Comments for NICE on appendix B

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Multiple Technology Appraisal (MTA)

Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262) [ID695]

Final scope

The brief correctly focuses on Infliximab, Adalimumab and Golimumab within their licensed indications for treating moderately to severely active ulcerative colitis.

Moderately to severely active ulcerative colitis is poorly defined, this is a widely recognised problem not unique to this MTA and was discussed in the background on Appendix B.

Although the brief refers to NICE Tag 140 for severe ulcerative colitis it does not highlight the NICE recommendation to give an induction course with 3 doses of Infliximab without a recommendation to continue with maintenance Infliximab treatment. This multiple technology appraisal is an opportunity to tackle the question of long term maintenance Infliximab.

The biological compounds currently, or soon likely to be, licensed for moderate to severe active ulcerative colitis are Infliximab, Adalimumab, Golimumab, Infliximab biosimilars (Remsima/Inflectra) and probably soon be Vedolizumab, if the biosimilars and the Vedolizumab are not included in the MTA it risks being overtaken by further appraisals.

The patient population is identified as patients with an inadequate response to conventional treatment including cortical steroids, thiopurines in patients with contraindications to such treatment. It might usefully be more tightly defined as an inadequate response to conventional treatment with each of amino salicylates, corticosteroids and thiopurines or medical contraindication to such therapies.

The question of which comparator the biological treatment should be compared to is difficult. Given the request for patients to have had an inadequate response to conventional therapy it seems illogical to have conventional therapy as the comparator. Perhaps the biological should just be compared to each other or to surgery.

Outcomes should explicitly include rates of steroid free remission as assessed on an intention to treat basis for a population of patients considering starting biological therapy.

The above comments are personal comments made by myself as an experienced Gastroenterologist dealing with inflammatory bowel disease. I am a former member of the BSG/IBD Committee and current member of BSG/IBD Clinical Research Group.

[redacted] (04/03/14)