NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline

Ulcerative colitis: management

Draft for consultation, December 2018

This guideline covers the care and treatment of adults, children and young people who have ulcerative colitis. It aims to help professionals to provide consistent high-quality care and it highlights the importance of advice and support for people with ulcerative colitis. The 2019 update makes new recommendations on inducing remission in mild to moderate ulcerative colitis.

Who is it for?

- Healthcare professionals
- Commissioners and providers
- People with ulcerative colitis, their families and carers

This guideline will update NICE guideline CG166 (published June 2013).

We have reviewed the evidence on inducing remission in mild to moderate ulcerative colitis. You are invited to comment on the new and updated recommendations. These are marked as **[2019]**.

You are also invited to comment on recommendations that NICE proposes to delete from the 2013 guideline.

We have not reviewed the evidence for the recommendations shaded in grey, and cannot accept comments on them. In some cases, we have made minor wording changes for clarification.

See update information for a full explanation of what is being updated.

This draft guideline contains:

- the draft recommendations
- recommendations for research
- rationale and impact sections that explain why the committee made the [2019] recommendations and how they might affect practice
- the guideline context.

Full details of the evidence and the committee's discussion on the 2019 recommendations are in the evidence reviews. Evidence for the 2013 recommendations is in the full version of the 2013 guideline.

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Contents

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

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 the NICE guideline on patient experience in adult NHS services. **[2013]**

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 the NICE guideline on medicines adherence. **[2013]**

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 guidelines on:

- colorectal cancer prevention: colonoscopic surveillance in adults with ulcerative colitis, Crohn's disease or adenomas
- suspected cancer: recognition and referral. **[2013]**

1.2 Inducing remission in people with ulcerative colitis

Treating mild-to-moderate ulcerative colitis

Proctitis

1.2.1 To induce remission in people with a mild-to-moderate first presentation or inflammatory exacerbation of proctitis, offer a topical aminosalicylate[1] as first-line treatment. **[2019]**

1.2.2 If remission is not achieved within 4 weeks, consider adding an oral aminosalicylate[2]. **[2019]**

1.2.3 If further treatment is needed, consider adding a topical or oral corticosteroid[3]. **[2019]**

1.2.4 For people who decline a topical aminosalicylate:

- consider an oral aminosalicylate as first-line treatment, and explain that this is not as effective as a topical aminosalicylate
- if remission is not achieved within 4 weeks, consider adding a topical or oral corticosteroid[3]. **[2019]**

1.2.5 For people who cannot tolerate aminosalicylates, consider a topical or an oral corticosteroid. **[2019]**

[1] At the time of consultation (December 2018), 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.

[2] At the time of consultation (December 2018), 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.

[3] At the time of consultation (December 2018), 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'. Additionally, budesonide (oral or rectal) and prednisolone foam are not licensed in children. 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.

Proctosigmoiditis and left-sided ulcerative colitis

1.2.6 To induce remission in people with a mild-to-moderate first presentation or inflammatory exacerbation of proctosigmoiditis or left-sided ulcerative colitis, offer a topical aminosalicylate as first-line treatment. **[2019]**

1.2.7 If remission is not achieved, consider:

- adding a high-dose oral aminosalicylate to the topical aminosalicylate **or**
- switching to a high-dose oral aminosalicylate and a topical corticosteroid. **[2019]**

1.2.8 If further treatment is needed, stop topical treatments and offer an oral corticosteroid and an oral aminosalicylate. **[2019]**

1.2.9 For people who decline any topical treatment:

- consider a high-dose oral aminosalicylate alone, and explain that this is not as effective as a topical aminosalicylate
- if remission is not achieved, offer an oral corticosteroid in addition to the high-dose aminosalicylate. **[2019]**

1.2.10 For people who cannot tolerate aminosalicylates, consider a topical or oral corticosteroid. **[2019]**

Extensive disease

1.2.11 To induce remission in people with a mild-to-moderate first presentation or inflammatory exacerbation of extensive ulcerative colitis, offer a topical aminosalicylate and a high-dose oral aminosalicylate as first-line treatment. **[2019]**

1.2.12 If remission is not achieved, stop the topical aminosalicylate and offer an oral corticosteroid with a high-dose oral aminosalicylate. **[2019]**

1.2.13 For people who cannot tolerate aminosalicylates, consider an oral corticosteroid. **[2019]**

All extents of disease

1.2.14 For guidance on biologics for treating moderately to severely active ulcerative colitis, see the NICE technology appraisal guidance on:

- infliximab, adalimumab and golimumab for moderately to severely active ulcerative colitis
- vedolizumab for treating moderately to severely active ulcerative colitis. **[2019]**

To find out why the committee made the 2019 recommendations on inducing remission in mild to moderate ulcerative colitis and how they might affect practice, see rationale and impact.

Treating acute severe ulcerative colitis: all extents of disease

The multidisciplinary team

1.2.15 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. **[2013]**

Step 1 therapy

1.2.16 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 1.2.22). **[2013]**

1.2.17 Consider intravenous ciclosporin[4] 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. **[2013]**

Step 2 therapy

1.2.18 Consider adding intravenous ciclosporin[4] 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. **[2013]**

1.2.19 Infliximab is recommended as an option for the treatment of acute exacerbations of severely active ulcerative colitis only in patients in whom ciclosporin is contraindicated or clinically inappropriate, based on a careful assessment of the risks and benefits of treatment in the individual patient. **[2008]**

[This recommendation is from the NICE technology appraisal guidance on infliximab for acute exacerbations of ulcerative colitis .]

1.2.20 In people who do not meet the criterion in 1.2.19, infliximab should only be used for the treatment of acute exacerbations of severely active ulcerative colitis in clinical trials. **[2008]**

[4] At the time of consultation (December 2018), 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 Prescribing guidance: prescribing unlicensed medicines for further information.

[This recommendation is from the NICE technology appraisal on infliximab for acute exacerbations of ulcerative colitis.]

Monitoring treatment

1.2.21 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 their family members or carers (as appropriate). **[2013]**

Assessing likelihood of needing surgery

1.2.22 Assess and document on admission, and then daily, the likelihood of needing surgery for people admitted to hospital with acute severe ulcerative colitis. **[2013]**

1.2.23 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). **[2013]**

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. **[2013]**

1.3.2 Ensure that the person and their family members or carers (as appropriate) have sufficient time and opportunities to think about the options and the implications of the different treatments. **[2013]**

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. **[2013]**

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. **[2013]**

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. **[2013]**

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. **[2013]**

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[5] alone (daily or intermittent) **or**
- an oral aminosalicylate[6] plus a topical aminosalicylate[5] (daily or intermittent) **or**
- an oral aminosalicylate[6] alone, explaining that this may not be as effective as combined treatment or an intermittent topical aminosalicylate alone. **[2013]**

[5] At the time of consultation (December 2018), 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 Prescribing guidance: prescribing unlicensed medicines for further information.

[6] At the time of consultation (December 2018), 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 Prescribing guidance: prescribing unlicensed medicines for further information.

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. **[2013]**

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[6,7]
- 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. **[2013]**

All extents of disease

1.4.4 Consider oral azathioprine[8] or oral mercaptopurine[8] to maintain remission:

- after 2 or more inflammatory exacerbations in 12 months that require treatment with systemic corticosteroids **or**
- if remission is not maintained by aminosalicylates. **[2013]**

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

- consider oral azathioprine[8] or oral mercaptopurine[8]
- consider oral aminosalicylates if azathioprine and/or mercaptopurine are contraindicated or the person cannot tolerate them. **[2013]**

[7] Dosing requirements for children should be calculated by body weight, as described in the BNF.
[8] Although use is common in UK clinical practice, at the time of consultation (December 2018) not all brands of azathioprine and mercaptopurine had 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 Prescribing guidance: prescribing unlicensed medicines for further information.

Dosing regimen for oral aminosalicylates

1.4.6 Consider a once-daily dosing regimen for oral aminosalicylates[9] 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. **[2013]**

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 not having treatment, and discuss this with her. Include information relevant to a potential admission for an acute severe inflammatory exacerbation. **[2013]**

1.6 Monitoring

Monitoring bone health

Adults

1.6.1 For recommendations on assessing the risk of fragility fracture in adults, refer to the NICE guideline on osteoporosis: assessing the risk of fragility fracture. **[2013]**

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

[9] At the time of consultation (December 2018), 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 Prescribing guidance: prescribing unlicensed medicines for further information.

- after recurrent active disease. **[2013]**

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. **[2013]**

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. **[2013]**

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. **[2013]**

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 allowed if possible and they should be instructed on how to do this. **[2013]**

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 the NICE guideline on patient experience in adult NHS services in relation to continuity of care. **[2013]**

Terms used in this guideline

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

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 wakening)	
	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)	

Recommendations for research

As part of the 2019 update, the guideline committee made an additional 3 research recommendations on inducing remission in mild to moderate ulcerative colitis.

Key recommendations for research

1 The effectiveness of immunomodulators in inducing remission in proctitis

In mild-to-moderate first presentation or inflammatory exacerbation of proctitis that is resistant to standard treatment, what is the effectiveness of topical

immunomodulators, such as tacrolimus, in achieving clinical remission and what is the most effective formulation (suppository/ointment)?

To find out why the committee made the research recommendation on immunomodulators for proctitis see rationale and impact.

2 The effectiveness of immunomodulators in unresponsive ulcerative colitis

What is the effectiveness of oral tacrolimus and systemic (intramuscular/subcutaneous/oral) methotrexate in the induction of remission in mild-to-moderate ulcerative colitis unresponsive to aminosalicylates?

To find out why the committee made the research recommendation on immunomodulators for unresponsive ulcerative colitis see rationale and impact.

3 The relative effectiveness of corticosteroids for inducing remission in ulcerative colitis

What is the clinical and cost effectiveness of prednisolone, budesonide, beclometasone in addition to aminosalicylates compared with each other and with aminosalicylate monotherapy for the induction of remission for people with mild-to-moderate ulcerative colitis?

To find out why the committee made the research recommendation on corticosteroids for the induction of remission in mild-moderate ulcerative colitis see rationale and impact.

Other recommendations for research

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?

Induction of remission for people with moderate ulcerative colitis: prednisolone compared with beclomethasone

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?

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?

Rationale and impact

This section briefly explains why the committee made the recommendations and how they might affect practice. It links to details of the evidence and a full description of the committee's discussion.

Inducing remission in people with mild-to-moderate ulcerative colitis

Recommendations 1.2.1 to 1.2.14

Why the committee made the recommendations

Proctitis

The evidence showed that topical aminosalicylates (suppositories or enema) are the most effective treatments for achieving remission in people with mild-to-moderate proctitis, so these were recommended as first-line treatments. The evidence did not show any difference in effectiveness between enema and suppository.

Topical aminosalicylates alone are recommended for up to 4 weeks because the evidence showed that they were the most effective treatment within this timeframe. There was no direct evidence for combining topical and oral aminosalicylates for people with proctitis. However, evidence showed that this combination was effective for people with proctosigmoiditis, and the committee agreed that this evidence was

also applicable to people with proctitis alone. The committee chose not to specify a dose for the oral aminosalicylate, leaving this open to clinical judgment depending on the specific situation. For example, the clinician could give a low dose if the person had not taken an aminosalicylate before, or a high dose if the person was already taking a low dose.

Some people will not achieve remission with topical and oral aminosalicylates. In clinical practice, oral or topical corticosteroids are commonly added at this stage, but there was no evidence on this combination. Despite no direct evidence for the effectiveness of topical or oral corticosteroids, the committee agreed that, based on their experience, these should be recommended to people who cannot tolerate aminosalicylates.

As the evidence showed that oral aminosalicylates are not as effective at inducing remission, the committee thought it was important to explain this to people who decline topical aminosalicylates. From the committee's experience, they agreed to consider a topical or an oral corticosteroid in people who cannot tolerate aminosalicylates.

Cost-effectiveness evidence showed that using an immunomodulator as the next line of treatment after oral or topical corticosteroids and oral aminosalicylates produced greater health benefits at lower total costs than other strategies. However, the clinical evidence on topical immunomodulators was limited and it was unclear how applicable it was to UK clinical practice. Because of this, the committee recommended the sequence without this final treatment, and recommended further research on topical immunomodulators.

Proctosigmoiditis or left-sided ulcerative colitis

There is evidence that topical aminosalicylates are effective for achieving remission in people with mild-to-moderate proctosigmoiditis or left-sided ulcerative colitis, so these are recommended as first-line treatment. Cost-effectiveness evidence showed that treatment sequences starting with topical aminosalicylates produced greater health benefits and incurred lower total costs than other strategies.

There is no direct evidence for the effectiveness of high-dose oral aminosalicylates combined with either topical aminosalicylates or topical corticosteroids. However,

there is evidence that topical or high-dose oral aminosalicylates individually provide some benefit. Therefore, the committee agreed it was reasonable to recommend combinations of these if remission is not achieved. While there was limited evidence for oral corticosteroids, in the committee's experience an oral corticosteroid may benefit people with proctosigmoiditis or left-sided disease if further treatment is needed. As a result, they recommended oral corticosteroids with oral aminosalicylates instead of topical treatment for these people. This reflects current practice for people who do not achieve remission with topical treatments and high-dose oral aminosalicylates.

In people who cannot tolerate aminosalicylates, topical or oral corticosteroids are recommended as they are also an effective treatment option.

Extensive ulcerative colitis

The evidence showed that people with mild-to-moderate extensive ulcerative colitis would benefit most from a combination of high-dose oral aminosalicylates with topical aminosalicylates as first-line treatment. There is evidence that an oral corticosteroid combined with a high-dose oral aminosalicylate is also effective, so the committee recommended this combination if remission is not achieved with aminosalicylates alone. In people who cannot tolerate aminosalicylates, oral corticosteroids are recommended as they are also an effective treatment option.

The sequence of drugs recommended was more effective than starting with a high-dose oral aminosalicylate alone. There was some uncertainty around the cost effectiveness of this sequence. The data on the effectiveness of high-dose oral aminosalicylates combined with topical aminosalicylates was from an 8-week clinical trial. The committee believed that in practice, people whose disease did not respond to treatment within 4 weeks would switch to another treatment. When the cost-effectiveness analysis allowed for early switching, the combination of a high-dose oral aminosalicylate and topical aminosalicylate was not cost effective. However, if it was assumed that everyone continued treatment as described in the trial, the combination of a high-dose oral aminosalicylate and topical aminosalicylate was more likely to be cost effective. The committee agreed that although allowing for

early switching was a better reflection of clinical practice, the other approach to the analysis more closely reflected the trial data.

There was some evidence on methotrexate for inducing remission, but it did not show a clear benefit. There was no evidence found on oral tacrolimus so the committee recommended further research to address the effectiveness of tacrolimus and methotrexate.

All extents of disease

There was limited evidence from paediatric populations, and the committee agreed that it is reasonable to generalise the recommendations made to all ages.

There is limited evidence on oral corticosteroids. In addition, the committee agreed that the use of oral corticosteroid is generally reserved for later lines of treatment because of concerns about side effects. It is not clear which corticosteroid is most effective for each extent of disease. There is also limited evidence on immunomodulators, specifically oral tacrolimus and systemic methotrexate for each extent of disease. The committee recommended further research to address these uncertainties.

How the recommendations might affect practice

The new recommendations classify the extents of ulcerative colitis differently. This will be clearer and more informative for people with mild–to-moderate ulcerative colitis and healthcare professionals. It more closely reflects current practice.

The recommendations in the 2013 guideline referred to specific corticosteroids. To better reflect the available evidence, the updated recommendations refer to corticosteroids as a class rather than recommending individual corticosteroids. This allows healthcare professionals and people with mild-to-moderate ulcerative colitis to choose the most appropriate corticosteroid, depending on patient preference, availability and acquisition cost.

Full details of the evidence and the committee's discussion are in evidence review: induction of remission in mild-moderate ulcerative colitis.

Context

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 defecate 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.

Finding more information and resources

To find out what NICE has said on topics related to this guideline, see our web page on inflammatory bowel disease.

Update information

This guideline is an update of NICE guideline CG166 (published June 2013) and will replace it.

We have reviewed the evidence on inducing remission for people with mild-to-moderate ulcerative colitis.

Recommendations are marked **[2019]** if the evidence has been reviewed.

Recommendations that have been deleted or changed

We propose to delete some recommendations from the 2013 guideline. Table 1 sets out these recommendations and includes details of replacement recommendations. If there is no replacement recommendation, an explanation for the proposed deletion is given.

In recommendations shaded in grey and ending **[2008]** or **[2013]**, we have not reviewed the evidence. In some cases minor changes have been made, for example, to update links or bring the language and style up to date without changing the intent of the recommendation. Minor changes are listed in table 2.

See also the previous NICE guideline and supporting documents.

Table 1 Recommendations that have been deleted

Recommendation in 2013 guideline	Comment
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 alone (suppository or enema, taking into account the person's preferences) or • consider adding an oral aminosalicylate to a topical aminosalicylate or • consider an oral aminosalicylate alone, taking into account the person's preferences and explaining that this is not as effective as a topical aminosalicylate alone or combined treatment. **[2013]**	Replaced by: Recommendations 1.2.1–14
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, taking into account the person's preferences. **[2013]**	
1.2.3 To induce remission in people with subacute proctitis or proctosigmoiditis, consider oral prednisolone, taking into account the person's preferences. **[2013]**	

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, taking into account the person's preferences. **[2013]**	
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, • consider adding a topical aminosalicylate or oral beclometasone dipropionate, taking into account the person's preferences (and those of their parents or carers as appropriate). **[2013]**	
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. **[2013]**	
1.2.7 Consider adding oral prednisolone 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. **[2013]**	

1.2.8 Consider adding oral tacrolimus 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. **[2013]**	
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). **[2013]**	

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2 **Table 2 Minor changes to recommendation wording (no change to intent)**

Recommendation numbers in current guideline	Comment
All recommendations except those labelled [2019]	Recommendations have been edited into the direct style (in line with current NICE style for recommendations in guidelines) where possible.

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