SHARED CARE AGREEMENT

Name of medicine Mercaptopurine

Indication For the treatment of inflammatory bowel disease (IBD)

Version: **3.0** Approval date: **December 2024** Review date: **December 2027**

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. Please refer to the policy for core roles and responsibilities that apply to all Shared Care Agreements.

Consultant

- Assessing the need for mercaptopurine 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 mercaptopurine 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
- Specialist service to refer patients for vaccinations which are out with routine vaccination schedules or recall programmes via the clinician referral form (NHS Lothian HSCP Vaccination Service (scot.nhs.uk). 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.
- Making arrangements for the patient to be kept under long term review.
- If patient is on triple immunosuppression with biologic/thiopurine/steroids, please consider prescribing pneumocystis pneumonia prophylaxis.

General Practitioner and primary care non-medical prescribers

- Prescribing mercaptopurine 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 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 specialist team:
  Inflammatory Bowel Disease patient helpline: 0131 537 1272 (WGH) or 01506 523861 (SJH)

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

Western General Hospital: Healthcare professionals can contact the WGH service for advice using the following email addresses:
loth.wghibdconsultants@nhs.scot 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.

- WGH GI registrar can be contacted via switchboard 0131 537 1000 for emergencies.

St. John's Hospital: Healthcare professionals can contact the SJH service for advice via the IBD helpline number: 01506 523861

Key Information on the Medicine

Refer to the 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

Mercaptopurine is an unlicensed therapy for inflammatory bowel disease (IBD) but is widely used.

Mercaptopurine 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 or where azathioprine is not tolerated.

Dosage and Administration

Mercaptopurine is usually commenced at a dose according to TPMT. However, mercaptopurine may be initiated at a lower dose of 0.5mg/kg whilst awaiting TPMT and then increased to target dose when TPMT is known and normal.

Target dose: normal TPMT; 1-1.5mg/kg or low TPMT; 0.5mg/kg

Renal impairment: Consideration should be given to reduce dosage as thiopurines are renally excreted. 25% dose reduction if CrCl 10-50ml/min and 50% dose reduction if CrCl<10ml/min

Monitoring

On initiation of treatment, patients are provided with pre-labelled forms for blood tests. Bloods are taken in primary care and reported to gastroenterology 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.

Monitoring

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	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, e.g. 50% of dose
		Platelets <100 WCC < 2.0 Neutrophils < 1.0	Withhold treatment and contact specialist service
		Haemoglobin < 100	Inform specialist service
		MCV > 105	Check serum folate, 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, e.g. 50% of dose
		ALT 50-100	Continue treatment and recheck
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 mercaptopurine during a serious infection.
- If patient is on triple immunosuppression with biologic/thiopurine/steroids, please consider prescribing pneumocystis pneumonia prophylaxis.

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

- Temporarily withdraw mercaptopurine 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 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.
- Mercaptopurine is cytotoxic and therefore pregnancy should always be discussed with specialist service.
- Mercaptopurine has not been found to impact the health of the baby or sperm quality in men taking the medicine.

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 50 years and over 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: Immunisation against infectious disease - GOV.UK

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.

For office use only:

Approved by the General Practice Prescribing Committee (GPPC) on 10th December 2024