

Original French opinion adopted by the Transparency Committee.

The legally binding text is the original French opinion version.

SUMMARY

semaglutide

OZEMPIC 0.5 mg and 1 mg

solution for injection in pre-filled pen

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 27 August 2025

Summary of opinion

Favourable opinion for reimbursement only for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

- as dual therapy with metformin,
- as triple therapy with metformin and a sulphonylurea,
- as triple therapy with metformin and basal insulin.

No clinical added value of the new forms compared to the forms already available.

Transparency Committee's conclusions

Clinical Benefit

- ➔ Diabetes is a chronic disease with potentially serious complications, particularly cardiovascular. The objective of treatment of type 2 diabetes is to prevent its numerous, serious and often disabling complications, that are often insidious, such as microangiopathy (affecting the retina, nerves, heart and kidneys) and sudden complications of macroangiopathy, such as myocardial infarction or stroke. Diabetes promotes the development of heart failure.
- ➔ This is a medicinal product intended to prevent diabetes complications.
- ➔ The efficacy/adverse effects ratio is moderate.
- ➔ If prescription of a GLP-1 analogue is envisaged, given the results observed in terms of reduction of the 3P-MACE endpoint with dulaglutide in the REWIND study, and with liraglutide in the LEADER study, the choice should preferentially lean towards TRULICITY (dulaglutide) and VICTOZA (liraglutide) or its fixed-dose combination XULTOPHY (liraglutide/insulin degludec). Given the lower level of evidence provided by the cardiovascular study (with a non-inferiority margin of 1.8), OZEMPIC (semaglutide) should not be favoured within its class.

→ Public health benefit

OZEMPIC (semaglutide) is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of OZEMPIC (semaglutide) is:

- moderate only “for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:
 - as dual therapy with metformin,
 - as triple therapy with metformin and a sulphonylurea,
 - as triple therapy with metformin and basal insulin”
- insufficient to justify public funding in the other MA situations.

The Committee issues a favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indication “for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:

- as dual therapy with metformin,
- as triple therapy with metformin and a sulphonylurea,
- as triple therapy with metformin and basal insulin”, and at the MA dosages.

→ Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 30%

Clinical Added Value

These medicinal products are range supplements that provide no clinical added value (CAV V) compared to the forms already listed.