South Tyneside and Sunderland
Area Prescribing Committee

SHARED CARE GUIDELINE
Sulfasalazine in Rheumatology

Implementation Date: 1st December 2019 Review Date: 1st December 2022

This guidance has been prepared and approved for use within Sunderland and South Tyneside in consultation within the CCGs, and Secondary Care Trust.
The guideline sets out the details of the transfer of prescribing and respective responsibilities of GPs and specialist services within shared care prescribing arrangements. It is intended to provide sufficient information to allow GPs to prescribe this treatment within a shared care setting

Approved by:

Committee	Date

Instructions for completion:

- ☐ Consultant to counsel patient on medication and ensure patient has been provided with information leaflet
- ☐ Consultant to ensure all clinical details completed on this document
- ☐ Consultant to ensure patient understands proposed monitoring and prescribing arrangements if a shared care agreement is entered into
- ☐ GP to complete final section of form and return to specialist prescriber within 28 days
- ☐ GP to retain copy of document on patient record within surgery

Clinical details:

SHARED CARE GUIDELINE					
Non-proprietary name	Sulfasalazine	Brand name	Salazopyrin En-Tabs	Licensed Y/N?	Yes
Dosage form and strength	EC tablets (Salazopyrin EN-Tabs) 500mg			BNF class	10.01.03
Indication	Inflammatory arthritis				
Dosage and Administration	Initially 500 mg daily, increased in steps of 500 mg every week, increased to 2–3 g daily in divided dose. Prescribe enteric coated tablets only.				
Eligibility criteria for shared care	Patients must be under the care of rheumatologist Patients who have been stabilised and have been treated by specialist for at least three months. Patients who are not stable should not be transferred to primary care for monitoring.				
Excluded patients	Not for patients under the age of 16 years.				
Initiation	Shared care to be initiated once patient has been stable on maintenance dose for three months				
Monitoring	**Baseline assessment will be completed by specialist prior to initiation** **Monitoring** Ongoing blood test monitoring of high risk or low risk patients according to monitoring schedules below and review of laboratory abnormalities prior to transfer.				

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<u>Monitoring of high risk patients</u>

The patient is ‘high risk’ if any of the following apply:
Extremes of weight: BMI <18 or >30kg/m2
Renal impairment: CKD stage III or above
Pre-existing liver disease (including NAFLD)
Significant other co-morbidity (e.g. malignancy)
Age >80 years
Previous DMARD toxicity.

Routine Bloods: FBC, U&E, ALT and/or AST, Albumin, eGFR
Frequency: Every two weeks until stable on a dose for 6 weeks.
Once on a stable dose: monthly blood tests.
Following a dose increase, bloods should be checked every two weeks for 6 weeks, then revert back to previous schedule

<u>For patients who are NOT high risk:</u>
Routine Bloods: FBC, U&E, ALT and/or AST, Albumin, eGFR

Once on a stable dose: monthly blood tests for 3 months
Then: at least every 12 weeks for the first 12 months of treatment
Following a dose increase bloods should be checked 2 weekly for 6 weeks, then revert back to previous schedule
Standard monitoring schedule for 12 months then no routine monitoring needed

Laboratory abnormalities requiring action
The abnormalities in table below should trigger action/review. <u>If any abnormal blood test results are obtained, withhold the medication and discuss with the patient’s consultant neurologist</u>. Do not forget to consider the possibility that the abnormal blood result may be unrelated to the immunosuppressant medication.
<table>
<tr><th>Test</th><th>Result</th></tr>
<tr><td>White cell count</td><td><3.5 * 10^9/l (or downward trend over 2 consecutive tests)</td></tr>
<tr><td>Neutrophils</td><td><1.6 * 10^9/l</td></tr>
<tr><td>Unexplained eosinophilia</td><td>>0.5 * 10^9/l</td></tr>
<tr><td></td><td></td></tr>
<tr><td>Platelet count</td><td><140 * 10^9/l</td></tr>
<tr><td>MCV</td><td>> 105 fL</td></tr>
<tr><td>Creatinine/ eGFR</td><td>Creatinine increase >30% over 12 months and/or GFR <60ml/min/1.73m2</td></tr>
<tr><td>ALT (and/or AST)</td><td>>100 U/L</td></tr>
<tr><td>Albumin</td><td>Unexplained reduction in albumin to <30g/l</td></tr>
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<td>Infections</td>
<td>Infections
Patients treated with immunosuppressant agents (IAs) are at increased risk for opportunistic infections (bacterial, fungal, viral and protozoal). During serious infections, the IA should be temporarily discontinued, until the patient has recovered from the infection. It is usually appropriate to continue them in minor infections (e.g. a treated, uncomplicated UTI or URTI).</td>
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Vaccinations	Live vaccinations are not recommended. Vaccinations against influenza and pneumococcus should be recommended. If herpes zoster occurs stop sulfasalazine and prescribe aciclovir. If patient is in contact with chicken pox, contact the rheumatology team (may need zoster immune globulin).
Pregnancy and breastfeeding	Seek specialist advice
Perioperative use	Steroid exposure should be minimised prior to surgical procedures and increases in steroid doses to prevent adrenal insufficiency are not routinely required DMARD therapy should not routinely be stopped in the perioperative period, although individualised decisions should be made for high-risk procedures.
Specialist Responsibilities	• The decision to initiate immunosuppressive therapy must be made in conjunction with the patient/carer and be supervised by an expert in the condition in question • Patients must be provided with education about their treatment • Patient will be provided with an sulfasalazine patient information leaflet • Patients must be assessed for contra-indications and co-morbidities • Where appropriate, patients should be advised about the impact of the immunosuppressive agent (IA) on fertility, pregnancy and breastfeeding • Vaccinations against pneumococcus and influenza are recommended • Interactions between the proposed IA and current medication should be identified and actioned • Direct the patient to report any sign of infection or side effect to their GP or hospital clinic • Conduct baseline monitoring • Prescribe medication until responsibility agreed to be transferred to patients GP • Supply general immunosuppressant background information to GP as per this guidance • Request GP participate in shared care in writing no sooner than 3 months after initiation and patient is stable • At least 4 weeks of medication supplied at point of transfer • The secondary care specialist will communicate with the patient and GP when treatment is changed and/or needs to be changed by GP on future prescriptions, and/or when any changes to the monitoring are required, usually within 24 hrs • Conduct routine monitoring as per schedule while prescribing responsibility with specialist – this could be during initiation or at any point in time where the responsibility has been transferred back to the specialist • Observe advice relating to vaccination, perioperative use, infections etc contained in this document Specialist responsible for ongoing **disease** monitoring– clinical response to therapy will be assessed by the hospital physician in all cases and communicated to the GP
GP Responsibilities	• The GP should reply to the request for shared care as soon as possible, but always within 14 days, either accepting shared care or informing the specialist why shared care is not felt appropriate in this case. • If GP declines shared care responsibilities it is still the GPs responsibility

	to record on the primary care record that the drug is being prescribed by secondary care • Shared care to be initiated once patient is stable and at least 3 months after initiation • Prescribe medication as per document • **Conduct routine monitoring as per schedule while responsible for prescribing** • Observe advice relating to vaccination, perioperative use, infections etc contained in this document
Adverse Effects, Precautions and Contraindications	**Contra-indications** • Patients with a known hypersensitivity to sulfasalazine, its metabolites or any of the excipients as well as sulfonamides or salicylates. • Patients with porphyria **Precautions** • Sulfasalazine should not be given to patients with impaired hepatic or renal function or with blood dyscrasias, unless the potential benefit outweighs the risk. • Sulfasalazine should be given with caution to patients with severe allergy or bronchial asthma. • Since sulfasalazine may cause haemolytic anaemia, it should be used with caution in patients with G-6-PD deficiency. • Oral sulfasalazine inhibits the absorption and metabolism of folic acid and may cause folic acid deficiency potentially resulting in serious blood disorders (e.g. macrocytosis and pancytopenia), this can be normalised by administration of folic acid or folinic acid (leucovorin). • Because sulfasalazine causes crystalluria and kidney stone formation, adequate fluid intake should be ensured during treatment. • Oligospermia and infertility may occur in men treated with sulfasalazine. Discontinuation of the drug appears to reverse these effects within 2 to 3 months. **Adverse Effects** Overall, about 75% of ADRs occur within 3 months of starting therapy, and over 90% by 6 months. Some undesirable effects are dose-dependent and symptoms can often be alleviated by reduction of the dose. The most commonly encountered ADRs are nausea, headache, rash, loss of appetite and raised temperature Clinician should review severity of side effect and contact specialist for advice if needed. **For a full list of contraindications/precautions/side effects please consult either the current BNF or SPC:** **https://bnf.nice.org.uk/** **https://www.medicines.org.uk/emc**
Common Drug Interactions	**Interactions:** • Digoxin absorption is reduced; this has been reported to result in non-therapeutic serum levels

	• Folic acid absorption is reduced; this may cause folic acid deficiency. This can be normalised by administration of folic acid or folinic acid. **For a full list of interactions please consult either the current BNF or SPC:** **https://bnf.nice.org.uk/** **https://www.medicines.org.uk/emc**
Communication/ Contact Details	• For acute advice: ○ Monday to Friday, 9.00 am to 5.00 pm, phone the on-call monitoring nurse, rheumatology registrar or rheumatology consultant on call via the switchboard on **(0191) 565 6256**. Please use the bleep number **53546** in order to contact the rheumatology monitoring nurse for routine queries. ○ Out of hours, phone the on-call medical registrar on **(0191) 565 6256**. • For non-acute advice, send a letter to the consultant in charge of the patient's care.

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the SPC or the BNF.

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Shared Care Request/Confirmation

Private and Confidential

Patient information:

To be completed by specialist prescriber:

		Patient details (use hospital label if preferred)	
Consultant	……	**Name**	……
Department	……	**Address**	……
Hospital	……		……
		Postcode	**Sex** ……..
		NHS or Hosp. Reg. No. ……	**DoB** ……..

Treatment Requested for Prescribing in Accordance with Shared Care Arrangement:

To be completed by specialist prescriber:

Drug name	
Dose	
Frequency	
Indication	
Other information	

Name (print)…….… Signature (of specialist prescriber)……..…….. Date……..

Acceptance/rejection of treatment under Shared Care Agreement:

To be completed by GP:

Please tick one box

I ACCEPT the proposed shared care arrangement for this patient ❑

or

I ACCEPT the proposed shared care arrangement with the caveats below ❑

or

I DO NOT ACCEPT the proposed shared care arrangement for this patient ❑

My caveats / reason(s) for not accepting include: ……
……

Name (print)……..… Signature (of GP)……..……..... Date….

N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the specialist prescriber and the patient's GP