HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
11 JULY 2022

The legally binding text is the original French opinion version

Certolizumab pegol
CIMZIA 200 mg

Reassessment

Key points

Reassessment for the indication of adult plaque psoriasis: Retention of approval for reimbursement for the entire marketing authorisation indication.

Role in therapeutic strategy?

Current psoriasis treatments do not definitively cure the condition, but help lesions temporarily resolve, more or less completely. The therapeutic arsenal includes topical and systemic treatments. Topical treatments may be used alone or in association with each other or with systemic treatments.

In the most severe forms, systemic treatments will be used: methotrexate (conventional treatment), ciclosporin as an alternative to methotrexate, retinoids (acitretin) in some clinical forms or in association with phototherapy.
According to the 2019 French Dermatology Society (SFD) guidelines, methotrexate remains the conventional systemic treatment for extensive or severe forms of psoriasis. The alternative is ciclosporin, for which the duration of treatment is often limited by renal toxicity and the risk of arterial hypertension. Retinoids (acitretin) have a benefit in some clinical forms, particularly diffuse forms, or in association with phototherapy.
Biological systemic treatments are proposed after conventional treatments have failed. Anti-TNF drugs (etanercept, adalimumab, infliximab, certolizumab pegol), an anti-IL-12/23 drug (ustekinumab), anti-IL17 drugs (secukinumab and ixekizumab), an anti-IL17 receptor (brodalumab), an anti-IL17A/17F drug (bimekizumab) and anti-IL23 drugs (guselkumab, risankizumab and tildrakizumab) are available. Apremilast, a phosphodiesterase 4 inhibitor is also available. Its role in the therapeutic strategy is poorly defined in the absence of comparison to biological systemic treatments. The SFD guidelines, particularly with respect to the ranking of use of these treatments, are currently being updated.
In its opinions of 5 May 2021, pertaining to the reassessment of 4 biological systemic medicinal products, considering:
- the reassuring data from the PSOBIOTEQ 1 observational study, on patients commencing ENBREL (etanercept), REMICADE (infliximab), HUMIRA (adalimumab) or STELARA (ustekinumab) treatment on compliance with conditions for placing patients under treatment in terms of symptom severity, extent of lesions, impact on quality of life, and previous treatment history, and
- the updated pharmacovigilance data demonstrating an overall unchanged safety profile,
the Committee deemed that these proprietary medicinal products were second-line systemic treatments for moderate to severe forms of adult plaque psoriasis in the event of failure (lack of efficacy, contraindication or intolerance) of a first-line non-biological systemic treatment (methotrexate, ciclosporin or acitretin), and of phototherapy if applicable. The Committee pointed out that methotrexate remained the conventional basic non-biological treatment, in accordance with French Dermatology Society guidelines (2019).
The decision whether to place under treatment must account for the disease history, the patient's characteristics, previous history of treatment and severity of the disease, assessed with regard to the appearance and extent of lesions, the impact of the disease on quality of life, and the significance of its psychosocial impact.

Role of the medicinal product:
Considering:
- the long-term efficacy data demonstrating the continued efficacy of these medicinal products;
- the reassuring data from the PSOBIOTEQ 2 observational study on compliance with the conditions for placing patients under treatment in terms of symptom severity, extent of lesions, impact on quality of life, and previous treatment history, among patients having commenced COSENTYX (secukinumab), TALTZ (ixekizumab), KYNTHEUM (brodalumab) treatment;
- the pharmacovigilance demonstrating the equivalence between infliximab by the subcutaneous (SC) route, and infliximab by the intravenous (IV) route (REMSIMA 100 mg (IV), a biosimilar of REMICADE, previously reassessed) among patients with rheumatoid arthritis and the non-inferiority of infliximab SC with respect to infliximab IV among patients with Crohn's disease or ulcerative colitis, supplemented by clinical data demonstrating the equivalence between the SC and IV forms of infliximab in patients with rheumatoid arthritis;
- the updated pharmacovigilance data demonstrating an overall unchanged safety profile for these medicinal products,

the Committee deems that the proprietary medicinal products REMSIMA 120 mg (SC) (infliximab), CIMZIA (certolizumab pegol), COSENTYX (secukinumab), TALTZ (ixekizumab), KYNTHEUM (brodalumab), TREMFYA (guselkumab), SKYRIZI (risankizumab) and ILUMETRI (tildrakizumab) are second-line systemic treatments for moderate to severe forms of adult plaque psoriasis in the event of failure (lack of efficacy, contraindication or intolerance) after a first-line non-biological treatment (methotrexate, ciclosporin or acitretin), and of phototherapy if applicable. The Committee points out that methotrexate remains the conventional basic non-biological treatment, in accordance with SFD guidelines (2019). The decision whether to place under treatment must account for the disease history, the patient's characteristics, previous history of treatment and severity of the disease, assessed with regard to the appearance and extent of lesions, the impact of the disease on quality of life, and the significance of its psychosocial impact.

COMMITTEE'S CONCLUSIONS

Actual Clinical Benefit

◗ Plaque psoriasis is a generally mild chronic inflammatory skin condition, which may, in its moderate to severe forms, have a significant impact on quality of life.

◗ CIMZIA (certolizumab pegol) falls within the scope of curative treatment.

◗ The efficacy/adverse effect ratio is significant.

◗ There are many alternative medications.

◗ This proprietary medicinal product is a second-line systemic treatment for moderate to severe forms of adult plaque psoriasis in the event of failure (lack of efficacy, contraindication or intolerance) of a first-line non-biological systemic treatment (methotrexate, ciclosporin or acitretin), and of phototherapy if applicable. The decision whether to place under treatment must account for the disease history, the patient's characteristics, previous history of treatment and severity of the disease, assessed with regard to the appearance and extent of lesions, the impact of the disease on quality of life, and the significance of its psychosocial impact (see Section 12. Role in therapeutic strategy).

Public health benefit

Considering:
- the severe impairment of patients in chronic forms of psoriasis resistant to non-biological systemic treatments or phototherapy, associated with a significant impairment of quality of life,
- the prevalence of moderate to severe forms of psoriasis,
- the identified incompletely met medical need,
- the partial response to the identified need due to the demonstrated impact in terms of morbidity but also treatment failure phenomena,
- the evidence of an impact in terms of quality of life versus placebo, in CIMPASI phase III studies 1 and 2, in the short term (16 weeks), and the continued impact in the long term (144 weeks),
- the lack of evidence of an additional impact in terms of delivery or care and/or the patient's life, CIMZIA 200 mg (certolizumab pegol) is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit of CIMZIA (certolizumab pegol) is significant in the marketing authorisation indication.

The Committee approves continued inclusion in the list of proprietary medicinal products qualifying for reimbursement under social security and in the list of proprietary products approved for community use in the indication and at the dosages of the marketing authorisation.

Clinical Added Value

Considering all of this information and after discussions and voting, the Committee deems that the clinical added value (CAV) remains unchanged in the marketing authorisation indication: CAV V with respect to biological systemic treatments (anti-TNFα and anti-interleukin drugs)