

Tepezza® (teprotumumab-trbw) - Updated indication

- On April 14, 2023, <u>Horizon Therapeutics announced</u> the FDA approval of <u>Tepezza</u>
 (<u>teprotumumab-trbw</u>), for the treatment of thyroid eye disease <u>regardless</u> of thyroid eye disease activity or duration.
 - Tepezza was previously approved for treatment of thyroid eye disease.
- The label update follows positive topline results from a randomized, double-masked, placebocontrolled Phase 4 clinical trial that were announced last week, which demonstrated that patients with an initial diagnosis of thyroid eye disease between two to 10 years and with low disease activity, achieved a statistically significant reduction in proptosis from baseline at Week 24 after receiving Tepezza compared to those receiving placebo.
- The recommended dose of Tepezza is an intravenous (IV) infusion of 10 mg/kg for the initial dose followed by an IV infusion of 20 mg/kg every three weeks for 7 additional infusions.



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