



国立保健医療科学院 保健医療経済評価研究センター
Center for Outcomes Research and Economic
Evaluation for Health (C2H), National Institute of
Public Health (NIPH) | URL:<https://c2h.niph.go.jp>

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[C2H2306] Summary of cost-effectiveness evaluation of semaglutide (Wegovy®)

1. Indications

Obesity

2. Price of the drug

Semaglutide for managing obesity has been reimbursed since November 2023, at JPY 1,876 for 0.25 mg, JPY 3,201 for 0.5 mg, JPY 5,912 for 1.0 mg, JPY 7,903 for 1.7 mg, and JPY 10,740 for 2.4 mg (as of March 2025). 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 the treatment of obesity. The scope of evaluation agreed upon at the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE) is described below.

Population	Overweight (body mass index [BMI] of 27 kg/m ² or more) with at least two of the weight-related comorbidities, including type-2 diabetes or obesity (BMI of 35 kg/m ²) with at least one of the following weight-related comorbidities: hypertension, dyslipidemia, or type-2 diabetes. (a) With type-2 diabetes (b) Without type-2 diabetes *The definition follows the Guidelines for the Management of Obesity Disease 2022 by the Japan Society for the Study of Obesity
Comparator	(a)(b) Diet and exercise

4. Evaluation of additional benefits

The manufacturer presented the patient's individual data from the STEP6 trial. A randomized controlled trial in patients with overweight or obesity was conducted to assess the additional benefits of semaglutide plus diet and exercise over diet and exercise alone. Evidence showed that semaglutide plus diet and exercise was associated with a statistically significant reduction in body weight from baseline compared to diet and exercise alone for the two groups based on type-2 diabetes. Similar findings were observed for systolic blood pressure, total cholesterol, and HbA1c in the two groups. Based on the findings, the manufacturer suggested that semaglutide including diet and exercise had additional benefits compared to diet and exercise alone. The academic group conducted a systematic review and identified three trials, consisting of STEP6, STEP1, and STEP2, from the literature. The results of the three trials in the literature were similar to those from STEP6 presented by the manufacturer. The academic group concluded that semaglutide had additional benefits compared with diet and exercise alone for patients with overweight or obesity.

5. Results of cost-effectiveness analysis

The manufacturer submitted a cost-effectiveness analysis over a 40-year time horizon using a multi-state Markov model simulating the progression of overweight or obesity with semaglutide plus diet and exercise versus diet and exercise alone. The academic group identified several challenges with the manufacturer's analysis. First, the drop-out rates of semaglutide and/or diet and exercise in the manufacturer's model were based on the studies in Italy and the US. The academic group used rates based on Japanese data to reflect actual clinical evidence in Japan. Second, the improvement of treatment (diet and exercise) adherence owing to early weight loss by semaglutide was sustained after stopping semaglutide. This sustained improvement was considered part of the treatment effects of semaglutide but was not supported by evidence, and the academic group updated their model to assume that the effect of semaglutide would disappear in 1–10 years after stopping semaglutide. Third, the benefits of diet and exercise (e.g., weight loss) at 9 months were maintained throughout life. The long-term effects of diet and exercise are uncertain. The academic group assumed that the effects of diet and exercise would disappear in 1–10 years after the first year of treatment. The ECCEE accepted the following results:

Population	Comparator	Additional benefit	ICER (JPY/QALY)
(a) With type-2 diabetes	Diet and exercise	Proven	18,216,862
(b) Without type-2 diabetes	Diet and exercise	Proven	13,095,027

* The academic group performed cost-effectiveness analysis on the condition that the effect of semaglutide would disappear within 10 years after stopping semaglutide.