Plaque psoriasis
Paediatrics
Sectors: Retail and hospital

HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
20 JANUARY 2021
The legally binding text is the original French opinion version

secukinumab

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

COSENTYX 150 mg powder for solution for injection
Inclusion in list

Key points

Favourable opinion for reimbursement only in the treatment of severe chronic plaque psoriasis in children and adolescents from the age of 6 years, defined by:

- failure (insufficient response, contraindication or intolerance) of at least two treatments including non-biologic systemic treatments and light therapy
- and an extensive form and/or significant psychosocial impact.

Unfavourable opinion for reimbursement in other situations.

What therapeutic improvement?

No clinical added value in the therapeutic strategy on the basis of currently available data.

Role in the care pathway?

The treatment of moderate to severe forms of plaque psoriasis in children is not very different to that in adults, but there are fewer validated treatments in children.

In forms resistant to topical treatments, treatment involves non-biologic systemic treatments (retinoids, ciclosporin, methotrexate) and light therapy. Calcitriol is the only vitamin D3 analogue to have a marketing authorisation in children and methotrexate only has a marketing authorisation in adults. The toxicity of these treatments limits their use over time and light therapy is not recommended in children. The prescription of acitretin is subject to a pregnancy prevention plan.

In the event of failure of these second-line treatments, TNF antagonists (etanercept and adalimumab) or interleukin inhibitors (ustekinumab or secukinumab) are used. Etanercept (ENBREL) and ustekinumab (STELARA) have a marketing authorisation in plaque psoriasis in children from 6 years of age and adalimumab (HUMIRA) from 4 years of age.

These treatments do not definitively cure the condition but can enable a transient and more or less complete disappearance of the lesions. The care pathway is “rotational”, due, in particular to resistance phenomena.

Role of the medicinal product in the care pathway

As with the other biologic therapies with an MA in paediatric psoriasis and as in adults, the Committee considers that the role of COSENTYX (secukinumab) in children and adolescents from the age of 6 years, is as second-line therapy only in the treatment of severe chronic plaque psoriasis, defined by:

- failure (insufficient response, contraindication or intolerance) of at least two treatments including non-biologic systemic treatments and light therapy
- and an extensive form and/or significant psychosocial impact.

Outside these situations, it has no role in the care pathway.

Special recommendations

Given the risk of hypersensitivity reactions with secukinumab administered subcutaneously (see section 4.4 of the SPC), but also with other biologics, the Transparency Committee recommends that the first subcutaneous injection of this medicinal product be given in an appropriate care structure.

COMMITTEE'S CONCLUSIONS

Clinical benefit

◗ Psoriasis is a chronic inflammatory skin condition, usually benign, that can, in its moderate to severe forms, have a significant impact on quality of life.

◗ The proprietary medicinal products COSENTYX 150 mg (secukinumab) solution for injection in pre-filled syringe or pre-filled pen and powder for solution for injection have a suspensive effect on symptoms.

◗ Their efficacy/adverse effects ratio is high. However, no long-term data is available.

◗ There are few therapeutic alternatives in children and adolescents (etanercept, adalimumab and ustekinumab).

◗ In children and adolescents from the age of 6 years, these medicinal products are second-line systemic therapies in the treatment of severe chronic plaque psoriasis, defined by:
- failure (insufficient response, contraindication or intolerance) of at least two treatments including non-biologic systemic treatments and light therapy
- and an extensive form and/or significant psychosocial impact.

Outside these situations, these proprietary medicinal products have no role.

Public health impact

Considering:
- the seriousness of the disease and the marked impairment in quality of life,
- its low prevalence in children,
- the partially met medical need in this population,
- the partial response to the identified need given the efficacy demonstrated versus placebo but the absence of robust comparative data versus the available alternatives,
- the lack of demonstrated impact on quality of life,
- the lack of additional impact demonstrated on the 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 (secukinumab) solution for injection in pre-filled syringe or pre-filled pen and powder for solution for injection is substantial only in the treatment of chronic severe plaque psoriasis in children and adolescents from the age of 6 years, defined by:
- **failure (insufficient response, contraindication or intolerance) of at least two treatments including non-biologic systemic treatments and light therapy**
- **and an extensive form and/or significant psychosocial impact.**

In other forms, the clinical benefit is insufficient to justify public funding cover.

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 only in the treatment of severe chronic plaque psoriasis in children and adolescents from the age of 6 years, defined by:
- **failure (insufficient response, contraindication or intolerance) of at least two treatments including non-biologic systemic treatments and light therapy**
- **and an extensive form and/or significant psychosocial impact.**

and at the MA dosages.

◗ **Recommended reimbursement rate: 65 %**

Clinical Added Value

Considering:

- **demonstration in a phase 3, randomised, double-blind study of the superiority of secukinumab compared to placebo with a clinically relevant difference at week 12 in terms of PASI 75 response (absolute difference of around 65% irrespective of dose) and IGA mod 2011 = 0 or 1 (absolute difference of around 64% for the low-dose group and 56% for the high-dose group) (primary co-endpoints),**
- **the short-term safety profile globally similar to that observed in adults,**

but taking into account:

- **the purely exploratory data versus ENBREL (etanercept) and the absence of comparison with the other alternatives available, HUMIRA (adalimumab) and STELARA (ustekinumab),**
- **uncertainties with respect to long-term safety given the experience limited to 52 weeks,**

the Transparency Committee considers that the proprietary medicinal product COSENTYX 150 mg (secukinumab) solution for injection in pre-filled syringe or pre-filled pen and powder for solution for injection provides no clinical added value (CAV V) in the treatment of severe chronic plaque psoriasis in children and adolescents from the age of 6 years.