DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
SHARED CARE AGREEMENT

Oral Sulfasalazine for patients 16+ years

1. REFERRAL CRITERIA
- Shared Care is only appropriate if it provides the optimum solution for the patient.
- Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient’s GP and the patient’s condition is stable or predictable.
- Safe prescribing must be accompanied by effective monitoring
- When transfer agreed the patient will be given a supply of sulfasalazine sufficient for at least 4 weeks maintenance therapy.

2. AREAS OF RESPONSIBILITY

<table>
<thead>
<tr>
<th>GP responsibilities</th>
<th>Consultant responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) If NOT participating in shared care reply to the request from the consultant/specialist as soon as practicable (see appendix 1)</td>
<td>a) Discuss the possible benefits and side effects of treatment with the patient.</td>
</tr>
<tr>
<td>b) Ensure compatibility with other concomitant medication.</td>
<td>b) Perform baseline tests (as recommended in section vii)</td>
</tr>
<tr>
<td>c) Prescribe the dose and formulation recommended.</td>
<td>c) Provide results of baseline tests</td>
</tr>
<tr>
<td>d) Perform monitoring tests as specified in section vii.</td>
<td>d) Prescribe sulfasalazine for the first three months or until medication monitoring is stable</td>
</tr>
<tr>
<td>e) Adjust the dose as advised by the specialist.</td>
<td>e) Recommend dose of the drug and frequency of monitoring.</td>
</tr>
<tr>
<td>f) Stop treatment on the advice of the specialist or immediately if any urgent need to stop treatment arise.</td>
<td>f) To contact patient’s GP to request prescribing under shared care and send a link to or copy of the shared care protocol.</td>
</tr>
<tr>
<td>g) Ensure the patient is offered an annual flu vaccination and a one off pneumococcal vaccination. Live vaccinations can be used with caution in patients taking traditional DMARDS at standard doses*</td>
<td>g) Annually review the patient and advise the GP promptly on when to adjust the dose, stop treatment or consult with the specialist.</td>
</tr>
<tr>
<td>h) Report any adverse effects to the referring specialist and the MHRA yellow card scheme.</td>
<td>h) Ensure that clear backup arrangements exist for GPs to obtain advice and support.</td>
</tr>
</tbody>
</table>

Patient responsibilities
- Report to the specialist or GP if there is not a clear understanding of the treatment and share any concerns in relation to treatment.
- Inform specialist or GP of any other medication being taken including over-the-counter products.
- Report any adverse effects or warning symptoms to the specialist or GP whilst taking the drug for example sore throat, unexplained bruising or rash.

3. COMMUNICATION AND SUPPORT

i. Hospital contacts:
Chesterfield Royal Hospital NHS Foundation Trust
Contact the referring consultant/nurse via switchboard: 01246 277271
Nurse advice line: 01246 513097
Available Monday-Thursday 9am-4:30pm, Friday 9am-12:30pm
IBD advice line 01246 512884 (answerphone) and GP mobile contact 07717700489

University Hospitals of Derby and Burton NHS Foundation Trust
Derby Hospitals
Rheumatology - Rheumatology helpline: 01332 787710
Gastroenterology - IBD helpline: 01332 785504
Consultant/specialist nurse via switchboard: 01332 340131

ii. Out of hours contacts and procedures:
Chesterfield:
Contact the CRH on-call Medic for the relevant speciality via switchboard: 01246 277271

Derby:
Pharmacy, UHDB, ask for on-call pharmacist via switchboard: 01332 340131
Messages can be left on the Derby Rheumatology nurse advice line: 01332 787710
The aim is to address these next working day
iii. Specialist support/resources available to GP including patient information:

**Rheumatology**

---

### 4. CLINICAL INFORMATION

<table>
<thead>
<tr>
<th>i. Prescribed Indications</th>
<th>Licensed</th>
<th>Unlicensed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ulcerative colitis</td>
<td>Ulcerative colitis</td>
<td>Sero-negative spondyloarthropathy including psoriatic arthritis and psoriasis</td>
</tr>
<tr>
<td>Crohn’s disease</td>
<td>Crohn’s disease</td>
<td></td>
</tr>
<tr>
<td>Rheumatoid Arthritis (Sulfasalazine EC only)</td>
<td>Rheumatoid Arthritis (Sulfasalazine EC only)</td>
<td></td>
</tr>
</tbody>
</table>

| ii. Therapeutic summary | *Remission*  
Active Crohn’s disease. 1-2g QDS until remission occurs |
|-------------------------|---------------------------------------------------------------|
|                         | *Maintenance*  
Maintenance of remission of ulcerative colitis 500mg QDS |
|                         | Active rheumatoid arthritis: Initially 500mg daily, increased in steps of 500mg every week to 2-3g in divided doses |
|                         | **Preparation:**  
Sulfasalazine plain tablets licenced for use in:  
- Ulcerative colitis  
- Crohn’s Disease |
|                         | Sulfasalazine EC tablets licenced for use in:  
- Ulcerative colitis  
- Crohn’s Disease  
- Rheumatoid arthritis |
|                         | For other indication see BNF or as per specialist advice |
|                         | Doses outside the recommended range may be considered with prior agreement with the specialist team and GP involved.  
Lower doses should be considered for frail elderly and patients with renal impairment. |

<table>
<thead>
<tr>
<th>iii. Dose &amp; Route of administration</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Medium to long term: depends on response to treatment, side effects and level of disease activity.</td>
</tr>
</tbody>
</table>

| iv. Duration of treatment | Common side effects as per SPC  
Fever, Blood disorders (including Heinz body anaemia, megaloblastic anaemia)  
Cough, Dizziness, Nausea, Headache, Tinnitus, Insomnia, Gastric distress, Arthralgia  
Pruritus, Rash, Stomatitis, Taste disturbances, Proteinuria, Yellow discoloration of skin, urine and other bodily fluid |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Because sulfasalazine causes crystalluria and kidney stone formation, adequate fluid intake should be ensured during treatment.</td>
</tr>
</tbody>
</table>
v. Immunisation

- **Live vaccinations** can be used with caution in standard doses of sulfasalazine. JCVI/Green book recommending that low dose corticosteroid (prednisolone <20mg daily) and oral traditional DMARD therapy at standard doses* are not a contraindication in most patients, although clinician discretion is advised.
- Annual flu vaccination is recommended.
- One off Pneumococcal vaccination recommended unless severely immunocompromised where a different schedule is needed. See JCVI for more information.

i. Monitoring Requirements

**Before commencing immunosuppressant therapy**

- Record patients blood pressure, height and weight if clinically indicated
- Screening for lung disease should be undertaken at clinician discretion on a case-by-case basis. The extent of screening should be influenced more by a patient’s clinical features and risk factors for lung disease (e.g. underlying autoimmune disease or smoking history) rather than subsequent immunomodulating choice. Pre-existing lung disease should not be considered and absolute contraindication to any immunomodulating medication.
- Consultant to consider ECG where appropriate especially when commencing medications associated with hypertension
- Screen for viral hepatitis B&C and HIV in all patients at increased risk of infection
- Investigate patient medical history including co-morbidities and previous immunomodulating medication use.

**Consultant/specialist monitoring schedule**

Baseline and 2 weekly until on a stable dose for at least 6 weeks

- FBC
- ALT and/or AST (BNF states LFTs) and albumin
- U&E including Creatinine/calculated GFR (SPC- Assessment of renal function including urinalysis) should be performed in all patients initially and at least monthly for the first three months of treatment.

Annually review the patient and advise the GP promptly on when to adjust the dose, stop treatment or consult with the specialist.

**GP responsibility monitoring schedule**

In patients following the 6 weeks of dose stability conduct monthly monitoring as above for three months followed by three monthly monitoring thereafter of:

- FBC
- ALT and/or AST (BNF states LFTs) and albumin
- U&E including Creatinine/calculated GFR

**Standard monitoring schedule stable for 12 months then to be monitored at 6 monthly intervals**

For rheumatic patients CRP/ESR may be done every 3 months (this is not done for dermatology patients). These tests are part of the assessment of the underlying rheumatic disease rather than a requirement for monitoring of immunomodulating therapy. The monitoring CRP/ESR may be coordinated between secondary and primary care on an individual basis.

**Actions to be taken**

1. Immunosuppressants prescribed to prevent transplant rejection **should not be stopped** without discussion with a member of the specialist team.
2. In addition to responding to absolute values in laboratory tests, it is also relevant to **observe trends in results** (e.g. gradual decreases in white blood cells (WBC) or albumin, or increasing liver enzymes)
3. Parameters below are to be used as a guide for clinicians rather than absolute values, where monitoring should be based on individualized basis. It is important to consider alternative explanations other than the immunomodulation agents, especially in patients who have been stable for prolonged periods

**NB** – a rapidly increasing or decreasing trend in any value should prompt caution irrespective of actual value.
If felt to be appropriate to restart sulfasalazine after an abnormality has settled, consider a lower dose (with discussion with specialist) and monitor as follows: repeat bloods in 2 weeks and then monthly for 3 months. Following this resume previous monitoring frequency.

### Dosage increase (on the recommendation of the clinician)

For dose increase, monitor 2 weekly until stable for 6 weeks, then revert back to previous schedule. Dose and monitoring to be agreed with consultant:
- FBC
- ALT and/or AST (BNF states LFTs) and albumin
- U&E including Creatinine/calculated GFR

When restarting treatment after an abnormality has been detected repeat bloods in 2 weeks and then monthly for 3 months. Following this resume monitoring frequency to what it was prior to the abnormality.

<table>
<thead>
<tr>
<th>Lab Values</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC &lt;3.5 x 10^9/l</td>
<td>Contact Specialist urgently and consider interruption</td>
</tr>
<tr>
<td>Neutrophils &lt;1.6 x 10^9/l</td>
<td>Contact Specialist urgently and consider interruption</td>
</tr>
<tr>
<td>Platelets &lt;140 x 10^9/l</td>
<td>Contact Specialist urgently and consider interruption</td>
</tr>
<tr>
<td>Unexplained eosinophilia &gt;0.5 x 10^9/l</td>
<td>Contact Specialist urgently and consider interruption</td>
</tr>
<tr>
<td>ALT and/or AST &gt;100 U/l</td>
<td>Contact Specialist urgently and consider interruption</td>
</tr>
<tr>
<td>Unexplained fall in albumin &lt;30g/l</td>
<td>Contact Specialist urgently and consider interruption</td>
</tr>
<tr>
<td>Mean cell volume &gt;105 f/l</td>
<td>Withhold and check serum B12, folate &amp; TFT and discuss with specialist team.</td>
</tr>
<tr>
<td>Creatinine increase for example &gt;30% over 12 months and/or calculated GFR &lt;60ml/min/1.73m²</td>
<td>Contact Specialist urgently and consider interruption</td>
</tr>
</tbody>
</table>

### Drug specific

- **Nausea, dizziness or headache**
  - If possible continue, may have to reduce dose or stop if symptoms severe. **Discuss with Specialist team**
- **Abnormal bruising or severe sore throat**
  - Check FBC immediately and withhold until results available. **Discuss with the specialist team, if necessary**
- **Unexplained acute widespread rash**
  - Withhold & seek **urgent specialist** (preferably dermatological) advice.
- **Oral ulceration**
  - Contact Specialist **urgently** and consider interruption

### CRP/ESR

Measured to allow disease activity evaluation

If felt to be appropriate to restart sulfasalazine after an abnormality has settled, consider a lower dose (with discussion with specialist) and monitor as follows: repeat bloods in 2 weeks and then monthly for 3 months. Following this resume previous monitoring frequency.

### vi. Clinically relevant drug interactions

*(For a full list of interactions please refer to the BNF)*

- Azathioprine
- Digoxin
- Mercaptopurine
- Folates

### vii. Contraindications and cautions

- **Contraindications**
  - Suspected serious infection (requiring IV antibiotics or hospitalization) treatment should be discontinued.
  - Patients with porphyria
  - not on SPC

### Pregnancy

Manufacturer advice only if clearly needed. (folic acid supplement)

### Breast feeding

Sulfasalazine and sulfapyridine are found in low levels in breast milk. Theoretical risk of neonatal haemolysis especially in G6PD-deficient infants. Manufacturer advice avoid.

### Cautions (as per SPC)

- Patients with impaired hepatic or renal function or with blood dyscrasias
- Patients with severe allergy or bronchial asthma
Patients with G-6-PD deficiency (sulfasalazine may cause haemolytic anaemia)

Oral sulfasalazine inhibits the absorption and metabolism of folic acid and may cause folic acid deficiency

Men of child bearing potential- there may be transient reversible oligospermia

Localised or systemic infection including hepatitis B or C and a history of TB.

Appropriate to continue with therapy in patients with minor infections (e.g. Uncomplicated urinary tract infections treated with a short course of antibiotics) seek advice from specialist

Unexplained anaemia and/or cytopenia associated with marrow failure.

viii. Supply of ancillary equipment

NA

ix. Supply, storage and reconstitution instructions

NA

Prepared by

The Shared Care Guidelines Group
Derby Hospitals
Chesterfield Royal Hospital

Reviewed by

Derbyshire Medicines Management Clinical Effectiveness Team

In consultation with

(2019)

Martin Shepherd, Head of Medicines Management Chesterfield Royal Hospital
Dr Badcock, ACD Consultant Rheumatology
Dr R Laxminaryan, Deputy ACD Rheumatology
Dr. K Fairburn, Consultant rheumatologist CRH
Angela Lawrence, Rheumatology Lead Clinical Nurse Specialist CRH
Kath Phillis, Advanced Clinical Nurse Specialist IBD CRH

The Derbyshire Medicines Management Shared Care and Guidelines Group

This does not replace the SPC, which should be read in conjunction with it

Date Prepared: October 2011 Reviewed: July 2019 Review Date: June 2022

References

1. EMC Summary of Product Characteristics for Sulfasalazine accessed online 08/03/2017, 2/7/19
2. British National Formulary accessed online 2/7/19
3. BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs, The British Society for Rheumatology, February 2017
4. The Green book, Immunisation against infection disease, September 2014, accessed online 08/03/2017, 2/7/19
Hospital No: «HOSPITAL_NUMBER»
NHS No: «NHS_NUMBER»

{Insert date}

PRIVATE & CONFIDENTIAL
«GP_TITLE» «GP_INITIALS» «GP_SURNAME»
«GP_ADDRESS_1»
«GP_ADDRESS_2»
«GP_ADDRESS_3»
«GP_ADDRESS_4»
«GP_POSTCODE»

DERBYSHIRE JAPC SHARED CARE AGREEMENT LETTER

Dear «GP_TITLE» «GP_SURNAME»

«FORENAME_1» «SURNAME» «DATE_OF_BIRTH»
«CURRENT_ADDRESS_1» «CURRENT_ADDRESS_2» «CURRENT_ADDRESS_3»
«CURRENT_ADDRESS_4» «CURRENT_POSTCODE»

Your patient was seen on {Insert date} with a diagnosis of {Insert diagnosis}. I have initiated the following medication {Insert drug name} and am writing to ask you to participate in the shared care for this patient.

This medication has been accepted as suitable for shared care by the Derbyshire Joint Area Prescribing Committee (JAPC). I agree to the secondary care responsibilities set out in the shared care agreement for this medication (available from www.derbyshiremedicinesmanagement.nhs.uk/clinical_guidelines/shared_care_guidelines). I am therefore requesting your agreement to share the care of this patient. Where preliminary tests are set out in the agreement I have carried these out and results are below.

<table>
<thead>
<tr>
<th>Dose Regimen</th>
<th>Date {Insert medicine name} started</th>
<th>Date for GP to start prescribing {Insert medicine name} from</th>
</tr>
</thead>
</table>

The baseline test results are (if applicable):
See overleaf for initiation criteria.

I confirm I have explained to the patient: the risks and benefits of treatment, the baseline tests conducted the need for monitoring, how monitoring will be arranged, and the roles of the consultant / nurse specialist, GP and the patient in shared care. I confirm the patient has understood and is satisfied with this shared care arrangement at this time.

If you do NOT wish to participate in shared care for this patient, usually under clinical grounds, please complete the attached form.

Yours sincerely

{Consultant name}
GP RESPONSE TO SHARED CARE (only complete & send if NOT participating in shared care)

Shared care is produced by GPs and specialists knowledgeable in the field of that drug usage. The shared care has been approved by the JAPC. This allows a more convenient service to the patient and cost effective use of NHS resources.

<table>
<thead>
<tr>
<th>Patient:</th>
<th>NHS No:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultant:</td>
<td>Medicine requested for shared care:</td>
</tr>
</tbody>
</table>

I will NOT be undertaking the GP responsibilities as described in the agreed shared care guideline. My clinical reasons for declining shared care for this patient are listed in the box below:

Yours sincerely

{GP name}
{Surgery}

Please send a copy of this response to:

1. The specialist/consultant requesting shared care
2. AN ANONYMISED COPY OF THIS FORM ONLY to the Medicines Management and Clinical Policies and Decisions Team, 1st Floor East Point, Cardinal Square, 10 Nottingham Road, Derby, DE1 3QT or E-MAIL: ddccg.medicinesmanagement@nhs.net

(Sending a copy of this form to the Medicines Management and Clinical Policies and Decisions Team will help to identify any inappropriate requests for shared care e.g. indication not covered, hospital monitoring requirements not fulfilled. It will also help to inform the CCG prescribing group of the reasons shared care is not being undertaken allowing for changes to be made in future updates to improve patient care).