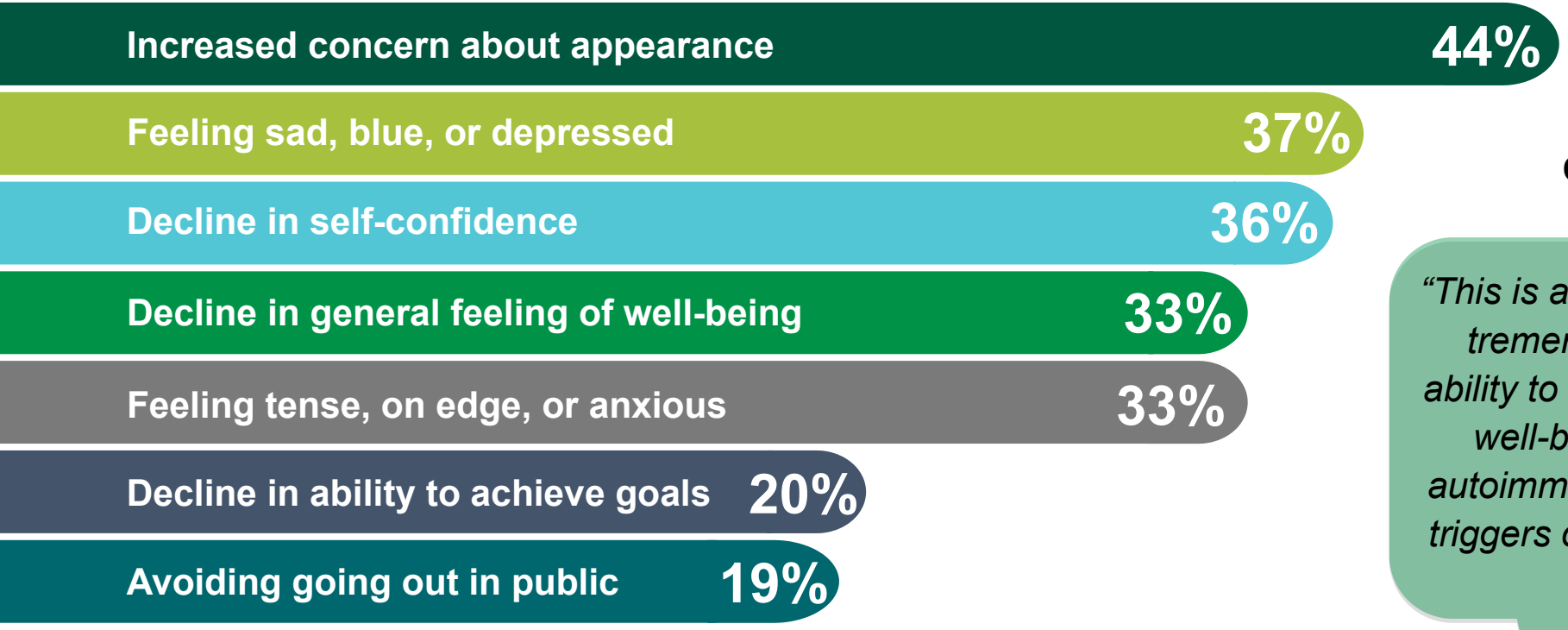
In a survey of patients with duration of TED <1 to >10 years (N=394),* respondents answered:

Which of the following have you experienced because of TED in the past 2 months?



Quote from a real patient with TED (from survey)

"This is a very difficult disease that causes tremendous damage to one's health, ability to be independent, and psychologic well-being. As is the case with other autoimmune diseases, it is unpredictable, triggers other significant health problems, and is always with you."

*In the full survey, 443 respondents were aged 18 to >80 years old, >90% female, and >80% from the United States. 41% had been diagnosed within <5 years, and 24% reported their disease was in the active phase, 51% in the inactive phase, and 25% unsure. 394 respondents completed the 3 quality of life (QOL) survey questions.

Smith TJ, et al. *Front Endocrinol.* 2023;14:1283374.

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Clinical Studies of TEPEZZA® (teprotumumab-trbw), the First and Only FDA-approved Treatment for TED Regardless of Disease Activity or Duration

TEPEZZA Was First Evaluated in Randomized, Double-masked, Placebo-controlled Phase 2 and Phase 3 Studies in Patients With High Disease Activity and Short Duration[1-3]

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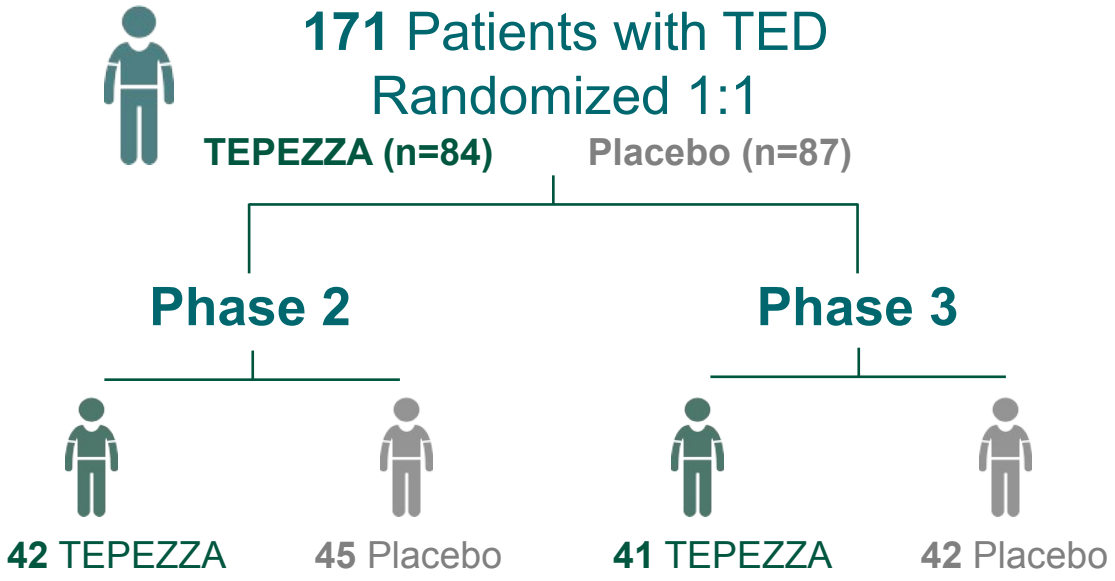

Received 8 infusions of TEPEZZA (10 mg/kg for initial dose followed by 20 mg/kg Q3W for 7 additional infusions) or placebo

Primary efficacy endpoint

- Proptosis responder rate at Week 24 (≥2-mm reduction, considered clinically meaningful)[1,4,*]

Other key efficacy endpoints

- Diplopia responder[†] rate[‡] at Week 24[1]
- Inflammatory signs/symptoms responder rate at Week 24 (CAS of 1 or 0)[2]

Key inclusion criteria[1-3]

- ≥18 to 80 years of age
- Inflammatory signs and symptoms of TED (CAS ≥4), including pain, redness, swelling, and/or diplopia, and/or proptosis
- Moderate-to-severe TED associated with lid retraction ≥2 mm, proptosis ≥3 mm above normal, moderate or severe soft- tissue involvement, and/or periodic or constant diplopia
- Euthyroid or had FT3 and FT4 <50% above or below normal limits

Efficacy analyses were performed in the intention-to-treat population. *Proptosis responder rate defined as the percentage of patients with ≥2-mm reduction in proptosis from baseline at Week 24 with no corresponding deterioration in the fellow (less severely impacted) eye. [†]Combined across Phase 2 and Phase 3. [‡]Diplopia responder defined as patient with baseline diplopia >0 and diplopia =0 at Week 24. FT3, free triiodothyronine; FT4, free thyroxine; Q3W, every 3 weeks.

1. TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon. 2. Douglas RS, et al. *N Engl J Med*. 2020;382(4):341-352. 3. Smith TJ, et al. *N Engl J Med*. 2017;376(18):1748-1761.
4. European Group on Graves' Orbitopathy (EUGOGO, et al. *Eur J Endocrinol*. 2006;155(3):387-389.

Phase 3: TEPEZZA Significantly Decreased Proptosis in Patients with High Disease Activity and Short Duration TED

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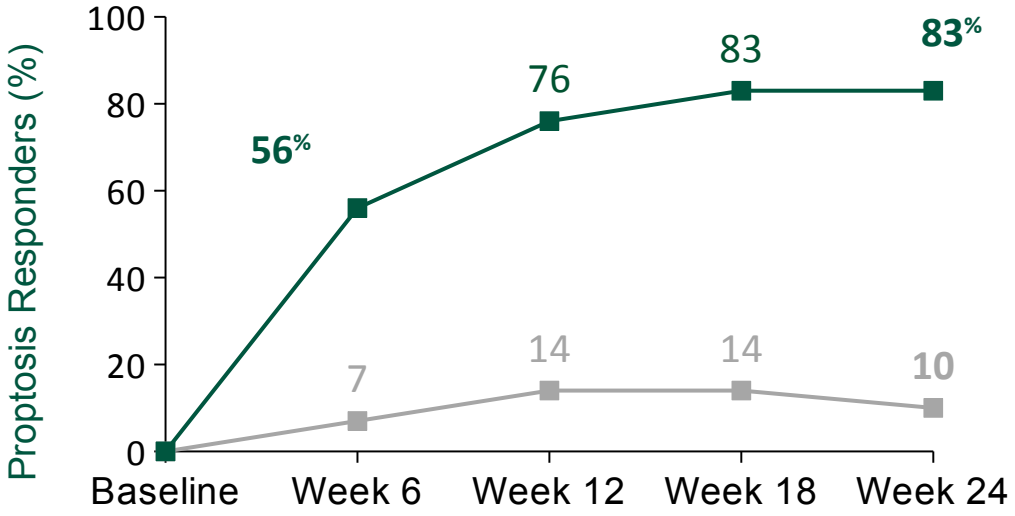
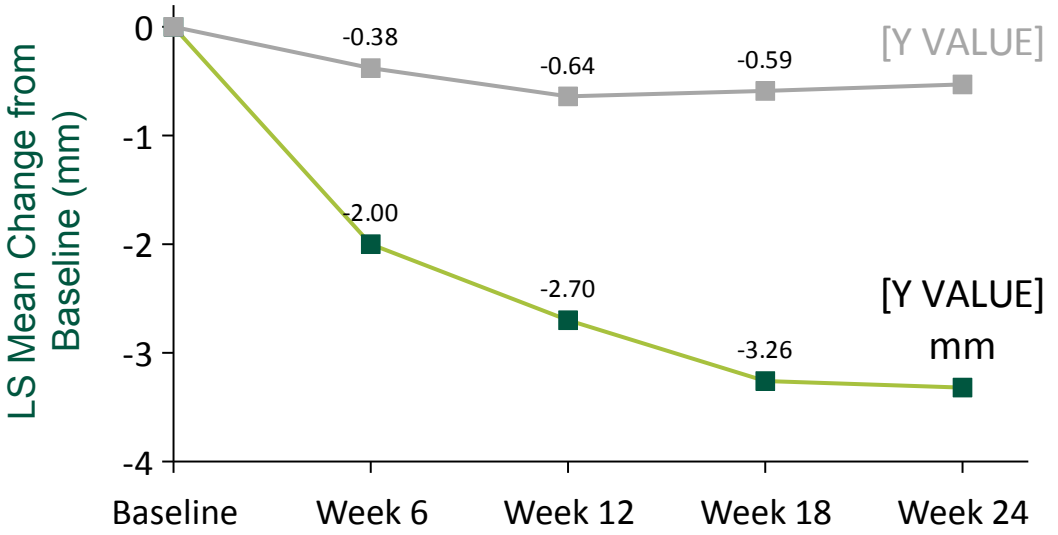
Primary Endpoint: Proptosis Responder Rate*† (Reduction of ≥2 mm)[1,2]



Change from Baseline in Proptosis to Week 24‡[1]



TEPEZZA (n=41)
Placebo (n=42)

†*P*<0.001 at all time points measured

‡*P*<0.01 at all time points measured

SELECT IMPORTANT SAFETY INFORMATION

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.

*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. LS, least-squares.

1. TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon. 2. Douglas RS, et al. *N Engl J Med*. 2020;382(4):341-352. 3. Data on File. Horizon, December 2019.

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TEPEZZA Was Evaluated in a Randomized, Double-masked, Placebo-controlled Phase 4 Study in Patients With Low Disease Activity and Long Duration TED

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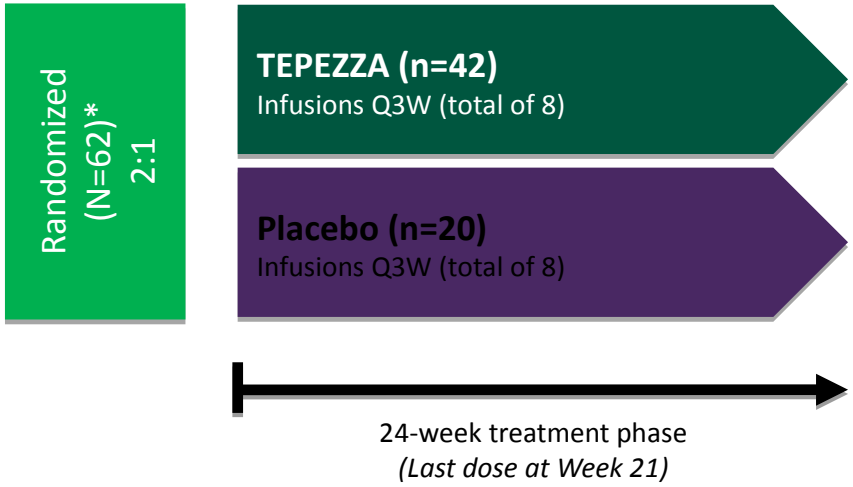

Primary efficacy outcome

- Change from baseline in proptosis (mm) at Week 24

Secondary efficacy outcome (Week 24)

- Proptosis responder rate

Key enrollment criteria

- ≥18 years old
- Initial diagnosis of TED ≥2 and <10 years prior to screening
- Participants could not have had prior orbital irradiation, orbital decompression surgery, or strabismus surgery
- CAS ≤1 in both eyes for at least 1 year prior to screening OR no progression in proptosis or diplopia and no new inflammatory TED symptoms for at least 1 year prior to screening
- Proptosis increase ≥3 mm from patient baseline before TED diagnosis and/or above normal for race and gender

*Intent-to-treat (ITT) analysis included all patients as originally allocated after randomization, even those who discontinued treatment early, were lost to follow-up, received the wrong study treatment, or received no treatment at all.

Douglas RS, et al. Efficacy and Safety of Teprotumumab in Thyroid Eye Disease Patients with Long Duration and Low Disease Activity. *J Clin Endocrinol Metab*. Published online October 31, 2023. doi:10.1210/clinem/dgad637.

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Significant and Continuous Reductions in Proptosis

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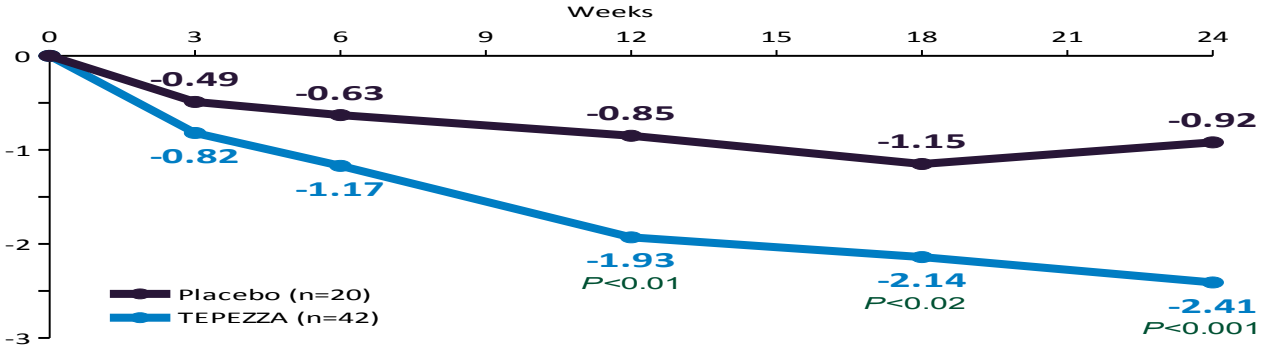
Phase 4 primary endpoint: Mean change from baseline in proptosis over 24 weeks

ITT analysis*



62% of patients (n=42) achieved ≥2-mm reduction in proptosis at Week 24 (secondary endpoint)† with TEPEZZA, vs

25% with placebo (n=20) (*P*<0.02)

SELECT IMPORTANT SAFETY INFORMATION

Infusion Reactions: 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.

*ITT analysis included all patients as originally allocated after randomization, even those who discontinued treatment early, were lost to follow-up, received the wrong study treatment, or received no treatment at all. †A proptosis responder was defined as having a ≥2-mm reduction in proptosis from baseline in the study eye without deterioration (≥2-mm increase in proptosis) in the nonstudy eye.

Douglas RS, et al. Efficacy and Safety of Teprotumumab in Thyroid Eye Disease Patients with Long Duration and Low Disease Activity. *J Clin Endocrinol Metab*. Published online October 31, 2023. doi:10.1210/clinem/dgad637.

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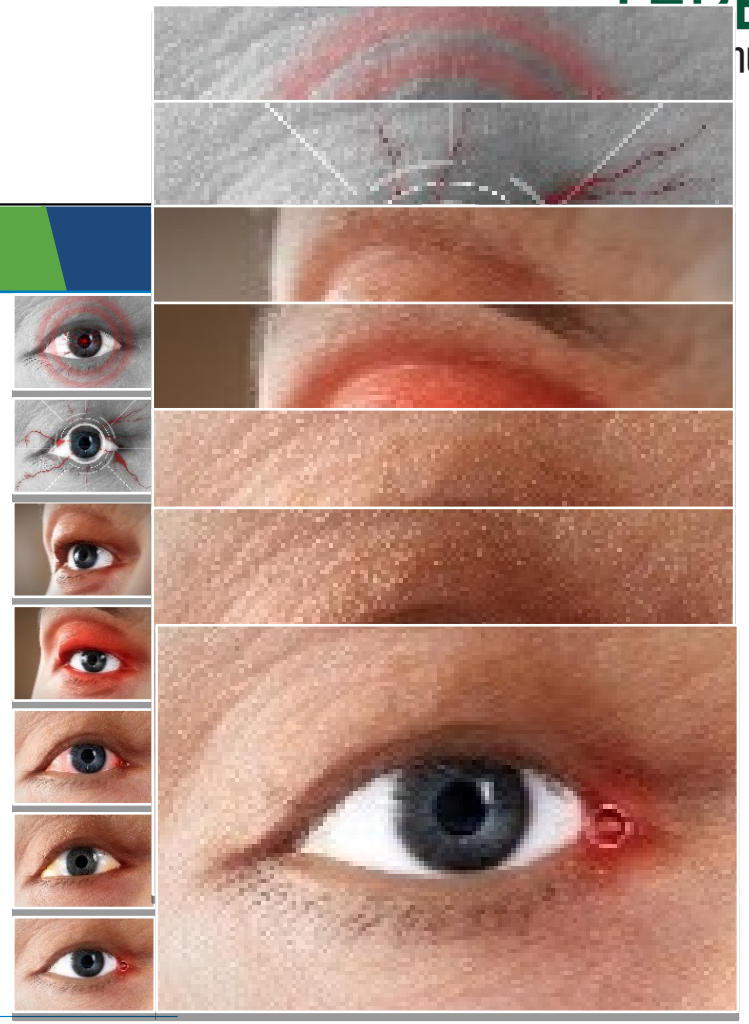
Assessment of Disease Activity Through Clinical Activity Score (CAS)

- The TEPEZZA clinical trial inclusion criteria were based on the initial CAS out of 7 points

1	Spontaneous orbital pain
2	Gaze-evoked orbital pain
3	Eyelid swelling that is considered to be due to active TED
4	Eyelid erythema (redness)
5	Conjunctival redness considered to be due to active TED
6	Chemosis (swelling of the conjunctiva)
7	Inflammation of caruncle OR plica



The CAS is a composite score with equal weighting of a number of factors (spontaneous orbital pain, gaze-evoked orbital pain, eyelid swelling that is considered to be due to active TED, eyelid erythema, conjunctival redness considered to be due to active TED, chemosis, and inflammation of caruncle or plica). However, the factors may not be of equal clinical weight either to the patients or to physicians treating the patients.

Barrio-Barrio J, et al. *J Ophthalmol*. 2015;2015:249125.

Clinical Trial (Phase 2): Before and After Pictures

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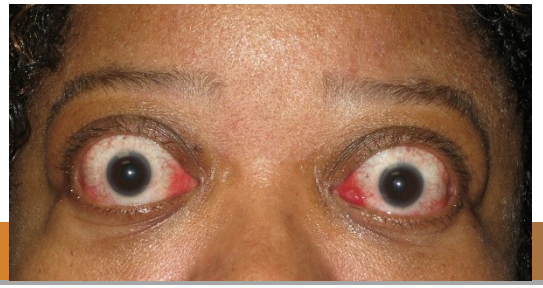
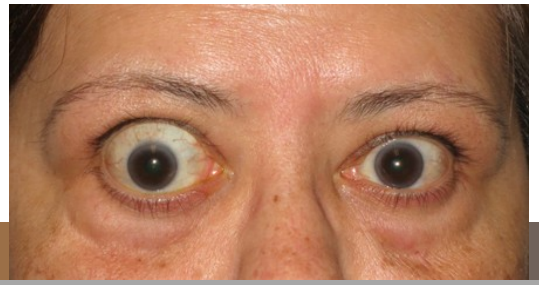
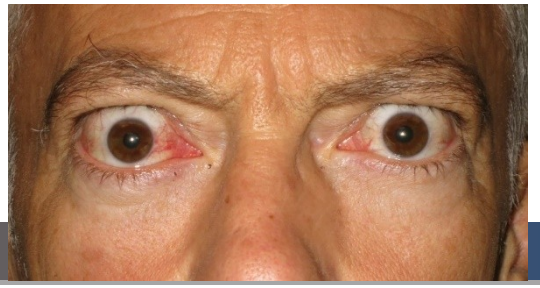
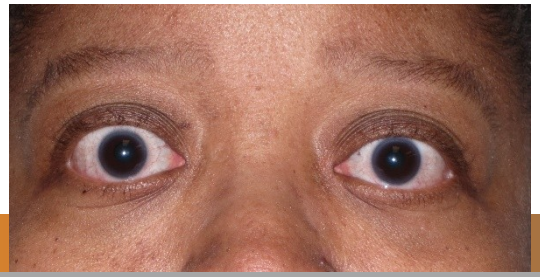
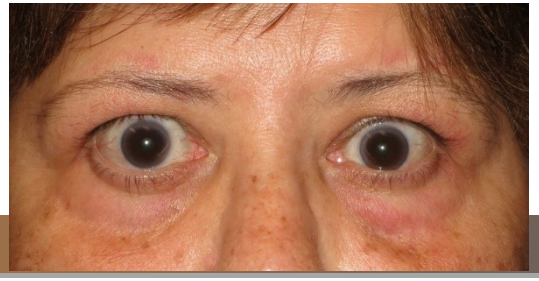
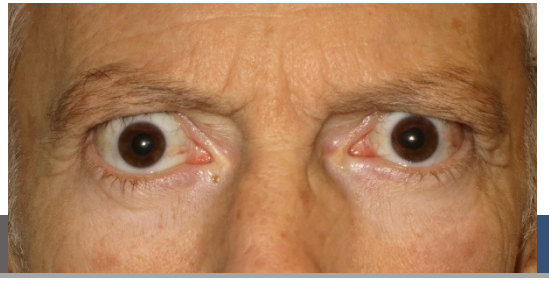
	Patient 1*	Patient 2	Patient 3
Baseline			
After 8 Infusions† (Week 24)			

Individual results may vary.

SELECT IMPORTANT SAFETY INFORMATION

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.

Actual patients from study. *Patient 1 provided consent to show images only. No data available. † In Phase 2 and Phase 3, 8 infusions was considered a full course of treatment.
Data on File. Horizon, January 2020.

Please see additional Important Safety Information throughout the presentation and on slides 23-24 and Full Prescribing Information at TEPEZZAhcp.com.

TEPEZZA Integrated Safety Overview

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Integrated Safety from Phase 2 and Phase 3: Adverse Reactions Occurring in ≥5% of Patients Treated with TEPEZZA and 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†	10 (12%)	6 (7%)
Hyperglycemia‡	8 (10%)	1 (1%)
Hearing impairment§	8 (10%)	0
Dysgeusia	7 (8%)	0
Headache	7 (8%)	6 (7%)
Dry skin	7 (8%)	0
Weight decreased	5 (6%)	0
Nail disorder‖	4 (5%)	0
Menstrual disorders (n=22 and n=25, respectively)**	5 (23%)	1 (4%)

Integrated Safety from Phase 2 and Phase 3:
Low discontinuation rate[1]

89% of patients completed full treatment course of TEPEZZA

vs

93% of patients completed full treatment course of placebo

- Most adverse events were mild or moderate, manageable, and resolved during or after treatment[2,3]
- No new safety signals were observed in patients with low disease activity and long duration TED in the Phase 4 Study[1,4]

*Patients received 10 mg/kg for the first infusion followed by 20 mg/kg every 3 weeks for 7 additional infusions. †Fatigue includes asthenia. ‡Hyperglycemia includes blood glucose increase. §Hearing impairment includes deafness, eustachian tube dysfunction, hyperacusis, hypoacusis, and autophony. ‖Nail disorder includes nail discoloration, nail disorder, and onychoclasis. **Menstrual disorders include amenorrhea, metrorrhagia, and dysmenorrhea.

1. TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon. 2. Douglas RS, et al. *N Engl J Med*. 2020;382(4):341-352. 3. Smith TJ, et al. *N Engl J Med*. 2017;376(18):1748-1761.
4. Douglas RS, Couch S, Wester ST, et al. Efficacy and Safety of Teprotumumab in Thyroid Eye Disease Patients with Long Duration and Low Disease Activity [published online ahead of print, 2023 Oct 31]. *J Clin Endocrinol Metab*. 2023;dgad637. doi:10.1210/clinem/dgad637

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Real-world Patient Case

The following case report is being provided by Amgen for your information. Items to note include:

- This is a case report of a patient with TED and individual experiences with TEPEZZA. Individual results may vary
- The patient's clinical presentation represents a range of patients with TED. Patients with prior surgery or orbital radiation treatment for TED, history of compressive optic neuropathy, and concomitant steroid use were excluded from the clinical trials for TEPEZZA
- *Use your clinical judgment to evaluate the data and relevancy to your clinical practice*

SELECT 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.

Real-world Case Report: TED with Proptosis, Inflammation, and Diplopia

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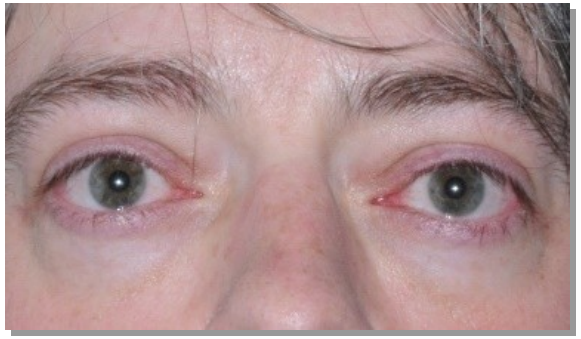
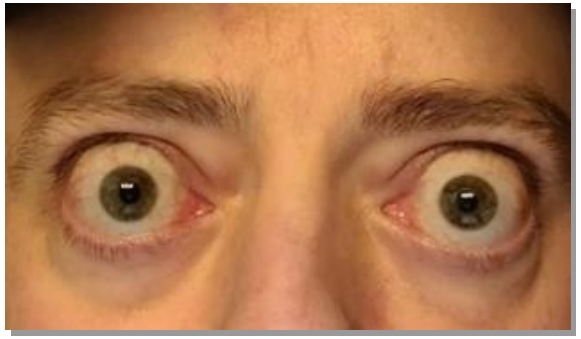
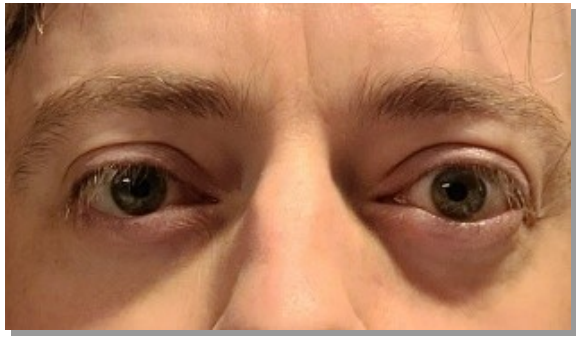
Initial Visit	After Steroids, Before TEPEZZA*	After 3 TEPEZZA Infusions	After 8 TEPEZZA Infusions
• VA: 20/20 OU with PERRLA • Intermittent diplopia mainly in the morning • Proptosis: 24 mm OD, 23 mm OS (mild resistance to retropulsion) • Inflammatory score: 2/7 OD, 3/7 OS	• VA: 20/20 OD, 20/25 OS • Proptosis: 26 mm OD, 26 mm OS **(increases of 2 mm OD and 3 mm OS since last exam)** • Inflammatory score: 3/7 OU • 2-mm lagophthalmos OU	• VA improvement to 20/20 OU • Proptosis: 21.5 mm OD, 21 mm OS **(reductions of 4.5-mm OD and 5-mm OS)** • Diplopia also significantly better (occasionally in the AM) • Inflammatory score: 2/7 OU • Trace lagophthalmos OU	• VA: 20/20 OU • Improved diplopia (rare) • Proptosis: 20.5 mm OD, 19.5 mm OS **(reductions of 5.5 mm OD and 6.5 mm OS)** • Inflammatory signs/symptoms resolved
			

Actual patient treated with TEPEZZA. Results may vary.

Photos provided with permission from Roger A. Dailey, MD, FACS.
*TEPEZZA treatment was initiated 10 months after treatment with steroids and 4 months after patient's TED examination, owing to insurance-related delays.
AM, morning.

Please see Important Safety Information throughout the presentation and on slides 23-24 and Full Prescribing Information at TEPEZZAhcp.com.

Important Patient Counseling Information

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Infusion 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. 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

Exacerbation of preexisting IBD

- Monitor patients for disease flare; if exacerbation is suspected, consider discontinuing TEPEZZA
- Advise patients on the risk of IBD and 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

Hyperglycemia

- 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
- In the Phase 2 and Phase 3 clinical trials, 10% of patients experienced hearing impairment including hearing loss
- Assess patients' hearing before, during, and after treatment with TEPEZZA and consider the benefit-risk of treatment with patients
- Instruct patients to contact their healthcare provider if they experience any signs or symptoms of hearing impairment or any changes in hearing

Pregnancy

- Advise women of childbearing potential that TEPEZZA can cause harm to a fetus and to inform their healthcare provider of a known or suspected pregnancy
- Women of childbearing potential need to use effective contraception before, during, and for 6 months after last dose

Most common adverse reactions

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

Coordinate with the co-management team and sites of care to ensure appropriate monitoring

TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon.

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TEPEZZA is a Specialty Infused Medicine* and Resources are Available to Support You and Your Patients

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The Horizon By Your Side team will provide information about patient support, logistical assistance, insurance benefits investigation, and financial assistance

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

COORDINATE
The Horizon By Your Side team will work with your patient and healthcare team to assist in coordination of non-medical and logistical aspects

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

Additional resources and support are available at TEPEZZAhcp.com

TED SPECIALIST FINDER
Find a co-managing physician using the TED specialist finder

REQUEST A REPRESENTATIVE
The SAM provides clinical education resources to you and your office and can connect you to all team members.
The PAL provides dedicated, one-on-one support for your patient

ADDITIONAL RESOURCES
Various resources on TED, TEPEZZA, and navigating access to TEPEZZA are available

PAL, patient access liaison; SAM, specialty account manager.
*TEPEZZA is administered as 8 IV infusions given every 3 weeks. It is typically administered at a specialty infusion center.
TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon.

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Summary

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- **TED is a lifelong and progressive autoimmune disease that is debilitating and potentially disfiguring and vision threatening[1-3]**

- **TEPEZZA is the first and only FDA-approved treatment for TED regardless of disease activity or duration[4]**
- **Over 15,000 patients have been treated with TEPEZZA[5]**

Your role is essential:
identify TED early and
initiate or refer for treatment

1. Bahn RS. *N Engl J Med*. 2010;362(8):726-738. 2. Cockerham KP, et al. *Ophthalmol Ther*. 2021;10(4):975-987. 3. Cockerham KP, et al. *Ophthalmol Ther*. 2022;11(2):923.
4. TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon. 5. Data on File. Horizon, July 2023.

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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.

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.

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Important Safety Information (cont'd)

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

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

ADVERSE REACTIONS

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

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

AMGEN Rare Disease

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THANK YOU!

On behalf of Amgen,
thank you for attending the program today.

INDICATION

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

Please see Important Safety Information throughout the presentation and on slides 23-24 and Full Prescribing Information at TEPEZZAhcp.com.

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Appendix

TEPEZZA Reduced Both Orbital EOM and Fat Volume

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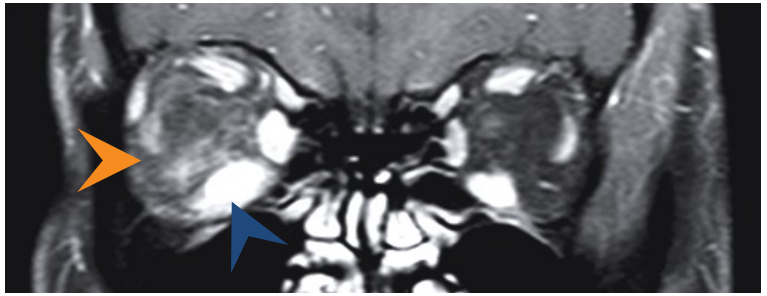
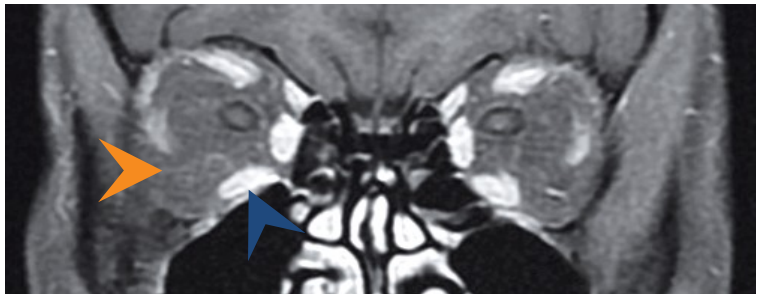
Phase 3 Study MRI (N=6)[1,2]

Baseline



Week 24

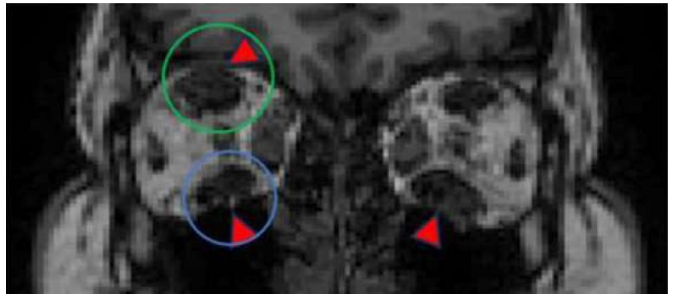


- Green and blue arrowheads point to the inferior rectus muscle and orbital fat, respectively
- Enhancement (indicating inflammation and edema) and EOM size were reduced at Week 24

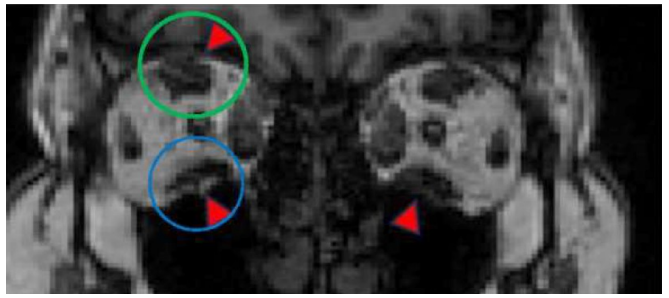
- **EOM volume reduction from baseline: 33% (*P*<0.01)[3,*]**
- **Fat volume reduction from baseline: 29% (*P*<0.05)[3,*]**

Phase 4 Study MRI (N=6)[4]

Baseline



Week 24



- The green and blue circles indicate the superior rectus and inferior rectus, respectively
- EOM size was reduced at Week 24

- **EOM volume reduction from baseline: 25% (*P*=0.0077)[†]**
- **Fat volume reduction from baseline: 35% (*P*<0.0001)[†]**

*Average reduction in the study orbits and non-study orbits across all patients. †Average reduction in the study orbits across all patients.
EOM, extraocular muscle; MRI, magnetic resonance imaging.

1. Douglas RS, et al. *N Engl J Med*. 2020;382(4):341-352. 2. Douglas RS, et al. [Supplemental Appendix]. *N Engl J Med*. 2020;382(4):341-352. 3. Jain AP, et al. *Br J Ophthalmol.* 2022;106(2):165-171. 4. Douglas RS, et al. Efficacy and Safety of Teprotumumab in Thyroid Eye Disease Patients with Long Duration and Low Disease Activity. *J Clin Endocrinol Metab*. Published online October 31, 2023. doi:10.1210/clinem/dgad637.