SHARED CARE AGREEMENT

Name of medicine Sulfasalazine

Indication For the treatment of inflammatory rheumatic diseases

Version: **2.2** Approval date: **September 2024** Review date: **September 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 sulfasalazine therapy.
- Undertaking and assessing the relevant baseline investigations.
- Stating the target dose.
- Arranging for the patient to receive verbal and written information on sulfasalazine.
- Treatment will be initiated by the consultant and the supply made by secondary care for the first 8 weeks. During this time rheumatology will provide comprehensive patient support including monitoring for adverse effects, addressing any treatment-related issues and responding to patient queries via the patient helpline.
- Arrange for the results of blood tests to be reviewed during the first 6 weeks of treatment.
- Arrange for the 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.
- Arrange for the patient to be kept under long term review.

General Practitioners and primary care non-medical prescribers

- Prescribing sulfasalazine in consultation with the specialist 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.
- General practitioners and primary care non-medical prescribers to arrange for blood tests to be taken at appropriate intervals after the first 8 weeks of treatment.
- Specific monitoring blood tests and side effects for sulfasalazine are detailed in "Monitoring" on page 2 and "Adverse effects" on page 3.
- Provide vaccinations in line with advice on page 3.

Patient, relatives, carers

- As listed in the NHS Lothian Policy and procedures for the Shared Care of Medicines.
- Ensuring adherence to phlebotomy throughout treatment.
- Patients can access advice via the rheumatology patient helpline by calling 0131 537 1405.

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

SPR or Rheumatology Consultant on call 13.00-17.00 on weekdays and 09.00-12.00 on Saturdays and public holidays via NHS Lothian switchboard (0131 537 1000). Urgent queries outwith 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@nhs.scot. Advice will be communicated back to the GP by e-mail. The GP 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.

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.

Helpful information on DMARDs can be found in the 2017 British Society for Rheumatology Guideline for the prescription and monitoring of non-biologic Disease-Modifying Anti-Rheumatic Drugs.
Link: https://www.rheumatology.org.uk/practice-quality/guidelines/

Background to disease and use of drug for the given indication

Sulfasalazine is used either as monotherapy or in combination with other DMARDs and biologic drugs in the management of various inflammatory rheumatic diseases.

Dosage and administration

Treatment is commenced at a dose of 500mg once daily for one week and then titrated upwards by 500mg each week until a target dose of 3g daily is achieved. In some patients a higher dose (up to 4g daily) may be prescribed on the advice of a rheumatologist. The total daily dose should be taken in 2-3 divided doses. Patients may continue on a lower maintenance dose depending on tolerability.

500mg enteric coated tablets should be used – this product is licensed for use in inflammatory rheumatic diseases and has lower incidence of gastrointestinal side effects.

An oral suspension is available (250mg/5ml) for those with swallowing difficulties.

Monitoring

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

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 for 12 months. After 12 months, no routine monitoring is needed. Revert to initial schedule in the event of a dose increase and when a new DMARD is added.	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 sulfasalazine dose by 500mg/day.
		Platelets < 100 WCC < 2.0 Neutrophils < 1.0 Lymphocytes <0.5 MCV > 105	Withhold treatment and contact rheumatology. MCV – check B12, folate, TFTs and consider discussing with rheumatology
LFTs		ALT >100	Withhold therapy for 2 weeks and recheck. If ALT <100, recommence at lower dose i.e. reduce sulfasalazine dose by 500mg/day.
		ALT 50-100	Continue treatment and recheck. If ALT stable, continue treatment. If ALT rising, contact rheumatology.
Creatinine /eGFR		Note trend	eGFR falling to <30ml/min contact Rheumatology and consider dose reduction with increased monitoring.

Cautions, contraindications
Refer to current Summary of Product Characteristics: www.medicines.org.uk for full details.

Fertility, Pregnancy and Lactation
Refer to current Summary of Product Characteristics: www.medicines.org.uk for full details.

- Sulfasalazine may be continued throughout pregnancy with the addition of folic acid supplementation (5mg daily folic acid).
- Low levels of sulfasalazine have been found in breast milk and the SPC for sulfasalazine does not recommend use during breastfeeding. However guidelines on pregnancy and breastfeeding from the British Society for Rheumatology (BSR) do state that sulfasalazine is compatible with breastfeeding. The decision should be made on a case by case basis.
- There is no need to discontinue sulfasalazine in men planning to conceive unless they are having difficulty conceiving. There is potential that men taking sulfasalazine may have reduced fertility but these effects can be reversed within 2-3 months of stopping the drug.

Adverse effects
Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

- Temporarily withdraw if the patient reports an unexplained **sore throat, bleeding or bruising, mouth ulcers** or other signs of blood dyscrasia. Perform repeat blood monitoring.
- In the event of an unexplained **acute widespread rash**, withhold sulfasalazine and seek urgent specialist (preferably dermatological) advice. Inform rheumatologist.

Drug interactions
Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

Vaccination

- Individuals with immunosuppression should be given inactivated vaccines in accordance with national recommendations.
- It is recommended that patients with autoimmune inflammatory diseases should be offered pneumococcal and influenza vaccination.
- Sulfasalazine is not considered significantly immunosuppressive as monotherapy and therefore live vaccines may be given.
- 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.

For office use only:

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