

Budesonide prolonged release multi-matrix tablets (Cortiment[®]) for ulcerative colitis

NHS Devon

Commissioning policy

The routine commissioning of budesonide 9mg prolonged release multi-matrix tablets used for up to 8 weeks treatment is not accepted in Devon for induction of remission in adults with mild to moderate active ulcerative colitis where 5-aminosalicylic acid (5-ASA) treatment is not sufficient. The Formulary Interface Group should not include this in locally defined treatment recommendations.

Rationale for the decision

Budesonide prolonged release multi-matrix tablet is a corticosteroid that is taken orally, and designed to exert its action topically in the colon. Compared to placebo a significantly higher proportion of patients with active mild to moderate ulcerative colitis achieved combined clinical and endoscopic remission at week 8 with budesonide 9mg tablets. There was no statistically significant difference between budesonide 9mg tablets and placebo for clinical improvement assessed independently at week 8. It is not known how budesonide prolonged release multi-matrix tablets compare to other treatments that are currently used when 5-ASA is insufficient, in terms of efficacy and safety for ulcerative colitis; no powered direct head-to-head evidence was available during the review, and as such a clinical advantage of over existing products has not been demonstrated.

In the clinical trials most adverse events were of mild to moderate intensity and of a non-serious nature. There appears to be a reduction in plasma cortisol following 8 weeks treatment with budesonide prolonged release multi-matrix tablets, and glucocorticoid-related adverse effects have been demonstrated in the trials, albeit at a similar rate to placebo. Although it was acknowledged that there may be a niche group of patients for whom this treatment might be considered appropriate it was considered that the clinical and safety evidence is limited at the present time.

The direct acquisition cost of budesonide 9mg prolonged release multi-matrix tablets is higher than other established oral corticosteroid treatment options. Given the limitations in the evidence it is considered that the cost of treatment is not justified by the effectiveness demonstrated.

Guidance notes on exceptionality

This general policy does not replace clinical judgement on the appropriate treatment of an individual patient. Where a specialist believes this treatment is the only option and other commissioned treatments are not appropriate, an application may be made to their acute trust's DTC for approval to use this treatment on an individual patient basis. If approved, the specialist shall retain responsibility for prescribing the treatment for that patient for a minimum of six months. If, after this time, the treatment has been shown to be successful, the specialist may ask the GP to take on prescribing.

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