SUMMARY

semaglutide

WEGOVY 0.25 mg, 0.5 mg, 1 mg, 1.7 mg, 2.4 mg

solution for injection

Second assessment of an unlisted medicinal product

Adopted by the Transparency Committee on 23 October 2024

Summary of opinion

Favourable opinion for reimbursement only "as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in adults with an initial body mass index (BMI) ≥ 35 kg/m² in the event of failure of well-conducted nutritional management (< 5% weight loss after six months)".

Unfavourable opinion for reimbursement in the other situations covered by the MA indication.

Transparency Committee's conclusions

Clinical Benefit

- Obesity is a chronic condition with potentially serious complications, with, in particular, an increase in cardiovascular risk, arterial hypertension, hyperlipidaemia and type 2 diabetes.
- This is a curative and symptomatic medicinal product.
- The efficacy/adverse effects ratio is high.
- This is a second-line treatment, as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, only in adults with an initial body mass index (BMI) ≥ 35 kg/m² in the event of failure of well-conducted nutritional management (< 5% weight loss after six months). WEGOVY (semaglutide) has no role in the care pathway in other situations.

➔ **Public health benefit**

Considering:

- the seriousness of the disease: the burden of obesity, through its morbid complications, its social impact and the impairment of quality of life that it causes, represents a significant public health burden,
- the inadequately met medical need insofar as no medicinal products to treat obesity have shown evidence of a reduction in cardiovascular morbidity and mortality,
- the partial response to the identified need given:
  - evidence of an additional impact on cardiovascular morbidity and quality of life, without any impact on mortality demonstrated to date,
  - the lack of evidence of an impact on the organisation of care, particularly with respect to reduced recourse to bariatric surgery, with, however, an expected favourable impact related to well-conducted management in specialised obesity centers.

WEGOVY (semaglutide) is likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of WEGOVY (semaglutide) is:

- **substantial only as an adjunct to a reduced-calorie diet and increased physical activity for weight management, including weight loss and weight maintenance, in patients with an initial body mass index (BMI) ≥ 35 kg/m² in the event of failure of well-conducted nutritional management (< 5% weight loss after six months);**
- **insufficient to justify public funding in the other MA situations.**

The Committee issues a favourable opinion for inclusion of WEGOVY (semaglutide) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use only within the scope retained and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Clinical Added Value

Considering:

- evidence in the phase 3 SELECT study of the superiority of semaglutide compared to placebo, for a clinically relevant cardiovascular endpoint, i.e. the reduction in events in the 3P-MACE composite endpoint, including cardiovascular death, non-fatal myocardial infarction and non-fatal stroke, with an HR=0.80; 95% CI [0.72; 0.90]; p<0.0001), in non-diabetic patients with obesity and a history of at least one cardiovascular disease,
- evidence in the phase 3 STEP HFpEF study of the superiority of semaglutide compared to placebo, for two co-primary endpoints, i.e. a quality of life endpoint assessed using the CSS score of the KCCQ-23 questionnaire and weight loss, after 52 weeks of treatment in patients with obesity and heart failure with preserved ejection fraction,
- the safety profile of semaglutide, primarily marked by gastrointestinal adverse events, characteristic of GLP-1 analogues,

but taking into account:

- the lack of evidence of a superiority of semaglutide versus placebo in the SELECT study for the first ranked secondary endpoint, which was cardiovascular death, interrupting the analysis of the other cardiovascular endpoints,
- the modest reduction in cardiovascular risk in the SELECT study (with, in particular, a reduction in the relative risk of one of the major cardiovascular events of the 3P-MACE composite endpoint of 20% compared to placebo),
- the absence of cardiovascular results in patients with a BMI of under 30 kg/m^{2,} as well as the absence of primary prevention data in patients,
- the to date unmet medical need to have access to medicinal products to treat obesity showing evidence of a reduction in cardiovascular morbidity and mortality,

the Committee deems that WEGOVY (semaglutide) provides a minor clinical added value (CAV IV) in the care pathway for adult patients with an initial body mass index (BMI) > 35 kg/m² in the event of failure of well-conducted nutritional management (< 5% weight loss after 6 months) and as an adjunct to a reduced-calorie diet and physical activity.