

# Ulcerative colitis: management

Clinical guideline

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## Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying 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.

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This guideline is the basis of QS81.

## Introduction

Ulcerative colitis is the most common type of inflammatory disease of the bowel. It has an incidence in the UK of approximately 10 per 100,000 people annually, and a prevalence of approximately 240 per 100,000. This amounts to around 146,000 people in the UK with a diagnosis of ulcerative colitis. The cause of ulcerative colitis is unknown. It can develop at any age, but peak incidence is between the ages of 15 and 25 years, with a second, smaller peak between 55 and 65 years (although this second peak has not been universally demonstrated).

Ulcerative colitis usually affects the rectum, and a variable extent of the colon proximal to the rectum. The inflammation is continuous in extent. Inflammation of the rectum is referred to as proctitis, and inflammation of the rectum and sigmoid as proctosigmoiditis. Left-sided colitis refers to disease involving the colon distal to the splenic flexure. Extensive colitis affects the colon proximal to the splenic flexure, and includes pan-colitis, where the whole colon is involved.

Symptoms of active disease or relapse include bloody diarrhoea, an urgent need to defaecate and abdominal pain.

Ulcerative colitis is a lifelong disease that is associated with significant morbidity. It can also affect a person's social and psychological wellbeing, particularly if poorly controlled. Typically, it has a relapsing–remitting pattern.

Current medical approaches focus on treating active disease to address symptoms, to improve quality of life, and thereafter to maintain remission. The long-term benefits of achieving mucosal healing remain unclear. The treatment chosen for active disease is likely to depend on clinical severity, extent of disease and the person's preference, and may include the use of aminosalicylates, corticosteroids or biological drugs. These drugs can be oral or topical (into the rectum), and corticosteroids may be administered intravenously in people with acute severe disease. Surgery may be considered as emergency treatment for severe ulcerative colitis that does not respond to drug treatment. People may also choose to have elective surgery for unresponsive or frequently relapsing disease that is affecting their quality of life.

Advice and support for people with ulcerative colitis is important, in terms of discussing the effects of the condition and its course, medical treatment options, the effects of medication and the

monitoring required. Around 10% of inpatients with inflammatory bowel disease reported a lack of information about drug side effects on discharge from hospital. Information to support decisions about surgery is also essential, both for clinicians and for people facing the possibility of surgery. This includes recognising adverse prognostic factors for people admitted with acute severe colitis to enable timely decisions about escalating medical therapy or predicting the need for surgery. It is also very important to provide relevant information to support people considering elective surgery.

The wide choice of drug preparations and dosing regimens, the judgement required in determining the optimum timing for surgery (both electively and as an emergency) and the importance of support and information may lead to variation in practice across the UK. This guideline aims to address this variation, and to help healthcare professionals to provide consistent high-quality care. Managing ulcerative colitis in adults and children overlaps in many regards, so the guideline incorporates advice that is applicable to children and young people, which again should help to address potential inconsistencies in practice.

## *Drug recommendations*

The guideline will assume that prescribers will use a drug's summary of product characteristics to inform decisions made with individual patients.

This guideline recommends some drugs for indications for which they do not have a UK marketing authorisation at the date of publication, if there is good evidence to support that use. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. The patient (or those with authority to give consent on their behalf) should provide informed consent, which should be documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information. Where recommendations have been made for the use of drugs outside their licensed indications ('off-label use'), these drugs are marked with a footnote in the recommendations.

## Patient-centred care

This guideline offers best practice advice on the care of people with ulcerative colitis.

Patients and healthcare professionals have rights and responsibilities as set out in the [NHS Constitution for England](#) – all NICE guidance is written to reflect these. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If the patient is under 16, their family or carers should also be given information and support to help the child or young person to make decisions about their treatment. Healthcare professionals should follow the [Department of Health's advice on consent](#). If someone does not have capacity to make decisions, healthcare professionals should follow the [code of practice that accompanies the Mental Capacity Act](#) and the supplementary [code of practice on deprivation of liberty safeguards](#). In Wales, healthcare professionals should follow [advice on consent from the Welsh Government](#).

NICE has produced guidance on the components of good patient experience in adult NHS services. All healthcare professionals should follow the recommendations in [Patient experience in adult NHS services](#).

If a young person is moving between paediatric and adult services, care should be planned and managed according to the best practice guidance described in the Department of Health's [Transition: getting it right for young people](#).

Adult and paediatric healthcare teams should work jointly to provide assessment and services to young people with ulcerative colitis. Diagnosis and management should be reviewed throughout the transition process, and there should be clarity about who is the lead clinician to ensure continuity of care.

## Key priorities for implementation

The following recommendations have been identified as priorities for implementation.

### *Patient information and support*

- Discuss the disease and associated symptoms, treatment options and monitoring:
  - with the person with ulcerative colitis, and their family members or carers as appropriate and
  - within the multidisciplinary team (the composition of which should be appropriate for the age of the person) at every opportunity.

Apply the principles in [Patient experience in adult NHS services](#) (NICE clinical guideline 138).

### *Inducing remission: step 1 therapy for mild to moderate ulcerative colitis*

- To induce remission in people with a mild to moderate first presentation or inflammatory exacerbation of proctitis or proctosigmoiditis:
  - offer a topical aminosalicylate<sup>[1]</sup> alone (suppository or enema, taking into account the person's preferences) or
  - consider adding an oral aminosalicylate<sup>[2]</sup> to a topical aminosalicylate or
  - consider an oral aminosalicylate<sup>[2]</sup> alone, taking into account the person's preferences and explaining that this is not as effective as a topical aminosalicylate alone or combined treatment.
- To induce remission in adults with a mild to moderate first presentation or inflammatory exacerbation of left-sided or extensive ulcerative colitis:
  - offer a high induction dose of an oral aminosalicylate
  - consider adding a topical aminosalicylate or oral beclometasone dipropionate<sup>[3]</sup>, taking into account the person's preferences.
- To induce remission in children and young people with a mild to moderate first presentation or inflammatory exacerbation of left-sided or extensive ulcerative colitis:
  - offer an oral aminosalicylate<sup>[2],[4]</sup>



- consider adding a topical aminosalicylate<sup>[1]</sup> or oral beclometasone dipropionate<sup>[5]</sup>, taking into account the person's preferences (and those of their parents or carers as appropriate).

### *Inducing remission: step 2 therapy for acute severe ulcerative colitis*

- Consider adding intravenous ciclosporin<sup>[6]</sup> to intravenous corticosteroids or consider surgery for people:
  - who have little or no improvement within 72 hours of starting intravenous corticosteroids or
  - whose symptoms worsen at any time despite corticosteroid treatment.

Take into account the person's preferences when choosing treatment.

### *Monitoring treatment*

- Ensure that there are documented local safety monitoring policies and procedures (including audit) for adults, children and young people receiving treatment that needs monitoring (aminosalicylates, tacrolimus, ciclosporin, infliximab, azathioprine and mercaptopurine). Nominate a member of staff to act on abnormal results and communicate with GPs and people with ulcerative colitis (and/or their parents or carers as appropriate).

### *Assessing likelihood of needing surgery*

- Assess and document on admission, and then daily, the likelihood of needing surgery for people admitted to hospital with acute severe ulcerative colitis.

### *Information about treatment options for people who are considering surgery*

- For people with ulcerative colitis who are considering surgery, ensure that a specialist (such as a gastroenterologist or a nurse specialist) gives the person (and their family members or carers as appropriate) information about all available treatment options, and discusses this with them. Information should include the benefits and risks of the different treatments and the potential consequences of no treatment.
- After surgery, ensure that a specialist who is knowledgeable about stomas (such as a stoma nurse or a colorectal surgeon) gives the person (and their family members or carers as

appropriate) information about managing the effects on bowel function. This should be specific to the type of surgery performed (ileostomy or ileoanal pouch) and could include the following:

- strategies to deal with the impact on their physical, psychological and social wellbeing
- where to go for help if symptoms occur
- sources of support and advice.

## *Maintaining remission*

- Consider a once-daily dosing regimen for oral aminosalicylates<sup>[7]</sup> when used for maintaining remission. Take into account the person's preferences, and explain that once-daily dosing can be more effective, but may result in more side effects.

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<sup>[1]</sup> At the time of publication (June 2013), some topical aminosalicylates did not have a UK marketing authorisation for this indication in children and young people. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[2]</sup> At the time of publication (June 2013), some oral aminosalicylates did not have a UK marketing authorisation for this indication in children and young people. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[3]</sup> At the time of publication (June 2013), beclometasone dipropionate only has a UK marketing authorisation 'as add-on therapy to 5-ASA containing drugs in patients who are non-responders to 5-ASA therapy in active phase'. For use outside these licensed indications, the prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[4]</sup> Dosing requirements for children should be calculated by body weight, as described in the BNF.

<sup>[5]</sup> At the time of publication (June 2013), beclometasone dipropionate did not have a UK marketing authorisation for this indication in children and young people. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should

be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[6]</sup> At the time of publication (June 2013), ciclosporin did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[7]</sup> At the time of publication (June 2013), not all oral aminosalicylates had a UK marketing authorisation for once-daily dosing. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

## 1 Recommendations

The following guidance is based on the best available evidence. The [full guideline](#) gives details of the methods and the evidence used to develop the guidance.

The wording used in the recommendations in this guideline (for example words such as 'offer' and 'consider') denotes the certainty with which the recommendation is made (the strength of the recommendation). See [About this guideline](#) for details.

### *Adults, children and young people*

This guideline covers people of all ages with a diagnosis of ulcerative colitis. All recommendations relate to adults, children and young people unless specified otherwise. These terms are defined as follows:

- adults: 18 years or older
- children: 11 years or younger
- young people: 12 to 17 years.

### *Severity of ulcerative colitis*

#### **Mild, moderate and severe**

In this guideline, the categories of mild, moderate and severe are used to describe ulcerative colitis:

- In adults these categories are based on the Truelove and Witts' severity index (see table 1). This table is adapted from the Truelove and Witts' criteria
- In children and young people these categories are based on the Paediatric Ulcerative Colitis Activity Index (PUCAI) (see [table 2](#)).

**Table 1 Truelove and Witts' severity index**

	Mild	Moderate	Severe
Bowel movements (no. per day)	Fewer than 4	4–6	6 or more plus at least one of the features of systemic upset (marked with * below)

Blood in stools	No more than small amounts of blood	Between mild and severe	Visible blood
Pyrexia (temperature greater than 37.8°C) *	No	No	Yes
Pulse rate greater than 90 bpm *	No	No	Yes
Anaemia *	No	No	Yes
Erythrocyte sedimentation rate (mm/hour) *	30 or below	30 or below	Above 30

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## Table 2 Paediatric Ulcerative Colitis Activity Index (PUCAI)

Disease severity is defined by the following scores:

- severe: 65 or above
- moderate: 35–64
- mild: 10–34
- remission (disease not active): below 10.

	Item	Points
1.	Abdominal pain	
	No pain	0
	Pain can be ignored	5
	Pain cannot be ignored	10
2.	Rectal bleeding	

	None	0
	Small amount only, in less than 50% of stools	10
	Small amount with most stools	20
	Large amount (50% of the stool content)	30
3.	Stool consistency of most stools	
	Formed	0
	Partially formed	5
	Completely unformed	10
4.	Number of stools per 24 hours	
	0-2	0
	3-5	5
	6-8	10
	>8	15
5.	Nocturnal stools (any episode causing waking)	
	No	0
	Yes	10
6.	Activity level	
	No limitation of activity	0
	Occasional limitation of activity	5
	Severe restricted activity	10
	Sum of PUCAI (0-85)	

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## Subacute

The term 'subacute' is also used in this guideline to describe ulcerative colitis, but this is not covered by the Truelove and Witts' severity index or the PUCAI. The following definition (based on that in NICE technology appraisal guidance 140) is used: subacute ulcerative colitis is defined as moderately to severely active ulcerative colitis that would normally be managed in an outpatient setting and does not require hospitalisation or the consideration of urgent surgical intervention.

## 1.1 *Patient information and support*

1.1.1 Discuss the disease and associated symptoms, treatment options and monitoring:

- with the person with ulcerative colitis, and their family members or carers as appropriate and
- within the multidisciplinary team (the composition of which should be appropriate for the age of the person) at every opportunity.

Apply the principles in [Patient experience in adult NHS services](#) (NICE clinical guideline 138).

1.1.2 Discuss the possible nature, frequency and severity of side effects of drug treatment for ulcerative colitis with the person, and their family members or carers as appropriate. Refer to [Medicines adherence](#) (NICE clinical guideline 76).

1.1.3 Give the person, and their family members or carers as appropriate, information about their risk of developing colorectal cancer and about colonoscopic surveillance, in line with the NICE clinical guidelines on:

- [Colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis, Crohn's disease or adenomas](#) (NICE clinical guideline 118)
- [Referral for suspected cancer](#) (NICE clinical guideline 27)<sup>[a]</sup>.

## 1.2 *Inducing remission in people with ulcerative colitis*

### Treating mild to moderate ulcerative colitis: step 1 therapy

#### *Proctitis and proctosigmoiditis*

1.2.1 To induce remission in people with a mild to moderate first presentation or inflammatory exacerbation of proctitis or proctosigmoiditis:

- offer a topical aminosalicylate<sup>[a]</sup> alone (suppository or enema, taking into account the person's preferences) or

- consider adding an oral aminosalicylate<sup>[10]</sup> to a topical aminosalicylate or
- consider an oral aminosalicylate<sup>[10]</sup> alone, taking into account the person's preferences and explaining that this is not as effective as a topical aminosalicylate alone or combined treatment.

1.2.2 To induce remission in people with a mild to moderate first presentation or inflammatory exacerbation of proctitis or proctosigmoiditis who cannot tolerate or who decline aminosalicylates, or in whom aminosalicylates are contraindicated:

- offer a topical corticosteroid or
- consider oral prednisolone<sup>[11]</sup>, taking into account the person's preferences.

1.2.3 To induce remission in people with subacute proctitis or proctosigmoiditis, consider oral prednisolone<sup>[11]</sup>, taking into account the person's preferences.

### ***Left-sided and extensive ulcerative colitis***

1.2.4 To induce remission in adults with a mild to moderate first presentation or inflammatory exacerbation of left-sided or extensive ulcerative colitis:

- offer a high induction dose of an oral aminosalicylate
- consider adding a topical aminosalicylate or oral beclometasone dipropionate<sup>[12]</sup>, taking into account the person's preferences.

1.2.5 To induce remission in children and young people with a mild to moderate first presentation or inflammatory exacerbation of left-sided or extensive ulcerative colitis:

- offer an oral aminosalicylate<sup>[10],[13]</sup>
- consider adding a topical aminosalicylate<sup>[9]</sup> or oral beclometasone dipropionate<sup>[14]</sup>, taking into account the person's preferences (and those of their parents or carers as appropriate).

1.2.6 To induce remission in people with a mild to moderate first presentation or inflammatory exacerbation of left-sided or extensive ulcerative colitis who cannot tolerate or who decline aminosalicylates, in whom aminosalicylates are



contraindicated or who have subacute ulcerative colitis, offer oral prednisolone<sup>[11]</sup>.

## Treating mild to moderate ulcerative colitis: step 2 therapy

### *All extents of disease*

- 1.2.7 Consider adding oral prednisolone<sup>[11]</sup> to aminosalicylate therapy to induce remission in people with mild to moderate ulcerative colitis if there is no improvement within 4 weeks of starting step 1 aminosalicylate therapy or if symptoms worsen despite treatment. Stop beclometasone dipropionate if adding oral prednisolone.
- 1.2.8 Consider adding oral tacrolimus<sup>[15]</sup> to oral prednisolone to induce remission in people with mild to moderate ulcerative colitis if there is an inadequate response to oral prednisolone after 2–4 weeks.
- 1.2.9 For guidance on infliximab for treating subacute ulcerative colitis (all extents of disease), refer to [Infliximab for subacute manifestations of ulcerative colitis](#) (NICE technology appraisal guidance 140).

## Treating acute severe ulcerative colitis: all extents of disease

### *The multidisciplinary team*

- 1.2.10 For people admitted to hospital with acute severe ulcerative colitis:
- ensure that a gastroenterologist and a colorectal surgeon collaborate to provide treatment and management
  - ensure that the composition of the multidisciplinary team is appropriate for the age of the person
  - seek advice from a paediatrician with expertise in gastroenterology when treating a child or young person
  - ensure that the obstetric and gynaecology team is included when treating a pregnant woman.

### **Step 1 therapy**

1.2.11 For people admitted to hospital with acute severe ulcerative colitis (either a first presentation or an inflammatory exacerbation):

- offer intravenous corticosteroids to induce remission and
- assess the likelihood that the person will need surgery (see [recommendation 1.2.16](#)).

1.2.12 Consider intravenous ciclosporin<sup>[16]</sup> or surgery for people:

- who cannot tolerate or who decline intravenous corticosteroids or
- for whom treatment with intravenous corticosteroids is contraindicated.

Take into account the person's preferences when choosing treatment.

### **Step 2 therapy**

1.2.13 Consider adding intravenous ciclosporin<sup>[16]</sup> to intravenous corticosteroids or consider surgery for people:

- who have little or no improvement within 72 hours of starting intravenous corticosteroids or
- whose symptoms worsen at any time despite corticosteroid treatment.

Take into account the person's preferences when choosing treatment.

1.2.14 For guidance on infliximab for treating acute severe ulcerative colitis (all extents of disease) in people for whom ciclosporin is contraindicated or clinically inappropriate, refer to [Infliximab for acute exacerbations of ulcerative colitis](#) (NICE technology appraisal guidance 163).

### **Monitoring treatment**

1.2.15 Ensure that there are documented local safety monitoring policies and procedures (including audit) for adults, children and young people receiving treatment that needs monitoring (aminosalicylates, tacrolimus, ciclosporin, infliximab, azathioprine and mercaptopurine). Nominate a member of staff to

act on abnormal results and communicate with GPs and people with ulcerative colitis (and/or their parents or carers as appropriate).

## Assessing likelihood of needing surgery

- 1.2.16 Assess and document on admission, and then daily, the likelihood of needing surgery for people admitted to hospital with acute severe ulcerative colitis.
- 1.2.17 Be aware that there may be an increased likelihood of needing surgery for people with any of the following:
- stool frequency more than 8 per day
  - pyrexia
  - tachycardia
  - an abdominal X-ray showing colonic dilatation
  - low albumin, low haemoglobin, high platelet count or C-reactive protein (CRP) above 45 mg/litre (bear in mind that normal values may be different in pregnant women).

## 1.3 *Information about treatment options for people who are considering surgery*

These recommendations apply to anyone with ulcerative colitis considering elective surgery. The principles can also be applied to people requiring emergency surgery.

### Information when considering surgery

- 1.3.1 For people with ulcerative colitis who are considering surgery, ensure that a specialist (such as a gastroenterologist or a nurse specialist) gives the person (and their family members or carers as appropriate) information about all available treatment options, and discusses this with them. Information should include the benefits and risks of the different treatments and the potential consequences of no treatment.
- 1.3.2 Ensure that the person (and their family members or carers as appropriate) has sufficient time and opportunities to think about the options and the implications of the different treatments.

- 1.3.3 Ensure that a colorectal surgeon gives any person who is considering surgery (and their family members or carers as appropriate) specific information about what they can expect in the short and long term after surgery, and discusses this with them.
- 1.3.4 Ensure that a specialist (such as a colorectal surgeon, a gastroenterologist, an inflammatory bowel disease nurse specialist or a stoma nurse) gives any person who is considering surgery (and their family members or carers as appropriate) information about:
- diet
  - sensitive topics such as sexual function
  - effects on lifestyle
  - psychological wellbeing
  - the type of surgery, the possibility of needing a stoma and stoma care.
- 1.3.5 Ensure that a specialist who is knowledgeable about stomas (such as a stoma nurse or a colorectal surgeon) gives any person who is having surgery (and their family members or carers as appropriate) specific information about the siting, care and management of stomas.

## Information after surgery

- 1.3.6 After surgery, ensure that a specialist who is knowledgeable about stomas (such as a stoma nurse or a colorectal surgeon) gives the person (and their family members or carers as appropriate) information about managing the effects on bowel function. This should be specific to the type of surgery performed (ileostomy or ileoanal pouch) and could include the following:
- strategies to deal with the impact on their physical, psychological and social wellbeing
  - where to go for help if symptoms occur
  - sources of support and advice.

## 1.4 *Maintaining remission in people with ulcerative colitis*

### Proctitis and proctosigmoiditis

1.4.1 To maintain remission after a mild to moderate inflammatory exacerbation of proctitis or proctosigmoiditis, consider the following options, taking into account the person's preferences:

- a topical aminosalicylate<sup>[9]</sup> alone (daily or intermittent) or
- an oral aminosalicylate<sup>[10]</sup> plus a topical aminosalicylate<sup>[9]</sup> (daily or intermittent) or
- an oral aminosalicylate<sup>[10]</sup> alone, explaining that this may not be as effective as combined treatment or an intermittent topical aminosalicylate alone.

### Left-sided and extensive ulcerative colitis

1.4.2 To maintain remission in adults after a mild to moderate inflammatory exacerbation of left-sided or extensive ulcerative colitis:

- offer a low maintenance dose of an oral aminosalicylate
- when deciding which oral aminosalicylate to use, take into account the person's preferences, side effects and cost.

1.4.3 To maintain remission in children and young people after a mild to moderate inflammatory exacerbation of left-sided or extensive ulcerative colitis:

- offer an oral aminosalicylate<sup>[10],[13]</sup> when deciding which oral aminosalicylate to use, take into account the person's preferences (and those of their parents or carers as appropriate), side effects and cost.

### All extents of disease

1.4.4 Consider oral azathioprine<sup>[17]</sup> or oral mercaptopurine<sup>[17]</sup> to maintain remission:

- after two or more inflammatory exacerbations in 12 months that require treatment with systemic corticosteroids or
- if remission is not maintained by aminosalicylates.

1.4.5 To maintain remission after a single episode of acute severe ulcerative colitis:

- consider oral azathioprine<sup>[17]</sup> or oral mercaptopurine<sup>[17]</sup>
- consider oral aminosalicylates in people who cannot tolerate or who decline azathioprine and/or mercaptopurine, or in whom azathioprine and/or mercaptopurine are contraindicated.

## Dosing regimen for oral aminosalicylates

- 1.4.6 Consider a once-daily dosing regimen for oral aminosalicylates<sup>[18]</sup> when used for maintaining remission. Take into account the person's preferences, and explain that once-daily dosing can be more effective, but may result in more side effects.

## 1.5 *Pregnant women*

- 1.5.1 When caring for a pregnant woman with ulcerative colitis:

- Ensure effective communication and information-sharing across specialties (for example, primary care, obstetrics and gynaecology, and gastroenterology).
- Give her information about the potential risks and benefits of medical treatment to induce or maintain remission and of no treatment, and discuss this with her. Include information relevant to a potential admission for an acute severe inflammatory exacerbation.

## 1.6 *Monitoring*

### Monitoring bone health

#### *Adults*

- 1.6.1 For recommendations on assessing the risk of fragility fracture in adults, refer to [Osteoporosis: assessing the risk of fragility fracture \(NICE clinical guideline 146\)](#).

#### *Children and young people*

- 1.6.2 Consider monitoring bone health in children and young people with ulcerative colitis in the following circumstances:
- during chronic active disease

- after treatment with systemic corticosteroids
- after recurrent active disease.

## Monitoring growth and pubertal development in children and young people

1.6.3 Monitor the height and body weight of children and young people with ulcerative colitis against expected values on centile charts (and/or z scores) at the following intervals according to disease activity:

- every 3–6 months:
  - if they have an inflammatory exacerbation and are approaching or undergoing puberty or
  - if there is chronic active disease or
  - if they are being treated with systemic corticosteroids
- every 6 months during pubertal growth if the disease is inactive
- every 12 months if none of the criteria above are met.

1.6.4 Monitor pubertal development in young people with ulcerative colitis using the principles of Tanner staging, by asking screening questions and/or carrying out a formal examination.

1.6.5 Consider referral to a secondary care paediatrician for pubertal assessment and investigation of the underlying cause if a young person with ulcerative colitis:

- has slow pubertal progress or
- has not developed pubertal features appropriate for their age.

1.6.6 Monitoring of growth and pubertal development:

- can be done in a range of locations (for example, at routine appointments, acute admissions or urgent appointments in primary care, community services or secondary care)
- should be carried out by appropriately trained healthcare professionals as part of the overall clinical assessment (including disease activity) to help inform the need for

timely investigation, referral and/or interventions, particularly during pubertal growth.

If the young person prefers self-assessment for monitoring pubertal development, this should be facilitated where possible and they should be instructed on how to do this.

- 1.6.7 Ensure that relevant information about monitoring of growth and pubertal development and about disease activity is shared across services (for example, community, primary, secondary and specialist services). Apply the principles in [Patient experience in adult NHS services](#) (NICE clinical guideline 138) in relation to continuity of care.

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<sup>[8]</sup> This guideline is being updated (publication date to be confirmed).

<sup>[9]</sup> At the time of publication (June 2013), some topical aminosalicylates did not have a UK marketing authorisation for this indication in children and young people. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[10]</sup> At the time of publication (June 2013), some oral aminosalicylates did not have a UK marketing authorisation for this indication in children and young people. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[11]</sup> Refer to the BNF for guidance on stopping oral prednisolone therapy.

<sup>[12]</sup> At the time of publication (June 2013), beclometasone dipropionate only has a UK marketing authorisation 'as add-on therapy to 5-ASA containing drugs in patients who are non-responders to 5-ASA therapy in active phase'. For use outside these licensed indications, the prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[13]</sup> Dosing requirements for children should be calculated by body weight, as described in the BNF.

<sup>[14]</sup> At the time of publication (June 2013), beclometasone dipropionate did not have a UK marketing authorisation for this indication in children and young people. The prescriber should follow



relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[15]</sup> At the time of publication (June 2013), tacrolimus did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[16]</sup> At the time of publication (June 2013), ciclosporin did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[17]</sup> Although use is common in UK clinical practice, at the time of publication (June 2013) azathioprine and mercaptopurine did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

<sup>[18]</sup> At the time of publication (June 2013), not all oral aminosalicylates had a UK marketing authorisation for once-daily dosing. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's [Good practice in prescribing and managing medicines and devices](#) for further information.

## 2 Research recommendations

The Guideline Development Group has made the following recommendations for research, based on its review of evidence, to improve NICE guidance and patient care in the future. The Guideline Development Group's full set of research recommendations is detailed in appendix M of the full guideline.

### 2.1 *Induction of remission for people with moderate ulcerative colitis: prednisolone compared with aminosalicylates*

What is the clinical and cost effectiveness of prednisolone compared with aminosalicylates for the induction of remission for people with moderate ulcerative colitis?

#### **Why this is important**

Currently, people with moderate active ulcerative colitis most frequently receive either aminosalicylates or prednisolone as treatment, but there is no direct trial evidence comparing these treatments. Therefore people may receive treatment that is either less effective (in terms of symptom reduction or resolution, quality of life or healing of the colonic mucosa) or associated with greater side effects (especially with prednisolone). This is an important question in children, but the use of steroids is more contentious in children and there may be greater reluctance to use them because of possible effects on growth and development. People with moderate exacerbations of ulcerative colitis would be recruited and randomised to receive either prednisolone plus a bone-protecting agent or high-dose aminosalicylates. Primary end-points should be clinical remission and endoscopic remission.

### 2.2 *Induction of remission for people with moderate ulcerative colitis: prednisolone compared with beclometasone*

What is the clinical and cost effectiveness of prednisolone plus an aminosalicylate compared with beclometasone plus an aminosalicylate for induction of remission for people with moderate ulcerative colitis?

#### **Why this is important**

Evidence exists about the effectiveness of beclometasone plus an aminosalicylate for induction of remission in people with moderate ulcerative colitis. It seems likely that any corticosteroid would have a similar effect to beclometasone (in combination with an aminosalicylate), but no evidence

was available to confirm this. Prednisolone is cheap and readily available. Evidence to show comparable or better clinical and cost effectiveness of prednisolone plus an aminosalicylate compared with beclometasone plus an aminosalicylate would represent a significant cost benefit and potentially increased or at least similar clinical efficacy. The research should take the form of a double-blind randomised controlled trial. The outcomes should include patient satisfaction measures.

### *2.3 Induction of remission for people with subacute ulcerative colitis that is refractory to systemic corticosteroids*

What are the benefits, risks and cost effectiveness of methotrexate, ciclosporin, tacrolimus, adalimumab and infliximab compared with each other and with placebo for induction of remission for people with subacute ulcerative colitis that is refractory to systemic corticosteroids?

#### **Why this is important**

The best drug treatment for people with subacute ulcerative colitis whose condition fails to respond to treatment with oral prednisolone (a systemic corticosteroid) is unclear. Without effective treatment the condition may deteriorate, and may lead to the person requiring hospital admission for intravenous corticosteroid treatment or even surgery. It is common clinical practice to offer treatment with methotrexate or a calcineurin inhibitor (ciclosporin or tacrolimus), but high-quality evidence to guide clinicians is lacking. The use of infliximab in such cases was not recommended by NICE in technology appraisal guidance 140. This question should be investigated by a multicentre randomised, placebo-controlled trial in adults in secondary care. Outcomes should include patient-centred outcome measures.

### *2.4 Maintenance treatment for people with mild to moderate ulcerative colitis*

What is the clinical and cost effectiveness of regular maintenance treatment compared with no regular treatment (but rapid standard treatment if a relapse occurs) in specific populations with mild to moderate ulcerative colitis?

#### **Why this is important**

Maintenance treatment reduces the chance of relapses occurring, but for much of the time a drug is being taken with no obvious benefit, and it may have side effects. An exacerbation of ulcerative colitis can usually be effectively treated or stopped if treatment is given when the first symptoms or

signs of a relapse appear. It may be both clinically and cost effective to manage ulcerative colitis in this way, with people receiving episodic treatment rather than taking a drug continuously. This form of treatment may be appropriate if relatively few (for example, 1 or 2) mild relapses occur per year. The study population would be people in whom mild to moderate ulcerative colitis of any extent is in remission and who are not taking immunomodulator or biological drugs.

## 2.5 *Risk tool for predicting the likelihood of needing surgery for adults with acute severe ulcerative colitis*

To develop and validate a risk tool that predicts the likelihood of needing surgery for adults admitted to hospital with acute severe ulcerative colitis.

### **Why this is important**

Acute severe ulcerative colitis is a life-threatening emergency. About 30% of people admitted to hospital with acute severe ulcerative colitis will require colectomy to avoid colonic perforation during the emergency admission. The Truelove and Witts' severity index is used to define the clinical severity of disease on admission but has not been validated as a predictor of the need for colectomy during treatment. The Travis (Oxford) criteria are used to predict the likelihood of colectomy after 3 days of treatment with intravenous steroids, but may be less useful later in the course. No tools have been developed and validated in patients receiving rescue therapy with anti-tumour necrosis factor (TNF) antibodies or ciclosporin. A validated tool that can reliably predict a person's likelihood of needing a colectomy over the course of an admission to hospital for treating acute severe ulcerative colitis would allow the medical and surgical teams and the person to prepare for colectomy and potentially inform decisions about introducing rescue therapy with ciclosporin or infliximab and when continued medical therapy is unlikely to be successful. There may also be psychological and nutritional benefits to the person and cost benefits to the NHS (for example, shorter length of inpatient stay; decreased risk of infection; less use of rescue therapy). The tool would be developed by a derivation study using a prospective cohort. The tool would be validated using a different prospective cohort from that of the derivation study.

## 3 Other information

### 3.1 *Scope and how this guideline was developed*

NICE guidelines are developed in accordance with a [scope](#) that defines what the guideline will and will not cover.

This guideline covers drug therapy for inducing and maintaining remission in people with mild to moderate and acute severe ulcerative colitis. Specific consideration is given to pregnant women with ulcerative colitis and the monitoring of bone health and growth and pubertal development in children and young people. The information needs of people considering surgery is also covered. The diagnosis of ulcerative colitis is not covered by this guideline.

#### How this guideline was developed

NICE commissioned the National Clinical Guideline Centre to develop this guideline. The Centre established a Guideline Development Group (see [section 4](#)), which reviewed the evidence and developed the recommendations.

The methods and processes for developing NICE clinical guidelines are described in [The guidelines manual](#).

### 3.2 *Related NICE guidance*

Details are correct at the time of publication of the guideline (June 2013). Further information is available on the [NICE website](#).

#### Published

##### *General*

- [Patient experience in adult NHS services](#). NICE clinical guidance 138 (2012).
- [Medicines adherence](#). NICE clinical guidance 76 (2009).

##### *Condition-specific*

- [Fertility](#). NICE clinical guideline 156 (2013).
- [Adalimumab for the treatment of moderate to severe ulcerative colitis \(terminated appraisal\)](#). NICE technology appraisal guidance 262 (2012).

- [Crohn's disease](#). NICE clinical guideline 152 (2012).
- [Osteoporosis: assessing the risk of fragility fracture](#) NICE clinical guideline 146 (2012).
- [Colorectal cancer](#). NICE clinical guideline 131 (2011).
- [Colonoscopic surveillance for prevention of colorectal cancer in people with ulcerative colitis, Crohn's disease or adenomas](#). NICE clinical guideline 118 (2011).
- [Infliximab for acute exacerbations of ulcerative colitis](#). NICE technology appraisal guidance 163 (2008).
- [Infliximab for subacute manifestations of ulcerative colitis](#). NICE technology appraisal guidance 140 (2008).
- [Irritable bowel syndrome in adults](#). NICE clinical guideline 61 (2008).
- [Faecal incontinence](#). NICE clinical guideline 49 (2007).
- [Injectable bulking agents for faecal incontinence](#). NICE interventional procedure guidance 210 (2007).
- [Nutrition support in adults](#). NICE clinical guideline 32 (2006).
- [Referral guidelines for suspected cancer](#). NICE clinical guideline 27 (2005).
- [Leukapheresis for inflammatory bowel disease](#). NICE interventional procedure guidance 126 (2005).

## 4 The Guideline Development Group, National Collaborating Centre and NICE project team

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## About this guideline

NICE clinical guidelines are recommendations about the treatment and care of people with specific diseases and conditions in the NHS in England and Wales.

NICE guidelines are developed in accordance with a [scope](#) that defines what the guideline will and will not cover.

This guideline was developed by the National Clinical Guideline Centre, which is based at the Royal College of Physicians. The Centre worked with a Guideline Development Group, comprising healthcare professionals (including consultants, GPs and nurses), patients and carers, and technical staff, which reviewed the evidence and drafted the recommendations. The recommendations were finalised after public consultation.

The methods and processes for developing NICE clinical guidelines are described in [The guidelines manual](#).

## *Strength of recommendations*

Some recommendations can be made with more certainty than others. The Guideline Development Group makes a recommendation based on the trade-off between the benefits and harms of an intervention, taking into account the quality of the underpinning evidence. For some interventions, the Guideline Development Group is confident that, given the information it has looked at, most patients would choose the intervention. The wording used in the recommendations in this guideline denotes the certainty with which the recommendation is made (the strength of the recommendation).

For all recommendations, NICE expects that there is discussion with the patient about the risks and benefits of the interventions, and their values and preferences. This discussion aims to help them to reach a fully informed decision (see also [Patient-centred care](#)).

## **Interventions that must (or must not) be used**

We usually use 'must' or 'must not' only if there is a legal duty to apply the recommendation. Occasionally we use 'must' (or 'must not') if the consequences of not following the recommendation could be extremely serious or potentially life threatening.

## **Interventions that should (or should not) be used – a 'strong' recommendation**

We use 'offer' (and similar words such as 'refer' or 'advise') when we are confident that, for the vast majority of patients, an intervention will do more good than harm, and be cost effective. We use similar forms of words (for example, 'Do not offer...') when we are confident that an intervention will not be of benefit for most patients.

## **Interventions that could be used**

We use 'consider' when we are confident that an intervention will do more good than harm for most patients, and be cost effective, but other options may be similarly cost effective. The choice of intervention, and whether or not to have the intervention at all, is more likely to depend on the patient's values and preferences than for a strong recommendation, and so the healthcare professional should spend more time considering and discussing the options with the patient.

## *Other versions of this guideline*

The full guideline, 'Ulcerative colitis: management in adults, children and young people' contains details of the methods and evidence used to develop the guideline. It is published by the National Clinical Guideline Centre.

The recommendations from this guideline have been incorporated into a [NICE Pathway](#).

We have produced [information for the public](#) about this guideline.

## *Implementation*

[Implementation tools and resources](#) to help you put the guideline into practice are also available.

## *Your responsibility*

This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. 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, and informed by the summaries of product characteristics of any drugs.

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 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.

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## *Accreditation*

