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First treatment against severe thyroid eye disease

25 April 2025

Tepezza significantly improves symptoms for patients with moderate-to-severe TED

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EMA has recommended granting a marketing authorisation in the European Union (EU) for Tepezza (teprotumumab), for the treatment of adults with moderate to severe thyroid eye disease.

Thyroid eye disease (TED), also known as Graves' eye disease, is a rare autoimmune disease that triggers inflammation of muscles, fat, and other tissues around and behind the eyes. This can cause the eyes to bulge (or protrude), and other symptoms, including puffy eyelids, eye redness and irritation, eye pain, double vision, and eyelid retraction (when the upper and/or lower eyelids are pulled back more than normal). In severe cases, TED can cause vision loss and facial disfigurement.

Treatment options for moderate-to-severe TED are limited and most patients are treated with corticosteroids, with some patients needing multiple reconstructive surgeries.

The active substance of Tepezza is teprotumumab, a monoclonal antibody (a type of protein) designed to block

the autoimmune activation of orbital fibroblasts (specialised cells in the eye sockets), potentially inhibiting the development and progression of TED.

The [CHMP](#)'s opinion is based on data from three randomised, placebo-controlled trials in a total of 225 patients with active TED, and one trial in 62 patients with chronic TED. After 24 weeks, patients treated with Tepezza experienced a significant reduction (-2 to -2.3 mm) in protrusion of the eyeball from the eye socket (proptosis) and in the Clinical Activity Score (CAS), a standard tool to evaluate inflammatory signs and symptoms of TED, compared to patients treated with placebo. The reduction in proptosis was smaller (-1.5mm) in patients with chronic TED.

The most common side effects in patients treated with Tepezza were muscle spasms, diarrhoea, alopecia (hair loss), hyperglycaemia (high blood glucose levels), fatigue, nausea and headache. Evidence from [clinical trials](#) and post-marketing experience show that Tepezza may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Pre-clinical studies have shown that Tepezza may pose risks for the development of the fetus. Additional risk minimisation measures will be implemented to mitigate these risks.

The opinion adopted by the [CHMP](#) is an intermediate step on Tepezza's path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide [marketing authorisation](#). Once a [marketing authorisation](#) has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of this medicine in the context of the national health system of that country.

Notes

- The applicant for Tepezza is Amgen Europe B.V.

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