

TRANSPARENCY COMMITTEE OPINION 06 NOVEMBER 2019

methotrexate
METOJECT, solution for injection in a pre-filled pen

New indication

► Key points

Approved for reimbursement in the indication for the treatment of mild to moderate forms of Crohn's disease, alone or in combination with corticosteroids, in adult patients resistant or intolerant to thiopurines.

► What therapeutic improvement?

No clinical added value.

► Role in the care pathway?

METOJECT is a second-line treatment for mild to moderate forms of Crohn's disease, in adults resistant or intolerant to thiopurines and corticosteroid-dependent; in moderate forms, an anti-TNF may also be prescribed.

COMMITTEE'S CONCLUSIONS

Actual benefit

In the treatment of Crohn's disease:

► Crohn's disease is a chronic inflammatory bowel disease. It progresses by flare-ups interspersed with remissions. It is a debilitating condition which can lead to a marked deterioration in quality of life.

► METOJECT is a symptomatic treatment.

► The efficacy/adverse effects ratio of subcutaneous methotrexate in the treatment of mild to moderate forms of Crohn's disease, alone or in combination with corticosteroids, in adults resistant or intolerant to thiopurines, is moderate.

► There are alternatives for the management of patients resistant or intolerant to thiopurines (see clinically relevant comparators paragraph).

► METOJECT is a second-line treatment for mild to moderate forms of Crohn's disease, in adults resistant or intolerant to thiopurines and corticosteroid-dependent; in moderate forms, an anti-TNF may also be prescribed.

Considering:

- the frequency and severity of Crohn's disease,
- the medical need identified in mild to moderate forms of Crohn's disease in adult patients who are resistant or intolerant to thiopurines,
- the partial response to the medical need identified in adult patients resistant or intolerant to thiopurines, with an established efficacy versus placebo, but with a moderate level of evidence,
- the lack of demonstrated impact on the organisation of care (hospitalisation, AE, etc.)

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

Given all of these elements, the Committee considers that the actual benefit of METOJECT is moderate in the MA indication.

The Committee issues a positive opinion for both hospital and retail formulary listing of reimbursed pharmaceutical products approved for use in the "treatment of mild to moderate forms of Crohn's disease, either alone or in combination with corticosteroids, in adult patients resistant or intolerant to thiopurines" and at the MA dosages.

Recommended reimbursement rate: 30%

Clinical Added Value

Considering:

- the demonstrated superiority of methotrexate over placebo in adult patients with mild to moderate Crohn's disease, active despite the use of corticosteroids, with a moderate level of evidence;
- lack of efficacy data in the METOJECT MA population, namely patients faced with thiopurine failure;
- the lack of data versus active treatment: 6-mercaptopurine (off-label) in mild forms and especially an anti-TNF in moderate forms after failure of at least one immunosuppressant;
- the safety profile of methotrexate, including troublesome digestive disorders causing patients to stop treatment;

the Transparency Committee considers that METOJECT does not provide any clinical added value (CAV V) in the management strategy for Crohn's disease.