



# **National Institute for Health and Clinical Excellence**

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## **News release**

### **NICE recommends two more treatments for Crohn's disease**

NICE has today (19 May) announced that it has recommended two treatments (infliximab and adalimumab) for people with severe Crohn's disease. The guidance approves use of the drugs for people who have not responded to, who are intolerant of, or are unable to take more commonly used therapies to treat the condition.

Crohn's disease is a chronic inflammatory condition of unknown cause affecting the gastrointestinal tract (gut). It is estimated that around 60,000 people in the UK have the disease, with approximately 3,000 (5%) having the most severe forms of the condition. The disease causes parts of the gastrointestinal tract to become inflamed, causing diarrhoea, pain in the abdomen, weight loss and tiredness. Ulcers can form in the wall of the gastrointestinal tract and when they heal the scar tissue makes the tract narrower. Sometimes Crohn's disease causes the formation of abnormal passageways (fistulas) between parts of the intestine, or between the intestine and the skin. It can also affect other parts of the body, such as the eyes or the joints. People with Crohn's disease can have recurrent attacks – that is, they have times when their disease flares up and in between they have periods of remission.

The guidance from NICE recommends infliximab and adalimumab as treatment options for adults with a severe, active form of the disease. Treatment should normally be started with the less expensive drug (taking into account drug administration costs, required dose and product price per dose). Infliximab is also recommended for adults with active, fistulising Crohn's disease, and for children and young people aged 6-17 years old with severe, active Crohn's disease.

**Dr Carole Longson, Health Technology Evaluation Centre Director said:**

“We are pleased to recommend these treatments for this debilitating, incurable condition. Our review of the evidence indicates that infliximab and adalimumab are clinically and cost effective options for some people with the most severe forms of Crohn's disease, and for those that standard treatments have failed, or are not an option. This guidance will be welcome news to those affected.”

**This final guidance now replaces local recommendations across the country; the NHS has three months to start implementing this new guidance.**

The guidance is available on the NICE website at <http://www.nice.org.uk/guidance/TA187>

**Ends**

**Notes to Editors**

**About the guidance**

1. The final guidance can be found at <http://www.nice.org.uk/guidance/TA187>
2. Infliximab (Remicade, Schering-Plough Ltd) and adalimumab (Humira, Abbott Laboratories) are TNF- $\alpha$  inhibitors.
3. TNF is a protein in the body that is believed to be partly responsible for causing the inflammation of the intestine in people with Crohn's disease.
4. A 100-mg vial of infliximab costs £419.62 (excluding VAT; 'British national formulary' [BNF], 58th edition). The drug cost differs between individuals because the dose is adjusted to each person's body weight. For example, if it is assumed that vials are not shared between patients, for a person weighing 73 kg the cost per infusion would be £1678, corresponding to four 100-mg vials needed for a dose of 365 mg. For a course of two infusions, with an assumed drug administration cost for each infusion of £258, the total cost is approximately £3872. The total cost of continuing therapy at a standard dosage for 12 months is approximately £12,584. Costs may vary in different settings because of negotiated procurement discounts.
5. Adalimumab costs £357.50 per 40-mg prefilled syringe (excluding VAT; BNF, 58th edition). Normal induction treatment costs approximately £1073 and the cost to continue treatment at a standard dosage for 12 months costs £9295. Costs may vary in different settings because of negotiated procurement discounts.
6. The guidance from NICE recommends infliximab or adalimumab as treatment options for adults with severe, active Crohn's disease 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.
7. Treatment should normally be started with the less expensive drug (taking into account drug administration costs, required dose and product price per dose).
8. Infliximab 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.

9. Infliximab is also recommended for children and young people aged 6-17 years old 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.
10. Treatment with 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 to determine whether ongoing treatment is still clinically appropriate.
11. Treatment with infliximab or adalimumab should only be started and reviewed by clinicians with experience of TNF inhibitors and of managing Crohn's disease.
12. Severe, active Crohn's disease is defined as very poor general health with one or more symptoms such as weight loss, fever, severe abdominal pain and usually frequent (3-4 or more) diarrhoeal stools daily.

## About NICE

- The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
- NICE produces guidance in three areas of health:
  1. **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
  2. **health technologies** – guidance on the use of new and existing medicines, treatments and procedures within the NHS
  3. **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS