HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
23 OCTOBER 2019

budesonide
CORTIMENT 9 mg, tablet

Reassessment

Key points

Approved for maintaining the reimbursement in the remission induction treatment of adult patients suffering from a mild to moderate active ulcerative colitis (UC) for which 5-ASA treatment is insufficient.

Actual clinical benefit now low (previously high) in the remission induction treatment of adult patients suffering from a mild to moderate form of active UC for which 5-ASA treatment is insufficient.

What therapeutic improvement?

No clinical added value in the management of ulcerative colitis.

Role in the care pathway?

CORTIMENT, a locally acting oral corticosteroid, is a treatment for inducing remission of mild to moderate forms of UC. It is used as a second-line treatment, after optimisation of 5-ASA treatment (increase in dosage, joint administration of a rectal treatment for lower forms) and before systemic corticosteroid therapy. It could reduce the use of systemic corticosteroid therapy and therefore, in part, the associated complications. It is particularly useful in case of contraindication or intolerance to systemic corticosteroid therapy and in patients refusing it. CORTIMENT has no role in maintenance treatment.

Nevertheless, the committee considers that this strategy must be confirmed by clinical data with good methodological quality comparing the efficacy of CORTIMENT to a systemic corticosteroid. Only these data would demonstrate that the expected reduction of some undesirable effects with CORTIMENT is not offset by a loss of chance for patients due to lower efficacy and/or the more rapid onset of corticosteroid resistance.

Given its modest efficacy, in case of worsening of the disease or clinical signs, more effective but less well tolerated systemic corticosteroids therapy should be considered immediately without any delay or using the additional step represented by CORTIMENT.

Special recommendations

The Committee once again notes that it is usually recommended to gradually reduce the dose of corticosteroid, but the current dosage form of CORTIMENT does not allow this.

COMMITTEE'S CONCLUSIONS

Clinical benefit

◗ UC is a chronic inflammatory bowel disease (IBD) that results in severe chronic bloody diarrhoea, progressing in flare-ups. It leads to a marked deterioration in quality of life and exposes patients to serious complications: acute colitis, dysplasia and colon cancer.
◗ CORTIMENT is part of a symptomatic treatment regimen.
◗ In view of its modest efficacy versus placebo and its safety profile with low risk of systemic adverse effects, its efficacy/adverse effects ratio is low in mild to moderate forms of the disease.
◗ CORTIMENT remains a second-line induction treatment after optimisation of treatment with 5-ASA and before the use of systemic corticosteroids.

Public health benefit

Considering:
- the frequency and severity of UC,
- the need for new effective and better tolerated treatments for mild to moderate forms of UC,
- the lack of demonstration, in the current state of the dossier, of a response to the identified need,

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

Given all of these elements, the Committee considers that the clinical benefit of CORTIMENT is low in the MA indication.

The Committee maintains a positive opinion for both hospital and retail formulary listing of reimbursed pharmaceutical products approved for use by market authorization and dosages.

◗ **Recommended reimbursement rate: 15 %**

Reassessment of the Clinical Added Value

The assessment made previously by the Committee remains unchanged. Considering:
- **the demonstrated superiority of CORTIMENT 9 mg over placebo in strict terms of remission, both clinical and endoscopic, but with an at best modest quantity of effect and,**
- **the lack of comparative data with another active medicinal product, when this was possible: 5-ASA and, more importantly, systemic corticosteroid,**

the Transparency Committee considers that CORTIMENT provides no clinical added value (CAV V) in the ulcerative colitis care pathway.