HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE

SUMMARY

09 SEPTEMBER 2020

The legally binding text is the original French opinion version

salmon calcitonin

MIACALCIC 50 IU/1mL, solution for injection or infusion

Reevaluation

Key points

Unfavourable opinion for reimbursement in the MA indications; i.e.:

- prevention of acute bone loss associated with sudden immobilisation, particularly for subjects with recent osteoporotic fractures;
- treatment of Paget's disease, only in patients for whom alternative treatments have been ineffective or cannot be used, for example patients with severe kidney disease and
- the treatment of malignant hypercalcaemia.

The clinical benefit is now insufficient (previously it was low) in the indications: Paget's disease and malignant hypercalcaemia.

The clinical benefit remains insufficient in the indication: prevention of bone loss.

What therapeutic improvement?

Not applicable.

Role in the care pathway?

The proprietary medicinal product MIACALCIC (salmon calcitonin) no longer has a role in the care pathway in view of the available alternatives.

COMMITTEE'S CONCLUSIONS

Clinical benefit

Paget's disease as a last resort and for a limited treatment duration

◗ In some cases, Paget's disease is characterised by progression towards disability and/or a deterioration in quality of life.

◗ This proprietary medicinal product is a symptomatic treatment.

◗ Due to:
- old efficacy data, of low methodological quality and not enabling assessment of the effect size,
- its poor safety profile (nausea, vomiting and vasomotor flushes observed in around 10% of patients treated with calcitonin) including an increased cancer risk in the event of long-term use,

the efficacy/adverse effects ratio of calcitonin by injection has not been adequately established.

◗ Considering:
- an inadequately established clinical benefit due to the low level of evidence of the efficacy data and the poor safety profile (nausea, vomiting and vasomotor flushes observed in around 10% of patients treated with calcitonin) including an increased cancer risk in the event of long-term use,
- the fact that calcitonin has been replaced in routine practice by bisphosphonates,

the proprietary medicinal product MIACALCIC (salmon calcitonin) has no role in the care pathway in view of the available alternatives.

◗ There are medicinal alternatives, in particular bisphosphonates, which are the reference treatment in Paget's disease.

◗ Public health impact:
Considering:
- the seriousness of the disease due to the risk of complications,
- but its low prevalence,
- the medical need already met by bisphosphonates, which are the reference treatment,
- the absence of response provided by calcitonin to the medical need met by bisphosphonates,
- the absence of a demonstrated impact in terms of morbidity given the low level of evidence of the efficacy data and the poor safety profile including an increased cancer risk in the event of long-term use,
- the lack of elements supporting the absence of a deterioration in the care and/or life pathway in the absence of quality of life data,
- the absence of any demonstrated impact on the organisation of care,

MIACALCIC (salmon calcitonin) is unlikely to have an impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of MIACALCIC (salmon calcitonin) is insufficient to justify its public funding cover in view of the alternatives available in the MA indication and dosages.

Malignant hypercalcaemia

◗ Malignant hypercalcaemia is a serious, potentially life-threatening condition.

◗ This proprietary medicinal product is a symptomatic treatment.

◗ Due to:
- old efficacy data, of low methodological quality and not enabling assessment of the effect size,
- its poor safety profile (nausea, vomiting and vasomotor flushes observed in around 10% of patients treated with calcitonin) including, in particular, an increased cancer risk in the event of long-term use,

the efficacy/adverse effects ratio of MIACALCIC (salmon calcitonin) has not been adequately established.

◗ Considering:
- an inadequately established clinical benefit due to the low level of evidence of the efficacy data and the poor safety profile (nausea, vomiting and vasomotor flushes observed in around 10% of patients treated with calcitonin) including an increased cancer risk in the event of long-term use,
- the fact that calcitonin has been replaced in routine practice by bisphosphonates,

the proprietary medicinal product MIACALCIC (salmon calcitonin) has no role in the care pathway in view of the available alternatives.

◗ There are medicinal alternatives in the treatment of malignant hypercalcaemia, in particular bisphosphonates.

◗ Public health impact:
Considering:
- the seriousness of the disease due to the risk of complications,
- but its low prevalence,
- the medical need already met by bisphosphonates, which are the reference treatment,
- the absence of response provided by calcitonin to the medical need met by bisphosphonates,
- the absence of a demonstrated impact in terms of morbidity given the low level of evidence of the efficacy data and the poor safety profile including an increased cancer risk in the event of long-term use,
- the lack of elements supporting the absence of a deterioration in the care and/or life pathway in the absence of quality of life data,
- the absence of any demonstrated impact on the organisation of care,

MIACALCIC (salmon calcitonin) is unlikely to have an impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of MIACALCIC (salmon calcitonin) is insufficient to justify its public funding cover in view of the alternatives available in the MA indication and dosages.

Prevention of acute bone loss associated with sudden immobilisation, particularly for subjects with recent osteoporotic fractures

◗ The seriousness of “acute bone loss associated with sudden immobilisation” cannot be specified.

◗ This proprietary medicinal product is a preventive treatment.

◗ There are no relevant clinical studies with an acceptable methodology available enabling assessment of the efficacy of calcitonin injections in this indication in a context in which calcitonin has a poor safety profile (nausea, vomiting and vasomotor flushes observed in around 10% of patients treated with calcitonin) including an increased cancer risk in the event of long-term use.

The efficacy/adverse effects ratio has not been adequately established.

◗ The role of calcitonin in the prevention of bone loss associated with sudden immobilisation cannot be specified in the absence of robust data. Consequently, the Committee considers that this medicinal product has no role in the care pathway.

◗ The therapeutic alternatives cannot be identified.

- In the absence of relevant data, calcitonin is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of MIACALCIC (salmon calcitonin) remains insufficient to justify its public funding cover in view of the alternatives available in the MA indication and dosages.

The Committee issues an unfavourable opinion for maintenance of inclusion of MIACALCIC (salmon calcitonin) in the hospital formulary list of reimbursed proprietary medicinal products approved for use in all the MA indications, i.e.: prevention of acute bone loss associated with sudden immobilisation, particularly for subjects with recent osteoporotic fractures, Paget's disease and malignant hypercalcaemia.

Clinical Added Value

Not applicable.