SUMMARY

ENBREL 10, 25 and 50 mg, HUMIRA 20 and 40 mg, STELARA 45 and 90 mg, COSENTYX 75, 150 and 300 mg

Reassessment

Original French opinion adopted by the Transparency Committee on 15 March 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion on reimbursement in its MA indication.

Role in the care pathway?

In view of the maintenance of the medium-term (W52) indeed long-term efficacy of etanercept (5 years) and of the absence of new signs related to tolerance observed after several years of use, the Committee now considers that**:**

- ENBREL (etanercept) is a second-line systemic treatment for use in the severe forms of chronic plaque psoriasis in children and adolescents from 6 years of age in the event of failure (insufficient efficacy, contraindication or intolerance) with a first-line non-biological systemic treatment or possibly phototherapy;
- HUMIRA (adalimumab) is a second-line systemic treatment for use in the severe forms of chronic plaque psoriasis in children and adolescents from 4 years of age in the event of failure (insufficient efficacy, contraindication or intolerance) with a first-line non-biological systemic treatment or possibly phototherapy;
- STELARA (ustekinumab) is a second-line systemic treatment for use in the moderate-to-severe forms of chronic plaque psoriasis in children and adolescents from 6 years of age in

the event of failure (insufficient efficacy, contraindication or intolerance) with a first-line non-biological systemic treatment or possibly phototherapy;

- COSENTYX (secukinumab) is a second-line systemic treatment for use in the moderate-to-severe forms of chronic plaque psoriasis in children and adolescents from 6 years of age in the event of failure (insufficient efficacy, contraindication or intolerance) with a first-line non-biological systemic treatment or possibly phototherapy;

The decision to initiate treatment must take account of the history of the disease, patient characteristics, treatment history and disease severity, which is appraised in terms of the appearance of the lesions as well as in terms of their extent, the impact of the disease on quality of life and the extent of its psychosocial impact.

The summary of product characteristics (SmPC) and the Risk Management Plan (RMP) must be respected.

The use of this medicinal product in pregnant or breastfeeding women must comply with the SmPC (http://lecrat.fr/).

Transparency Committee's Conclusions

Clinical Benefit

ENBREL (etanercept)

- Plaque psoriasis is a chronic inflammatory dermatosis, most often benign which can, in its moderate-to-severe forms, have a significant impact on quality of life.
- ENBREL (etanercept) is a suspensive symptomatic treatment.
- The efficacy/adverse effect ratio is significant.
- There are therapeutic alternatives.
- This medicinal product is a second-line systemic treatment for use in the severe forms of chronic plaque psoriasis in children and adolescents from 6 years of age in the event of failure (insufficient efficacy, contraindication or intolerance) with a first-line non-biological systemic treatment or possibly phototherapy.

Public health benefit

In view of:

- the gravity of the disease and the significant deterioration in quality of life and its low prevalence in children,
- the partially met medical need in this population,
- the partial response to the partially met need identified, in view of:
  - the impact demonstrated versus placebo in the PASI 75, but of the absence of robust comparative data versus the available alternatives,
  - the absence of proven impact on quality of life,
  - the absence of proven impact on the organisation of care, the patient's care pathway and life course,

ENBREL (etanercept) is not liable to have an additional impact on public health.

HUMIRA (adalimumab)

- Plaque psoriasis is a chronic inflammatory dermatosis, most often benign which can, in its moderate-to-severe forms, have a significant impact on quality of life.
- HUMIRA (adalimumab) is a suspensive symptomatic treatment.
- The efficacy/adverse effect ratio is significant.
- There are therapeutic alternatives.
- This medicinal product is a second-line systemic treatment for use in the severe forms of chronic plaque psoriasis in children and adolescents from 4 years of age in the event of failure (insufficient efficacy, contraindication or intolerance) with a first-line non-biological systemic treatment or possibly phototherapy.

Public health benefit

In view of:

- the gravity of the disease, the significant deterioration in quality of life and its low prevalence in children,

- the partially met medical need in this population,
- the partial response to the partially met need identified, in view of:
  - the impact demonstrated versus methotrexate on the percentage of PASI 75 responders but of the failure to demonstrate superiority with regard to the percentage of PGA 0 or 1 responders
  - the absence of proven impact on quality of life,
  - the absence of proven impact on the organisation of care, the patient's care pathway and life course,

HUMIRA (adalimumab) is not liable to have an additional impact on public health.

STELARA (ustekinumab)

- Plaque psoriasis is a chronic inflammatory dermatosis, most often benign which can, in its moderate-to-severe forms, have a significant impact on quality of life.
- STELARA (ustekinumab) is a suspensive symptomatic treatment.
- The efficacy/adverse effect ratio is significant.
- There are therapeutic alternatives.
- This medicinal product is a second-line systemic treatment for use in the moderate-to-severe forms of chronic plaque psoriasis in children and adolescents from 6 years of age in the event of failure (insufficient efficacy, contraindication or intolerance) with a first-line non-biological systemic treatment or possibly phototherapy.

Public health benefit

In view of:

- the gravity of the disease, the significant deterioration in quality of life and its low prevalence in children,
- the partially met medical need in this population,
- the partial response to the partially met need identified, in view of:
  - the expected impact but of the limited clinical data in children based on descriptive data on efficacy, tolerance and pharmacokinetics, but supported by clinical and pharmacokinetic data in adults and adolescents,
  - the absence of robust data on quality of life,
  - the absence of proven impact on the organisation of care, the patient's care pathway and life course,

STELARA (ustekinumab) is not liable to have an additional impact on public health.

COSENTYX (secukinumab)

- Plaque psoriasis is a chronic inflammatory dermatosis, most often benign which can, in its moderate-to-severe forms, have a significant impact on quality of life.
- COSENTYX (secukinumab) is a suspensive symptomatic treatment.
- The efficacy/adverse effect ratio is significant.
- There are therapeutic alternatives.
- This medicinal product is a second-line systemic treatment for use in the moderate-to-severe forms of chronic plaque psoriasis in children and adolescents from 6 years of age in the event

of failure (insufficient efficacy, contraindication or intolerance) with a first-line non-biological systemic treatment or possibly phototherapy.

➔ Public health benefit

In view of:

- the gravity of the disease, the significant deterioration in quality of life and its low prevalence in children,
- the partially met medical need in this population,
- the partial response to the partially met medical need identified, in view of:
  - the impact demonstrated versus placebo in the PASI 75 response and the IGA/01 response but of the absence of robust comparative data versus the available alternatives,
  - the absence of proven impact on quality of life,
  - the absence of proven impact on the organisation of care, the patient's care pathway and life course,

COSENTYX (secukinumab) is not liable to have an additional impact on public health.

In view of all of these elements, the Committee considers that the clinical benefit provided by the medicinal products HUMIRA (adalimumab), ENBREL (etanercept), STELARA (ustekinumab) and COSENTYX (sécukinumab) becomes significant in their respective MA indications.

The Committee gives a favourable opinion on the maintenance of inclusion on the list of medicinal products reimbursable to persons insured under social insurance schemes and on the list of medicinal products approved for the use of communities in the indication and at the MA doses.

Recommended reimbursement rate: 65 %