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

GP responsibilities	Consultant responsibilities
a) If NOT participating in shared care reply to the request from the consultant/specialist as soon as practicable (see appendix 1) **b)** Ensure compatibility with other concomitant medication. **c)** Prescribe the dose and formulation recommended. **d)** Perform monitoring tests as specified in section vii. **e)** Adjust the dose as advised by the specialist. **f)** Stop treatment on the advice of the specialist or immediately if any urgent need to stop treatment arise. **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* **h)** Report any adverse effects to the referring specialist and the MHRA yellow card scheme	**a)** Discuss the possible benefits and side effects of treatment with the patient. **b)** Perform baseline tests (as recommended in section vii) **c)** Provide results of baseline tests **d)** Prescribe sulfasalazine for the first three months or until medication monitoring is stable **e)** Recommend dose of the drug and frequency of monitoring. **f)** To contact patient's GP to request prescribing under shared care and send a link to or copy of the shared care protocol. **g)** Annually review the patient and advise the GP promptly on when to adjust the dose, stop treatment or consult with the specialist. **h)** Ensure that clear backup arrangements exist for GPs to obtain advice and support. **i)** Report any adverse effects to the MHRA yellow card scheme and GP **j)** Advise on the suitability for herpes zoster vaccination in accordance with national screening programme. **k)** Alongside the recommendations for routine monitoring more frequent monitoring may be appropriate in patients at high risk of toxicity. These will be communicated to the GP on a case by case basis. **l)** Communicate any dose increase to the GP and transfer monitoring to GP when monitoring is stable or predictable following 6 weeks period of dose titration.

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

Burton Hospitals Switchboard: 01283 511511 / 566333 Rheumatology Dr R Laximinarayan ext. 3167 Dr S Das ext. 3211 Dr D Ray ext. 3247 Clinical Rheumatology Nurse Specialist ext. 4112 Bhft.rheumatologynurses@nhs.net Gastroenterology Dr Palejwala / Dr Dor secretary ext. 3004 Dr Watmough / Dr Guerra secretary ext. 3002 IBD Nurse Specialist ext. 5854 (voicemail service only) Bleep: 590 Dhft.ibdcns@nhs.net	**Burton:** Burton Hospitals 01283 511511 / 566333 ask for on-call pharmacist via switchboard Burton Rheumatology Messages can be left on the nurse advice line out of hours on 01283 511511 ext 4112. If the advice line is not staffed, messages may be left 24 hours a day. The team aim to respond at latest within two working days. The specialist nurses may also be bleeped via switchboard for urgent enquiries.

iii. Specialist support/resources available to GP including patient information:

Rheumatology

British Society of Rheumatology Specialist website: http://www.rheumatology.org.uk/

Arthritis Research Campaign Patient Information website: http://www.arthritisresearchuk.org/arthritis-information.aspx

4. CLINICAL INFORMATION

i. Prescribed Indications	**Licensed** Ulcerative colitis Crohn's disease Rheumatoid Arthritis (Sulfasalazine EC only)	**Unlicensed** Sero-negative spondylo-arthropathy including psoriatic arthritis and psoriasis
ii. Therapeutic summary	Affects varios inflammatory mediators. The key actions are unknown.Time to response: minimum of three months	
iii. Dose & Route of administration	*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 Salazopyrin is the preferred cost-effective brand 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.	
iv. Duration of treatment	Medium to long term: depends on response to treatment, side effects and level of disease activity.	
Adverse effects	**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 Because sulfasalazine causes crystalluria and kidney stone formation, adequate fluid intake should be ensured during treatment.	

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
vi. 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.

WBC <3.5 x10^9 /1	Contact Specialist **urgently** and consider interruption
Neutrophils <1.6 x 10^9/l	Contact Specialist **urgently** and consider interruption
Platelets <140 x 10^9/l	Contact Specialist **urgently** and consider interruption
Unexplained eosinophilia >0.5x10^9/l	Contact Specialist **urgently** and consider interruption
ALT and/or AST >100 U/l	Contact Specialist **urgently** and consider interruption
Unexplained fall in albumin <30g/l	Contact Specialist **urgently** and consider interruption
Mean cell volume >105 f/l	Withhold and check **serum B12, folate & TFT** and discuss with specialist team.
Creatinine increase for example >30% over 12 months and/or calculated GFR <60ml/min/1.73m²	Contact Specialist **urgently** and consider interruption
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.** D**iscuss 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

<u>Dosage increase (on the recommendation of the clinician)</u>
For dose **<u>increase</u>**, 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.

vii. Clinically relevant drug interactions
(For a full list of interactions please refer to the BNF)

- Azathioprine
- Digoxin
- Mercaptopurine
- Folates

viii. 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.
ix. Supply of ancillary equipment	NA
x. Supply, storage and reconstitution instructions	NA
Prepared by **Reviewed by** **In consultation with (2019)**	The Shared Care Guidelines Group Derby Hospitals Chesterfield Royal Hospital Derbyshire Medicines Management Clinical Effectiveness Team 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

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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

Sample Transfer Letter

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.

Dose Regimen	Date ***{Insert medicine name}*** started	Date for GP to start prescribing ***{Insert medicine name}*** from
The baseline test results are (if applicable): **See overleaf for initiation criteria.**		

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient	*Yes / No*
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	*Yes / No*
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	*Yes / No*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*

I have included with the letter copies of the information the patient has received	*Yes / No*
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

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*)
* For completeness please record medication on GP clinical system as per guidance- 'Recording medicines prescribed and issued by other Healthcare Providers'

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.

Patient:	NHS No:
Consultant:	Medicine requested for shared care:

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:

		Tick which apply
1.	**The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care** As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	
2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	
3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	
5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed. For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	
6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible.

Yours sincerely

{GP name}
{Surgery}

Please send a copy of this response to the specialist/consultant requesting shared care