Shared Care Guideline:
Sulfasalazine

County Durham and Darlington NHS
NHS Foundation Trust

NHS
County Durham and Darlington
Area Prescribing Committee

Overview	Sulfasalazine is a disease modifying anti-rheumatic drug, but is not immunosuppressive.
Indication	Licensed • Rheumatoid arthritis • Ulcerative Colitis • Active Crohn's Disease Unlicensed • Psoriatic arthritis • Scleroderma • Enteropathic arthritis
Dose:	Initial dose of 500mg ONCE daily. Increase daily dosage by 500mg each week up to 2 to 3g in daily divided doses. Note that in gastroenterology the starting doses can be much higher at 1 to 2grams up to FOUR times a day
Specialist's Responsibilities	**Initial investigations:** Full Blood Count (FBC), calculated Creatinine Clearance (CrCl) / estimated Glomerular Filtration Rate (eGFR), Liver Function Tests (LFTs), Erythrocyte Sedimentation Rate (ESR) /C-Reactive Protein(CRP) **Initial prescribing until stable:** **Prescribing responsibility and monitoring to stay with the specialist until patient has been on a stable dose for at least 6 weeks at which point shared care is requested.** Specialist to issue a prescription for enough medication to last until shared care is accepted by GP. This will usually be a minimum of 28 days. **Communication and Documentation to GP:** • Obtaining agreement of GP to participate in shared-care arrangement for sulfasalazine therapy (by sending a copy of this document and letter to the GP). • Inform GP when monitoring can stop based on blood tests • Prompt communication with the GP regarding the patient's progress, any reassessment and changes in treatment. • Provide additional information and advice to the GP on actions he/she may need to take e.g. on dosage adjustment, other changes in therapy and management of adverse effects, as required. • Clinic letters and results to GP.
GP's Responsibilities	**Maintenance prescription** Prescribe Sulfasalazine in accordance with the specialist's recommendations as outlined in the shared care request letter **Clinical monitoring:** Continue to clinically monitor patient in line with this shared care agreement and referral letter from specialist (as described in clinical monitoring section below) **Criteria Requiring Specialist contact:** • Failure to attend for review or undertake blood tests

- Intolerance of drugs
- Communications failure

Documentation to specialist:

- Accepting or rejecting request for shared care within 28 days, if rejecting please state concerns and reasons Blood results to specialist via use of patient-held record.

Clinical monitoring:

FBC, calculated CrCl /eGFR, LFTs and ESR/CRP

Frequency:
Fortnightly until on stable dose for SIX weeks then monthly for THREE months
After THREE months reduce frequency of monitoring to THREE monthly
Once blood results have been stable for a year, monitoring may be stopped, **on the advice of a specialist**

NOTE – this guideline sets out the standard monitoring requirements, however it is essential that each patient is considered on an individual basis and monitoring frequency should reflect this. The GP should be made aware of any deviations.

Safety monitoring:

Please refer to Summary of Product Characteristics (SPC) or BNF /eBNF for full details of adverse effects, contraindications, cautions and drug interactions.

- Monitoring for response and adverse drug reactions (ADRs) during the initiation period.
- Ask about the following at each visit
  - sore throat
  - bruising or bleeding
  - rash
  - oral ulceration

Adverse Events

Adverse event	Action to be taken
WBC less than 3.5 x 10^9/L	Withhold and discuss with specialist team
Neutrophils less than 1.5 x 10^9/L	Withhold and discuss with specialist team
Platelets less than 120 x 10^9/L	Withhold and discuss with specialist team
More than a TWO fold rise in Alanine transaminase (ALT) / Aspartate aminotransferase (AST) from upper limit of normal	Withhold and discuss with specialist team
Oral ulceration	Withhold and discuss with specialist team
Nausea, dizziness, headache	If mild continue if possible, if severe discuss with specialist, may need to reduce dose
Mean Cell Volume (MCV) more than 105	check B12, folate, Thyroid Function Tests(TFTs) and discuss with specialist team
Severe breathlessness	Withhold and discuss urgently with specialist team
Abnormal bruising or sore throat	Withhold, check FBC and discuss with specialist team
Rash	Withhold and discuss with specialist team (urgently if rash is widespread).

Please note: Any rapid fall or consistent downward trend for blood counts or rapid rise or consistent upward trend for liver enzymes should prompt caution. Action may be required even if values are within normal range. If in doubt please contact specialist team.

Approximately 75% of side effects occur within THREE months of starting therapy and over 90% by 6 months. Some side effects are dose dependant and can be alleviated by dose

	reduction. This list is not exhaustive. • Nausea, diarrhoea, abdominal pain • Anorexia • Stomatitis, mouth ulcers • Rash, urticaria • Alopecia • Leucopenia, thrombocytopenia, megaloblastic anaemia, pancytopenia All suspected serious reaction should be reported to the specialist and the MHRA.
Contra-indications	• Known hypersensitivity to sulfasalazine.
Cautions	• Porphyria. • Stage 4 or 5 Chronic Kidney Disease (dose should be reduced by 50%) • Hepatic impairment or blood dyscrasias • Severe allergy or bronchial asthma. • G-6-PD deficiency.
Drug Interactions	• Increased risk of bone marrow suppression or leucopenia when sulfasalazine is prescribed concomitantly with 6-mercaptopurine or azathioprine. • Can reduce absorption of digoxin or folate.
Other Information	**Fertility, Pregnancy and Breastfeeding** • The British Society for Rheumatology (BSR) gives the following advice to men taking sulfasalazine and trying to conceive "Sulfasalazine can cause reversible oligospermia. "Men taking SSZ may have reduced fertility. There is no evidence, however, that conception is enhanced by stopping Sulfasalazine for 3 months prior to conception unless conception is delayed more than 12 months when other causes of infertility should also be considered" • Use of sulfasalazine in pregnancy is supported by the BSR, however, even though considered to be safe in pregnancy, the dose of sulfasalazine should not exceed 2g per day. • There is a theoretical risk of neonatal haemolyisis in third trimester. The BSR state that the woman MUST have DAILY folate supplementation with 5mg folic acid • Small amounts of sulfasalazine are excreted in breast milk and are not thought to be a risk to a healthy, full term infant. Use of sulfasalazine in breastfeeding mothers is therefore is supported by the BSR in most circumstances, however caution should be exercised, particularly for premature infants and those deficient in G-6-PD. • More information on use of sulfasalazine in pregnancy and breastfeeding can be found on the BSR website **https://www.guidelines.co.uk/BSR/RA-in-pregnancy-and breastfeeding/252703.article** **General:** • Staining of contact lenses (orange) • Alter Urine colour (orange)
Contact Details	Thank you for sharing the care of this patient. If you have any concerns or queries, please contact the Consultant, secretary or call the appropriate helpline below. UHND Rheumatology Helpline: 0191 3332763 DMH Rheumatology Helpline: 01325 743881 UHND Gastroenterology helpline 0191 3332995 DMH Gastroenterology helpline 01325 743434

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Department of Rheumatology
County Durham and Darlington Foundation Trust

GP name
GP address

Dear Dr ……

Request for Shared Care of SULFASALAZINE **Date:**

Re: Patient's name DOB:
Address Hospital Number:

This patient has been prescribed **Sulfasalazine** for the management of

□ Rheumatoid arthritis □ Ulcerative Colitis □ Active Crohn's Disease
□ Psoriatic arthritis (unlicensed) □ Scleroderma □ Enteropathic Arthritis (unlicensed)

The patients' current dose is ……per day

The patient was commenced on this drug on ……..and has been stable on the current dose since……

I would now like to ask you to take over the responsibility for prescribing this medication for this patient, as agreed by your CCGs and the Area Prescribing Committee.

The shared care document lists the monitoring requirements for this medication. Can I ask that any problems are reported back into secondary care.

The next blood monitoring is due on …… and should be continued in line with the shared care guideline.

This is part of the shared care guideline approved by the Area Prescribing Committee, available at http://medicines.necsu.nhs.uk/guidelines/durham-darlington/.

The patient will remain under regular clinical review by his or her usual consultant/ specialist nurse as described in the shared care agreement.

Please send back the second part of this letter, with 28 days, so we know that we have your agreement to this arrangement. If you are not happy to accept this patient or have any concerns, then please contact my secretary as soon as practically possible

Yours sincerely

Consultant name
Contact details

GP Agreement

Patient's Name:
DOB:
Hospital No:

I agree to take over the prescribing and monitoring of Sulfasalazine in line with the approved shared care document as found at http://medicines.necsu.nhs.uk/guidelines/durham-darlington/

Dose to be prescribed ……..

Dated ……/……/

Signed: …….

GP's Name:

GP contact details

Please return to Consultant's secretary. You may wish to keep a copy for your records.