**SUMMARY**

tirzepatide

# MOUNJARO 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg and 15 mg

**solution for injection in pre-filled pen**

Indication extension

**Adopted by the Transparency Committee on 17 July 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, hypertension, hyperlipidaemia and type 2 diabetes.
- This is a curative and symptomatic medicinal product.
- Its efficacy/adverse effect ratio is moderate given that the efficacy data relating to MOUNJARO (tirzepatide) are only based on intermediate endpoints.
- This is a second-line treatment in view of the therapies available.

### 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 medical need partially met by the available alternatives,
- the lack of additional response to the identified need, given:
  - the lack of evidence of an additional impact of tirzepatide on morbidity and mortality,
  - the lack of data making it possible to assess the additional impact on the care and life pathway, and the organisation of care in terms of referral for surgery for example,

MOUNJARO (tirzepatide) is unlikely to have an additional impact on public health.

**Considering all these elements, the Committee deems that the clinical benefit of MOUNJARO (tirzepatide) 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 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).**
- **insufficient to justify public funding cover in view of the available alternatives in the other MA situations.**

**The Committee issues the following opinions:**

- **favourable opinion for inclusion of MOUNJARO (tirzepatide) 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,**
- **unfavourable opinion for inclusion of MOUNJARO (tirzepatide) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the other situations covered by the MA indication.**

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

## Clinical Added Value

Considering:

- the evidence of superiority of tirzepatide versus placebo on weight loss endpoints in four phase 3 clinical studies:
  - with a mean weight loss change after 72 weeks of treatment (co-primary efficacy endpoint), of approximately 3% in the placebo groups, and -13 to -24% in the tirzepatide groups, depending on the doses and the studies,
  - with a percentage of patients achieving weight loss of > 5% after 72 weeks of treatment (co-primary efficacy endpoint), of 11 to 30% in the placebo groups and approximately 95% in the tirzepatide groups all doses combined in the SURMOUNT 1 to 3 studies,
  - with a mean weight change between week 36 and 88, ranging from +14% in the placebo group to – 6% in the tirzepatide group all doses combined in the SURMOUNT-4 study,
- the absence of data demonstrating a clinical benefit of MOUNJARO (tirzepatide) on clinically relevant endpoints such as cardiovascular morbidity and mortality,
- the safety profile of tirzepatide, which appears to be favourable with limited follow-up in clinical trials, characterised by gastrointestinal events, like GLP-1 analogues,

- uncertainties regarding the long-term safety of tirzepatide, particularly related to its GIP receptor agonist component, monitoring for the development of medullary or pancreatic cancers, complications of diabetic retinopathy,
- indirect comparisons with a low level of evidence, meaning that it is not possible to determine the role of MOUNJARO (tirzepatide) compared to semaglutide (WEGOVY), and the absence of comparative data versus SAXENDA (liraglutide),

the Transparency Committee deems that, based on the data currently available, MOUNJARO (tirzepatide) provides no clinical added value (**CAV V**) in the current 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 six months) and as an adjunct to a reduced-calorie diet and physical activity.