SUMMARY

secukinumab

COSENTYX 150 mg and 300 mg

solution for injection in pre-filled syringe and pen

Indication extension

Original French opinion adopted by the Transparency Committee on 4 October 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- Hidradenitis suppurativa is a dermatological condition that can progress to an incapacitating chronic form significantly impairing quality of life.
- This is a symptomatic medicinal product.
- The efficacy/adverse effects ratio is low given a very modest efficacy demonstrated versus placebo and the absence of a demonstrated benefit in terms of quality of life, which is nonetheless particularly impaired in moderate to severe forms of this disease.
- COSENTYX (secukinumab) is a second-line treatment following an inadequate response to antibiotic therapy in active moderate to severe HS in adults. COSENTYX (secukinumab) may be used after antibiotic therapy or in combination with it. In the absence of comparative data versus HUMIRA (adalimumab, TNFα antagonist), the role of COSENTYX (secukinumab) compared to this medicinal product cannot be specified.

- **Public health benefit**

Considering:

- the chronic nature of the disease and its significant impact in terms of quality of life,
- its low prevalence,
- the partially met medical need in moderate to severe forms of HS, particularly in the event of an inadequate response to conventional systemic treatment (antibiotic therapy) for HS,
- the partial response to the identified need:

- the modest additional impact demonstrated on morbidity in the short term versus placebo but without a demonstrated impact on the quality of life of patients,
- the lack of evidence of an additional impact compared to adalimumab,
- the lack of evidence of an additional impact on the organisation of care, in particular recourse to elective surgery (cancellation or reduction of its extent),
- the lack of evidence of an additional impact on the care 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 (secukinumab) 150 and 300 mg solution for injection in pre-filled syringe and pen is low in the MA indication.

The Committee issues a favourable opinion for inclusion of COSENTYX (secukinumab) 150 mg and 300 mg solution for injection in pre-filled syringe in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 15%**

Clinical Added Value

Considering:

- demonstration in two phase 3 studies with the same protocol having included adult patients with moderate to severe hidradenitis suppurativa, most of whom were treated with antibiotic therapy (approximately 83%) before inclusion:
  - of the superiority of secukinumab (300 mg every two weeks) compared to placebo **in the SUNSHINE and SUNRISE studies**, with a modest effect size on all the endpoints, including the proportion of responders on the HiSCR50 score (primary endpoint; differences approximately of 11%, p = 0.007 and p = 0.0149), decrease in the number of inflammatory lesions and improvement in the NRS30 skin pain score (grouped analysis of both studies),
  - of the superiority of secukinumab (300 mg every 4 weeks) compared to placebo **only in the SUNRISE study,** with a modest effect size, on the percentage of responders on the HiSCR50 score (difference of 15%, p = 0.0022), decrease in the number of inflammatory lesions and decrease in the number of flares;
- exploratory medium-term results, at week 52, suggesting maintenance of the clinical responses observed at week 16 for the two dosage regimens;
- the safety profile of secukinumab in the short term (16 weeks) and medium term (52 weeks) similar to that established in the other MA indications, and similar between the two dosage regimens;
- the absence of a demonstrated benefit in terms of quality of life, which is nonetheless particularly impaired in moderate to severe forms of this disease, with the exception of the NRS30 pain score for the Q2W dosage regimen only;
- the lack of evidence of an impact on recourse to elective surgery (cancellation or reduction of its extent);

- the absence of comparison with adalimumab (HUMIRA), another treatment with a MA in hidradenitis suppurativa with an identical indication wording as that of COSENTYX (secukinumab),

the Committee deems that COSENTYX (secukinumab) 150 mg and 300 mg solution for injection in pre-filled syringe and pen provides no clinical added value (CAV V) in the care pathway for the treatment of active moderate to severe hidradenitis suppurativa in adults.