HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
19 FEBRUARY 2020

methotrexate
METOJECT solution for injection in a pre-filled pen

New indication

Key points

Favourable opinion for reimbursement in the treatment of moderate psoriasis in adult patients who are candidates for systemic therapy.

What therapeutic improvement?

No clinical added value compared to first-line systemic therapies.

Role in the care pathway?

The therapeutic arsenal for the treatment of psoriasis includes topical treatments (dermocorticosteroids, vitamin D3 analogues, retinoids) for the treatment of mild forms and systemic treatments aimed at moderate to severe forms: methotrexate, light therapy, retinoids, ciclosporin, and, if these treatments fail or are contraindicated or not tolerated, apremilast, TNFα inhibitors and interleukin inhibitors (IL12/IL23 inhibitors, IL17 inhibitors, IL17 receptor inhibitors and IL23 inhibitors).
Recent French Dermatology Society recommendations (2019) relative to the treatment of moderate to severe plaque psoriasis specified the role of these different treatments in the care pathway.
Due to its low efficacy, the use of acitretin as monotherapy is not recommended, except in patients in whom methotrexate and ciclosporin are contraindicated.
Ciclosporin cannot be used as a long-term treatment due to its toxicity. It is recommended in patients requiring rapid control of the disease as an alternative to methotrexate (Grade B) and in pregnant or breastfeeding women or patients wishing to conceive (women and men), in whom methotrexate is contraindicated (Grade A).
Narrow-band UVB light therapy can be used as first-line treatment as an alternative to methotrexate (Grade A). However, this therapy is not widely available in France. It is recommended that it be proposed, where available, to treatment-compliant patients who cannot follow a PUVA therapy protocol.
PUVA therapy and an acitretin-PUVA therapy combination, rather than narrow-band UVB light therapy, are recommended in patients with extensive, thick plaques, except in young women (Grade C).
A PUVA therapy and acitretin combination is recommended if PUVA therapy alone has failed.
These treatments do not definitively cure the condition but can enable a transient and more or less complete disappearance of the lesions, and the care pathway is “rotational”, due, in particular to resistance phenomena.

Role of the medicinal product in the care pathway

In the indication extension to moderate psoriasis in adult patients who are candidates for systemic therapy, METOJECT (methotrexate) solution for injection in a pre-filled pen is a first-line systemic therapy.

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.
- METOJECT (methotrexate) is a symptomatic treatment.
- Its efficacy/adverse effects ratio in moderate psoriasis in adult patients who are candidates for systemic therapy is high.
- In moderate psoriasis in adult patients who are candidates for systemic therapy, this proprietary medicinal product is a first-line systemic therapy.
- There are therapeutic alternatives.

Public health impact:

Considering:

- the seriousness of the disease, which can impair quality of life in moderate forms,
- the prevalence of moderate forms in adults, estimated to be a maximum of 135,000 patients,
- the partially met medical need,
- the absence of robust data on quality of life,
- the lack of any demonstrated impact on the organisation of care,
- the contribution of METOJECT (methotrexate), in the same way as other first-line systemic therapies, to meeting the identified medical need,

METOJECT (methotrexate) is unlikely to have an additional impact on public health.

Considering these elements, the Committee deems that the clinical benefit of METOJECT (methotrexate) is substantial in the treatment of moderate psoriasis in adult patients who are candidates for systemic therapy and at the MA dosages.

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 indication extension to "treatment of moderate psoriasis in adult patients who are candidates for systemic therapy" and at the MA dosages.

Clinical Added Value

Considering:
- **the demonstrated superiority of methotrexate for injection compared to placebo in adult patients with moderate to severe psoriasis in terms of PASI 75 responders, who are candidates for systemic therapy,**
- **the absence of any comparison with other first-line systemic therapies,**

the Transparency Committee considers that METOJECT (methotrexate) provides no clinical added value (CAV V) compared to other first-line systemic therapies in the treatment of moderate psoriasis in adult patients who are candidates for systemic therapy.