

Leukapheresis for inflammatory bowel disease

Interventional procedures guidance

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[nice.org.uk/guidance/ipg126](https://www.nice.org.uk/guidance/ipg126)

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 Current evidence suggests that there are no major safety concerns for the use of leukapheresis for inflammatory bowel disease.
- 1.2 Leukapheresis may be beneficial in carefully selected patients with ulcerative colitis, but the evidence on efficacy is not yet adequate to support its use in

these patients without special arrangements for consent and for audit or research as set out in 1.4.

1.3 There is inadequate evidence to draw any conclusions about the efficacy of leukapheresis in patients with Crohn's disease and it should only be used in accordance with special arrangements for consent and audit as set out in 1.4.

1.4 Clinicians wishing to undertake leukapheresis for inflammatory bowel disease should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of the Institute's [information for the public](#) is recommended.
- Audit and review clinical outcomes of all patients having leukapheresis.

1.5 Publication of current and future research studies will be useful. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 *Indications*

2.1.1 Ulcerative colitis and Crohn's disease are the most common forms of inflammatory bowel disease. Ulcerative colitis causes inflammation and ulceration of the rectum and colon. Symptoms include bloody diarrhoea and rectal bleeding. Crohn's disease usually causes inflammation and ulceration of the small intestine, but it can affect any part of the digestive tract. The main symptoms are abdominal pain, diarrhoea and weight loss. Both ulcerative colitis and Crohn's disease are chronic conditions characterised by periods of clinical relapse and remission.

2.1.2 Conservative treatments include dietary measures and medication to control inflammation, which may include immunosuppressants. Patients with ulcerative colitis that does not respond to medical therapy may be treated with surgery to remove the colon. Although surgery may also be used for patients with Crohn's

disease, it may not be curative and the disease often recurs in a different part of the digestive tract.

2.2 *Outline of the procedure*

- 2.2.1 Leukapheresis involves extracorporeal removal of leukocytes from the blood, either by centrifugation or through an adsorptive system. In each system, venous blood is removed in a continuous flow, anticoagulated, processed to deplete the leukocytes and returned to the circulation.
- 2.2.2 Different apheresis systems remove different populations of white blood cells. Leukapheresis using centrifugation removes a proportion of neutrophils and lymphocytes. Filter columns, which may contain cellulose acetate beads or a polyester fibre filter, remove a large proportion of granulocytes and monocytes and some also remove lymphocytes. The exact mode of action of these procedures is unknown.

2.3 *Efficacy*

- 2.3.1 In one randomised controlled trial of patients with ulcerative colitis, 74% (29/39) of patients treated with leukapheresis had an 'excellent' or 'moderate' improvement in symptoms, compared with 38% (14/37) of patients treated with high-dose steroids ($p = 0.005$).
- 2.3.2 In four case series, 54% (24/44) to 82% (32/39) of patients with ulcerative colitis had an initial remission of disease after treatment. In one study, the proportion of patients in clinical remission dropped from 82% (32/39) at 12 weeks to 67% (26/39) at 12 months after the final treatment. In two further studies, 30% (10/33) and 39% (13/33) of patients relapsed during maintenance therapy after initial complete remission.
- 2.3.3 In a small randomised controlled trial of patients with Crohn's disease, 100% (12/12) of patients treated with leukapheresis were successfully withdrawn from steroid therapy, compared with 67% (10/15) of patients who were not treated with leukapheresis ($p = 0.074$). There was no significant difference between the two groups in disease recurrence at 18-month follow-up. For more details, refer to the Sources of evidence.

2.3.4 The Specialist Advisors stated that some uncertainty remained about the efficacy of leukapheresis for inflammatory bowel disease because data from randomised controlled trials were insufficient.

2.4 *Safety*

2.4.1 Most studies reported only mild adverse events such as dizziness, light headedness, headache and flushing. In three case series, the proportion of patients experiencing at least one non-severe adverse event ranged from 9% (5/53) to 18% (7/39).

2.4.2 In a randomised controlled trial, the incidence of adverse events was significantly lower in the group treated with leukapheresis than in the group treated with high-dose steroids (24% versus 47%, $p < 0.001$). In the same trial, adverse events were described as moderate or severe in 12% (5/42) of patients treated with leukapheresis: one patient had toxic shock, one patient had chest pain, one patient had anaemia and two patients had a headache. For more details, refer to the Sources of evidence.

2.4.3 The Specialist Advisors stated that potential adverse events included infection, headache, palpitations, nausea, vomiting, fever, chills, respiratory distress and chest discomfort.

2.5 *Other comments*

2.5.1 It was noted that leukapheresis is an established technique for other conditions.

2.5.2 It was also noted that there are different techniques for leukapheresis, and these may have different risk and benefit profiles.

Andrew Dillon
Chief Executive
June 2005

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of leukapheresis for inflammatory bowel disease', August 2004.

Information for patients

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Changes since publication

The guidance was considered for reassessment in June 2008 and it was concluded that NICE will not be updating this guidance at this stage. However, if you believe there is new evidence which should warrant a review of our guidance, please [contact us](#).

24 January 2012: minor maintenance.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).