National shared care protocol adapted for local use:

Dermatological Conditions: Azathioprine for patients within adult services (non-transplant indications)

As well these protocols, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) 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 a 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 provide the appropriate counselling (see section 11) to enable the patient to reach an informed decision. Obtain and document patient 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. Once the patient is known to be tolerating the medicine, transfer to shared care would normally take place. It is expected that at least one hospital review will occur before transfer to shared care occurs. Transfer to primary care is normally after the patient has been treated for 3 months and with satisfactory investigation results for at least 4 weeks.
- 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).
- The specialist should also provide the details of the treatment to be undertaken by the GP. Including the reasons for the choice of treatment, medicine combination, frequency of treatment, and the next review date by the specialist.
- Prescribe sufficient medication (usually 12 weeks) to enable transfer to primary care, including where there are unforeseen delays to transfer of care. 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.
- Conduct the required monitoring in section 8 and communicate the results in writing to primary care within 14 days, where possible. After each review, provide primary care with a written summary within 14 days, advising whether treatment should be continued, confirming the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.
- Give advice to primary care on continuing treatment if a woman becomes or wishes to become pregnant or breastfeed.

- Provide advice to primary care on the management of adverse effects if required.
- Review patients annually.
- Provide the patient with a patient information sheet 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 to 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 account any potential drug interactions in section 7.
- Adjust the dose of azathioprine prescribed as advised by the specialist and communicate any changes made to the patient.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- 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 (section 7).
- Manage any adverse effects as detailed in section 10 and discuss them with the specialist team when required. Refer the patient back to the specialist team if further investigation is 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 (section 10).
- Contact the specialist team for advice if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.
- Contact details for primary care prescribers will be made available.
- 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 their primary care prescriber or specialist.
- Tell anyone who prescribes them a medicine that they are taking azathioprine.

- Attend regularly for monitoring and review appointments, routine influenza and pneumococcal vaccinations with primary care and specialist. If unable to attend, inform the relevant practitioner as soon as possible and arrange an alternative appointment. 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 (OTC) medications to their prescriber and be aware they should discuss the use of azathioprine with their 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 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 a disease modifying anti-rheumatic drugs (DMARD). It is used as an immunosuppressant anti-metabolite either alone or, more commonly, in combination with other agents (usually corticosteroids) to influence the immune response. Therapeutic effect may be evident only after weeks or months and can include a steroid sparing effect, thereby reducing the toxicity associated with high dosage and prolonged usage of corticosteroids.

Azathioprine may be used to treat severe or troublesome eczema, where other treatments are ineffective or inappropriate. Azathioprine has a cumulative action; improvement usually occurs within 6-8 weeks.

Treatment is usually continued for a minimum of 12 months if there is a good clinical response. Azathioprine has a cumulative action, and a clinical improvement can take up to 3 months.

Azathioprine is not licensed for all the conditions it is used to treat. However, its use for the indications below is established and supported by various sources and bodies including the BNF, NICE, British Association of Dermatologists (BAD).

This shared care protocol applies to adults aged 18 and over. It does not include use of azathioprine for transplant or oncology indications.

2. Indications

Back to top

Licensed indications vary with the brand. See the relevant summary of product characteristics (see SPC) for full details.

This shared care protocol also includes treatment of chronic inflammatory conditions where off-label use of azathioprine is appropriate, including, but not limited to the following conditions:

- Atopic eczema, autoimmune blistering conditions

The initiating specialist must specify the indication for each patient when initiating shared care and clearly state when the use is off label.

3. Locally agreed off-label use

Back to top

Severe and atopic eczema, autoimmune blistering conditions

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 & 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): should be avoided in patients taking azathioprine at a dose greater than 3 mg/kg/day. Please refer to the Green Book Chapter 6 for current advice regarding the use of live vaccines in patients taking immune modulators. Contact the specialist if further guidance is required. N.B. Routine influenza and pneumococcal vaccinations are highly recommended.
- 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 minimise the risk of skin cancer and photosensitivity.
- Patients with low thiopurine methyltransferase (TPMT) activity are at increased risk of myelosuppression. Substantial dose reduction is generally required.
- Severe infection, including hepatitis B or C and history of tuberculosis.
- Severely impaired hepatic or bone marrow function.
- Pregnancy and breastfeeding (see section 12).

- 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. Varicella–zoster immunoglobulin (VZIG) is recommended for individuals who are at increased risk of severe varicella (including patients taking immunosuppressant medicines, (e.g., azathioprine, ciclosporin, methotrexate, leflunomide) who have no antibodies to varicella–zoster virus, and who have significant exposure to chickenpox or herpes zoster. If the patient is infected with VZV, appropriate measures should be taken, which may include antiviral therapy and supportive care.
- 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:

- Elderly patients
- Impaired renal function. Dose reduction may be required in moderate or severe renal impairment (CrCl<20ml/min). Please discuss with the renal team.
- 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 at least 12 weeks, and when the patient dose has been optimised and with satisfactory investigation results for at least 4 weeks.
- 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.

Initial stabilisation:

There is a wide dose range depending on the indication. The selected dose will be tailored to the individual patient and decided by the specialist.

The initial stabilisation period must be prescribed by the initiating specialist.

The duration of treatment will be determined by the specialist based on clinical response and tolerability.

Maintenance dose (following initial stabilisation):

Azathioprine is given orally as a single daily dose.

The usual maintenance dose is in the range of 100mg - 200mg per day.

(1mg-3mg/kg for normal/high TPMT levels. 0.5mg-1.5mg/kg for intermediate TPMT levels). See BNF

Some patients may respond to lower doses. Please note patients may be initiated on more than one DMARD.

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, in elderly patients, 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
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. **Tablets should be taken at least 1 hour before or 2 hours after milk or dairy products.** 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:	Providing the film coating of azathioprine tablets remains intact, there is no risk or additional precautions required when handling tablets. Azathioprine is cytotoxic. It is recommended that they are handled following local recommendations for the handling and disposal of cytotoxic agents.

7. Significant medicine interactions

Back to top

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

The following drugs must not be prescribed 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) can be given to patients on stable long term low dose corticosteroid therapy (defined as ≤20mg prednisolone per day for >14 days) alone or in combination with low dose non-biological oral immune modulating drugs (e.g., azathioprine up to 3mg/kg/day). Clinician discretion is advised. Please refer to the Green Book Chapter 6 for current advice, and advice for patients taking higher doses.

- **Warfarin** – thiopurines may reduce anticoagulant effects of warfarin. Consider increasing the dose of the anticoagulant and monitor closely.
- **Phenytoin, sodium valproate, carbamazepine** absorption may be reduced by azathioprine.
- **Co-trimoxazole / trimethoprim** – should be avoided. 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.

Baseline investigations:

- Weight
- 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
- Screening for viral infections as per local policy, e.g., HIV, hepatitis B and C, varicella zoster, Epstein Barr virus, cytomegalovirus should be undertaken at clinician discretion.
- Screening for lung disease, including tuberculosis, should be undertaken at clinician discretion on a case-by-case basis.
- Confirm cervical screening is up to date.
- Provide or request appropriate vaccination prior to treatment initiation, according to local arrangements (e.g., pneumococcal, shingles, influenza, COVID-19)

Initial monitoring and at dose change:

To be repeated every 2 weeks until the dose has been stable for 6 weeks, then monthly for 3 months, and then 3 monthly thereafter.

- FBC

- U&Es, including creatinine and CrCl
- LFTs, including AST and/or ALT, and albumin

Following a dose change repeat every 2 weeks until the dose has been stable for 6 weeks, then revert to previous schedule. More frequent monitoring is appropriate in patients at higher risk of toxicity. ~~A~~wareness of TPMT levels is required before consideration of dose adjustment.

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 9 remains appropriate.

9. Ongoing monitoring requirements to be undertaken by primary care

Back to top

See section 10 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	At least every 12 weeks, and more frequently in patients at higher risk of toxicity, as advised by the specialist team. **The exact frequency of monitoring to be communicated by the specialist in all cases**.
• Patients aged from 50 years who are severely immunosuppressed and have not received the shingles vaccine before will be eligible for the shingles vaccine (varicella zoster). This will be provided as two doses of the non-live vaccine. If patient is taking additional DMARDs, check advice for all drugs. Please refer to Green Book Chapter 6 and Chapter 28a (Shingles) for further details. • **Annual** influenza (The Green Book, Chapter 19) vaccinations are highly recommended • **COVID-19** vaccination is safe and recommended (see The Green Book, Chapter 14a).	• Shingles vaccination: Chapter 28a (Shingles). • Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list. • Other vaccinations as per national schedule, e.g., pneumococcal vaccine, COVID-19.

• **Repeat** pneumococcal vaccine may be indicated. See Green Book Chapter 25 for advice.	

(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 a full list of side effects and information on incidence of ADRs, refer to the BNF or see relevant summaries of product characteristics.

IF YOU ARE IN ANY DOUBT ABOUT ANY POTENTIAL ADVERSE REACTION, PLEASE CONTACT THE DERMATOLOGY 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. Other benchmark values may be set by secondary care in specific clinical circumstances. This will be communicated by the specialist.	
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. NB - Isolated lymphopenia or eosinophilia is often a feature of the underlying autoimmune indication and is rarely an indication to discontinue azathioprine. Withhold until discussed with the specialist team - eosinophilia is commonly seen in patients with eczema and therefore not 'unexplained'
Mean cell volume >105 fl NB: Reversible, dose-related increases in mean corpuscular volume are a known effect of thiopurines.	This does not usually signify a medical problem. 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	Consider interruption in treatment. Check FBC immediately and discuss with the specialist team. See haematological monitoring above.

bruising with or without sore throat, mouth ulcers	
Infections: Infection requiring antibiotics	Temporarily withhold thiopurine until the patient has recovered. Consider additional investigations (e.g., FBC), if clinically appropriate.
Liver function tests: • ALT or AST >100 units/L, or any sudden increases (e.g., double of baseline), OR • Unexplained fall in serum albumin <30g/L (in the absence of active disease) • 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 e.g., severe abdominal pain	Withhold and discuss with specialist team. Measure amylase levels.
Severe general malaise and flu-like symptoms	This maybe an early hypersensitivity reaction. Withhold and discuss with specialist team.

11. Advice to patients and carers

Back to top

The specialist will counsel the patient 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 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 should be advised:

- Azathioprine should not be taken with dairy products (at least 1 hour before or 2 hours after milk or dairy products).

- During a serious infection azathioprine should be temporarily discontinued until the patient has recovered from the infection.
- Vaccination in line with current national advice (e.g., for COVID-19, 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.
- All women aged 25-64 years old should be encouraged to participate in national cervical cancer screening programmes. There is no need to attend more frequently than recommended.
- 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 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. For detailed advice on risk assessment and post exposure prophylaxis following exposure to chicken pox and shingles, see:
  - the Green Book (Chapter 34)
  - UKSHA guidance: Guidelines on post exposure prophylaxis (PEP) for varicella/shingles April 2022

Patient information:

- British Association of Dermatologists.

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 providing 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 use of azathioprine during pregnancy needs to be supervised in specialist units and treatment should not generally be initiated during pregnancy. A review of risk vs benefit will be undertaken.

Information for healthcare professionals: Azathioprine in pregnancy (Bumps)

Information for patients and carers: Azathioprine in pregnancy (Bumps)

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 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 foetal effects relating to paternal use.

Information for healthcare professionals: Paternal Exposure

13. Specialist contact information

Back to top

ADVICE ON ANY ASPECT OF DMARD THERAPY IS AVAILABLE Monday to Friday 9-5

Primary care practitioners should contact the consultant's secretary/specialist nurse's secretary during working hours.

Nottingham Treatment Centre (0115 9194477)

Secretaries for Dermatology Consultants and Nurse Specialists. **Ext 78941**

Sherwood Forest NHS Foundation Trust Contacts (Kings Mill Hospital 01623 622515 ext. 3117/3191)

Consultant Dermatologist and Clinical Nurse Specialists. **01623 672310**

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.

15. References

Back to top

- eBNF accessed via https://bnf.nice.org.uk/ on 22/02/2024.
- Azathioprine 50mg tablets (Imuran®). Aspen. Date of revision of the text: April 2021. Accessed via https://www.medicines.org.uk/emc/product/3823 on 22/02/2024.
- Azathioprine 50mg tablets (Azapress®). Ennogen. Date of revision of the text: 29/06/2016. Accessed via www.medicines.org.uk/emc.
- British Association of Dermatologists. 2011. Guidelines for the safe and effective prescribing of azathioprine.
- British Association of Dermatologists. 2007 (updated 2016). Patient information leaflet: azathioprine. Accessed 22/02/2024.
- Public Health England. Immunisation against infections disease: The Green Book.

- Specialist Pharmacy Service. Lactation Safety Information: azathioprine. Reviewed September 2020. Accessed via https://www.sps.nhs.uk/medicines/.
- UK Teratology Information Service. Toxbase monograph: Azathioprine or mercaptopurine in pregnancy. December 2019. Accessed via www.toxbase.org.
- UK Teratology Information Service. Toxbase monograph: Paternal use of azathioprine or mercaptopurine. December 2019. Accessed via www.toxbase.org.

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 information sheets at the APC website.
- Prescribing and monitoring responsibility will only be transferred when it is agreed by the specialist and the patient's primary care prescriber that the patient is stabilised on their medication regimen without adverse effect and with benefits demonstrated.
- 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.
- Should the patient's condition change, the GP should contact the relevant specialist using the details provided with the shared care request letter.