

NICE technology Appraisal of Infliximab for use in acute exacerbations of Ulcerative Colitis

I would like to express the views of the UK paediatric inflammatory bowel disease (IBD) working group on the use of Infliximab in paediatric patients with severe ulcerative colitis. I am aware that it is not licensed for this use in children in the UK but we feel that it should have been considered in this appraisal.

Children with severe colitis have very similar rates of colectomy as those in adult patients and recent data have shown patients in the paediatric age range are more likely to present with pancolitis (total colitis) at presentation and if not, to progress to total colitis more quickly than in the adult population. Thus the need for effective treatment quickly may be greater in the paediatric group.

Intravenous steroids are used as in the adult population so after 3 days of intravenous steroids if not responding (> 8 stools per day or $CRP > 45\text{mg/dl}$) further treatment is considered. Paediatric gastroenterologists would then commence intravenous cyclosporine 2mg/kg but it is extremely difficult to establish satisfactory blood levels which are the yardstick used to confirm effective dosage of cyclosporine. Inadequate trough levels in the blood then necessitate need to increase the dose of cyclosporine and obviously delay the time taken to reach effective intravenous levels. In addition, there is great concern about toxicity in patients receiving cyclosporine particularly adverse effects on renal function, hypertension, increased risk of infection and mortality. Surgeons are unhappy to operate on patients who are rendered more immunocompromised by their treatment in conjunction with their underlying colitis.

Paediatric gastroenterologists are increasingly using Infliximab instead of Cyclosporin as we have become familiar with its use and consider that it has fewer potential side-effects than cyclosporine. In addition, cost effectiveness in this population may be even more favourable than in the adult population as there may be fewer vials of Infliximab used per patient due to their lower weight. Although there has been no formal audit, it is not at all certain that in the setting of severe acute colitis whether all patients receive 3 doses but it is likely most will receive two. There is no need to emphasize how important it is for paediatric patients also to have time to adjust to the possibility that colectomy may become a necessity if medical treatment fails.

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