SHARED CARE AGREEMENT

Name of medicine	Azathioprine
Indication	For the treatment of adults with inflammatory rheumatic, bowel and skin diseases

Version: **2.0** Approval date: **December 2022** Review date: **December 2025**

The Shared Care Agreement (SCA) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. It does not contain all of the relevant product information, which should be sought using the current British National Formulary and manufacturer's Summary of Product Characteristics. The SCA must be used in conjunction with the NHS Lothian Procedure for the Shared Care of Medicines, available here.

Roles and responsibilities

Listed below are specific responsibilities that are additional to those included in the NHS Lothian Policy and Procedures for Shared Care. Refer to policy for core roles & responsibilities that apply to all Shared Care Agreements.

Consultant

- Assessing the need for azathioprine therapy
- Stating the target dose
- Undertaking and assessing baseline investigations (including thiopurine methyltransferase (TPMT) assay).
- Arranging for the patient to receive verbal and written information on azathioprine for the relevant indication
- Advising the patient regarding fertility, pregnancy and the need for contraception as appropriate
- Treatment will be initiated by the consultant and the supply made by secondary care for the first 8 weeks. During this time the specialist service will provide comprehensive patient support including monitoring for adverse effects, addressing any treatment-related issues and responding to patient queries
- Making arrangements for results of blood tests to be reviewed during the first 6 weeks of treatment
- Making arrangements for patient to be reviewed 3-4 months after initiation of treatment to assess response
- Providing advice to the GP regarding monitoring, adverse effects and dose modifications when required
- Making arrangements for the patient to be kept under long term review.
- If gastroenterology patient is on triple immunosuppression with biologic/thiopurine/steroids, please consider prescribing pneumocystis pneumonia prophylaxis
- Specialist service to refer patients for vaccinations which are out with routine vaccination schedules or recall programmes via the clinician referral form (http://intranet.lothian.scot.nhs.uk/Directory/publichealth/Immunisation/Pages/VTP-(Vaccine-Transformation-Programme).aspx). Please note that Patient Specific Directions (PSD) are required for bespoke vaccination schedules where there is no PGD in place. The referral forms should be sent to the partnership that is responsible for administering vaccinations to their residents.

General Practitioner and primary care non-medical prescribers

- Prescribing azathioprine in consultation with the specialist service after the first 8 weeks
- On initiation of treatment, the specialist service will provide patients with pre-labelled forms for blood tests. Bloods are taken in primary care and reported to the specialist service during the first 6 weeks of treatment. The GP is to arrange for blood tests to be taken at appropriate intervals thereafter as detailed in "Monitoring"
- Monitoring for side effects after the first 8 weeks of treatment as detailed in the manufacturer`s Summary of Product Characteristics and under "Monitoring"
- Advising on a suitable form of contraception where relevant
- Encouraging participation in relevant national cancer screening programmes
- If gastroenterology patient is on triple immunosuppression with biologic/thiopurine/steroids, please consider prescribing pneumocystis pneumonia prophylaxis

Patient, Relatives, Carers

- As listed in the NHS Lothian Policy and Procedures for the Shared Care of Medicines.
- Ensuring adherence to phlebotomy requirements throughout treatment.
- Patients should report immediately any evidence of infection, unexplained bruising, bleeding or jaundice and any new/suspicious skin lesions or lymph node swellings.
- Patients should be advised to purchase and use sunscreens (SPF 50 or above) and protective clothing to reduce sunlight exposure.
- Patients can access advice from the relevant specialist team as follows:
    - Rheumatology patient helpline: 0131 537 1405
    - Inflammatory Bowel Disease patient helpline: 0131 537 1272 (WGH) or 01506 523861 (SJH)
    - Dermatology - contact the relevant consultant's secretary via switchboard: 0131 536 1000

Support and Advice for the GP and primary care non-medical prescribers

Rheumatology

SPR or Rheumatology Consultant on call 13.00-17.00 on weekdays and 09.00-12.00 on Saturdays and public holidays via the switchboard (0131 537 1000). Urgent queries out with these times will be dealt with by the on-call medical team.

GPs can access advice from the rheumatology specialist service using the rheumatology on call e-mail which aims to give advice with a 24 hour response time: rheumatology.oncall@nhslothian.scot.nhs.uk. Advice will be communicated back to the GP by e-mail. E-mail requests should copy in the practice's clinical e-mail address and ask that the reply is sent to all, so that the reply is picked up even if the sender is not available.

Dermatology

Contact the relevant consultant's secretary as detailed on clinic letter. For urgent queries please contact the Dermatology registrar on call via the switchboard (0131 536 1000), available Monday to Thursday 9am-9pm (excluding bank holidays), Friday to Sunday 9am-5pm (and bank holidays)..

Gastroenterology

Western General Hospital: SPR on call via switchboard 0131 537 1000 Bleep: 8279

Healthcare professionals can also contact the service for advice using the following email addresses: WGH.IBDConsultants@nhslothian.scot.nhs.uk or loth.ibdnurseswgh@nhs.scot. E-mail requests should copy in the practice's clinical e-mail address and ask that the reply is sent to all, so that the reply is picked up even if the sender is not available.

Royal Infirmary of Edinburgh: SPR on call via switchboard 0131 536 1000 Bleep: 2117

St. John's Hospital: SJHGastro@nhslothian.scot.nhs.uk or 01506 523861

Key Information on the Medicine

Refer to current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of drug for the given indication

Rheumatology: Azathioprine is used generally as monotherapy and rarely in combination with other DMARDs in the management of a number rheumatological inflammatory conditions.

Gastroenterology: Azathioprine is used as monotherapy or in combination with anti-TNF inhibitors for patients with moderate to severe Crohn's disease or steroid resistant ulcerative colitis.

Dermatology: Azathioprine is an effective treatment option for adult patients with autoimmune and inflammatory skin conditions. This SCA applies to prescribing of azathioprine either alone or in combination with corticosteroids for adults over 16 years of age for the management of its licensed dermatological indications – systemic lupus erythematosus, pemphigoid vulgaris, dermatomyositis, polyarteritis nodosa, pyoderma gangrenosa. Azathioprine is also used widely for the treatment of atopic eczema as per Lothian Joint Formulary section 13.5.1

Dosage and Administration

Azathioprine is usually commenced at a dose of 50mg once daily for 1-2 weeks then, if tolerated, dose is increased weekly by 50mg or to target dose.

Target dose:

- Rheumatology: 2-3mg/kg/day: Standard initiation prescription is 50mg daily for 2 weeks then 100mg daily for 2 weeks then 150mg daily maintenance if TPMT normal.
- Gastroenterology: maximum dose for inflammatory bowel diseases is 2.5mg/kg/day depending on TPMT. Azathioprine may be initiated at a lower dose of 1mg/kg whilst awaiting TPMT and then increased to target dose when TPMT is known and normal.
- Dermatology: 1-3mg/kg/day depending on TPMT activity.

Renal impairment requires dose adjustment (see www.bnf.org).

Monitoring

On initiation of treatment, patients are provided with pre-labelled forms for blood tests. Bloods are taken in primary care and reported to the specialist service during the first 6 weeks of treatment.

Note that abnormal trends in blood monitoring should prompt extra vigilance and may be a sign of toxicity even if absolute levels are normal.

Test	Frequency	Abnormal Result	Action if Abnormal Result
FBC	Every 2 weeks* until on a stable dose for 6 weeks Then monthly for 3 months Thereafter every 3 months Revert to initial schedule in the event of a dose increase and when a new DMARD is added *Dermatology may request weekly bloods for first month	Platelets 100-140 WCC 2.0-3.5 Neutrophils 1.0-1.6	Withhold therapy for 2 weeks and recheck. If normal recommence at lower dose i.e. reduce azathioprine dose by 50mg/day.
		Platelets < 100 WCC <2.0 Neutrophils < 1.0	Withhold treatment and contact specialist service
		Haemoglobin <100	Inform specialist service
		MCV >105	Check serum folate and B12 & TSH. Treat any underlying abnormality. If results normal discuss with specialist team.
LFTs		ALT >100	Withhold therapy for 2 weeks and recheck. If ALT <100, recommence at lower dose i.e. reduce azathioprine dose by 50mg/day.
		ALT 50-100	Continue treatment and recheck. If ALT stable, continue treatment. If ALT rising, contact specialist service.
U&Es		Creatinine: note trend	If rising, reduce dose by 50%, and contact specialist service.

Contraindications - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Cautions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

- Temporarily discontinue azathioprine during a serious infection.

Adverse effects - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

- Temporarily withdraw azathioprine if the patient reports an unexplained sore throat, bleeding or bruising, mouth ulcers or other signs of blood dyscrasia or evidence of infection.
  Perform repeat blood monitoring and withhold azathioprine until FBC results are available.

Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Pregnancy & Fertility

- Risk/benefit should be considered
- Azathioprine is not known to be teratogenic but pregnancy should always be discussed with specialist service
- Limited evidence suggests that azathioprine can be continued in males around the time of conception and throughout a partner's pregnancy

Vaccinations

- Individuals who on immunosuppressant therapy should be given inactivated vaccines in accordance with national recommendations.
- It is recommended that patients with autoimmune inflammatory diseases on immunosuppressant therapy should be offered pneumococcal, COVID19 and influenza vaccination.
- Immunosuppressed patients who are 70 to 79 years of age should be offered the varicella-zoster vaccine, Shingrix, to help protect them against shingles. Shingrix is a non-live alternative to the live shingles vaccine, Zostavax.
- When considering suitability for live vaccines concurrent DMARD therapy should also be taken into account.
- For further information see: https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

The presence of this SCA does not compel a primary care prescriber to prescribe if they feel that it is out with the scope of their competencies (as per GMC guidance on safe prescribing) or resources, as ultimate responsibility lies with the prescribing, not the recommending, clinician.

Approved for use by the General Practice Prescribing Committee December 2022 – *IBD nurses email address ONLY- updated September 2025*