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[C2H2407] Summary of cost-effectiveness evaluation of teprotumumab (TEPEZZA®)

1. Indications

Active thyroid eye disease

2. Price of the drug

Teprotumumab has been reimbursed since November 2024 at JPY 979,920 for 500 mg (as of February 2026). The price was calculated based on the cost-calculation method, and this product was designated as an H1 cost-effectiveness evaluation item.

3. Scope of cost-effectiveness evaluation

This product is indicated for treating patients with active thyroid eye disease. The evaluation scope, which was agreed upon during the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE), is described below.

Population	(a) mild active thyroid eye disease (b) moderate-to-severe thyroid eye disease (CAS < 3) (c) moderate-to-severe thyroid eye disease (CAS ≥ 3)
Comparator	(a) symptomatic treatment (b), (c) combination therapy of steroid pulse therapy and radiotherapy

4. Evaluation of additional benefits

The manufacturer conducted a systematic review; however, no evaluable randomized controlled trials (RCTs) were identified for populations (a) and (b). For population (c), in the absence of direct comparative RCTs, a matching-adjusted indirect comparison (MAIC) using the TED01RV and OPTIC trials and RCTs of steroid pulse therapy was performed, assuming equivalence between steroid pulse therapy alone and the combination therapy. MAIC demonstrated a significant improvement in proptosis, whereas diplopia outcomes were considered supportive of additional benefits. Despite limited evidence, the Academic Technology Assessment Group (ATAG) accepted the analysis and concluded that teprotumumab provided additional

benefits only in population (c).

5. Results of cost-effectiveness analysis

To analyze population (c), a cost-effectiveness analysis using a Markov model was conducted, comparing teprotumumab with a combination of steroid pulse therapy and radiotherapy. The manufacturer assumed a recurrence rate of 0% after teprotumumab based on the absence of observed recurrence at Week 28 in the TED01RV trial, whereas the ATAG adopted a 24% recurrence rate based on Kahaly et al. (2024) and estimated recurrence during 24–48 weeks after treatment using an exponential model. For combination therapy, the manufacturer assumed a recurrence rate of 30.5%, whereas the ATAG adopted a recurrence rate of 18.4%, based on Kahaly et al. (2018). Furthermore, the drug costs for teprotumumab were estimated based on dosage data aggregated from the National Database of Health Insurance Claims and Specific Health Checkups of Japan, and a reanalysis was performed. The ECCEE accepted the following results:

Population	ICER (JPY/QALY)
(a) mild active thyroid eye disease	Impossible to analyze
(b) moderate-to-severe thyroid eye disease (CAS < 3)	Impossible to analyze
(c) moderate-to-severe thyroid eye disease (CAS ≥ 3)	9,355,796