SUMMARY

secukinumab

COSENTYX 150 and 300 mg

solution for injection in pre-filled syringe and pen

Reassessment at the request of the TC

Original French opinion adopted by the Transparency Committee on 14 February 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for maintenance of reimbursement in the MA indication: “treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy”.

Transparency Committee’s conclusions

Clinical Benefit

- Ankylosing spondylitis is a chronic disease which, in its severe form with inadequate response or intolerance to NSAIDs, is painful, and affects spinal mobility and functional capacities.
- This is a symptomatic medicinal product.
- The efficacy/adverse effects ratio remains high.
- This is a third-line treatment in view of the therapies available, i.e. after inadequate response or intolerance to at least one TNF inhibitor.

Public health benefit

Considering:

- the seriousness and prevalence of ankylosing spondylitis;
- the medical need related to treatment failure and/or tolerance phenomena of the medicinal products currently available;
- the partial response to the identified need, in view of:

- the lack of evidence of an additional impact of COSENTYX (secukinumab) on morbidity and mortality and quality of life compared to the medicinal alternatives,
- the lack of evidence of an impact on the organisation of care and the patient's life pathway,

COSENTYX (secukinumab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of COSENTYX (secukinumab) remains substantial in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion of COSENTYX (secukinumab) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

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

Clinical Added Value

Considering:

- demonstration of a superiority compared to placebo,
- the lack of evidence of a superiority compared to adalimumab,
- the absence of robust comparative data versus the other biological medicinal products available,

the Committee deems that COSENTYX (secukinumab) provides no clinical added value (CAV V) in the current care pathway, which includes the relevant comparators.