BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Sulfasalazine
Amber *one month*	
Indication	Inflammatory arthritis
Speciality / Department	Rheumatology
Trust(s)	Weston Area Health Trust
	University Hospital Bristol Foundation Trust
	North Bristol Trust

Section 2: Treatment Schedule

Usual dose and frequency of administration	A typical dose regimen is 500mg daily, increasing by 500mg each week to a maintenance dose of 2-3g daily, usually taken in two divided doses. This should be continued as long as clinically indicated unless there is a serious side effect or the drug becomes ineffective.
Route and formulation	Oral tablet
Duration of treatment	Long term. As long as clinically indicated- unless a serious side effect occurs or the drug becomes ineffective.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate
Pre-treatment assessment: This will be the performed by the rheumatology department. Height, weight, blood pressure, FBC, renal function/GFR, LFT's, and screening for viral infection (HIV, Hep B, Hep C) will be done prior to commencing sulfasalazine. In patients with a clinical suspicion of parenchymal lung disease, formal lung function testing and appropriate imaging (chest radiograph with or without high-resolution CT imaging) should be performed and referral to a respiratory specialist be considered. Some rheumatology departments may arrange baseline chest X-Ray routinely for all patients. Any patient currently smoking should be offered access to smoking cessation services.
Subsequent tests - where appropriate
Monitoring: This will be performed primarily by the patient's GP, with support from the rheumatology team in the event of abnormal results (see below). Check FBC, creatinine/calculated GFR, ALT and/or AST and albumin every **2 weeks** until on stable dose for 6 weeks; Once on stable dose, **monthly** FBC, creatinine/calculated GFR, ALT and/ or AST and albumin for 3 months. Thereafter, FBC, creatinine/calculated GFR, ALT and/or AST and albumin **at least every 12 weeks for 12 months,** then no routine monitoring needed. More frequent monitoring is appropriate in patients at higher risk of toxicity. Dose increases should be monitored by FBC, creatinine/calculated GFR, ALT and/or AST and albumin every 2 weeks until on stable dose for 6 weeks, then revert back to previous schedule. This is the responsibility of primary care. Note that a rise in alkaline phosphatase may reflect disease activity rather than drug toxicity. Similarly a low WCC may be a feature of the underlying disease. If in doubt please contact the patient's rheumatologist. Chickenpox or shingles infection – treat with aciclovir

Section 4: Side Effects

Please list the most common side effects and management. Please provide guidance on when the GP should refer back to the specialist.

Side effects and management	**Common or very common:** blood disorders, cough, dizziness, fever, insomnia, anaemia, proteinuria, pruritus, taste disturbance, tinnitus and headache **Uncommon:** alopecia, convulsions, depression, dyspnoea, vasculitis **Unknown frequency:** aseptic meningitis, rash, hallucinations, GI intolerance. Urine may become yellow- orange, as may tears with consequent staining of contact lenses, and other body fluids.

	Serious side effects are rare. This includes bone marrow suppression (usually occur within the first three to six months of treatment) and allergic hepatitis.
Referral back to specialist	**Actions to be taken by patient's GP:** Sulfasalazine should be WITHHELD if any of the following occur. WCC <3.5x10^9/L Neutrophils <1.6 x10^9/L Platelets <100 x10^9/L Unexplained eosinophilia >0.5 x10^9/L Mean cell volume >105 f/l ALT >twice upper limit of reference range Unexplained reduction in albumin Renal impairment: Creatinine increase >30% over 12 months and/or unexplained reduction in calculated GFR stop drug if acute change. If gradual may need dose reduction. Rash or oral ulceration Severe sore throat, abnormal bruising: immediate FBC and withhold until the result of FBC is available. **Please repeat monitoring bloods in 1 week and if still low/high then discuss with the rheumatology team. Falling trends may also prompt discussion.**

Section 5: Drug Interactions

Please list clinically significant drug interactions (eMC link please click here)

Significant Drug Interactions	Sulfasalazine possibly reduces the absorption of digoxin and folic acid. Co-prescription of azathioprine may contribute to bone marrow toxicity.
Reminder to ask patient about specific problems	Nil

Section 6: Contra-indications, Cautions and Special Recommendations

Please list

Cautions:
Moderate renal impairment: may cause significant crystalluria and must ensure high fluid intake (eGFR 10-50: dose as in normal renal function but use with caution; eGFR <10: avoid, or start at very low dose and monitor).
Hepatic impairment
Glucose-6-phosphate dehydrogenase deficiency: may cause haemolysis
Pregnancy: analysis of risks and benefits to the mother should be undertaken. Sulfasalazine is generally considered to be safe to use in pregnancy but doses should not exceed 2g/day and 5mg Folic acid should be prescribed during conception, pregnancy and breastfeeding. If sulfasalazine use is not considered essential to the health of the mother during pregnancy, the drug should be discontinued for one full menstrual cycle before attempts at conception.
Breastfeeding: sulfasalazine is compatible in healthy full-term infants only. Diarrhoea in a nursing child whose mother was taking sulfasalazine has been reported.
Can be prescribed to men of childbearing age but may cause transient reversible oligospermia. Some men

also experience infertility. These complications are entirely reversible with drug discontinuation and conception may be enhanced by stopping sulfasalazine for 3 months prior to conception.

Contra-indications:
Hypersensitivity to sulphonamides/co-trimoxazole or aspirin
Acute porphyria

Section 7: Advice to the patient

Advice for prescribing clinician to inform patient

1. Discuss potential benefits and side-effects of treatment with the Specialist and/or GP.
2. Share any concerns they have in relation to their treatment.
3. To report any side-effects to the Specialist and/or GP (see individual drug fact sheet for specific information).
4. To ensure that the patient held record is presented at every consultation (in primary or secondary care).
5. To agree to and attend for the monitoring of therapy (including having blood tests carried out at agreed intervals) and assessment of outcomes, to assist health professionals to provide safe, appropriate treatment.
6. To use adequate contraception (both male and females), report any suspected pregnancy to the GP and/or Specialist and inform Specialist in a timely manner if plans to conceive.
7. To inform GP/Specialist/pharmacist of all medicines (including OTC preparations) that they are currently taking.

Section 8: Responsibilities for Secondary Care

Core responsibilities

1. Confirm diagnosis and indication for drug treatment.
2. Discuss potential benefits and side-effects of treatment with patient.
3. Carry out baseline monitoring requirements and initiate therapy. The GP will receive copies of the baseline blood test results.
4. The specialist will advise the GP of any dose adjustments required. The GP will then take over prescribing and blood test monitoring responsibilities.
5. An initial prescription will be provided by the specialist for 1 month.
6. Secondary care will advise on the appropriate monitoring blood tests as well as frequency.
7. Monitor the patient's response to therapy.
8. Decide when to stop therapy on safety grounds and inform the GP.
9. Secondary care will direct the GP to a copy of the concise drug information sheet and the shared care guidelines via the BNSSG Joint Formulary website.
10. Secondary care will supply the patient with a 'patient held record' and explain its role.
11. The dosage regimen should be clearly explained to the patient.
12. The patient should be asked to report side-effects (see individual drug fact sheet for specific information) and the GP should be informed if any side effects are reported to secondary care. Serious side-effects should be reported to the MHRA via the yellow card scheme.

Other specific to drug

Nil

Section 9: Responsibilities for Primary Care

Core responsibilities

1. Take on shared care proposal from the specialist after the first month of treatment (including prescription and blood monitoring).
2. If shared care is declined, an arrangement should be made with the rheumatology department to ensure patients are adequately supported. The GP practice and rheumatology department should also inform the interface pharmacists at the CCG, see contact details section below.
3. To ensure that all relevant staff and patients are aware of the shared care arrangements. Blood test results, dosage adjustments, should be recorded in the patient held record and GP medical record. Any dosage adjustments should also be recorded in computer-based prescribing systems.
4. The dosage regimen should be clearly explained to the patient.
5. Contact the specialist to discuss any significant changes in the blood test results or patient's condition e.g.; the medication becomes less effective.
6. Respond to dosage changes advised and prescribe appropriately. Receive copies of any blood test results carried out in secondary care for information and record in patient's record appropriately.
7. Monitor the patient for any side-effects to therapy and refer back to the Specialist should any serious side-effect occur. Side-effects / discontinuation of medication should be documented in the patient held record.

Other specific to drug

Nil

Section 10: Contact Details

Organisation	Contact	Contact details	Availability
University Hospitals Bristol Foundation Trust, Bristol Royal Infirmary	Rheumatology Telephone Advice Line	Tel: 0117 3424881 Registrar bleep: 7021	**Mon – Thu 9am to 5pm** **Fri 9am to 1pm**
North Bristol Trust, Southmead Hospital	Consultant secretary as per clinic letter OR Rheumatology Telephone Advice Line	Tel: 0117 4140600 Fax: 0117 4140570 Tel: 07894800989 On Call Tel: 07894800989 Sat/Sun 9am-noon (GP service for existing NBT rheum patients only)	**Mon – Fri 9am to 5pm**
Weston Area Health Trust, Weston General Hospital	Rheumatology Telephone Advice Line	Tel:01934 881075 Fax: 01934 647025 On Call registrar bleep: 279	**Mon – Fri 9am to 5pm**
BNSSG CCG	Emily Knight and Tash Mogford (Interface Pharmacists)	Emilyknight1@nhs.net Natasha.mogford@nhs.net	**Mon-Fri 9am to 5pm**

Section 11: Document Details

Date prepared	August 2017
Prepared by	Collated and updated from previous guidelines by Dr Randa Alshakh on behalf of Bristol and Weston Rheumatology consultants
Date approved by JFG	January 2018
Date of review	January 2020
Document Identification: Version	V3.1

Section 12: Collaboration

Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

This document has been sent to rheumatology consultants across Bristol and Weston for comment and approval.

Section 13: References

Please list references

1. BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs, February 2017
2. BSR and BHPR guideline on prescribing drugs in pregnancy and breastfeeding—Part I: standard and biologic disease modifying anti-rheumatic drugs and corticosteroids, January 2016
3. BNF 73 (March –September 2017)
4. https://www.uptodate.com/contents/use-of-antiinflammatory-and-immunosuppressive-drugs-in-rheumatic-diseases-during-pregnancy-and-lactation?source=search_result&search=use%20of%20antiinflammatory%20and%20immunosuppressive&selectedTitle=1~150
5. https://www.uptodate.com/contents/sulfasalazine-in-the-treatment-of-rheumatoid-arthritis?source=see_link