

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA187; Infliximab (review) and adalimumab for the treatment of Crohn's disease

This guidance was issued May 2010 with a review date of September 2011

Background

At the GE meeting of 14 December 2010 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	The guidance should be incorporated, verbatim, into the ongoing Clinical Guideline: 'Crohn's disease: the management of Crohn's disease'. TA187 will remain in existence alongside the clinical guideline and will be moved to the static guidance list.
Rationale for selecting this proposal	The guidance will be incorporated, verbatim, into the clinical guideline currently under development 'Crohn's disease: the management of Crohn's disease'. This has been stated in the final scope for this clinical guideline. TA187 will remain in existence alongside the clinical guideline and will be moved to the static guidance list. This proposal will have the consequence of preserving the funding direction.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	The guidance should be incorporated, verbatim, into the ongoing Clinical Guideline: 'Crohn's disease: the management of Crohn's disease'. TA187 will remain in existence alongside the clinical guideline and will be moved to the static guidance list.
--	---

Respondent	Response to proposal	Details	Comment from Technology Appraisals
NHS Quality Improvement Scotland	No comment	NHS QIS has no comment to make on the proposal to update existing guidance into an ongoing clinical guideline.	
The Royal College of Nursing (RCN)	Commented	<p>The Royal College of Nursing welcomes the opportunity to review this document. The RCN's response to the questions on which comments were requested is set out below:</p> <p>1.4 Treatment with infliximab or adalimumab (see 1.1 and 1.3) should only be continued if there is clear evidence of ongoing active disease as determined by clinical symptoms, biological markers and investigation, including endoscopy if necessary. Specialists should discuss the risks and benefits of continued treatment with patients and consider a trial withdrawal from treatment for all patients who are in stable clinical remission. People who continue treatment with infliximab or adalimumab should have their disease reassessed at least every 12 months to determine whether ongoing treatment is still clinically appropriate. People whose disease relapses after treatment is stopped should have the option to start treatment again.</p> <p>We would like to comment that the above statement is rather counter intuitive. If a patient has ongoing disease despite being on treatment this would seem to suggest that the treatment is not working, in which case, why would one carry on treating with a very expensive medication? This makes little sense.</p> <p>We would agree wholeheartedly that once treatment has been</p>	<p>Comment noted. This issue was discussed in detail at the Committee meetings for this appraisal and additional data about stopping treatment was provided. The Committee heard from patient experts and clinical specialists that reasons for stopping or continuing treatment varied and that it was difficult to define which patients should stop treatment and when. The clinical specialists considered it reasonable to review the need for biological treatment in patients who were in stable remission. The</p>

Respondent	Response to proposal	Details	Comment from Technology Appraisals
		established and is working then yearly review is obviously sensible, although clearer guidance on how this assessment is made would be helpful and could help to improve equality of service. It would also allow PCTs to better police the guideline as ultimately they are currently paying for it.	Committee therefore agreed to the condition in section 1.3 of the FAD and noted that additional research or data collection on the discontinuation of treatments was unlikely.
Sanofi-Aventis	Commented	No objections.	Comment noted.
British Society of Gastroenterology	Commented	Whilst the British Society of Gastroenterology sees NICE's incorporation of its recently published Technology Appraisal Guidance No. 187 (Infliximab and Adalimumab for the treatment of Crohn's disease) into its ongoing guideline on Crohn's Disease as logical we hope this does not mean that the whole process of care is again re-examined. There has been a lot of change in this area and we would recommend/urge that changes to the guideline should represent evolution rather than starting to reconstruct care plans again.	Comment noted.
Royal College of Physicians	Commented	The Royal College of Physicians has had sight and would like to endorse the response submitted by the British Society of Gastroenterology to this review proposal.	Comment noted.

No response received from:

<u>Manufacturers/sponsors</u>	<u>General</u>
-------------------------------	----------------

- Abbott Laboratories (adalimumab)
- Schering Plough (infliximab)

Patient/carer groups

- Afiya Trust
- Black Health Agency
- Bladder and Bowel Foundation
- Chinese National Healthy Living Centre
- Colostomy Association
- Counsel and Care
- Crohn's and Colitis UK
- Equalities National Council
- IA: Ileostomy and Internal Pouch Support Group
- Muslim Council of Britain
- Muslim Health Network
- Ostomy Lifestyle Centre
- South Asian Health Foundation
- Specialised Healthcare Alliance

Professional groups

- Association of Coloproctology of Great Britain and Ireland
- British Association for Services to the Elderly
- British Geriatrics Society
- Royal College of General Practitioners
- Royal College of Pathologists
- Royal College of Radiologists
- Royal Pharmaceutical Society of Great Britain
- Royal Society of Medicine

- Board of Community Health Councils in Wales
- British National Formulary
- Care Quality Commission
- Commissioning Support Appraisals Service
- Department of Health, Social Services and Public Safety for Northern Ireland
- Medicines and Healthcare products Regulatory Agency
- National Association of Primary Care
- NHS Alliance
- NHS Commercial Medicines Unit
- NHS Confederation
- Public Health Wales NHS Trust
- Scottish Medicines Consortium

Possible comparator manufacturer(s)

- Actavis UK (azathioprine, metronidazole, sulfasalazine)
- Almus Pharmaceuticals (metronidazole, sulfasalazine)
- AstraZeneca UK (budesonide)
- Dr Falk Pharma UK (mesalazine, budesonide)
- Ferring Pharmaceuticals (mesalazine)
- Forest Laboratories UK (prednisolone)
- GlaxoSmithKline (azathioprine, mercaptopurine)
- Kent Pharmaceuticals (azathioprine, mesalazine, sulfasalazine)
- Mayne Pharma (methotrexate)
- Novartis Pharmaceuticals (ciclosporin)
- Pfizer (methotrexate and sulfasalazine)
- Procter and Gamble Pharmaceuticals (UK) (mesalazine)
- Sandoz (mesalazine, metronidazole)

- United Kingdom Clinical Pharmacy Association
- Society and College of Radiographers
- British Institute of Radiology

Others

- Department of Health
- NHS Croydon
- NHS North Somerset
- Welsh Assembly Government

- Shire Pharmaceuticals (balsalazide sodium, mesalazine)
- Teva UK (azathioprine, mesalazine, methotrexate, sulfasalazine)
- UCB Pharma (olsalazine sodium)
- Winthrop Pharmaceuticals UK (metronidazole)
- Wockhardt UK (methotrexate)

Relevant research groups

- CORE - The Digestive Disorders Foundation
- MRC Clinical Trials Unit
- National Institute for Health Research
- Policy Research Institute on Ageing and Ethnicity
- Research Institute for the Care of Older People

Assessment Group

- National Institute for Health Research Health Technology Assessment Programme
- Tbc

Associated Guideline Groups

- National Clinical Guideline Centre

Associated Public Health Groups

- none

GE paper sign-off: Janet Robertson, Associate Director – Technology Appraisals Programme

Contributors to this paper:

Technical Lead: João Vieira

Technical Adviser: Rebecca Trowman

Project Manager: Kate Moore

17 February 2011