# Specialist Pharmacy NICE Bites June 2



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# A summary of prescribing recommendations from NICE guidance

This edition includes one guideline.

# Ulcerative colitis: management

This guideline covers the management of ulcerative colitis (UC) in children, young people and adults. It aims to help professionals to provide consistent high-quality care and it highlights the importance of advice and support for people with UC.

# Information and support - see pathway.

# Pharmacological management – inducing remission Mild-to-moderate ulcerative colitis

# **Proctitis**

- Offer a topical aminosalicylate <sup>U1</sup> as first-line treatment for people with a mild-to-moderate first presentation or inflammatory exacerbation of proctitis.
- If remission is not achieved within 4 weeks, consider adding an oral aminosalicylate<sup>U2</sup>.
- If further treatment is needed, consider adding a time-limited course of a topical or oral corticosteroid<sup>U3</sup> (normally 4-8 weeks, depending on the steroid).
- 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 time-limited course of a topical or oral corticosteroid<sup>U3</sup>.
- For people who cannot tolerate aminosalicylates, consider a time-limited course of a topical or oral corticosteroid.

# Proctosigmoiditis and left-sided ulcerative colitis

- Offer a topical aminosalicylate as first-line treatment for people with a mild-to-moderate first presentation or inflammatory exacerbation of proctosigmoiditis or left-sided UC.
- If remission is not achieved within 4 weeks, consider:
  - > adding a high-dose oral aminosalicylate, OR
  - switching to a high-dose oral aminosalicylate and a timelimited course of a topical corticosteroid.
- If further treatment is needed, stop topical treatments and offer an oral aminosalicylate and a time-limited course of an oral corticosteroid.
- 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 within 4 weeks, offer a timelimited course of an oral corticosteroid in addition to the highdose aminosalicylate.
- For people who cannot tolerate aminosalicylates, consider a time-limited course of a topical or an oral corticosteroid.

# **Extensive disease**

- Offer a topical aminosalicylate and a high-dose oral aminosalicylate as first-line treatment for people with a mild-tomoderate first presentation or inflammatory exacerbation of extensive UC.
- If remission is not achieved within 4 weeks, stop the topical aminosalicylate and offer a high-dose oral aminosalicylate and a time-limited course of an oral corticosteroid.
- For people who cannot tolerate aminosalicylates, consider a time-limited course of a topical or oral corticosteroid.

# Moderately to severely active ulcerative colitis

#### All extents of disease

- For guidance on biologics and Janus kinase inhibitors for moderately to severely active UC, see NICE Technology Appraisals:
  - NICE TA329: Infliximab, adalimumab and golimumab for moderately to severely active UC
  - NICE TA342: Vedolizumab for treating moderately to severely active UC
  - > NICE TA547: Tofacitinib for moderately to severely active UC

# Acute severe ulcerative colitis

# All extents of disease

# Step 1 therapy

- For people admitted to hospital with acute severe UC (either a first presentation or an inflammatory exacerbation):
- > offer intravenous corticosteroids to induce remission AND
  > assess the likelihood that the person will need surgery.
   Consider intravenous ciclosporin<sup>U4</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 preference when choosing treatment.

# Step 2 therapy

- Consider adding intravenous ciclosporin<sup>U4</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 preference when choosing treatment.
- Infliximab is recommended as an option for the treatment of acute exacerbations of severely active UC 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.
- In people who do not meet this criterion, infliximab should only be used for the treatment of acute exacerbations of severely active UC in clinical trials. See <u>NICE TA163 – infliximab for UC</u>

# Multidisciplinary team

For people admitted to hospital with acute severe UC – see <u>pathway</u>.

Surgery - see full guideline.

**Definition** - for the definition of mild, moderate and severe ulcerative colitis, see <u>full guideline</u>.

Please go to <u>www.nice.org.uk</u> to check for any recent updates to this guidance.





# Ulcerative colitis.....continued NICE NG130 2019

#### Box 1

#### Monitoring

Drug monitoring
 Ensure 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 UC and their family members or carers (as appropriate).

#### Monitoring bone health in adults

 For recommendations on assessing the risk of fragility fracture in adults, refer to NICE guideline <u>CG146</u>: <u>Osteoporosis: assessing the risk of fragility fracture</u>.

#### Monitoring bone health in children and young people

- Consider monitoring bone health in children and young people with UC 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 – see <u>full guideline</u>.

# Pharmacological management - maintaining remission

# Proctitis and proctosigmoiditis

- 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>U1</sup> alone (daily or intermittent), OR
    > an oral aminosalicylate<sup>U2</sup> plus a topical aminosalicylate<sup>U1</sup>
  - (daily or intermittent), OR
    > an oral aminosalicylate <sup>U2</sup> alone, explaining that this may not
  - Set oral aminosalicylate alone, explaining that this may not be as effective as combined treatment or an intermittent topical aminosalicylate alone.

# Left-sided and extensive UC

- To maintain remission in adults after a mild-to-moderate inflammatory exacerbation of left-sided or extensive UC:
  - > 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.
- To maintain remission in children and young people after a mild-to-moderate inflammatory exacerbation of left-sided or extensive UC:
  - > offer an oral aminosalicylate<sup>U2, U5</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

- Consider oral azathioprine<sup>U6</sup> or oral mercaptopurine<sup>U6</sup> to maintain remission:
  - > after ≥2 inflammatory exacerbations in 12 months that require treatment with systemic corticosteroids, OR
  - $\succ$  if remission is not maintained by aminosalicylates.
- To maintain remission after a single episode of acute severe UC:
  - > consider oral azathioprine<sup>U6</sup> or oral mercaptopurine<sup>U6</sup>.
  - consider oral aminosalicylates if azathioprine and/or mercaptopurine are contraindicated or the person cannot tolerate them.

#### Dosing regimen for oral aminosalicylates

 Consider a once-daily dosing regimen for oral aminosalicylates<sup>U7</sup> when used for maintaining remission. Take into account the person's preferences, and explain that oncedaily dosing can be more effective, but may result in more side effects.

#### **Pregnant women**

- When caring for a pregnant woman with UC:
  - Ensure effective communication and information-sharing across specialities (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.

#### Monitoring - see Box 1

#### Box 2

# Unlicensed prescribing

**U1** – some **topical** aminosalicylates are not licensed for this indication in children and young people.

U2 – some **oral** aminosalicylates are not licensed for this indication in children and young people.

**U3** – 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.

U4 – ciclosporin is not licensed for this indication.

U5 – dosing requirements for children should be calculated by body weight, as described in the BNF.

**U6** – although use is common in UK clinical practice, not all brands of azathioprine and mercaptopurine are licensed for this indication.

**U7** – at the time of publication, not all oral aminosalicylates are licensed 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 <u>Prescribing guidance: prescribing</u> <u>unlicensed medicines</u> for further information.

**Recommendations –** wording used such as 'offer' and 'consider' denote the <u>strength of the recommendation</u>. **Drug recommendations** – the guideline assumes that prescribers will use a drug's <u>Summary of Product</u> Characteristics (SPC) to inform treatment decisions.

Please go to <u>www.nice.org.uk</u> to check for any recent updates to this guidance.

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