



A summary of prescribing recommendations from NICE guidance

Ulcerative colitis

NICE CG166; 2013

This guideline covers the management of ulcerative colitis in children (≤11 years), young people (12 to 17 years) and adults (≥18 years).

Definition of terms

IV	intravenous
CI	contraindication / contraindicated

Severity of ulcerative colitis

- ◆ For definitions of mild, moderate and severe ulcerative colitis: [see NICE pathway](#).
- ◆ 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 consideration of urgent surgical intervention.

Treatment and management

Also see Box 1: **Prescribing** (over page)

Step 1 treatment – mild to moderate ulcerative colitis

Proctitis and proctosigmoiditis

- ◆ To induce remission in people with a mild to moderate first presentation or inflammatory exacerbation:
 - > give a topical aminosalicilate***U^c** alone (suppository or enema), **OR**
 - > consider adding an oral aminosalicilate***U^c** to a topical aminosalicilate*, **OR**
 - > consider an oral aminosalicilate***U^c** alone. Explain that this is not as effective as a topical aminosalicilate* alone or combined treatment.
- ◆ In people who decline treatment with, cannot tolerate or have a CI to aminosalicilates:
 - > offer a topical corticosteroid*, **OR**
 - > consider oral prednisolone*.
- ◆ In people with subacute proctitis or proctosigmoiditis, consider oral prednisolone*.

Left-sided or extensive ulcerative colitis

Adults

- ◆ To induce remission in people with a mild to moderate first presentation or inflammatory exacerbation:
 - > offer a high induction dose of an oral aminosalicilate*,
 - > consider adding a topical aminosalicilate* **OR** oral beclometasone dipropionate***U**.

Children and young people

- ◆ To induce remission in those with a mild to moderate first presentation or inflammatory exacerbation:
 - > give an oral aminosalicilate***U^c**,
 - > consider adding a topical aminosalicilate***U^c** **OR** oral beclometasone dipropionate***U^c**.

Adults, children and young people

- ◆ To induce remission for a first presentation or inflammatory exacerbation in those who decline, cannot tolerate, or have a CI to aminosalicilates, or in subacute ulcerative colitis:
 - > give oral prednisolone*.

Step 2 treatment – all extents of disease

- ◆ If there is no improvement within 4 weeks of starting step 1 aminosalicilate therapy or if symptoms worsen despite treatment, consider adding oral prednisolone* to induce remission in people with mild to moderate ulcerative colitis.
- ◆ Stop beclometasone dipropionate if adding oral prednisolone.
- ◆ If there is an inadequate response to oral prednisolone after 2 to 4 weeks consider adding oral tacrolimus***U** to induce remission in people with mild to moderate ulcerative colitis.
- ◆ Infliximab is **NOT** recommended for the treatment of subacute manifestations of moderately to severely active ulcerative colitis. [See TA140:Ulcerative colitis:infliximab](#)

Acute severe ulcerative colitis (person admitted to hospital)

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

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.
- ◆ 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) >45mg/litre (bear in mind that normal values may be different in pregnant women).

Information about treatment options for people who are considering surgery – see NICE pathway

Step 1 treatment

- ◆ Assess the likelihood that the person will need surgery.
- ◆ Give IV corticosteroids* to induce remission.
- ◆ Consider IV ciclosporin***U** or surgery for people who decline, cannot tolerate or have CI to IV corticosteroids.

* See Summary of Product Characteristics for full prescribing information.

U^c some preparations are not licensed for this indication in children/young people. Obtain and document informed consent.

U unlicensed indication. Obtain and document informed consent.

[See NICE pathway: Ulcerative colitis](#)

Ulcerative colitis continued.....

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Step 2 treatment

- ◆ Consider adding IV ciclosporin***U** to IV corticosteroids* **OR** consider surgery for people:
 - who have little or no improvement within 72 hours of starting IV corticosteroids, **OR**
 - whose symptoms worsen at any time despite corticosteroid treatment.
- ◆ In patients in whom ciclosporin is CI or clinically inappropriate infliximab* is recommended as an option for treatment of acute exacerbations of severely active ulcerative colitis, based on careful assessment of the risks and benefits of treatment in the individual patient. [See TA163:Ulcerative colitis:infliximab](#)
- ◆ In people who do not meet the above criteria, infliximab should only be used in clinical trials.

Maintaining remission**Proctitis and proctosigmoiditis**

- ◆ To maintain remission after a mild to moderate inflammatory exacerbation consider the following options:
 - a topical aminosalicylate***U^c** alone (daily or intermittent), **OR**
 - an oral aminosalicylate***U^c** and a topical aminosalicylate***U^c** (daily or intermittent), **OR**
 - an oral aminosalicylate* alone. Explain that this may not be as effective as combined treatment or an intermittent topical aminosalicylate alone.

Left-sided and extensive ulcerative colitis

- ◆ To maintain remission after a mild to moderate inflammatory exacerbation in:
 - **adults:** offer a low maintenance dose of an oral aminosalicylate*,
 - **children and young people:** offer an oral aminosalicylate***U^c**.
- ◆ Take into account the person's preferences (and/or parents/carers as appropriate), side effects and cost.

Dosing regimen for oral aminosalicylates

- ◆ Consider a once-daily dosing regimen for oral aminosalicylates**U** 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.

All extents of disease

- ◆ Consider oral azathioprine***U** or mercaptopurine***U** to maintain remission:
 - after ≥2 inflammatory exacerbations in 12 months that require treatment with systemic corticosteroids, **OR**
 - if remission is not maintained by aminosalicylates.
- ◆ To maintain remission after a single episode of acute severe ulcerative colitis consider:
 - oral azathioprine***U** or mercaptopurine***U**, **OR**
 - oral aminosalicylates* in people who decline, cannot tolerate or with a CI to azathioprine and/or mercaptopurine.

Colonoscopic surveillance – see NICE pathway**Pregnant women**

- ◆ Ensure effective communication and information-sharing across specialties (e.g. primary care, obstetrics and gynaecology, and gastroenterology).
- ◆ Give information and discuss the potential risks and benefits of medical treatment to induce or maintain remission and of no treatment. Include information relevant to a potential admission for an acute severe inflammatory exacerbation.
 - * See Summary of Product Characteristics for full prescribing information

Monitoring

- ◆ Ensure that there are documented local safety 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/carers as appropriate).

Bone health**Adults**

- ◆ For information on assessing the risk of fragility fracture in adults see [NICE Pathway:Osteoporosis](#).

Children and young people

- ◆ Consider monitoring bone health:
 - during chronic active disease,
 - after treatment with systemic corticosteroids,
 - after recurrent active disease.

Growth and pubertal development

- ◆ Monitor height and body weight of children and young people with ulcerative colitis against expected values on centile charts (and/or z scores).
- ◆ Monitor every 3 to 6 months if they:
 - have an inflammatory exacerbation and are approaching or undergoing puberty, **OR**
 - have chronic active disease, **OR**
 - are being treated with systemic corticosteroids.
- ◆ Monitor every 6 months during pubertal growth if the disease is inactive.
- ◆ Monitor every 12 months if none of the criteria above are met.

Box 1**Prescribing**

- ◆ Children's doses should be calculated by body weight as per BNFC.

Aminosalicylates

- ◆ When choosing a preparation consider the following:
 - patient's preferences, including parent/carer as appropriate,
 - route of administration e.g. oral, rectal,
 - preferred formulation e.g. suppository, enema, foam,
 - licensed indications (these differ for each product).
- ◆ Oral mesalazine products are not interchangeable. The delivery characteristics of preparations may vary. See [BNF/BNFC](#)
- ◆ Advise patients to report any unexplained bleeding, bruising, purpura, sore throat, fever or malaise that occurs during treatment. A blood count should be performed and the drug stopped immediately if there is suspicion of a blood dyscrasia.
- ◆ For monitoring requirements see Summary of Product Characteristics (SPC) for individual products.

Azathioprine and mercaptopurine

- ◆ Do a full blood count weekly for at least the first 4 weeks of treatment (more frequently if clinically indicated). Then monitor at least every 3 months. See individual SPCs for monitoring requirements.
- ◆ Monitor for neutropenia even if the person has normal TPMT (thiopurine methyltransferase) activity.

Corticosteroids

- ◆ Patients on corticosteroids should be given a steroid treatment card.
- ◆ Corticosteroids should not be stopped suddenly. For patients who have been taking corticosteroids for >3 weeks reduce dose gradually.