HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE

SUMMARY

16 SEPTEMBER 2020

secukinumab

COSENTYX 150 mg solution for injection in pre-filled syringe and pen

New indication

Key points

Favourable opinion for reimbursement in the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs).

What therapeutic improvement?

No therapeutic improvement compared to TNF inhibitors.

Role in the care pathway?

The joint objectives of treatment in patients with axial spondyloarthritis (axSpA) are to control symptoms (inflammation, pain and spinal stiffness) and prevent structural damage in order to preserve or improve the functional capacities, autonomy, social participation and quality of life of patients and obtain clinical remission or, failing this, a low level of disease activity.

The first-line medicinal treatment of axSpA is based on the use of NSAIDs (prescription on demand, adapted to the patient and the evolution of symptoms, up to the maximum dose) as a symptomatic treatment. In the event of failure or an inadequate effect of an NSAID used at the maximum tolerated dose, a switch of NSAID can be performed.

Adjuvant therapies such as analgesics can be combined with the NSAIDs for residual pain but systemic or local corticosteroid therapy is not justified in axial forms. Conventional synthetic disease-modifying

anti-rheumatic drugs (csDMARDs) (e.g., methotrexate, leflunomide, sulfasalazine) only appear to be effective in forms with peripheral joint involvement refractory to symptomatic treatment. Their efficacy in purely axial forms has not been demonstrated.

As second-line treatment, biologic therapies (bDMARDs) should be considered in patients with active disease despite NSAIDs. However, in the absence of inflammation demonstrated by laboratory tests or MRI, these biologic therapies are not indicated in nr-axSpA. A total of four TNF inhibitors (adalimumab, certolizumab pegol, etanercept, golimumab) and two IL-17A inhibitors (ixekizumab, secukinumab) have an MA in active nr-axSpA in the event of failure, inadequate response, intolerance or contraindication to NSAIDs.

According to the guidelines published by the French Radiology Society (SFR), TNF inhibitors are preferred as first-line treatment given current experience; however the lack of direct comparative data between them means that it is not possible to determine a hierarchy. In the event of loss of response, primary inefficacy or intolerance to a first TNF inhibitor, a rotation to a second TNF inhibitor or a switch to an IL-17A inhibitor are alternatives deemed to be beneficial.

Role of the medicinal product in the care pathway

The role of COSENTYX (secukinumab) in the treatment of active non-radiographic axial spondyloarthritis in patients who have responded inadequately to NSAIDs is as second-line therapy, following the failure of TNF inhibitors. In these patients, the available data do not enable a hierarchy between COSENTYX (secukinumab) and TALTZ (ixekizumab) to be determined.

Special recommendations

The Committee reiterates:

- that it is recommended to administer the first subcutaneous injection of this medicinal product in an appropriate healthcare setting given the rare but serious potential risk of systemic reactions to the injection, including anaphylactic reactions with subcutaneous secukinumab, as with other bDMARDs,
- and that it is important to manage cardiovascular risk factors given the increased cardiovascular risk in chronic inflammatory arthritis.

COMMITTEE'S CONCLUSIONS

Clinical benefit

◗ Axial spondyloarthritis without radiographic signs is a chronic disease which, in its severe form with an inadequate response or intolerance to NSAIDs, is painful and affects spinal mobility and functional capacities.
◗ These medicinal products are symptomatic disease-modifying treatments.
◗ Considering a size effect deemed to be modest, the efficacy/adverse effects ratio of COSENTYX is modest.
◗ There are therapeutic alternatives, i.e., TNF inhibitors (adalimumab, certolizumab pegol, etanercept and golimumab).
◗ In the treatment of patients with non-radiographic axial spondyloarthritis who have responded inadequately to NSAIDs, COSENTYX (secukinumab) is a second-line treatment to be used following the failure of TNF inhibitors (see paragraph 09 of this opinion).

Public health impact
Considering:
- the impact of active non-radiographic axial spondyloarthritis on the quality of life and functional capacities of patients, in particular in those in whom NSAIDs have failed,
- its prevalence,
- the medical need partially met by TNF inhibitors,
- demonstration of the superiority of secukinumab compared to placebo in terms of disease activity, functional capacities and quality of life in a randomised, double-blind, placebo-controlled study conducted in 555 adult patients with active non-radiographic axial spondyloarthritis who have responded inadequately to NSAIDs, but with a modest effect size,
- the lack of elements supporting the absence of a deterioration in the care and/or life pathway in the absence of comparative data versus clinically relevant comparators, i.e., TNF inhibitors, and the exploratory nature of the analysis conducted in patients in whom TNF inhibitors have failed (lack of management of multiplicity and small number of patients),
- the lack of any demonstrated impact on the organisation of care (hospitalisation, AE, etc.),
- the partial response to the identified medical need,

COSENTYX (secukinumab) is not expected to have an impact on public health in the treatment of non-radiographic axial spondyloarthritis.

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

The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the marketing authorisation indication and dosages.

Clinical Added Value

Considering :

- **the modest clinical benefit demonstrated versus placebo in the PREVENT study in terms of ASAS 40 responder rates in anti-TNFα-naïve patients (primary endpoint) and on all the ranked secondary endpoints, in particular quality of life,**
- **the absence of comparison with other TNF inhibitors, despite this being feasible,**

the Transparency Committee considers that the proprietary medicinal product COSENTYX (secukinumab) provides no clinical added value (CAV V) compared to TNF inhibitors in the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs).