

# Crohn's disease

## Appendix A

*Clinical Guideline <...>*

*Scope*

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# 1 Appendix A

FINAL

## NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

### SCOPE

#### 1 Guideline title

Crohn's disease: the management of Crohn's disease

##### 1.1 *Short title*

Crohn's disease

#### 2 The remit

The Department of Health has asked NICE: 'To prepare a clinical guideline on the management of Crohn's disease'.

#### 3 Clinical need for the guideline

##### 3.1 *Epidemiology*

- a) Crohn's disease is a chronic inflammatory disease that mainly affects the gastrointestinal tract. It can occur at any age and the cause is unknown. The prevalence of Crohn's disease is estimated to be about 150 cases per 100,000 population (adults, young people and children) in England and Wales, although expert opinion has indicated that the number with Crohn's disease may be one and a half times greater than current estimates. Between 3000 and 6000 new cases are diagnosed each year. An estimated 5% of patients have severe disease. The proportion of people with moderate Crohn's disease is unclear.
- b) Typically people with Crohn's disease have recurrent attacks, with acute 'flares' of the disease interspersed with periods of remission or less active disease.

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- c) People with severe Crohn's disease can present with evidence of systemic toxicity (for example, fever and raised pulse rate), weight loss and often other complications (see sections 3.1.d and 3.1.e). Investigation reveals severe and usually extensive intestinal inflammation, with associated biochemical and haematological evidence of clinically significant systemic disturbance (for example, very high levels of C-reactive protein and low albumin levels). People with severe Crohn's disease often do not respond to standard drug therapy, including immunosuppressants.
- d) Crohn's disease can be complicated by the development of intestinal obstruction, fistulae or perianal disease. Fistulae develop in about one third of people with Crohn's disease. Perianal disease is a frequent complication of colonic and ileocolonic disease and is characterised by fissures, fistulae or abscesses. Spontaneous healing is rare, and surgical management is often needed, although it is not always possible or wholly successful.
- e) Other complications include acute dilatation and perforation of the gastrointestinal tract, and significant haemorrhage, particularly if the disease affects the colon. As well as these intestinal problems, the disease may cause symptoms in the joints, eyes, liver and skin. These non-intestinal symptoms have been reported in more than 15% of patients, mainly in people with colonic Crohn's disease. There is also evidence of an increase in the incidence of cancer of the small and large intestine in people with Crohn's disease.
- f) Between 50 and 80% of people with Crohn's disease will eventually need surgery. The main reasons for surgery are strictures causing symptoms of obstruction, medical therapy not giving sufficient relief, and complications such as fistulae.
- g) Most people with Crohn's disease lead active lives. Nevertheless, 5 years after onset, 15–20% of patients are disabled by their disease to some degree [see 'Infliximab (review) and adalimumab

for the treatment of Crohn's disease', NICE technology appraisal guidance 187, 2010].

### **3.2**      *Current practice*

Management options for Crohn's disease include drug therapy, attention to nutrition and, in severe or chronic active disease, surgery. The aims of drug treatment are to reduce symptoms and maintain or improve quality of life, while minimising toxicity over both the short term and long term.

Corticosteroids, aminosalicylates, antibiotics and immunosuppressive drugs form the basis of drug treatment. Enteral nutrition may be used as an additional treatment. Studies suggest that tumour necrosis factor (TNF) alpha inhibitors are effective in inducing and maintaining remission.

This guideline is intended to show the place of new and established treatments in the wider care pathway for Crohn's disease. This will be useful because many new drugs have been licensed for Crohn's disease within the last decade. The guideline will also help to improve the care offered to people with severe Crohn's disease and provide information about the clinical and cost effectiveness of potential care pathways.

Management of Crohn's disease in specific populations (for example, in pregnancy) may require special consideration.

## **4**      **The guideline**

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

## **4.1**     ***Population***

### **4.1.1**    **Groups that will be covered**

- a)       Adults and children with a diagnosis of Crohn's disease.
- b)       Consideration will be given to specific needs, if any, in pregnancy and females of child-bearing potential.

### **4.1.2**    **Groups that will not be covered**

- a)       None.

## **4.2**     ***Healthcare setting***

- a)       NHS settings in which treatment for Crohn's disease is delivered.

## **4.3**     ***Clinical management***

### **4.3.1**    **Key clinical issues that will be covered**

- a)       Drug therapy, including the following drug categories:
  - corticosteroids
  - immunomodulators – azathioprine, mercaptopurine and methotrexate
  - aminosalicylates

Note that guideline recommendations will normally fall within licensed indications; exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

- b)       Enteral nutrition versus medical management or combination therapy.
- c)       Aspects of surgical management, for example:



- disease of the terminal ileum (medical versus surgical management)
  - strictures.
- d) Information and support for people with Crohn's disease and their families and carers as appropriate.
- e) Monitoring for:
- osteopenia
  - early relapse

#### **4.3.2 Clinical issues that will not be covered**

- a) Diagnosis.
- b) Treatment of extraintestinal manifestations of Crohn's disease.
- c) Surgical techniques (except those aspects listed in section 4.3.1c).
- d) The following approaches to management:
- photopheresis
  - granulocyte-macrophage colony-stimulating factor (GM-CSF)
  - probiotics
  - fish oil
  - anti-tuberculosis drugs for treatment of *Mycobacterium avium paratuberculosis*
  - cyclosporin.

#### **4.4 Main outcomes**

- a) Mortality.
- b) Response or disease remission as measured by:
- Crohn's disease activity index (CDAI) or
  - Harvey–Bradshaw index (HBI) or
  - Paediatric Crohn's disease activity index (PCDAI).

- c) Health-related quality of life as assessed by:
  - Inflammatory Bowel Disease Questionnaire (IBDQ) or
  - IMPACT questionnaire.
- d) Generic measures of health-related quality of life (where reported) as assessed by:
  - EuroQol (EQ-5D) for adults or
  - Health Utilities Index (HUI2) for children.
- e) Growth in children.
- f) Onset of puberty.
- g) Premature termination of treatment.
- h) Adverse events.
- i) Hospitalisation (including length of stay).

#### **4.5** *Economic aspects*

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see 'Further information').

#### **4.6** *Status*

##### **4.6.1** *Scope*

This is the final scope.

#### **4.6.2 Timing**

The development of the guideline recommendations will begin in September 2010.

### **5 Related NICE guidance**

#### **5.1 *Published guidance***

##### **5.1.1 NICE guidance to be incorporated**

This guideline will incorporate the following NICE guidance:

- Infliximab (review) and adalimumab for the treatment of Crohn's disease. NICE technology appraisal guidance 187 (2010). Available from [www.nice.org.uk/guidance/TA187](http://www.nice.org.uk/guidance/TA187)

##### **5.1.2 Other related NICE guidance**

- Extracorporeal photopheresis for Crohn's disease. NICE interventional procedure guidance 288 (2009). Available from [www.nice.org.uk/guidance/IPG288](http://www.nice.org.uk/guidance/IPG288)
- Medicines adherence. NICE clinical guideline 76 (2009). Available from [www.nice.org.uk/guidance/CG76](http://www.nice.org.uk/guidance/CG76)
- Irritable bowel syndrome in adults. NICE clinical guideline 61 (2008). Available from [www.nice.org.uk/guidance/CG61](http://www.nice.org.uk/guidance/CG61)
- Smoking cessation services. NICE public health guidance 10 (2008). Available from [www.nice.org.uk/guidance/PH10](http://www.nice.org.uk/guidance/PH10)
- Varenicline for smoking cessation. NICE technology appraisal guidance 123 (2007). Available from [www.nice.org.uk/guidance/TA123](http://www.nice.org.uk/guidance/TA123)
- Brief interventions and referral for smoking cessation. NICE public health guidance 1 (2006). Available from [www.nice.org.uk/guidance/PH1](http://www.nice.org.uk/guidance/PH1)
- Nutrition support in adults. NICE clinical guideline 32 (2006). Available from [www.nice.org.uk/guidance/CG32](http://www.nice.org.uk/guidance/CG32)
- Leukapheresis for inflammatory bowel disease. NICE interventional procedure guidance 26 (2005). Available from [www.nice.org.uk/guidance/IPG126](http://www.nice.org.uk/guidance/IPG126)

- Fertility. NICE clinical guideline 11 (2004). Available from [www.nice.org.uk/guidance/CG11](http://www.nice.org.uk/guidance/CG11)
- Wireless capsule endoscopy for investigation of the small bowel. NICE interventional procedure guidance 101 (2004). Available from [www.nice.org.uk/guidance/IPG101](http://www.nice.org.uk/guidance/IPG101)

## **5.2** *Guidance under development*

NICE is currently developing the following related guidance (details available from the NICE website).

- Colonoscopic surveillance for colorectal cancer in high risk groups. NICE clinical guideline. Publication expected October 2011.

## **6** **Further information**

Information on the guideline development process is provided in:

- 'How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS'
- 'The guidelines manual'.

These are available from the NICE website ([www.nice.org.uk/GuidelinesManual](http://www.nice.org.uk/GuidelinesManual)). Information on the progress of the guideline will also be available from the NICE website ([www.nice.org.uk](http://www.nice.org.uk)).