SUMMARY

secukinumab

COSENTYX 150 and 300 mg

solution for injection in pre-filled syringe and pen

Modification of the listing conditions

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: “COSENTYX, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.”

Transparency Committee’s conclusions

Clinical Benefit

- Psoriatic arthritis is a chronic disease, which can be serious and disabling in certain forms.
- The proprietary medicinal product COSENTYX (secukinumab) is a symptomatic disease-modifying treatment.
- The efficacy/adverse reaction ratio remains moderate in the absence of evidence compared to other TNF inhibitors, of robust comparative data versus the other biological medicinal products available and specific data in patients intolerant or responding inadequately to at least one TNF inhibitor.
- It is a third and later-line treatment in view of the therapies available, i.e. after inadequate response or intolerance to one or more DMARDs including at least one TNF inhibitor.

➔ Public health benefit

Considering:

- the seriousness and prevalence of psoriatic arthritis,
- the partially met medical need due to failures and intolerance to available treatments and resistance phenomena,
- the absence of any demonstrated additional impact on morbidity or quality of life compared to the available medicinal products but the partial response to the identified partially met need due to resistance phenomena and/or the safety associated with these medicinal products,
- the lack of expected additional impact on the patient's care and/or 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 150 mg and 300 mg (secukinumab) solution for injection in pre-filled syringe and pen remains moderate in this MA indication.

The Committee issues a favourable opinion for maintenance of inclusion of COSENTYX 150 mg and 300 mg (secukinumab) solution for injection in pre-filled syringe and pen 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: 30%

Clinical Added Value

In the absence of:

- robust comparative data versus the other biological medicinal products available,
- and specific data in patients intolerant or responding inadequately to at least one TNF inhibitor,

the Committee deems that COSENTYX 150 mg and 300 mg (secukinumab) solution for injection in pre-filled syringe and pen provide no clinical added value (CAV V) in the current care pathway, which includes the relevant comparators.

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