NHS ENGLAND SPECIALISED SERVICES

CLINICAL PANEL REPORT

Date: 19 June 2019

Intervention: Vedolizumab

Indication: children and adolescents with paediatric ulcerative colitis

ID: 1862

Gateway: 2 (Round 1)

Programme: Women and Children

CRG: Paediatric Medicine

Information provided to the panel

Cover Note from the Programme of Care

Policy Proposition

Evidence Review undertaken by NICE Medicines and Technologies Programme

CPAG Summary Report

Key elements discussed

This is a not for routine commissioning policy proposition for active ulcerative colitis and not responding to current treatment. This treatment, an immunosuppressive biological medication, is licensed in adults so this would be an off-label use (NICE have a Technology Appraisal covering recommending this in adults with this condition, with evidence based on three large multi-centre trials which is a different evidence base to this group).

The evidence review consisted of one multi-centre retrospective observational study with no comparison of efficacy and safety with other treatment. There was a mix of presentation, received intravenous infusion, some had an increased. Did not show evidence of clinical effectiveness.

The outcome measure in the study was remission. There was some reduction in steroid use from baseline to 12 months demonstrated however, no statistical analysis was presented in the paper regarding the significance of this. There was a reduction in stool calprotectin level and colonoscopic assessment showed that some healing was achieved in two patients at follow up. Marginal benefit was shown but this study included children with other inflammatory bowel conditions and it was a poorly designed study so difficult to draw any conclusions from this.

No standard dosing regimen was used in the studies reviewed. The induction regime in the presented study was different than in the licensed indication and did not evidence intravenous delivery benefit. Some patients had their dose increased after the initial induction course.

Panel considered there was no evidence base for pre-pubertal children. Discussion took place regarding the proposition title as the Programme of Care recommended changing the title to pre-pubescent children so post pubescent children would be able to access through the NHS England Medicines for Children policy.

Minor adverse events noted, however usage was discontinued in 22% children due to poor response.

Recommendation

Clinical Panel recommend progressing as a not for routine policy proposition, as proposed.

Why the panel made these recommendations

The evidence base is sparse in pre-pubertal children and evidence is supported by a NICE appraisal in adults which could be translatable in post pubescent children, hence they would be able to access treatment through the NHS England Medicines for Children policy.

Documentation amendments required

Change the policy proposition title to pre-pubertal children rather than children and young people.

Declarations of Interest of Panel Members: None

Panel Chair: James Palmer, Medical Director

Post Panel Note:

Policy proposition name changed as requested by Clinical Panel.