SUMMARY

denosumab

XGEVA 120 mg,

solution for injection in a pre-filled syringe

Inclusion on list: First listing

Range supplement

Original French opinion adopted by the Transparency Committee on 15 May 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement in the following indications:

- Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with an advanced solid tumour involving bone.
- Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity.
  (For more information see the MA)

Unfavourable opinion in the other indications, i.e. in the prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with other advanced malignancies, including multiple myeloma, involving bone.

No clinical added value of the new XGEVA 120 mg solution for injection in pre-filled syringe form compared to the forms already available.

Transparency Committee's conclusions

Clinical Benefit

Prevention of skeletal related events

➔ Skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in patients with solid tumours with bone metastases are common, particularly

in advanced breast or prostate cancer. These complications can significantly affect patients' quality of life. They can be life-threatening, particularly in the case of spinal cord compression. Radiotherapy and bone surgery can be associated with an excess risk of morbidity and mortality.

- XGEVA is a preventive treatment for skeletal related events in patients with a solid tumour with bone metastases.
- The efficacy/adverse effects ratio is high.
- It is a first-line treatment.

Public health benefit

XGEVA (denosumab) 120 mg solution for injection in a 1.0 mL pre-filled syringe (120 mg/mL) is unlikely to have an additional impact on public health compared to XGEVA (denosumab) 120 mg solution for injection in a 1.7 mL vial (70 mg/mL).

The Committee considers that the clinical benefit of XGEVA 120 mg (denosumab) solution for injection in a 1.0 mL pre-filled syringe (120 mg/mL) is:

- substantial only in the "prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with an advanced solid tumour involving bone";
- insufficient to justify its public funding cover in the other MA situations, i.e. in the "prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with other advanced malignancies, including multiple myeloma, involving bone".

The Committee issues the following opinions:

- **a favourable opinion for inclusion of XGEVA 120 mg (denosumab) solution for injection in a 1.0 mL pre-filled syringe (120 mg/mL) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use only in the prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with an advanced solid tumour involving bone, and at the MA dosages;**
- **an unfavourable opinion for inclusion of XGEVA 120 mg (denosumab) solution for injection in a 1.0 mL pre-filled syringe (120 mg/mL) 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, i.e. in the "prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with other advanced malignancies, including multiple myeloma, involving bone".**

Treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity

- Giant cell bone tumours are serious diseases that can be life-threatening.
- XGEVA is a specific curative treatment for giant cell bone tumours.
- The efficacy/adverse effects ratio is moderate in this indication.
- There are no medicinal alternatives at this stage of the disease.
- This is a first-line treatment in the absence of available therapies.

➔ Public health benefit

XGEVA (denosumab) 120 mg solution for injection in a 1.0 mL pre-filled syringe (120 mg/mL) is unlikely to have an additional impact on public health compared to XGEVA (denosumab) 120 mg solution for injection in a 1.7 mL vial (70 mg/mL).

The Committee considers that the clinical benefit of XGEVA 120 mg (denosumab) solution for injection in a 1.0 mL pre-filled syringe (120 mg/mL) is moderate in the "treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity".

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 "treatment of adults and skeletally mature adolescents with giant cell tumour of bone that is unresectable or where surgical resection is likely to result in severe morbidity", and at the MA dosages.

Clinical Added Value

This medicinal product is a range supplement that does not provide any clinical added value (CAV V) compared to the forms already listed.