Shared care protocol:

Azathioprine for the Management of Inflammatory Bowel Disease in Children and Young People over 12 years old

As well these protocols, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF)/ BNFc or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within the scope of this shared care protocol section 2 and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and parent/ carer and provide the appropriate counselling (see section 11) to enable an informed decision to be reached. Obtain and document consent. Provide an appropriate patient information leaflet.
- Assess for contraindications and cautions (see section 4), and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in section 5.
- Transfer to primary care is normally after the patient has been treated for around 4 months and with satisfactory investigation results for at least 4 weeks. On transferring shared care, the specialist will provide at least 4 weeks' worth of medication to enable the practice to receive and process the shared care agreement and set up prescribing and ongoing monitoring. Further prescriptions will be issued if, for unforeseen reasons, arrangements for shared care are not in place. Patients should not be put in a position where they are unsure where to obtain supplies of their medication The specialist team will be responsible for monitoring and prescribing the medicine during this initial period.

- Any bloods required within the 4 weeks should be requested/organised and followed up by the specialist.
- There is variation in children and young people's community phlebotomy services in Nottinghamshire. Care should only be transferred to the GP when arrangements for taking blood samples in primary care have been confirmed for the individual patient. Monitoring results should be accessible to all clinicians involved in the patients' care.
- If shared care is considered appropriate, and once treatment is optimised, write to the patient's GP practice, and request shared care; detailing the diagnosis, the current and ongoing dose, baseline, and most recent test results, confirm the monitoring schedule and when the next monitoring is required. Include the specialist service contact information (section 13).
- Conduct the required monitoring in section 8 and communicate the results to primary care. After each review, advise primary care in writing within 14 days, where possible whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.
- Give advice to primary care on continuing treatment if a patient becomes or wishes to become pregnant or breastfeed.
- Provide advice to primary care on the management of adverse effects if required.
- Provide the patient/ carer with a patient information leaflet and details of their treatment, including any dosage changes made, follow-up appointments, monitoring requirements, and specialist team contact details. Highlight the importance of monitoring the patient and explain the potential withdrawal of treatment if monitoring appointments are not attended.

Primary care responsibilities

- If shared care is not accepted, inform the specialist of the decision in writing within 14 days with reasons as to why shared care cannot be entered into. If shared care is accepted, ensure knowledge and understanding of the therapeutic issues relating to the patient's clinical condition. Undergo any additional training necessary to carry out the prescribing and monitoring requirements.
- Agree that, in their opinion, the patient should receive shared care for the diagnosed condition unless good reasons exist for the management to remain within the secondary care.If accepted, prescribe ongoing treatment as detailed in the specialist's request and as per section 5 taking into any account potential drug interactions in section 7.
- Adjust the dose of azathioprine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9.
- Ensure the patient is given the appropriate follow-up and monitoring appointments. If a patient fails to attend, contact the patient in a timely manner to arrange alternative appointments. It is the GP's responsibility to decide whether to continue treatment in a patient who does not attend follow-up and monitoring appointments. If the patient regularly

fails to attend the monitoring appointment, the GP may withhold the prescription and inform the consultant responsible for the patient's care.

- Assess for possible interactions with azathioprine when starting new medicines (see section 7).
- Manage any adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop azathioprine and discuss urgently with the specialist if bone marrow suppression is suspected.
- Discuss other adverse effects with the specialist team as clinically appropriate (see section 10).
- Contact the specialist team for advice if the patient becomes or plans to become pregnant.
- Stop treatment if advised to do so by the specialist.
- Offer patients vaccination in line with the current Joint Committee on Vaccination and Immunisation advice. (Immunisation against infectious disease).

Patient and/or carer responsibilities

- Take azathioprine as prescribed and do not stop taking it without speaking to the primary care prescriber or specialist.
- Tell anyone who prescribes them a medicine that they are taking azathioprine.
- Attend regularly for monitoring and review appointments with primary care and specialist. Be aware that medicines may be stopped if they do not attend appointments.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter medications to their prescriber and be aware they should discuss the use of azathioprine with a pharmacist before purchasing any OTC medicines.
- Store the medication securely away from children.
- Read the information supplied by the GP, specialist, and pharmacist, and contact the relevant practitioner if they do not understand any of the information given.
- Inform the specialist or primary care prescriber as soon as possible if they become pregnant or wish to become pregnant.

Community pharmacist responsibilities

- The community pharmacist will professionally check prescriptions to ensure they are safe for the patient and contact the GP if necessary.
- Fulfil the legal prescriptions unless they are considered unsafe.
- Counsel the patient/ carer on the proper use of their medication.
- Advise patients suspected of experiencing an adverse reaction with their medicines to contact their GP.

1. Background

Back to top

Azathioprine is an immunosuppresant and is used either alone or, more commonly, in combination with other agents (usually corticosteroids) to influence the immune response. The therapeutic effect may only be evident after weeks or months of use, and can include a steroid sparing effect, thereby reducing the toxicity associated with high dosage and prolonged usage of corticosteroids.

2. Indications

Back to top

Maintenance of remission of acute ulcerative colitis and Crohn's disease in children and young people > 12 years of age.

See the relevant summary of product characteristics (see SPC) for full details.

3. Locally agreed off-label use

Back to top

NA

4. Contraindications and cautions

Back to top

This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see BNF/ BNFc & SPC for comprehensive information.

Contraindications:

- Known hypersensitivity to the active substance or any excipients. Hypersensitivity to 6-mercaptopurine (6-MP) should alert the prescriber to probable hypersensitivity to azathioprine.
- Absent or very low thiopurine methyltransferase (TPMT) activity – risk of life-threatening pancytopenia.

Cautions:

- Live vaccines (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever, intranasal influenza): should be avoided in patients taking azathioprine. Contact the specialist if further guidance is required.
- Patients with active/history of pancreatitis.
- Concomitant prescribing of allopurinol or febuxostat, see section 7.
- Patients receiving azathioprine are at an increased risk of developing lymphoproliferative disorders and other malignancies, notably skin cancers, sarcomas and uterine cervical cancer in situ. Exposure to sunlight and UV light should be limited and patients should wear protective clothing and use a sunscreen with a high protection factor to minimize the risk of skin cancer and photosensitivity.
- Patients who have no history of exposure to varicella zoster virus (VZV) i.e. chickenpox or herpes zoster (shingles), should avoid contact with individuals with chickenpox or herpes zoster. Contact the on-call microbiologist via the hospital switchboard for advice regarding those who have no antibodies to varicella–zoster virus and who have had significant exposure to chickenpox or herpes zoster. See The Green Book - Chapter 34 for detailed guidance. If the patient is infected with VZV, appropriate measures should be taken, which may include antiviral therapy and supportive care.
- Patients with low thiopurine methyltransferase (TPMT) activity are at increased risk of myelosuppression. Substantial dose reduction is generally required.
- Severe infection.
- Severely impaired hepatic or bone marrow function.
- Pregnancy and breastfeeding (see section 12).
- Patients' heterozygote for TPMT – use with caution due to increased risk of toxicity. The Specialist Team will recommend increased monitoring if necessary.

Treatment may need to be monitored more frequently in the following:

- Impaired renal function
- Mild/moderately impaired hepatic function
- Mild/moderately impaired bone marrow function

5. Initiation and ongoing dose regimen Back to top

- Transfer of monitoring and prescribing to primary care is normally after 4 months of treatment and when the patient's dose has been optimised with satisfactory investigation results for at least 4 weeks.
- There is variation in children and young people's community phlebotomy services in Nottinghamshire. Care should only be transferred to the GP when arrangements for taking blood samples in primary care have been confirmed for the individual patient. Monitoring results should be accessible to all clinicians involved in the patients' care.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
- Termination of treatment will be the responsibility of the specialist.

The selected dose will be tailored to the individual patient and decided by the specialist.

Azathioprine must be prescribed by the initiating specialist for the duration of the initial stabilisation period.

Maintenance dose (following initial stabilisation):

Usual dose range**:**

- Patients with a low TPMT will be started on a low dose of 1mg/kg/day.
- The maintenance dose for patients with normal TPMT levels is 2mg-2.5mg/kg/per day. This will be rounded to the nearest 25mg for those taking tablets.

This can be taken as a once daily dose or divided into 2 doses per day.

The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

Lower doses may be required if there is significant renal or hepatic impairment, and in patients with mild/moderately impaired bone marrow function, TPMT deficiency or NUDT15 mutation (see SPC) .

6. Pharmaceutical aspects Back to top

Route of administration:	Oral

Formulation:	Azathioprine 25mg and 50mg tablets Oral suspension 50mg/5ml (for those unable to take tablet formulation)
Administration details:	The tablets should be swallowed whole and not split / crushed. Can be taken either with or without food, but patients should standardise which method is chosen. Taking with or after food may relieve nausea, however the oral absorption of azathioprine may be reduced. Consideration should be given to monitoring therapeutic efficacy more closely if patient is taking azathioprine consistently with food.
Other important information:	Azathioprine is cytotoxic. However, providing the film coating of azathioprine tablets remains intact, there is no risk or additional precautions required when handling tablets. Oral suspension should not be handled by those who are pregnant, planning to be pregnant or breast-feeding. Hands should be washed before and after administering a dose and to decrease the risk of exposure, parents and care givers are advised to wear disposable gloves.

7. Significant medicine interactions

Back to top

The following list is not exhaustive. Please see BNF/ BNFc or SPC for comprehensive information and recommended management.

The following drugs must not be prescribed alongside azathioprine without consultation with the specialist:

- **Allopurinol** has the potential to cause thiopurine toxicity and should be avoided, except with specialist input.
- **Febuxostat** has the potential to cause thiopurine toxicity; avoid in combination with azathioprine.
- **Live vaccines** (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever, intranasal influenza) should be avoided. Contact the specialist if further guidance is required.
- **Warfarin** – thiopurines may reduce anticoagulant effects of warfarin.
- **Co-trimoxazole / trimethoprim** – Prolonged courses (>4 weeks) of co-trimoxazole and trimethoprim should be used with caution – can cause life threatening haematotoxicity. (Note: occasionally, some patients are on co-trimoxazole for special circumstances. E.g., PCP prophylaxis).
- **Clozapine** - avoid due to increased risk of agranulocytosis.

- **Ribavirin** - increased risk of haematological toxicity when azathioprine given concurrently and this combination should be avoided.
- **Aminosalicylates** (sulfasalazine, mesalazine or olsalazine) - increased risk of haematological toxicity with concomitant thiopurine due to TPMT inhibition. Dose adjustment of azathioprine and additional monitoring of FBC may be required.

The following drugs may be prescribed with caution:

- **ACE inhibitors** - increase the risk of anaemia and or leukopenia.
- **Cimetidine and indomethacin** - concomitant administration of thiopurines may increase the risk of myelosuppression.

8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

Back to top

Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in the immediate future will prescribing and monitoring be transferred to primary care. Transfer to primary care is normally after the patient has been treated for 4 months and with satisfactory investigation results for at least 4 weeks. Care should only be transferred once arrangements for taking blood samples in primary care has been confirmed.

Baseline investigations:

- Height and weight.
- Blood pressure.
- Full blood count (FBC).
- Urea and electrolytes (U&Es) & creatinine clearance (CrCl).
- Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST), and albumin.
- Baseline thiopurine methyl transferase (TPMT) status.
- ESR and CRP
- Screening for viral infections as per local policy, e.g. HIV, hepatitis B and C, varicella zoster, Epstein Barr virus, cytomegalovirus.
- Screening for lung disease, including tuberculosis, should be undertaken at clinician discretion on a case by case basis.

Provide or request appropriate vaccination prior to treatment initiation, according to local arrangements (e.g. pneumococcal, influenza, COVID-19).

Initial monitoring and at dose change:

To be repeated weekly for the first 4 weeks, then fortnightly for 4 weeks, then monthly for 2 months, then every 2-3 months:

- FBC
- U&Es, including creatinine and CrCl
- LFTs, including AST and/or ALT, and albumin
- CRP and ESR (from 4 weeks)

Following a dose increase, repeat fortnightly for 4 weeks then monthly for 2 months then revert to previous schedule. More frequent monitoring is appropriate in patients at higher risk of toxicity eg. those heterozygote for TPMT.

Ongoing monitoring:

The specialist will retain the responsibility for monitoring the patient's ongoing response to treatment and advise if a dose change or treatment cessation is appropriate. This should usually be undertaken annually.

After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 8 remains appropriate.

9. Ongoing monitoring requirements to be undertaken by primary care

Back to top

See section 9 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring and actions	Frequency
• FBC • U&Es including creatinine and CrCl • ALT and/or AST, and albumin • CRP and ESR	Following initial schedule described above, every 2-3 months, and more frequently in patients at higher risk of toxicity, as advised by the specialist team. Following any dose change, monitoring should be increased to- fortnightly for 4 weeks then monthly for 2 months then revert to previous schedule. **The exact frequency of monitoring to be communicated by the specialist in all cases**.
Annual influenza (The Green Book, Chapter 19) vaccinations are recommended	• Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list.

COVID-19 vaccination is safe and recommended (see The Green Book, Chapter 14a). Repeat pneumococcal vaccine may be indicated. See Green Book Chapter 25 for advice.	COVID-19 vaccination as per national schedule.
(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.	

10. Adverse effects and other management

Back to top

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics.

IF YOU ARE IN ANY DOUBT ABOUT ANY POTENTIAL ADVERSE REACTION, PLEASE CONTACT THE SPECIALIST TEAM.

Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance	
Full blood count: • White blood cells less than $3.5x10^9$/L • Lymphocytes less than $0.5x10^9$/L • Neutrophils less than $1.6x10^9$/L • Platelets less than $140x10^9$/L • Eosinophilia greater than $0.5x10^9$/L	Discuss urgently with specialist team, and consider interruption. If neutrophils are less than $1x10^9$/L withhold and discuss urgently with specialist team. NB: Isolated lymphopenia or eosinophilia is often a feature of the underlying autoimmune indication, and is rarely an indication to discontinue azathioprine.
Mean cell volume >105 fl NB: Reversible, dose-related increases in mean corpuscular volume are a known effect of thiopurines.	Consider interruption in treatment if there is a significant increase from baseline. Check serum folate, B12, alcohol history and TSH and treat any underlying abnormality. If

	results of these additional investigations are normal discuss with specialist team urgently.
Signs or symptoms of bone marrow suppression, e.g. unexplained bleeding or bruising with or without sore throat, mouth ulcers	Consider interruption in treatment. Check FBC immediately and discuss with the specialist team. See haematological monitoring above.
Severe general malaise	This maybe part of a hypersensitivity reaction. Withhold until discussed with specialist team.
Infections: Severe infection e.g. resulting in hospital admission requiring IV antibiotics	Temporarily withhold thiopurine until the patient has recovered. Consider additional investigations (e.g. FBC), if clinically appropriate.
Liver function tests: ALT or AST >twice upper limit of reference range, or any sudden increases (e.g. double of baseline), OR Unexplained fall in serum albumin <30g/L Jaundice	Withhold and discuss with specialist team. Check any other reason for risk of hepatic dysfunction such as alcohol history and drug interactions, including OTC or complementary medication.
Renal function: - Creatinine rise >30% over 12 months, or calculated GFR reduces to <60ml/min	Withhold and discuss with specialist team
Gastrointestinal disorders: Nausea, vomiting or diarrhoea.	Review for reversible causes. Advise patient to take with food. If no improvement contact specialist team.

Suspected pancreatitis eg severe abdominal pain.	Withhold. Measure amylase and/ or lipase and discuss with specialist team.

11. Advice to patients and carers

Back to top

The specialist will counsel the patient/ carer with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient/ carer should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

Signs or symptoms indicating haematological toxicity, e.g. sore throat, infection, unexplained or abnormal bruising or bleeding.

Signs or symptoms of pancreatitis, e.g. abdominal pain, nausea, or vomiting

Signs of symptoms of hepatic toxicity, e.g. Jaundice (yellowing of the skin or whites of the eyes)

The patient/ carer should be advised:

- During a serious infection azathioprine should be temporarily discontinued until the patient has recovered from the infection.
- That vaccination in line with current national advice (e.g. for COVID-19, inactivated influenza) is safe and recommended.
- To tell anyone who prescribes them a medicine that they are taking azathioprine. Always ask a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe.
- To inform their specialist or primary care prescriber promptly if pregnancy occurs or is planned.
- Patients have a small increased risk of skin cancers so should be advised to wear high factor sunscreen and to wear a hat and protective clothing when in strong sunshine. Sun beds should be avoided. Patients/ carers should be advised to carry out regular self-examination of the skin and report if there are any new lesions and/or changes to skin.
- Patients taking azathioprine should be advised to avoid contact with people with chicken pox or shingles and report any such contact urgently to their primary care prescriber. If the patient is exposed, contact the specialist for advice.

Patient information:

- https://www.crohnsandcolitis.org.uk/about-crohns-and-colitis/publications/azathioprine-mercaptopurine
- Crohn's disease in children and young people (cicra.org)

- ulcerative colitis in children and young people (cicra.org)
- Azathioprine for inflammatory bowel disease – Medicines For Children

12. Pregnancy, paternal exposure and breast feeding

Back to top

It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for reiterating this advice rests with both the primary care prescriber and the specialist.

All patients should be informed of the risks and benefits of taking this medicine during pregnancy and breastfeeding. The specialist team should be contacted if a patient becomes pregnant or is planning to become pregnant or breastfeed.

Pregnancy:

The British Society of Gastroenterology consensus guidelines on the management of inflammatory bowel disease advises that both maintenance and flares can be treated as normal with thiopurines (azathioprine and mercaptopurine) during pregnancy.

Information for healthcare professionals: USE OF AZATHIOPRINE OR MERCAPTOPURINE IN PREGNANCY – UKTIS

Information for patients and carers: bumps - best use of medicine in pregnancy

Breastfeeding:

Azathioprine is compatible with breastfeeding, although the active metabolite mercaptopurine is present in breast milk. A risk versus benefit assessment is advised. If used during breastfeeding, monitor the infant for signs of infection or immunosuppression. If high doses of azathioprine are used, monitor infant blood counts.

Information for healthcare professionals:

- https://www.sps.nhs.uk/medicines/azathioprine/

Paternal exposure:

Azathioprine is compatible with paternal exposure. There is currently no evidence of adverse fetal effects relating to paternal use.

- Information for healthcare professionals: bumps - best use of medicine in pregnancy (medicinesinpregnancy.org)

13. Specialist contact information

Back to top

Children's Gastroenterology Nurse Specialists:

0115 924 9924 ext 84137

Email: paedgastronurses@nuh.nhs.uk

Consultant Paediatric Gastroenterologists:

0115 9924 ext 82439

14. Additional information

Back to top

Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

Where a young person treated with azathioprine is approaching their 18th birthday, it is expected that the specialist team will refer to the appropriate adult service if a need for ongoing treatment is anticipated. NICE Guidance NG43: Transition from children's to adults' services for young people using health or social care services should be followed. Also see the Nottinghamshire Area Prescribing Committee shared care protocol for the Management of Inflammatory Bowel Disease in adults with azathioprine at: https://www.nottsapc.nhs.uk/shared-care/

15. References

Back to top

- Rheenen Patrick F van et al. , The Medical Management of Paediatric Crohn's Disease: an ECCO-ESPGHAN Guideline Update, *Journal of Crohn's and Colitis*, Volume 15, Issue 2, February 2021, Pages 171–194, https://doi.org/10.1093/ecco-jcc/jjaa161
- eBNFc accessed via BNFC (British National Formulary for Children) | NICE on 10/06/2023.
- eBNF accessed via https://bnf.nice.org.uk/ on 05/10/2021.
- Azathioprine 50mg tablets (Imuran®). Aspen. Date of revision of the text: April 2021. Accessed via https://www.medicines.org.uk/emc/product/3823 on 08/07/2021.
- Azathioprine 50mg tablets (Azapress®). Ennogen. Date of revision of the text: 29/06/2016. Accessed via www.medicines.org.uk/emc on 01/10/2020.
- British Society of Rheumatology and British Health Professionals in Rheumatology. 2017. Guidelines for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs. Accessed 01/10/2020.

- British Society of Rheumatology and British Health Professionals in Rheumatology. 2016. Guideline on prescribing drugs in pregnancy and breastfeeding – Part I: standard and biologic disease modifying anti-rheumatic drugs and corticosteroids. Accessed 01/10/2020.
- British Association of Dermatologists. 2011. Guidelines for the safe and effective prescribing of azathioprine (update in progress). Accessed 01/10/2020.
- British Association of Dermatologists. 2007 (updated 2016). Patient information leaflet: azathioprine. Accessed 01/10/2020.
- British Thoracic Society in collaboration with the Thoracic Society of Australia and New Zealand and the Irish Thoracic Society. 2008. Interstitial lung disease guideline (archived). Accessed 01/10/2020.
- British Society of Gastroenterology. 2019. Consensus guidelines on the management of inflammatory bowel disease in adults. Accessed 01/10/2020.
- British Society of Gastroenterology. 2011. Guidelines on the management of autoimmune hepatitis. Accessed 01/10/2020.
- Association of British Neurologists. 2015. Myasthenia gravis: management guidelines. Accessed 01/10/2020.
- Public Health England. Immunisation against infections disease: The Green Book. Accessed 01/10/2020.
- Specialist Pharmacy Service. Lactation Safety Information: azathioprine. Reviewed September 2020. Accessed via https://www.sps.nhs.uk/medicines/ on 08/07/2021.
- Specialist Pharmacy Service. Lactation Safety Information: mercaptopurine. Reviewed September 2020. Accessed via https://www.sps.nhs.uk/medicines/mercaptopurine/ on 06/10/2021.
- UK Teratology Information Service. Toxbase monograph: Azathioprine or mercaptopurine in pregnancy. December 2019. Accessed via www.toxbase.org on 06/10/2021.
- UK Teratology Information Service. Toxbase monograph: Paternal use of azathioprine or mercaptopurine. December 2019. Accessed via www.toxbase.org on 06/10/2021.
- The Renal Drug Database. Mercaptopurine monograph. Accessed via: https://renaldrugdatabase.com/monographs/mercaptopurine on 09/12/21
- NICE Guidance: Crohn's disease: management (NG129) May 2019. Accessed via: https://www.nice.org.uk/guidance/ng129 on 09/12/21
- NICE Guidance: Ulcerative colitis: management (NG130) May 2019. Accessed via: https://www.nice.org.uk/guidance/ng130 on 09/12/21

16. Other relevant national guidance

Back to top

- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/

- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

17. Local arrangements for referral

Back to top

Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

- The request for shared care should be accompanied by individual patient information, outlining all relevant aspects of the patient's care and which includes direction to the shared care protocols on the APC website.
- The specialist will request shared care with the GP in writing.
- If the GP doesn't agree to shared care, they should inform the specialist of their decision in writing within 14 days, outlining the reason for the decline. The agreement can be assumed if the GP does not provide a written decline.
- In cases where shared care arrangements are not in place or where problems have arisen within the agreement, and patient care may be affected, the responsibility for the patient's management, including prescribing, reverts back to the specialist.
- There is variation in children and young people's community phlebotomy services in Nottinghamshire. Care should only be transferred to the GP when arrangements for taking blood samples in primary care has been confirmed.
- Should the patient's condition change, the GP should contact the relevant specialist using the details provided with the shared care request letter.