HAUTE AUTORITÉ DE SANTÉ

RHEUMATOLOGY
New indication
April 2016

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

COSENTYX (secukinumab), anti-interleukin-17A immunosuppressant

No clinical benefit demonstrated by comparison with anti-TNF therapy in the treatment of ankylosing spondylitis

Main points

- COSENTYX has Marketing Authorisation for the treatment of active ankylosing spondylitis in adults in case of inadequate response to conventional treatment.
- Given the lack of direct comparison of secukinumab to anti-TNF therapy and more significant long-term data with the latter, COSENTYX must be reserved as second line, after failure of anti-TNF therapy.

Pre-existing indications[i]

COSENTYX has Marketing Authorisation in the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Therapeutic use

- Drug treatment of ankylosing spondylitis mainly involves the use of NSAIDs as first-line symptomatic therapy during episodes. If one NSAID fails or is not effective enough at the maximum tolerated dose, the NSAID used can be changed. Adjuvant treatments such as analgesics (e.g. corticosteroid injections) can be combined with them.
- The efficacy of disease-modifying antirheumatic drugs (DMARDs) (e.g. Sulfasalazine, methotrexate) in purely axial forms has not been demonstrated. In case of failure, insufficient response, intolerance or contraindication to NSAIDs, 5 TNF inhibitors are available: adalimumab, etanercept, infliximab, golimumab and certolizumab pegol. Due to the lack of direct comparison data, these different TNF inhibitors cannot be ranked. In the case of loss of response, primary inefficacy or intolerance to a first TNF inhibitor, a switch to a second TNF inhibitor may be considered. In case of failure of NSAIDs and TNF inhibitors, there is no alternative.
- **Role of the medicinal product in the therapeutic strategy**

  In the treatment of ankylosing spondylitis where NSAIDs have failed, TNF inhibitors should be favoured in 1st line. In the absence of any alternative medication, secukinumab, anti-interleukin-17A monoclonal antibody, is a new option in a disease where there is a therapeutic need, especially in patients who have failed anti-TNF therapy.

  Whatever the indication concerned, there is a potential rare but serious risk of a systemic reaction to the injection, including anaphylactic reactions with subcutaneous secukinumab, but also with other biologic DMARDs. The 1st subcutaneous injection of this medicinal product should be done at the hospital.

Clinical data

- In the only study that has evaluated the solution for injection in prefilled syringe and the approved dosing regimen of COSENTYX (induction and maintenance with 150 mg subcutaneous), 219 patients were randomised to receive secukinumab 75 mg once monthly (dosage not retained in the Marketing Authorisation), secukinumab 150 mg (only recommended dosage, n = 72) or placebo. The proportion of anti-TNF naïve patients was 61.2%.
  Concomitant treatments with NSAIDs, analgesics, corticosteroids and non-biologic DMARDs (sulfasalazine and/or methotrexate or other) were authorised under certain conditions. The superiority of secukinumab 150 mg at the approved dosage regimen compared to placebo was demonstrated in terms of the proportion of patients obtaining

[i] This summary does not cover this indication.

an ASAS 20 at week 16 (primary endpoint), absolute difference 32.7%. Subgroup analysis of a non-optimal level of evidence and on a small number suggested that secukinumab 150 mg was superior to placebo in both patients who had never received anti-TNF therapy and in those who were previously treated (absolute benefit 37.1% in naïve patients and 25.9% in previously treated patients). No study compared secukinumab to a TNF inhibitor, although at the date of completion of the studies, four TNF inhibitors had a Marketing Authorisation in this disease and the majority of the patients included were naïve to anti-TNF therapy.

- No new safety signals have been identified in this indication; long-term safety data are limited.

Special prescribing conditions

- Medicine for initial annual hospital prescription
- Initial and repeat prescription restricted to specialists in dermatology, rheumatology or internal medicine.

Benefit of the medicinal product

- In the treatment of ankylosing spondylitis, the actual clinical benefit* of COSENTYX is significant.
- COSENTYX does not provide improvement of actual clinical benefit** (IACB V) by comparison with anti-TNF therapy.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 20 April 2016 (CT-14979) and is available at **www.has-sante.fr**

* The actual clinical benefit (ACB) of a medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. HAS Transparency Committee assesses the ACB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The improvement of actual clinical benefit (IACB) describes the improvement in treatment provided by a medicinal product compared with existing treatments. HAS Transparency Committee assesses the degree of IACB on a scale from I (major) to IV (minor). A level V IACB (equivalent of “no IACB”) means "no clinical added value".