Sulfasalazine EC tablets : Shared Care Agreement

Shared Care: Introduction

The NHS England guidance and Welsh Ministerial circular published in 2018 (Responsibility for prescribing between Primary & Secondary/Tertiary Care for England and the All Wales Communication Standards between Primary and Secondary care HC/2018/014) and the basic premise that:

- Transfer of prescribing and monitoring responsibility under shared care requires a formal written request from the specialist and acceptance by the primary care prescriber
- If the primary care prescriber is unable to take on shared care, a dialogue is required between all relevant parties to identify any further information or support to enable shared care. If shared care is not in the best interest of the patient alternative arrangements are required

Patients will not be used as a conduit for transferring any information required for shared care
Aligning clinical and prescribing responsibility enhances patient safety. The prescriber is responsible for ensuring that the required monitoring is undertaken and reviewing the necessary results as set out below.

Prescribers are responsible for the prescriptions they sign and they must be prepared to explain and justify their decisions and actions. Details provided in this agreement combined with written correspondence from the specialist provide the information required to enable primary care prescribing. Contact details for specialist advice are provided for circumstances not covered under this agreement

Shared care must be agreed before the patient is directed to primary care to avoid patients being put in a position of uncertainty where to obtain supplies of their medication.

Inclusion criteria for shared care

Patients appropriate for shared care include those where:

- Treatment is for a specified indication
- Prescribing has been initiated in secondary care
- Appropriate monitoring has been reviewed to establish a stable dose (usually takes 3 months
- Shared care has been requested on a case by case basis and specialist team is in receipt of the acceptance signed by primary care prescriber and patient

Exclusion criteria for shared care

Where shared care is not appropriate:

- Where the patient does not consent to shared care
- Where the primary care prescriber does not consent to shared care

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Name, strength and formulation of medication

Sulfasalazine 500mg enteric coated tablets

Licenced indications

Licensed indications: It is used in the treatment of adults with severe, active, classical or definite rheumatoid arthritis who are unresponsive or intolerant to conventional therapy.

Adult dosage and administration

Initially 500 mg daily, increased in steps of 500 mg every week, increased to 2–3 g daily in divided doses, enteric coated tablets to be administered.

All dose adjustments will be the responsibility of the initiating specialist unless directions have been specified in writing to the primary care prescriber.

Contraindications and cautions

Contraindications:

- Sensitivity to sulfasalazine
- Sensitivity to salicylate
- Sensitivity to Co-trimoxazole
- Patients with porphyrias

Cautions:

- G6PD deficiency
- Risk of haematological toxicity
- Slow acetylator status
- Mild/moderate/severe renal impairment from any cause
- Impaired hepatic function
- Severe allergy or bronchial asthma
- Folate deficiency

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Side Effects

Common or very common

- Arthralgia; cough; diarrhoea; dizziness; fever; gastrointestinal discomfort; headache; leucopenia; nausea; skin reactions; vomiting, Yellow discoloration of skin and body fluids including urine, sweat, tears and soft contact lenses

Uncommon

- Alopecia; depression; dyspnoea; myalgia; photosensitivity reaction; thrombocytopenia

Rare or very rare

- Agranulocytosis; bone marrow disorders; cardiac inflammation; hepatitis; neutropenia; pancreatitis; peripheral neuropathy; renal impairment; respiratory disorders

Frequency not known

- Angioedema; eosinophilia; haemolytic anaemia; nephritis tubulointerstitial; oligozoospermia (reversible); ulcerative colitis aggravated

Common drug interactions

For a comprehensive list of interactions see the BNF or product SPC.

Patients receiving hypoglycemic agents and sulfasalazine should be closely monitored.

Azathiopurine and sulfasalazine should not be co-prescribed.

Reduced absorption of digoxin occurred with co-administration.

Pregnancy and breastfeeding and Contraception

Sulfasalazine can be prescribed in pregnant or breastfeeding patients. In these instances, prescribing should remain with the consultant.

In breastfeeding children small amounts of sulfasalazine are secreted in breastmilk. Patients should avoid breastfeeding while taking this medicine.

Vaccinations

Consultants should identify patients requiring immunisation in line with JCVI recommendations. Once administered the primary care prescriber will provide written confirmation that the vaccine has been administered then treatment will be commenced. Annual flu vaccines are recommended.

Check patient has had ONE DOSE of pneumococcal vaccine. Additional doses are not routinely recommended.

Low levels of immunosuppression are not absolute contraindication to the use of live vaccines, these should be discussed with a specialist on a case by case basis.

All patients which are immunosuppressed due to a conventional DMARD should be encouraged to receive a COVID-19 vaccine, regardless of treatment regimen or underlying diagnosis. The benefits of the COVID-19 vaccination outweigh the risks and by having the vaccine, they reduce the risk of developing severe complications due to COVID-19. Some may have a sub-optimal response. If there is any uncertainty regarding advice to give patients please contact the Rheumatology team at RJAH on the contact details below.

The Joint Committee of Vaccination and Immunisation (JCVI) hasn't advised a vaccine preference for any specific population, advising that all give very high protection against severe disease and have good safety profiles. This information on COVID-19 vaccinations is under constant review. The latest updated information can be found in The Green book.

Monitoring

At Initiation

Test		Frequency	Monitored and acted on by
FBC	Full Blood Count including differential	• 2 weekly for 6 weeks • THEN monthly until stable (for a minimum of 3 months from initiation) ONCE stable suitable for maintenance monitoring	Specialist Blood taken • locally at patient's surgery • **OR** at Specialist Centre
LFT	Liver Function Tests		
&E, CC	Urea Electrolytes Creatinine including eGFR		
Height		At initiation	Periodically at specialist review
Weight		At initiation	Periodically at specialist review

Maintenance Monitoring - Delivered under a Shared Care Agreement

Test		Frequency	Monitored and acted on by
FBC	Full Blood Count including differential	• Every 3 months until 12 months then no routine monitoring required More frequent monitor may be required. Up every 1 month. Request in writing from the specialist required	primary care prescriber Blood taken • locally at patient's surgery
LFT	Liver Function Tests		
U&E and CC.	Urea Electrolytes Creatinine including eGFR		

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Managing adverse events and side-effects

Result	Action	By whom
WBC < 3.5 x 10^9 /L	Withhold until discussed with rheumatology team	**Primary care prescriber**
Neutrophils < 1.6 x 10^9 /L	Withhold until discussed with rheumatology team	**Primary care prescriber**
Platelets < 140 x 10^9 /L	Withhold until discussed with rheumatology team	**Primary care prescriber**
ALT or AST > 2 xs ULN OR >100units/L minor elevations are common	Withhold until discussed with rheumatology team. Check other causes such as alcohol, drug interaction including OTC.	**Primary care prescriber**
Unexplained eosinophilia >0.5x10^9 /L	Withhold until discussed with rheumatology team	**Primary care prescriber**
Unexplained fall in albumin	Withhold until discussed with rheumatology team	**Primary care prescriber**
MCV >105 fl	Check serum folate, B12, alcohol history, and TSH. Treat any underlying abnormality. If results normal discuss with rheumatology team.	**Primary care prescriber**
Oral ulceration, sore throat, fever, malaise, purpura or pallor	Potentially indicative of myelosuppression or haemolysis Reduce dose or withhold if severe. Check FBC and discuss with rheumatology team.	**Primary care prescriber**
Unexplained rash, jaundice, bleeding or bruising	Potentially indicative of hepatotoxicity. Reduce dose or withhold if severe. Check LFTs and discuss with rheumatology team.	**Primary care prescriber**
Nausea and vomiting, diarrhoea	Withhold until discussed with rheumatology team	**Primary care prescriber**
Decline in renal function. Indicator: a rise in serum creatinine >30% from baseline over 12 months and / or calculated GFR < 60ml/min/1.73m^2	Use clinical judgement to eliminate acute causes. Repeat in one week and if still deranged discuss with rheumatology team.	**Primary care prescriber**

Specialist responsibilities

Provide primary care prescribers with specialist advice when required as outlined below

Nurse led helpline Telephone:	01691 404432
Rheumatology Secretaries:	01691 404592
Rheumatology e- mail	rjah.rheumatologynurses@nhs.net
Out of hours advice	Medical on call at Shrewsbury Hospital

The specialist team will initiate treatment in all patients, monitoring until the patient is on a stable dose (this usually takes 3 months).

Deliver pre-treatment screened. This is at the discretion of specialist but may include

- Pre-viral screen in all patients (HepB, HebC, HIV)
- Varicella zoster immune status
- Screening for lung disease – chest x-ray

Identify patients requiring immunisation and write to the primary care prescriber requesting vaccination. Once administered the primary care prescriber will provide written confirmation that the vaccine has been administered then treatment will be commenced.

Deliver drug counselling to the patient in addition to any written support material. This will include:

- dose of medication
- monitoring during initiation and maintenance
- likely side effects
- identifying adverse events and how to report these
- the need for adequate contraception
- The process for shared care how this will happen and what to expect

Check for interactions with other medicines.

Produce prescriptions in line with MHRA guidance as set out in the ‘Adult dosage and administration’ section.

Identify and report adverse events to the primary care prescriber and the MHRA (via yellow card).

Complete and sign the shared care agreement and send to the primary care prescriber

Repeat the shared care process when a second DMARD is required. ie Initial prescribing and monitoring carried out by the specialist. A separate shared care document is required for each medication.

Review the patient at agreed, specified intervals, sending a written summary to the primary care prescriber whenever the patient is reviewed.

Communicate details of any hospital supplied medication (other DMARDs or biologics) to enable addition to the patient’s primary care record of hospital only medicines.

Primary Care responsibilities

Respond to the shared care request within 14 days of receipt. Please sign the document and return it to the Rheumatology Department.

Should a primary care prescriber be unable to provide shared care a dialogue is required with the specialist team so that additional support or information can be provided. It is essential this occurs as soon as the shared care request is received.

Enable delivery of vaccinations as per the green book.

Monitor the patient as outlined in the monitoring schedule

Ensure there is a system in place to review all required monitoring in advance of issuing prescriptions. This should include the management of patients who do not attend monitoring appointments.

Ensure there is no drug interactions with the patient's other medicines.

Check patient is compliant with the contraception advice outlined in the Pregnancy and Breast feeding and Contraception section above.

Identify and report adverse events to the specialist and the MHRA (via yellow card).

Produce prescriptions be in line with MHRA guidance as set out in the 'Adult dosage and administration' section.

If patient develops symptoms/signs of systemic infection, this should be treated promptly and medication withheld until the infection has cleared and seek advice from the secondary care team.

Add details of any hospital supplied medications to the "Hospital Medicine" section of the patient record for example biologic DMARDs or SC methotrexate.

Prescribers need to be aware of the

~~References~~

GMC: Prescribing guidance: Shared care www.gmc-uk.org/guidance/ethical_guidance/14321.asp(accessed 20/10/2014)

NMC : Standards of proficiency for nurse and midwife prescribers http://www.nmc-uk.org/Documents/NMC-Publications/NMC-Standards-proficiency-nurse-and-midwife-prescribers.pdf (accessed 3/11/2014)

SPC sulphasalazine : https://www.medicines.org.uk/emc/product/3838/smpc

Ledingham et al. (2008 BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs. Rheumatology 56(6), February 2017.

https://www.sps.nhs.uk/wp-content/uploads/2018/02/2006-NRLS-0102-Towards-safer-umethotrexate-2004-v1.pdf

Green book Chapter 28a Shingles

Communication between primary care and secondary care – England https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

Communication between primary care and secondary care – Wales

NHS England: Responsibility for prescribing between Primary & Secondary/Tertiary Care: January 2018

4.4 Shared care

4.4.1 Shared care agreements are a specific approach to the seamless prescribing and monitoring of medicines which enables patients to receive care in an integrated and convenient manner. Shared care is a particular form of the transfer of clinical responsibility from a hospital or specialist service to general practice in which prescribing by the primary care prescriber, or other primary care prescriber, is supported by a shared care agreement.

4.4.2 When a specialist considers a patient's condition to be stable or predictable, they may seek the agreement of the primary care prescriber concerned (and the patient) to share their care. In proposing shared care agreements, a specialist should advise which medicines to prescribe, what monitoring will need to take place in primary care, how often medicines should be reviewed, and what actions should be taken in the event of difficulties. Classification:

4.4.3 At a system level, medicines and conditions suitable for shared care are usually identified through a traffic light system determined by an Area Prescribing Committee (APC). Shared care typically applies to medicines for which a shared care agreement must be in place before prescribing responsibility is transferred. This contrasts with medicines which are categorised as suitable for routine prescribing in primary care, or those that should remain the responsibility of specialist prescribers only. All prescribers have a responsibility to be aware of medicines identified through the traffic light system, so that prescribing decisions can be made most effectively.

4.4.4 At an individual patient level, patients themselves and/or carers must be centrally involved in any decision-making process. They should be supported by good quality information that helps them to both come to an informed decision about engagement in a shared care arrangement and sets out the practical arrangements for ongoing supplies of medicines. Given the increasing use of, and benefits derived from, the Summary Care Record and other digital innovations, it is important that a comprehensive primary care record is in general practice, particularly in situations where not all medicines for a patient are prescribed by their primary care prescriber and supplied by their community pharmacy.

4.4.5 When clinical responsibility for prescribing is transferred to general practice, it is important that the primary care prescriber, or other primary care prescriber, is confident to prescribe the necessary medicines. Shared care agreements play a key role in enabling primary care prescribers to prescribe medicines with which they may not initially be familiar. For this reason it is important that agreements reflect the principles set out in **Annex 1**, and are agreed locally through an APC or an equivalent authoritative committee.

4.4.6 Prescribers are responsible for the prescriptions they sign and they must be prepared to explain and justify their decisions and actions. Service Condition 11.4 of the NHS Standard Contract 2017/19 makes clear that when a shared care protocol exists and where the primary care prescriber has confirmed willingness to accept the transfer of care, the hospital must initiate and abide by that agreement.

4.4.7 When a primary care prescriber accepts responsibility for prescribing medicines which are not usually dispensed in the community, and where the patient is stabilised on a particular medication, there should be liaison with the transferring hospital and if appropriate the relevant community pharmacist to ensure continuity of treatment.

4.4.8 To overcome some of the challenges associated with shared care agreements, this guidance is accompanied by 'Shared Care Prescribing Guidelines' – local policies which enable primary care prescribers to agree to the prescribing and monitoring of medicines/treatment in primary care, in agreement with the specialists and patient.

4.4.9 The purpose of these guidelines is to provide a framework for seamless transfer of care for a person from a hospital or specialist service setting to general practice, where it is appropriate and in their best interest. These are set out in **Annex 1**, and form part of this guidance. It is recommended that all professionals from primary and secondary care follow these principles when developing shared care agreements in collaboration with patients.

Shared Care: Initiation Form

Name		**Medication**	
NHS No.		**Date Started**	
D.O.B.		**Diagnosis**	

Secondary Care Section

Specialist Name		**Signature**	
Role / Grade		**Date**	

Information leaflet given to patient	Signature	Date
Patient Counselling delivered	Signature	Date
One copy of agreement & monitoring schedule sent to primary care prescriber	Signature	Date
One copy of agreement sent to patient	Signature	Date
One copy of agreement filed in patients notes	Signature	Date

Patient Section

I have understood the information provided to me on the following:

- dose of medication
- dose interval medication
- monitoring during initiation and once dose is stable
- likely side effects
- identifying adverse events and how to report these
- the need for adequate contraception where appropriate
- the process for entering into shared care and what to expect

Patient Signature		**Date**	

Primary Care Section

I agree*/don't agree* to enter into a shared care arrangement for the treatment of the above patient with this medicine (*delete as appropriate)

primary care prescriber Signature		**Date**	

Once signed please detach this sheet and email to rjah.rheumatology@nhs.net
Scan copy into patient's record and assign appropriate read code

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The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust

Detach and Hand to Patient

Patient Information:

Medicines Prescribed through a Shared Care Agreement

What is a Shared Care Agreement?

- A document that provides information from a hospital clinician to a primary care prescriber. This enables a primary care prescriber to prescribe a specialist drug.
- Initially your medication will be provided from your specialist. After an initiation period supplies will be provided from your primary care prescriber
- This allows you to receive your specialist medication from your local pharmacy along with your other repeat medication, avoiding trips to the hospital to collect medication

The shared care agreement is individual to you and includes;

- Details about you; name, NHS number, diagnosis and the medication for shared care
- Information about the drug; including side effects, doses and any blood tests you require
- Advice to assist the primary care prescriber in managing simple complications of treatment, including details of how to access specialist advice

Your responsibilities as a patient taking a shared care medicine

- Take your medication as directed by your specialist or primary care prescriber
- Inform your specialist of any significant side effects to treatment
- Follow or seek advice should an event occur where you need to pause your treatment for example when you have an infection or a wound
- Attend for regular blood tests as outlined by your specialist
- Attend your outpatient clinic appointments
- Ensure your address and contact details are up to date
- Store your medication correctly and dispose of waste as directed

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