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Crohn's disease - infliximab (review) and adalimumab: NICE appraisal consultation document

Paediatric gastroenterologists are pleased that NICE will be recommending the use of Infliximab for children and adolescents with severe Crohn's disease but would like further consideration of the following:

1. There is lack of guidance for episodic versus maintenance therapy for paediatric patients implying it is at the discretion of the clinicians. We welcome the latter but feel concerned that primary care trusts (PCTs) may use this lack of clarity as a reason not to approve funding for maintenance therapy.

2. The committee are aware of the particularly strong arguments for maintenance therapy around puberty; a process which continues for several years. To avoid unnecessary and/or prolonged use, a caveat could be added for maintenance therapy in paediatric patients that there should be annual reassessment of the need to continue therapy.

3. In 4.2.11, it is stated that Infliximab is cost effective for induction, but not maintenance, therapy for paediatric patients. This is derived from data in adults where the comparison is standard care; however this does not include liquid diet therapy (LDT). LDT is standard care in paediatric Crohn's disease and should be part of any cost analysis of standard care versus biologic therapies (4.3.13.) The committee acknowledge the potential harm of corticosteroid therapy (CST) for paediatric Crohn's patients. To avoid CST, LTD is used as standard therapy both to establish remission and for any subsequent relapse, provided the child or teenager agrees. This therapy can be labour intensive and is usually given for 6 weeks. Recent costing of this therapy varies according to supplement used but for 6 weeks is £400.00 with a polymeric feed eg Modulin or £700.00 with an elemental feed eg E028. The cost of one course of LDT or one dose of biologic is similar.

4. There also needs to be recognition that some patients in this age group who may not have 'severe' disease according to Crohn's disease activity score (CDAI) will need this therapy; for example those with disfiguring refractory orofacial Crohn's disease, those with complex perianal disease, or those who have disease-related growth and pubertal delay.

Finally, in view of serious side-effects with biologics, including a few cases of a fatal hepatosplenic lymphoma in adolescent boys receiving biologics and concomitant azathioprine or 6-mercaptopurine we would argue strongly for registration of all childhood and teenage patients on either biologic therapy.

This would be complemented by written material outlining benefits and risks of biological therapy, together with written informed consent. Until the true prevalence of such rare but very serious complications are known, this will provide the best protection currently possible for children and teenagers, their families, prescribing paediatric gastroenterologists and for the manufacturing companies.

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Chair UK paediatric IBD working gp of British Society of Paediatric Gastroenterology, Hepatology & Nutrition (BSPGHAN) & written on their behalf