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[C2H2007] Summary of cost-effectiveness evaluation of semaglutide (Rybelsus®)

1. Indications

Type 2 diabetes mellitus (T2DM)

2. Price of the drug

Semaglutide has been reimbursed from November 2020 at JPY 143.20 for 3 mg, JPY 334.20 for 7 mg, and JPY 501.30 for 14 mg (as of August 2022). The price was calculated using a similar efficacy comparison method (I), with a usefulness premium (II) of 5%, a foreign average price adjustment, and a price maintenance premium. This product is designated as an H1 cost-effectiveness evaluation item.

3. Scope of the cost-effectiveness evaluation

This product is indicated for the treatment of T2DM. The scope of evaluation agreed upon at the first session of the Expert Committee of Cost-Effectiveness Evaluation (ECCEE) is described below.

Population	(A) T2DM patients with inadequate glycemic control using oral hypoglycemics, including dipeptidyl peptidase 4 (DPP-4) inhibitors. They need to be treated with other oral hypoglycemics. (B) T2DM patients with inadequate glycemic control using oral hypoglycemics, excluding DPP-4 inhibitors. They need to be treated with other oral hypoglycemics. (C) T2DM patients with inadequate glycemic control using oral hypoglycemics. They need be treated with glucagon-like peptide-1 (GLP-1) receptor agonists (injection).

Comparator	Population (A): DPP-4 inhibitors and sodium-glucose cotransporter-2 (SGLT2) inhibitors with the lowest price combination Population (B): SGLT2 inhibitors with the lowest price Population (C): GLP-1 receptor agonist (injection) with the lowest price

4. Evaluation of additional benefits

In the systematic review, the manufacturer conducted a network meta-analysis based on clinical trials in previously treated Japanese patients with T2DM for populations (A) and (B). The systematic review demonstrated significant improvements in glycated hemoglobin (HbA1c) with semaglutide and the manufacturer deduced that semaglutide had an additional benefit over comparators. In response, the academic group added other publications and reconducted the network meta-analysis with a different network diagram. From the view of the academic group, there was no significant difference in the change HbA1c and body weight for populations (A) and (B), and a point estimate of the difference in these endpoints was not clinically meaningful. The academic group concluded that semaglutide has ”no additional benefit.”

For population (C), the manufacturer and the academic group concluded that semaglutide has additional benefits compared with GLP-1 receptor agonist (injection) because the PIONEER 10 study showed that semaglutide significantly reduced body weight versus the existing GLP-1 receptor agonist (injection).

The third session of the ECCEE concluded that the results of the academic group are more appropriate. Based on the discussion, semaglutide has additional benefits only for population (C).

5. Results of the cost-effectiveness analysis

The academic group conducted a cost-minimization analysis for populations (A) and (B). For population (C), the academic group conducted a cost-effectiveness analysis after modifying the parameters of effectiveness, quality of life (QOL) values, and health-related cost. The ECCEE accepted the following:

Population	ICER (JPY/QALY)
(A) T2DM patients with inadequate glycemic control using oral hypoglycemics, including DPP-4	Cost increase

inhibitors. They need to be treated with other oral hypoglycemics.	
(B) T2DM patients with inadequate glycemic control using oral hypoglycemics, excluding DPP-4 inhibitors. They need to be treated with other oral hypoglycemics.	Cost increase
(C) T2DM patients with inadequate glycemic control using oral hypoglycemics. They need be treated with GLP-1 receptor agonists (injection).	Dominant