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# 5.30.064

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	April 1, 2025
<b>Subsection:</b>	Endocrine and Metabolic Drugs	<b>Original Policy Date:</b>	February 28, 2020
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**Last Review Date:** March 7, 2025

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## Tepezza

### Description

#### Tepezza (teprotumumab-trbw)

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#### Background

Tepezza (teprotumumab-trbw) is an insulin-like growth factor-1 receptor inhibitor (IGF-1R) injection, given via intravenous infusion. The mechanism of action has not been fully characterized but may be due to Tepezza binding to IGF-1R and blocking its activation and signaling (1).

#### Regulatory Status

FDA approved indication: Tepezza is indicated for the treatment of Thyroid Eye Disease (1).

Tepezza may cause infusion reactions. Signs and symptoms of infusion-related reactions include transient increases in blood pressure, feeling hot, tachycardia, dyspnea, headache, and muscular pain. Infusion reactions may occur during any of the infusions or within 1.5 hours after an infusion. Reported infusion reactions are usually mild or moderate in severity and can usually be successfully managed with corticosteroids and antihistamines. In patients who experience an infusion reaction, consideration should be given to pre-medicating with an antihistamine, antipyretic, corticosteroid, and/or administering all subsequent infusions at a slower infusion rate (1).

Patients treated with Tepezza should be monitored for elevated blood glucose and symptoms of hyperglycemia. Patients with pre-existing diabetes should be under appropriate glycemic control before receiving Tepezza (1).

The safety and effectiveness in pediatric patients less than 18 years of age have not been established (1).

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## Related policies

### Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Tepezza may be considered **medically necessary** if the conditions indicated below are met.

Tepezza may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age** 18 years of age or older

### Diagnosis

Patient must have the following:

Thyroid Eye Disease

**AND ALL** of the following:

1. Prescriber agrees to monitor for infusion reactions
2. Prescriber agrees to monitor blood glucose
3. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Tepezza and for 6 months after the last dose

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## Prior – Approval *Renewal* Requirements

None

### Policy Guidelines

## Pre - PA Allowance

None

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## Prior - Approval Limits

**Quantity** 8 intravenous infusions (weight-based)

**Duration** 6 months (only one PA approval per lifetime)

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## Prior – Approval *Renewal* Limits

None

### Rationale

#### Summary

Tepezza (teprotumumab-trbw) is an insulin-like growth factor-1 receptor inhibitor (IGF-1R) injection, given via intravenous infusion. The mechanism of action has not been fully characterized but may be due to Tepezza binding to IGF-1R and blocking its activation and signaling. The safety and effectiveness in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Tepezza while maintaining optimal therapeutic outcomes.

#### References

1. Tepezza [package insert]. Lake Forest, IL: Horizon Therapeutics USA, Inc.; July 2023.

### Policy History

Date	Action
February 2020	Addition to PA
March 2020	Annual review
June 2020	Annual review
February 2021	Revised PA limits from 8 IV infusions per lifetime to 8 IV infusions in 6 months. Added clarifying statement indicating that only one PA approval is allowed per member's lifetime
June 2021	Annual review
December 2022	Annual review and reference update. Changed policy number to 5.30.064
December 2023	Annual review and reference update
March 2024	Annual review
March 2025	Annual review

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## Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.**