

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## GUIDANCE EXECUTIVE (GE)

### Technology Appraisal Review Proposal paper

#### Review of TA187; Infliximab and adalimumab for the treatment of Crohn's disease

<b>Original publication date:</b>	March 2010
<b>Review date</b>	N/A
<b>Existing recommendations:</b>	Infliximab – Recommended Adalimumab - Recommended  To see the complete existing recommendations and the original remit for TA187, see Appendix A.

#### 1. Proposal

The guidance should be updated in an on-going clinical guideline. That we consult on this proposal.

#### 2. Rationale

TA187 was added to the static list in [March 2011](#). In March 2015 the Institute considered the available evidence and decided that the guidance [should remain on the static list](#) as no new robust new evidence was available that would be likely to lead to a change in the existing recommendations.

The Institute is now proposing to undertake a partial update of the clinical guideline on [Crohn's disease management \(CG152\)](#). During surveillance a considerable amount of evidence was identified which assessed the efficacy of anti-TNF therapy for maintenance of remission of Crohn's disease after surgery.

Currently TA187 does not provide any recommendations for anti-TNF therapy for maintenance of remission of Crohn's disease after surgery. The update to CG152 provides an appropriate context for these recommendations to be made, especially as the recommendations can then be placed into wider context within clinical practice.

Subsequently, it is recommended that the recommendations made in TA187 should be updated in the upcoming partial update of the clinical guideline CG152. Upon the publication of the new clinical guideline, TA187 will be superseded and the guidance withdrawn.

**GE paper sign off: Meindert Boysen, 23 June 2017**

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### Appendix A – Information from existing guidance

#### 1. Original remit(s)

To appraise the clinical and cost effectiveness of the tumour necrosis factor alpha (TNF  $\alpha$ ) inhibitors and natalizumab within their licensed indications for the treatment of Crohn's disease.

#### 2. Current guidance

- 1.1 Infliximab and adalimumab, within their licensed indications, are recommended as treatment options for adults with severe active Crohn's disease (see 1.6) whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments), or who are intolerant of or have contraindications to conventional therapy. Infliximab or adalimumab should be given as a planned course of treatment until treatment failure (including the need for surgery), or until 12 months after the start of treatment, whichever is shorter. People should then have their disease reassessed (see 1.4) to determine whether ongoing treatment is still clinically appropriate.
- 1.2 Treatment as described in 1.1 should normally be started with the less expensive drug (taking into account drug administration costs, required Commercial in confidence information has been removed Page 3 of 11 dose and product price per dose). This may need to be varied for individual patients because of differences in the method of administration and treatment schedules.
- 1.3 Infliximab, within its licensed indication, is recommended as a treatment option for people with active fistulising Crohn's disease whose disease has not responded to conventional therapy (including antibiotics, drainage and immunosuppressive treatments), or who are intolerant of or have contraindications to conventional therapy. Infliximab should be given as a planned course of treatment until treatment failure (including the need for surgery) or until 12 months after the start of treatment, whichever is shorter. People should then have their disease reassessed (see 1.4) to determine whether ongoing treatment is still clinically appropriate.
- 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.

- 1.5 Infliximab, within its licensed indication, is recommended for the treatment of people aged 6–17 years with severe active Crohn’s disease whose disease has not responded to conventional therapy (including corticosteroids, immunomodulators and primary nutrition therapy), or who are intolerant of or have contraindications to conventional therapy. The need to continue treatment should be reviewed at least every 12 months.
- 1.6 For the purposes of this guidance, severe active Crohn’s disease is defined as very poor general health and one or more symptoms such as weight loss, fever, severe abdominal pain and usually frequent (3–4 or more) diarrhoeal stools daily. People with severe active Crohn’s disease may or may not develop new fistulae or have extra-intestinal manifestations of the disease. This clinical definition normally, but not exclusively, corresponds to a Crohn’s Disease Activity Index (CDAI) score of 300 or more, or a Harvey-Bradshaw score of 8 to 9 or above.
- 1.7 When using the CDAI and Harvey-Bradshaw Index, healthcare professionals should take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the scores and make any adjustments they consider appropriate. Commercial in confidence information has been removed Page 4 of 11 1.8 Treatment with infliximab or adalimumab should only be started and reviewed by clinicians with experience of TNF inhibitors and of managing Crohn’s disease.

## Appendix B – Explanation of options

When considering whether to review one of its Technology Appraisals NICE must select one of the options in the table below:

Options	Consequence	Selected – ‘Yes/No’
A review of the guidance should be planned into the appraisal work programme. The review will be conducted through the specify STA or MTA process.	A review of the appraisal will be planned into the NICE’s work programme.	No
The decision to review the guidance should be deferred to specify date or trial.	NICE will reconsider whether a review is necessary at the specified date.	No
A review of the guidance should be combined with a review of a related technology appraisal. The review will be conducted through the MTA process.	A review of the appraisal(s) will be planned into NICE’s work programme as a Multiple Technology Appraisal, alongside the specified related technology.	No
A review of the guidance should be combined with a new technology appraisal that has recently been referred to NICE. The review will be conducted through the MTA process.	A review of the appraisal(s) will be planned into NICE’s work programme as a Multiple Technology Appraisal, alongside the newly referred technology.	No
The guidance should be incorporated into an on-going clinical guideline.	<p>The on-going guideline will include the recommendations of the technology appraisal. The technology appraisal will remain extant alongside the guideline. Normally it will also be recommended that the technology appraisal guidance is moved to the static list until such time as the clinical guideline is considered for review.</p> <p>This option has the effect of preserving the funding direction associated with a positive recommendation in a NICE technology appraisal.</p>	No

## Appendix B

Options	Consequence	Selected – ‘Yes/No’
The guidance should be updated in an on-going clinical guideline <sup>1</sup> .	<p>Responsibility for the updating the technology appraisal passes to the NICE Clinical Guidelines programme. Once the guideline is published the technology appraisal will be withdrawn.</p> <p>Note that this option does not preserve the funding direction associated with a positive recommendation in a NICE Technology Appraisal. However, if the recommendations are unchanged from the technology appraisal, the technology appraisal can be left in place (effectively the same as incorporation).</p>	Yes
The guidance should be transferred to the ‘static guidance list’.	The guidance will remain in place, in its current form, unless NICE becomes aware of substantive information which would make it reconsider. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	No
The guidance should be withdrawn	<p>The guidance is no longer relevant and an update of the existing recommendations would not add value to the NHS.</p> <p>The guidance will be stood down and any funding direction associated with a positive recommendation will not be preserved.</p>	No

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<sup>1</sup> Information on the criteria for NICE allowing a technology appraisal in an ongoing clinical guideline can be found in section 6.20 of the [guide to the processes of technology appraisal](#).