SUMMARY

abaloparatide

ELADYNOS 80 µg

Solution for injection in pre-filled pen

First listing

Adopted by the Transparency Committee on 11 December 2024

Summary of opinion

Favourable opinion for reimbursement only in the treatment of osteoporosis in postmenopausal women with either a history of at least one vertebral fracture or a history of at least two fractures.

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

Transparency Committee's conclusions

Clinical Benefit

- Osteoporosis is a condition for which the seriousness is related to the fracture risk. Severe fractures, particularly femoral neck fractures, can seriously impair quality of life and are associated with excess mortality.
- This is a preventive medicinal treatment for osteoporotic fractures in women at high risk of fractures.
- Considering:
  - evidence of the efficacy of abaloparatide compared to placebo on the incidence of new vertebral fractures at 18 months, with a modest effect size, and on non-clinical endpoints of change in BMD at 18 months at the hip, femoral neck and lumbar spine,
  - the absence of a statistically significant difference between abaloparatide and placebo for the ranked secondary endpoint of incidence of non-vertebral fractures, despite this being a relevant endpoint in the indication,
  - the absence of quality of life data,
  - uncertainties concerning the safety profile and, in particular, the cardiovascular safety,

  the efficacy/adverse effects ratio is low.
- The Committee considers that ELADYNOS (abaloparatide) is a therapeutic option in the treatment of osteoporosis in postmenopausal women with either a history of at least one vertebral fracture or a history of at least two fractures.
- In the other situations of the MA indication, the Committee considers that ELADYNOS (abaloparatide) has no role in the care pathway.

➔ Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the partially met medical need,
- the absence of a partial response to the identified need given:
  - the lack of evidence of an additional impact on morbidity and mortality and on quality of life compared to the available alternatives,
  - the absence of an additional impact on the care or life pathway for patients or their families. It should be noted that due to the safety profile of abaloparatide marked by the occurrence of orthostatic hypotension and increased heart rate, the first injection(s) of abaloparatide should be performed under the supervision of a healthcare professional.

ELADYNOS (abaloparatide) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of ELADYNOS (abaloparatide) 80 micrograms subcutaneous injection is:

- **low only in the treatment of osteoporosis in postmenopausal women with either a history of at least one vertebral fracture or a history of at least two fractures,**
- **insufficient to justify public funding in view of the available alternatives in the other MA situations.**

The Committee issues the following opinions:

- **a favourable opinion for inclusion of ELADYNOS (abaloparatide) in the list of covered drugs for outpatients and/or the list of covered drugs for inpatients approved for use only in the treatment of osteoporosis in postmenopausal women with either a history of at least one vertebral fracture or a history of at least two fractures and at the MA dosages,**
- **an unfavourable opinion for inclusion of ELADYNOS (abaloparatide) 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.**

Clinical Added Value

Considering:

- evidence of the superiority of abaloparatide compared to placebo in women with postmenopausal osteoporosis for the incidence of new vertebral fractures at 18 months and for change in BMD at 18 months at the hip, femoral neck and lumbar spine,
- a suggested maintenance of efficacy over time (data at 43 months) in women having switched to treatment with alendronate at 18 months for vertebral fractures,

but in view of:

- the modest effect size observed for the primary endpoint of incidence of vertebral fractures,
- the low clinical relevance of the ranked secondary endpoints of change in BMD at 18 months at the hip, femoral neck and lumbar spine,
- the lack of evidence of a efficacy versus placebo for the endpoint of incidence of non-vertebral fractures, a relevant clinical endpoint in this disease,

- the absence of useable comparative data versus teriparatide, given their exploratory nature in the ACTIVE study,
- the medical need partially met by the existence of teriparatide, having demonstrated an efficacy on the incidence of vertebral and non-vertebral fractures.

the Committee deems that ELADYNOS (abaloparatide) provides no clinical added value (CAV V) in the treatment of osteoporosis in postmenopausal women with either a history of at least one vertebral fracture or a history of at least two fractures.