Shared Care Agreement: Azathioprine and mercaptopurine for patients in adult services (non-transplant indications)

This Shared Care Protocol sets out details for the sharing of care for patients prescribed azathioprine and mercaptopurine. This protocol is for use within adult services for non-transplant indications.

It should be read in conjunction with the latest Summary of Product Characteristics (SPC) available at www.medicines.org.uk/emc/.

As outlined in NHS England Guidance 2018 "Responsibility for Prescribing between Primary & Secondary/Tertiary Care. When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the GP concerned (and the patient) to share their care.

This document provides information on drug treatment for the shared commitment between the consultant and primary care clinician concerned. The primary care clinician may accept or decline shared care. If shared care is declined the primary care clinician practice must discuss the reason for refusal with the consultant within 14 days. Where appropriate, the clinical responsibility will then remain with the consultant.

Introduction

This shared care guideline sets out details to support the transfer of responsibility for prescribing azathioprine and mercaptopurine for any of the indications listed in section 2, from specialist to primary care. For further information please click on the links below:

British National Formulary

http://www.medicines.org.uk/emc/

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Cambridgeshire & Peterborough Integrated Care System

NHS Cambridgeshire & Peterborough

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Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber) 20

Appendix 2: Shared Care Refusal Letter (Primary Care Prescriber to Specialist) ..... **Error! Bookmark not defined.**

The content of this shared care protocol was correct as of January 2022. 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 diagnosis; ensure that this diagnosis is within 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.
- 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. Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, baseline and most recent test results, confirm the monitoring schedule and when the next monitoring is required. Include contact information (section 13).
- Conduct the required monitoring in section 8 and communicate the results to primary care. 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.
- 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.

Primary care responsibilities

- If accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5 taking into any account potential drug interactions in section 7.
- If refusing, refuse the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being made, where possible.
- Adjust the dose of azathioprine or mercaptopurine prescribed as advised by the specialist.
- Conduct the required monitoring as outlined in section 9.

- Assess for possible interactions with azathioprine or mercaptopurine 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 or mercaptopurine 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 as advised by the specialist.

Patient and/or carer responsibilities

- Take azathioprine or mercaptopurine 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 or mercaptopurine.
- 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 or mercaptopurine with their pharmacist before purchasing any OTC medicines.

Inform the specialist or primary care prescriber as soon as possible if they become pregnant or wish to become pregnant.

1. Background

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Azathioprine and mercaptopurine are disease modifying anti-rheumatic drugs (DMARDs). They are used as immunosuppressant anti-metabolites 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 and mercaptopurine are not licensed for all the conditions they are used to treat, as noted below. However, their use for the indications below are established and supported by various sources and bodies including the BNF, NICE, British Society for Rheumatology (BSR) and British Health Professionals in Rheumatology (BHPR), British Association of Dermatologists

(BAD), British Thoracic Society (BTS), Association of British Neurologists (ABN) and British Society of Gastroenterology (BSG).

2. Indications

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Azathioprine

The licensed indications for azathioprine include:

- Autoimmune hepatitis
- Autoimmune haemolytic anaemia
- Chronic refractory idiopathic thrombocytopenic purpura
- Dermatomyositis
- Inflammatory bowel disease (IBD)
- Pemphigus vulgaris
- Polyarteritis nodosa
- Polymyositis
- Pyoderma gangrenosum
- Rheumatoid arthritis
- Systemic lupus erythematosus (SLE)

Licensed indications vary with brand. See 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 specialities and conditions:

- Dermatology (e.g. severe eczema)
- Neurology (e.g. myasthenia gravis, demyelinating conditions)
- Ophthalmology (e.g. uveitis, scleritis)
- Oral medicine (e.g. Behçet's disease, refractory inflammatory oral disease)
- Renal medicine (e.g. immune-mediated nephritis)
- Respiratory disease (e.g. interstitial lung disease)
- Rheumatology (e.g. inflammatory arthritis, connective tissue disease, vasculitis, giant cell arteritis)
- Gastroenterology (inflammatory bowel disease)

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

Mercaptopurine

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

- Inflammatory bowel disease

- Autoimmune encephalitides
- Autoimmune hepatitis

These indications are off-label. The specialist *must specify the indication for each patient* when initiating shared care and clearly state when use is off-label.
This shared care protocol applies to adults aged 18 and over. It does not include use of azathioprine or mercaptopurine for transplant or oncology indications.

3. Locally agreed off-label use

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See above.

4. Contraindications and cautions

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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, or mercaptopurine greater than 1.5 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.
- Patients with active/history of pancreatitis.
- Concomitant prescribing of allopurinol: A 75% dose reduction of azathioprine /mercaptopurine is required, see section 7.
- Patients receiving azathioprine or mercaptopurine 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 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).

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

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

5. Initiation and ongoing dose regimen

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- Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient's 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.

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.

Transfer of monitoring and prescribing to primary care is usually after 3 months. The duration of treatment will be determined by the specialist based on clinical response and tolerability.

Maintenance dose (following initial stabilisation):

Usual dose range**:**

- **Azathioprine: 0.5–3 mg/kg daily**, adjusted according to response.
- **Mercaptopurine: 1-1.5mg/kg daily,** adjusted according to response.

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

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

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Route of administration:	Oral
Formulation:	Azathioprine 25mg and 50mg tablets Azathioprine 10 mg/mL oral suspension (Jayempi®) Mercaptopurine 10mg and 50mg tablets Mercaptopurine 20mg/ml oral suspension (Xaluprine®)
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 or mercaptopurine may be reduced. Consideration should be given to monitoring therapeutic efficacy more closely if patient is taking azathioprine or mercaptopurine consistently with food. For azathioprine or mercaptopurine oral suspension, the bottle should be shaken vigorously for at least 30 seconds to ensure the suspension is well mixed.
Other important information:	Providing the film coating of azathioprine tablets remains intact, there is no risk or additional precautions required when handling tablets. Azathioprine and mercaptopurine are cytotoxic. It is recommended that they are handled following local recommendations for the handling and disposal of cytotoxic agents. Mercaptopurine tablets and oral suspension are not bioequivalent with respect to peak plasma concentration; increased haematological monitoring is advised if switching between formulations. When prescribing mercaptopurine, remain vigilant with regards to the similarity in name with mercaptamine.

7. Significant medicine interactions

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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. Allopurinol may be recommended in combination with thiopurines by the specialist for IBD patients, particularly in those who are unable to tolerate to or do not respond to treatment with a thiopurine alone. The dose of azathioprine or mercaptopurine should be reduced by 75% if used concurrently with allopurinol. If considering prescribing allopurinol, discuss with the specialist for advice and a dose adjustment.

- **Febuxostat** has the potential to cause thiopurine toxicity; avoid in combination with azathioprine or mercaptopurine.
- **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 or mercaptopurine up to 1.5mg/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.
- **Co-trimoxazole / trimethoprim** – possible increased risk of haematological toxicity, however evidence is conflicting and this combination is often used in practice.
- **Clozapine** - avoid due to increased risk of agranulocytosis.
- **Ribavirin** - increased risk of haematological toxicity when azathioprine and mercaptopurine 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 or mercaptopurine 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

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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 immediate future will prescribing and monitoring be transferred to primary care.

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
- Screening for viral infections as per local policy, e.g. HIV, hepatitis B and C, varicella zoster, Epstein Barr virus, cytomegalovirus
- 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:

Azathioprine

Dermatology patients:

More frequently than every 3 months:

- FBC
- LFTs

Gastroenterology patients:

14 days after starting, then at 4, 8 and 12 weeks, then 3 monthly:

- FBC
- U&Es, including creatinine and CrCl
- LFTs

Rheumatology patients:

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

- FBC
- U&Es, including creatinine and CrCl
- LFTs

Following a dose increase 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.

Mercaptopurine

At week 2, 4, 8 and 12:

- FBC
- LFTs
- U&Es, including creatinine and CrCl

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

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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 • LFTs	Monthly for three months, unless already completed in secondary care. Thereafter 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 60-79 years old could be eligible for the shingles vaccine (varicella zoster). For patients taking prednisolone exceeding 20mg daily or azathioprine exceeding 3mg/kg/day a non-live vaccine should be used. Specialist input may be required. 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 recommended 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.	• Shingles vaccination: one-off course of two doses. • Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list. 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

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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.

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.

Result	Action for primary care
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.
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.
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 Jaundice	Withhold and discuss with specialist team. When used for hepatology indications, continue treatment and discuss with specialist urgently. 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	Review for reversible causes. Advise patient to take with food. If no improvement contact specialist team.
Suspected pancreatitis	Withhold and discuss with specialist team.

11. Advice to patients and carers

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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 to:

- During a serious infection azathioprine or mercaptopurine 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, influenza) is safe and recommended.
- Tell anyone who prescribes them a medicine that they are taking azathioprine or mercaptopurine. 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.
- Pregnant patients should talk to their primary care clinician or midwife immediately if they experience symptoms of cholestasis of pregnancy, such as intense itching without a rash, nausea and loss of appetite.

- 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 at a dose of 3 mg/kg or more, or mercaptopurine at a dose of 1.5 mg/kg/day or more 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:

- General information: https://www.nhs.uk/medicines/azathioprine/
- General information: https://patient.info/medicine/azathioprine-azapress-imuran
- Rheumatology: https://www.versusarthritis.org/about-arthritis/treatments/drugs/azathioprine/
- Dermatology: https://www.bad.org.uk/for-the-public/patient-information-leaflets/azathioprine
- Patient information leaflets are also available from https://www.medicines.org.uk/emc/search?q=azathioprine

Gastroenterology:

- https://www.crohnsandcolitis.org.uk/about-crohns-and-colitis/publications/azathioprine-mercaptopurine
- https://gutscharity.org.uk/advice-and-information/conditions/crohns-disease/
- https://gutscharity.org.uk/advice-and-information/conditions/ulcerative-colitis/

12. Pregnancy, paternal exposure and breast feeding

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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:

Cholestasis of pregnancy has rarely been reported in association with azathioprine, and this risk is believed to also apply to mercaptopurine. This may occur earlier than in pregnancy than the non drug-induced cholestasis of pregnancy, and it may not respond to ursodeoxycholic acid. Withdrawal and dose reduction of thiopurine drugs may improve liver function tests and minimise the impact on the foetus. Remain vigilant to signs and symptoms of cholestasis of pregnancy, and discuss any concerns with the specialist managing the patient's immunosuppressant therapy and a hepatologist, if necessary. If cholestasis of pregnancy occurs, a case-by-case assessment is required to determine the appropriate course of action. Consider the risk and benefits of remaining on the product against the risks and benefits of stopping.

In patients with cholestasis of pregnancy, measure serum bile acids to identify pregnancies at particular risk of spontaneous pre-term birth (≥40 uM) or stillbirth (non-fasting serum bile acids ≥100uM)

The BSR and BHPR guideline on prescribing DMARDs in pregnancy and breastfeeding advises that azathioprine is compatible throughout pregnancy at doses ≤2mg/kg/day.

Current available data do not suggest that mercaptopurine exposure during pregnancy increases the risk of miscarriage, congenital malformation, intrauterine death, fetal growth restriction, or preterm delivery but the data are limited for some outcomes. A careful assessment of risk versus benefit should be made before mercaptopurine is prescribed to patients who are pregnant.

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: https://www.medicinesinpregnancy.org/bumps/monographs/USE-OF-AZATHIOPRINE-OR-MERCAPTOPURINE-IN-PREGNANCY/

Information for patients and carers: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Azathioprinemercaptopurine/

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. If mercaptopurine is used, monitor infant's blood count and liver function.

Information for healthcare professionals:

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

Paternal exposure:

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

- Information for healthcare professionals: https://www.medicinesinpregnancy.org/bumps/monographs/PATERNAL-USE-OF-AZATHIOPRINE-OR-MERCAPTOPURINE/

13. Specialist contact information

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Cambridge University Hospitals NHS Foundation Trust

CUH Dermatology Department:

Name	Role	Contact details
Dr Nigel Burrows	Consultant Dermatologist	01223 216459
Dr Shiu Kwan Chan	Consultant Dermatologist	01223 216501
Dr Niamh Flanagan	Consultant Dermatologist	01223 586678
Dr Julia Gass	Consultant Dermatologist	01223 216501
Dr Thomas Ha	Consultant Dermatologist	01223 216459
Dr Andre Khoo	Consultant Dermatologist	01223 216501
Dr Shaheen Haque Hussain	Consultant Dermatologist	01223 216501
Dr Paul Norris	Consultant Dermatologist	01223 216459
Dr Natasha Stembridge	Consultant Dermatologist	01223 216459
Dr Justyn Thomas	Consultant Dermatologist	01223 216459
Dr Pamela Todd	Consultant Dermatologist	01223 216459
Dr Vanessa Van de Velde	Consultant Dermatologist	01223 216459
Dr Marc Wallace	Consultant Dermatologist	01223 216459

CUH Rheumatology Department:

Decisions to alter or discontinue treatment are usually discussed via the Rheumatology Helpline on 01223 217398. The on-call rheumatology specialist registrar (SpR) may also be contacted via the Addenbrooke's Contact Centre.

Name	Role	Contact details
Dr Frances Hall	Consultant Rheumatologist	01223 349674
Dr Anoop Kuttikat	Consultant Rheumatologist	01223 349674
Dr Shipa	Consultant Rheumatologist	01223 349674
Dr Maliha Shaikh	Consultant Rheumatologist	01223 256883
Dr Mark Lillicrap	Consultant Rheumatologist	01223 256883
Dr Chris Chan	Consultant Rheumatologist	01223 216774
Prof Kenneth Poole	Consultant Rheumatologist	01223 216774

Dr Nicholas Shenker	Consultant Rheumatologist	01223 216774
Dr Gaffar Massawi	Consultant Rheumatologist	01223 349675
Dr Ei Ei Phyu Htut	Consultant Rheumatologist	01223 349675
Dr Qutab Shah	Locum Consultant Rheumatologist	01223 349675
Dr Andra Negoescu	Consultant Rheumatologist	01223 274561
Dr Anshuman Malaviya	Consultant Rheumatologist	01223 274561
Dr Carmel Stober	Consultant Rheumatologist	01223 274561
Dr Paivi Miettunen	Consultant Rheumatologist	01223 349674

CUH Hepatology Department

For all non-urgent requests, please write to us using advice and guidance pathways.

Email: add-tr.hepatology@nhs.net

Autoimmune hepatitis helpline: 01223 216109 (voicemail)

For clinically urgent queries, the on-call hepatology specialist registrar (SpR) may also be contacted via the Addenbrooke's Contact Centre.

Name	Role
Dr Gwilym Webb	Consultant Hepatologist
Dr Rachel Smith	Consultant Hepatologist
Janeane Hails	Specialist Nurse
Leslie Wong	Specialist Pharmacist

CUH Gastroenterology Department

Inflammatory Bowel Disease Helpline 01223 257212 (voicemail)

For all non-urgent requests, please write to us using advice and guidance pathways.

IBD nurse specialist Email: add-tr.ibdnurses@nhs.net

Gastroenterology consultant secretaries: cuh.DL-Gastroenterology-secretaries@nhs.net

For clinically urgent queries, the on-call gastroenterology specialist registrar (SpR) may also be contacted via the Addenbrooke's Contact Centre.

Name	Role	Contact details
Dr Timothy Raine	Consultant Gastroenterologist – IBD clinic lead	01223 216226

North West Anglia NHS Foundation Trust

NWAFT Rheumatology Department

Name	Role	Contact details
Dr Wiranthi Gunasekera	Consultant Rheumatologist	01733 676762

Dr Poonam Sharma	Consultant Rheumatologist	01480 416744
Dr Sandeep Dahiya	Consultant Rheumatologist	01733 676764
Dr John Pradeep	Consultant Rheumatologist	01480 442824
Dr Maeve Fifield	Consultant Rheumatologist	01733 676762
Rheumatology advice line		01733 676766

NWAFT Neurology Department

Name	Role	Contact details
Dr Dirk Baumer	Consultant Neurologist	01733 673549
Dr Sybil Stacpoole	Consultant Neurologist	01733 673549
Dr Tom Stoker	Consultant Neurologist	01733 673549
Dr John Thorpe	Consultant Neurologist	01733 673549
Dr Tejal Mitchell	Consultant Neurologist	01733 673549
Dr Tracey Graves	Consultant Neurologist	01480 847533

NWAFT Gastroenterology Department

Name	Role	Contact details
Dr Irfan Amin	Consultant Gastroenterologist	01733 677525
Dr Tapas Kumar Das	Consultant Gastroenterologist	01733 677526
Dr Anita Gibbons	Consultant Gastroenterologist	01480 442853
Dr Mohamed Habieb	Consultant Gastroenterologist	01480 416416
Dr Rizwan Kassam	Consultant Gastroenterologist	01480 418742
Dr Mary Ninkovic	Consultant Gastroenterologist	01733 677527
Dr Philip Roberts	Consultant Gastroenterologist	01480 442852
Dr Syed Shaukat	Consultant Gastroenterologist	01480 442854

NWAFT Dermatology Department

Name	Role	Contact details
Nick Errington Rachel Casbon	Dermatology Nurses	01733 673581 nwangliaft.dermnurses@nhs.net
Dr Onoshoke Abiola Dr Ayesha Khokhar Dr Richard Mallett Dr Kerry Shalders Dr Vanessa Smith Dr Mahmood Tabra	Consultant Dermatologists	01733 673586 nwangliaft.dermatologysecretaries@nhs.net

Dr Cedric Banfield

Royal Papworth Hospital NHS Foundation Trust

RPH – Interstitial Lung Disease Team

Name	Role	Contact details
Dr Nicky Simler	Consultant Respiratory Physician	01223 639793
Dr Muhunthan Thillai	Consultant Respiratory Physician	01223 639793
Dr Christine Fiddler	Consultant Respiratory Physician	01223 639793
Dr Helen Parfrey	Consultant Respiratory Physician	01223 639556
Dr Jennifer Dickens	Consultant Respiratory Physician	01223 639556
Dr Gauri Saini	Consultant Respiratory Physician	01223 639556
Dr Hannah Woodcock	Consultant Respiratory Physician	01223 639463
Dr Davinder Dosanjih	Consultant Respiratory Physician	01223 639463
Emma Harris	Nurse Consultant	01223 639864
Specialist Nurse helpline	Specialist nurses	01223 638018
Email contacts		papworth.ildsecretaries@nhs.net papworth.ildnursesecretaries@nhs.net
Faith Imali	Specialist pharmacist for transplant, ILD and Sleep medicine.	01223 638179
Medicines helpline	Non-urgent medicines information queries for patients	01223 638777

14. Additional information

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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

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- MHRA Drug Safety Update. (2025). *Thiopurines and intrahepatic cholestasis of pregnancy*. [online] GOV.UK. Available at: https://www.gov.uk/drug-safety-update/thiopurines-and-intrahepatic-cholestasis-of-pregnancy.

16. Other relevant national guidance

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- 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

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

If there are any concerns in relation to the patient or their condition changes, primary care prescribers should contact the relevant initiating specialist using the **Specialist contact information** detailed above.

Specialist teams should contact primary care prescribers via the usual communication routes agreed locally.

Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*
Date of birth: *[insert date of birth]*
NHS Number*:* *[insert NHS Number]*
Diagnosis: *[insert diagnosis]*

As per the agreed *[insert APC name]*shared care protocol for *[insert medicine name]* for the treatment of *[insert indication],* this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient	*Yes / No*
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	*Yes / No*
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	*Yes / No*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*
I have included with the letter copies of the information the patient has received	*Yes / No*
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

Treatment was started on *[insert date started]* and the current dose is *[insert dose and frequency]*.

If you are in agreement, please undertake monitoring and treatment from *[insert date]*
NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible. Acceptance will assumed if no response is received within 14 days.