Tepezza

Description

Tepezza (teprotumumab-trbw)

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 and older have not been established (1).

**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** for patients 18 years of age and older for the treatment of Thyroid Eye Disease and if the conditions indicated below are met.

Tepezza may be considered **investigational** in patients less than 18 years of age and 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

**Prior – Approval Renewal Requirements**

None

**Policy Guidelines**
Pre - PA Allowance
None

Prior - Approval Limits
Quantity 8 intravenous infusions per lifetime

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 and older 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

Policy History

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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 18, 2020 and is effective on July 1, 2020.