Sussex MSK Partnership

WORKING IN PARTNERSHIP WITH

Brighton and Hove Clinical Commissioning Group
Crawley Clinical Commissioning Group
Horsham and Mid Sussex Clinical Commissioning Group

OPT-OUT SHARED CARE GUIDELINE

It is assumed that shared care **will** be accepted unless the specialist is informed otherwise within 28 days of receipt of the request at the end of this document.

MEDICATION NAME: **Sulfasalazine EC Tablets**

INDICATIONS COVERED: Rheumatoid Arthritis and other chronic inflammatory conditions in adults

NHS Brighton and Hove CCG, Crawley CCG and Horsham and Mid-Sussex CCG
Traffic Light System Classification: Amber

NOTES to the general practitioner (GP) or primary care prescriber

For drugs which require specialist initiation and/or dose titration and specific ongoing monitoring. For initiation, dose stabilisation and prescribing (including monitoring) by a specialist until the patient is stabilised (usually for 3 months) after which the GP may be asked to work under shared care through the use of approved shared care guidelines.
The expectation is that these guidelines should provide sufficient information to enable GPs or primary care prescribers to be confident to take clinical and legal responsibility for prescribing these medicines.

The questions below will help you confirm this:

- Is the patient currently under your care (e.g. shared care should not be agreed if the patient is currently in intermediate care following hospital discharge)?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this effective shared care guideline?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility. It is assumed that shared care will be accepted unless the specialist is informed otherwise with 28 days of receipt of this request.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should inform the consultant or specialist within 28 days, outlining your reasons for NOT prescribing. If you do not have the confidence to prescribe, we suggest you discuss this with your local Trust or specialist service, who will be willing to provide training and support. If you still lack the confidence to accept clinical responsibility, you still have the right to decline. Your CCG medicines management pharmacist will assist you in making decisions about shared care if you are unsure.

Prescribing unlicensed medicines or medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescriber's professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines.

The GP or primary care prescriber has the right to refuse to agree to shared care, in such an event the total clinical responsibility will remain with the consultant or specialist.

Reason for update: New	**Prepared by:** Dr.U.Davies, D.Finney, Dr.S.Griffith, Dr.K.Jordan, Dr.R.Makadsi, Dr.G.Papasavvas, Dr.W.Shattles, SCT Medicines Management Team	**Updated by:** N/a
Approved by (Specialist or Consultant): Dr. K. Jordan on behalf of the Sussex MSK Partnership Consultant Rheumatologists.		
Approved by (Chief Trust Pharmacist): Iben Altman, Sussex Community NHS Trust/ Sussex MSK Partnership		
Approved by (CCG Medicines Management Pharmacist): Stewart Glaspole, Specialist Interface Pharmacist		
Approved by NHS Brighton and Hove CCG on: 22.09.2015/02.12.2015		
Approved by Crawley CCG, Horsham and Mid-Sussex CCG on: 26.01.16		

Information

This information sheet does not replace the Summary of Product Characteristics (SPC), which should be read in conjunction with this guidance. Prescribers should also refer to the appropriate paragraph in the current edition of the BNF.

1. **Link to the relevant SPC website**: http://www.medicines.org.uk/emc/

2. **Background to use for the indication(s), including licence status:**

Sulfasalazine (enteric coated tablet) is a disease modifying anti-rheumatic drug (DMARD). It has a marketing authorisation for the treatment of rheumatoid arthritis.

3. **Dose & administration:**

WEEK 1: 500mg each morning.
WEEK 2: 500mg each morning and 500mg each evening.
WEEK 3: 1g each morning and 500mg each evening.
WEEK 4: 1g each morning and 1g each evening.

Thereafter continue with 1g twice a day. Occasionally doses of up to 3g per day may be prescribed. It may be between 6 to 12 weeks before a marked effect is seen.

4. **Cautions (including for pregnancy):**

- Patients with severe allergy or bronchial asthma.
- Patients with G-6-PD deficiency – can cause haemolytic anaemia in this patient group.
- Patients with impaired hepatic function – use only if potential benefit outweighs the risk.
- Patients with impaired renal function – use only if potential benefit outweighs the risk.
- Patients with blood dyscrasias – use only if potential benefit outweighs the risk.
- Pregnancy – Oral sulfasalazine inhibits the absorption and metabolism of folic acid and may cause folic acid deficiency. The possibility of harm cannot be completely ruled out therefore sulfasalazine should only be used if potential benefits outweigh the risks. Doses should not exceed 2g per day. Adequate folate supplements should be prescribed for those trying to conceive and during pregnancy.
- May cause oligospermia and infertility in men. Discontinuation of the medication usually reverses these effects within 2 to 3 months.

This list is not exhaustive; refer to the Summary of Product Characteristics (SPC) or BNF for further guidance.

5. **Contraindications:**

- Patients with known hypersensitivity to sulfasalazine, its metabolites or any of the excipients.
- Patients with known hypersensitivity to sulfonamides or salicylates.
- Patients with Porphyria.
- Breastfeeding mothers.

This list is not exhaustive; refer to the Summary of Product Characteristics (SPC) or BNF for further guidance.

6. **Side effects:**

About 75% of Adverse Drug Reactions (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 side effects are:

- Nausea.
- Headache.
- Rash.
- Loss of appetite.
- Raised temperature.

Other side effects include , abdominal pain, arthralgia, blood disorders, cough, diarrhoea, dizziness, fever, headache, insomnia, proteinuria, pruritus stomatitis, taste disorders, tinnitus and vomiting – this list is not exhaustive refer to the Summary of Product Characteristics or BNF for further guidance.

Note – Sulfasalazine can cause a yellow/brown discolouration of urine and contact lenses.

This list is not exhaustive; refer to the Summary of Product Characteristics (SPC) or BNF for further guidance.

Table 1. Side effects and actions to take for abnormal results

SIDE EFFECT	ACTIONS
WBC < 3.5 x 10^9/l, or Neutrophils <1.5 x 10^9/l, or Platelets <150 x 10^9/l	Withhold and repeat WBC. If abnormal discuss with specialist.
Liver Function AST/ALT > twice upper limit of reference range	Withhold and look for other causes. If abnormal discuss with specialist.
MCV > 105fl	Check folate, TSH, B12 and treat if appropriate. If normal results, continue treatment and discuss with specialist.
Acute widespread skin rash	Withhold and seek urgent specialist (preferably dermatological) advice.
Oral Ulceration	Withhold, urgent FBC, investigate alternative cause. If settles promptly re-challenge with a lower dose. If symptoms recur stop and contact specialist.
Abnormal bruising, sore throat, unexplained bleeding	Withhold and check FBC urgently. Discuss with specialist as necessary.
Nausea, vomiting, dizziness, headache	Often transient. If possible continue with anti-emetic or reduce dose by 500mg. If symptoms severe, stop and discuss with specialist.
Diarrhoea	Reduce dose by 500mg. If persistent consult specialist.

Please note that in addition to absolute values, a rapid fall/rise or consistent downward/upward trend in haematological or biochemical index should prompt caution and extra vigilance.

7. Notable drug interactions:

- Digoxin – Sulfasalazine possibly reduces absorption of digoxin.
- Azathioprine and sulfasalazine may be used together but there may be an increased risk of leukopenia.

This list is not exhaustive; refer to the Summary of Product Characteristics (SPC) or BNF for further guidance.

8. Criteria for use:

Specialist has initiated and dose stabilised (usually for a minimum 3 months).
GP or Primary Care Prescriber confident to take clinical and legal responsibility for prescribing this medication.

9. Any further information (e.g. supporting therapies):

Sulfasalazine is split by intestinal bacteria to sulfapyridine and 5-aminosalicylate so ADRs to either sulfonamide or salicylate are possible.

Sulfonamides bear some chemical similarities to some oral hypoglycaemic agents. . Patients receiving both sulfasalazine and hypoglycaemic agents should be closely monitored, hypoglycaemia has occurred with co-administration.

Concomitant administration of sulfasalazine and methotrexate to rheumatoid arthritis patients does not alter the pharmacokinetic disposition of the drugs; however, an increased incidence of gastrointestinal adverse events, especially nausea is possible.

Oral sulfasalazine inhibits the absorption and metabolism of folic acid and may cause folic acid deficiency, which can be normalised by administration of folic acid.

10. References:

- Brighton and Hove CCG, Effective Shared Care Agreement (ESCA): Sulfasalazine Tablets. January 2013. Available at: http://www.gp.brightonandhoveccg.nhs.uk/files/sharedcareguidelines080715 (accessed 08.04.15).
- Chakravarty, K. et al, *BSR/BHPR guideline for disease-modifying anti-rheumatic drug (DMARD) therapy in consultation with the British Association of Dermatologists, British Society for Rheumatology*, Oxford University Press, 2008. Available at: http://www.rheumatology.org.uk/includes/documents/cm_docs/2009/d/diseasemodifying_antirheumatic_drug_dmard_therapy.pdf (accessed 09/03/15).
- Crawley CCG, Horsham and Mid-Sussex CCG, Effective Shared Care Agreement (ESCA): Sulfasalazine Tablets. August 2011. Available at: http://www.horshamandmidsussexccg.nhs.uk/intranet/clinical/programmes/medicines-management/ (accessed 09.04.15).
- Joint Formulary Committee. *British National Formulary; Sulfasalazine,* March 2015, British Medical Association and Royal Pharmaceutical Society. London. Available at:

https://www.medicinescomplete.com/mc/bnf/current/index.htm (accessed 09/03/15).

- Summary of Product Characteristics, *Salazopyrin EN-Tabs®.* Pfizer Limited. Last update 25.02.14. Available at: http://www.medicines.org.uk/emc/medicine/10722 (accessed 05.03.15).
- Surrey CCG Prescribing Advisory Database. *Shared Care Prescribing Guideline: Sulfasalazine for Rheumatoid Arthritis.* September 2014.Available at: http://pad.res360.net/

RESPONSIBILITIES and ROLES

Consultant or Specialist responsibilities	
1	Confirm diagnosis and indication for treatment with sulfasalazine EC.
2	To discuss fully the aims, benefits, risks and side effects of treatment and a treatment plan with the patient and/or carer and for written information to be supplied to the patient and/or carer.
3	Prior to treatment ask GP whether patient has had pneumococcal vaccination and flu vaccination and, if not, immunise (unless contra-indicated). Inform patient not to start medication until after immunisation.
4	Inform GP when initiating treatment so the GP is aware what is being prescribed and can add to GP clinical record.
5	Undertake baseline monitoring as required.
6	Record other medications and address potential drug interactions before starting therapy.
7	Exclude existing pregnancy in women with child bearing potential.
8	To discuss the potential implications of pregnancy and breastfeeding in women of child bearing potential and agree a risk minimisation strategy where appropriate.
9	To initiate treatment by prescribing and monitoring usually for a minimum of 3 months
10	Undertake monitoring if dose changed.
11	Monitor and prescribe according to guidelines until handover is appropriate (including when dose changes are made).
12	Discuss the possibility of shared care with the patient and/or carer and ensure that they understand the plan for their subsequent treatment.
13	Supply GP with a summary of the patient's review (including anticipated length of treatment) and a link to, or a copy of, the shared care guideline when requesting transfer of prescribing to GP or primary care prescribers.
14	Advise GP if treatment dose changes or treatment is discontinued.
15	Inform GP if patient does not attend planned follow-up.

GP or Primary Care Prescriber responsibilities	
1	Continue prescribing of sulfasalazine E/C at the dose recommended and undertake monitoring requirements.
2	Undertake all relevant monitoring as outlined in the monitoring requirements section below, and take appropriate action as set out in this shared care guideline.
3	Monitor for adverse effects throughout treatment and check for drug interactions on initiating new treatments.
4	Add information about the medicine to patient record, initially as "hospital prescribed", and highlight the importance that this medicine is only to be prescribed under a shared care guideline in primary care.
5	Inform the consultant or specialist of any issues that may arise.
6	Inform patient to report immediately any unexplained bleeding, bruising, purpura, sore throat, fever, pallor, jaundice or malaise and take the actions outlined in this shared care guideline.
7	Refer patient back to the Consultant/Specialist if any concerns.
8	Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the shared care guideline (e.g. ensuring the patient record is correct in the event of a patient moving surgery).

Monitoring requirements and appropriate dose adjustments (if relevant to specific medicines)	
1	**Pre-treatment**: FBC, U&E's, creatinine, LFTs, ESR and / or CRP.
2	**Initiation: Weeks 2, 4, 6, 8, 10, 12:** FBC, LFTs, U&Es, ESR and / or CRP.
3	**Thereafter:** Every 3 months FBC, LFTs ESR and / or CRP. After 1st year monitoring frequency can be reduced to every 6 months.
4	**Dose change**: recheck FBC, LFTs, ESR and / or CRP one month after any dose increase. If stable, revert to monitoring as per (5).
5	Monitor for adverse drug reactions throughout treatment.
6	Check for drug interactions on initiating new treatments.
7	Pregnancy – Maximum dose of 2g daily. See caution section re folic acid.

Patient's or Carer's role	
1	Make sure that you understand the treatment and ask for more information, if needed.
2	Share any concerns in relation to treatment with whoever is prescribing this medicine for you.
3	Tell the prescriber of this medication about any other medication being taken, including over-the-counter products.
4	Read the patient information leaflet included with your medication and report any side effects or concerns you have to whoever is prescribing this medicine for you.
5	Attend the follow up appointments with the consultant or specialist.
6	Attend any monitoring appointments (e.g. blood tests).

SHARED CARE GUIDELINE

DRUG NAME: Sulfasalazine E/C Tabs

INDICATION: Rheumatoid Arthritis and other inflammatory conditions in Adults

DATE OF REQUEST:

Agreement to transfer prescribing to general practice or primary care prescriber:

Patient details:

Name:

Address:

DoB:

NHS No:

Hospital No:

Medication name, form and strength: Sulfasalazine E/C tablets

The following tests and investigations have been carried out:

Date treatment initiated:

At the last patient review the drug appeared to be effectively controlling symptoms or providing benefit: Yes/No

The patients has now been stabilised on a dose of:

The patient has been given written information about their medication:
Yes/No

The patient understands that this medication is being prescribed under a shared care agreement between their GP and specialist and that they have responsibilities under the agreement to ensure they attend their GP to be regularly monitored.
Yes/No

The patient has been informed that the GP can opt-out of taking on prescribing responsibility if they do not feel clinically able to prescribe or if the patient persistently does not attend for monitoring:
Yes/No

Date of next clinic appointment:

If the practice declines shared care, then the named consultant or specialist should be informed within 28 days of receipt of this request. Forms used to decline prescribing can be found here:

Brighton and Hove CCG: http://www.gp.brightonandhoveccg.nhs.uk/prescribing/joint-formulary-supporting-information

Crawley CCG, Horsham and Mid Sussex CG:
http://www.horshamandmidsussexccg.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=415216

BACK-UP ADVICE AND SUPPORT

	Name and position	Telephone	Email
Specialist or Consultant:	**Professor Kevin Davies**	**01273 696955 ext 4631**	**Kevin.davies@bsuh.nhs.uk**
	Dr Ursula Davies	**01737 768511 ext 1798**	**Ursula.Davies@sash.nhs.uk**
	Diana Finney	**01273 560273**	**diana.finney@nhs.net**
	Dr Sian Griffith	**01737 768511 ext 6657**	**Sian.Griffith@sash.nhs.uk**
	Dr Vijay Hajela	**01273 696955 ext 3553**	**Vijay.hajela@bsuh.nhs.uk**
	Dr Kelsey Jordan	**01273 696955 ext 4631**	**Kelsey.jordan@bsuh.nhs.uk**
	Dr Raad Makadsi	**01737 768511 ext 6857**	**Raad.Makadsi@sash.nhs.uk**
	Dr George Papasavvas	**01273 696955 ext 4631**	**George.papasavvas@bsuh.nhs.uk**
	Dr Ramasamy Selvaraju	**01273 696955 ext 3553**	**Ramasamy.selvaraju@bsuh.nhs.uk**
	Dr Warren Shattles	**01293 600300 ext 3672**	**Warren.Shattles@sash.nhs.uk**
	Dr Brenda Stuart	**01444 441881 ext 5432**	**bstuart@nhs.net**
Alternative specialist (e.g. departmental contact)	**Sussex MSK Partnership**	**03003038063**	**n/a**
Specialist pharmacist	**Medicines Management Team**	**01273 696011 ext 3074**	**n/a**
Out of hours (e.g. medical team on call)	**n/a**	**n/a**	**n/a**

Link to full SCG: http://sussexmskpartnershipcentral.co.uk/