The Princess Alexandra Hospital NHS NHS Trust

NHS West Essex Clinical Commissioning Group

Shared Care Agreement

SULFASALAZINE

This shared care agreement does not cover mesalazine, balsalazide or olsalazine

For up to date version of Shared Care Agreement contact specialist team or latest version on website https://westessexccg.nhs.uk/your-health/medicines-optimisation-and-pharmacy/shared-care-medicines

Referral Criteria

- These guidelines are for patients over 16 years of age.
- 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 patients' GP
- Safe prescribing must be accompanied by effective monitoring
- When transfer is agreed, the patient will be given a supply of sulfasalazine sufficient for 4 week maintenance therapy
- **The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.**

SHARED CARE RESPONSIBILITIES

Consultant

1. Undertake the necessary testing to confirm a diagnosis for which sulfasalazine treatment is recommended
2. Ensure the patient's concurrent drug therapy is stabilised and there are no contra-indications to treatment with sulfasalazine.
3. Ensure that patient is aware of risks and benefits of medication and has read appropriate information leaflet.
4. Ensure the patient understands the shared care agreement and has signed the Patient Agreement Letter (page 7-8)
5. Perform baseline tests (see Monitoring section) and provide results to GP
6. Initiate treatment and prescribe until the patient has been on a stable dose for minimum of SIX weeks
7. Send a letter to the GP requesting shared care for this patient.
8. Review the patient in outpatients as clinically appropriate and advise the GP promptly after these reviews on when to adjust the dose, stop treatment or consult with the specialist.
9. Inform GP, by letter, of each clinic attendance and action taken for the management of the patient ensuring current dose, most recent blood results and frequency of monitoring are stated.
10. Evaluate any reported adverse effects by GP or patient.
11. Inform GP of patients who do not attend clinic appointments, admin to contact patient to rearrange.
12. Ensure that backup advice is available at all times. (see Contacts section) and respond to any GP queries as soon as practicable.
13. Report any adverse effects to the GP and CHM:

General Practitioner

1. Monitor patient's overall health and well-being.
2. Consider request to prescribe under shared care arrangements and reply only if you do not agree to share care, in a timely manner within 14 days as outlined on page 6 with clinical reasons and return to Consultant and Pharmacy department.
3. Ensure compatibility with other concomitant medication.
4. Prescribe at the dose recommended or query with the Consultant.
5. Monitor U&E, creatinine, FBC and LFTs for the first 12 months at recommended frequencies (see Monitoring section) and refer if abnormal.
6. Adjust the dose as advised by the specialist.
7. Stop treatment on advice of specialist, or immediately, if any urgent need to stop treatment arises (see Monitoring section).
8. Report any adverse events to the specialist and CHM
9. https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
10. Inform specialist of any change in the medical condition of patient which may have effect on disease / medications.
11. Ensure patient is offered an annual flu vaccination and a one off pneumococcal vaccination

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Patient

1. Report to specialist or GP if there is not a clear understanding of their treatment and discuss any concerns in relation to treatment
2. Report any adverse effects to their Specialist whilst taking Sulfasalazine, especially unexplained bruising/bleeding, sore throat, rash, infections or mouth ulcers which should be reported immediately.
3. Report any changes in disease symptoms to Specialist whilst taking Sulfasalazine.
4. Alert GP and/or specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy whilst taking Sulfasalazine.
5. Inform GP or specialist of any other medicines being taken including over-the-counter products.
6. Attend for regular reviews and blood monitoring tests.

CONTACT NUMBERS FOR ADVICE AND SUPPORT

Advice and guidance: Access Advice & Guidance tool via e-RS referral system selecting the relevant specialty for non-urgent queries

Princess Alexandra Hospital NHS Trust - Gastroenterology	
Consultant	**For GPs only**: contact Gastroenterologist of the week via switchboard if urgent **Email for GPs only**: tpa-tr.gastroadminclinicalcorrespondence@nhs.net
Specialist Gastroenterology Pharmacist: Clare Macpherson	Bleep 272 Direct dial: 01279 278224 (voicemail if not answered) Claremacpherson@nhs.net for medication issues
IBD Specialist Nurse	Direct dial:01279 278223 (voice mail only) usual response within 48 hours Paht.ibd@nhs.net

Princess Alexandra Hospital NHS Trust - Rheumatology	
Consultant:	**For GPs only**: contact Rheumatologist via switchboard if urgent tpa-tr.rheumatologyadminclinicalcorrespondence@nhs.net for non-urgent queries.
Rheumatology Specialist Nurse DMARDs	**01279827434 helpline (voice mail only) for non-urgent queries only** **Lily Robinson**
Rheumatology Specialist Nurse / Pharmacist - Biologics	**01279827819 helpline (voice mail only) for non-urgent queries only** **Mona Kamal Zou / Sachini Amarasekera**
	Patients can email tpa-tr.rheumatologyadminclinicalcorrespondence@nhs.net for non-urgent queries.

Princess Alexandra Hospital NHS Trust - Dermatology	
Consultant:	**For GPs only**: contact Dermatologist via switchboard if urgent 01279 444455 Ext 7431 / 7421 for non-urgent queries only tpa-tr.dermatologyclinicalcorrespondence@nhs.net
Specialist Pharmacist Dermatology	Noemi.corrao@nhs.net

Princess Alexandra Hospital NHS Trust - Pharmacy	
Medicines Information (for medicines related queries)	01279 827054

CLINICAL INFORMATION

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Prescribed Indications

Licensed indications	Rheumatoid arthritis Ulcerative Colitis Crohn's Disease
Unlicensed Indications	Seronegative inflammatory Arthritis[1] Psoriasis[2] Psoriatic arthritis[1]

Therapeutic Summary

Sulfasalazine suppresses the processes responsible for the chronic inflammation of rheumatoid arthritis. It is composed of sulfapyridine (a sulfonamide) and 5-aminosalicylic acid joined together by an azo bond. When taken orally, the majority of the dose reaches the colon where the azo bond is cleaved to release the separate components. In RA, sulfasalazine is thought to act as a disease modifying agent. Clinical and haematological response may be seen after one month of treatment, but may be delayed for up to 12 weeks. NSAID and simple analgesics should be continued but doses can be reduced once sulfasalazine therapy is established. Sulfasalazine does not possess any analgesic properties; it exhibits a disease modifying effect.

Dose and Route of Administration

Typically treatment is started at 500mg daily and increased by 500mg weekly to a maximum of 3g daily in two to four divided doses. The British Society for Rheumatology states that occasionally doses above 3g are prescribed (unlicensed). For IBD doses usually start at 3g daily.

Duration of Treatment

Time to response is a minimum of three months. Treatment is continued medium to long term, depending on response, side effects and level of disease activity

Adverse Effects and Management

- **Yellow Discoloration**: is well recognised side effect of Sulfasalazine and is often noted in urine, soft contact lenses or skin, however bilirubin levels should be checked if this occurs.
- **Loss of appetite / Nausea**: may occur in some patients but usually resolve spontaneously over time. May add an anti-emetic if persistent or severe. In case of poor response STOP the drug and discuss with the specialist team or may reduce the dose until symptoms resolve and gradually go back to the original dose.
- **Vertigo and tinnitus**: have been rarely noted in some patients but may resolve with reduction of the dose.
- **Abnormal bruising / bleeding**: Check FBC immediately and STOP the drug if results are abnormal. Inform the specialist team.
- **Common side effects**: Diarrhoea, abdominal pain, headache, rashes
- **Less common side effects**: Bone marrow toxicity, hepatotoxicty, oral ulceration

Cautions

- Glucose-6-phosphate dehydrogenase deficiency – may cause haemolysis
- Renal impairment – in moderate renal impairment (eGFR 30-59 ml/min) may cause significant crystalluria. Ensure high fluid intake. Avoid in severe impairment (eGFR ≤29 ml/min).
- Slow acetylators of the drug: may cause drug induced lupus-like syndrome, although not necessary to assess acetylator status.
- May impair folate absorption

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Contraindications

- Hypersensitivity to sulphonamides, co-trimoxazole or salicylates.
- Patients with porphyria

Pregnancy and Lactation

If sulphasalazine is prescribed during pregnancy, an analysis of risks and benefits to the mother should be undertaken, against the possible small risk to the unborn child. Doses should not exceed 2g/day. Folic acid should be prescribed to those trying to conceive and throughout pregnancy.
Sulphasalazine can be prescribed to men of childbearing potential but there may be transient reversible oligospermia, caution in males with fertility problems.
Sulfasalazine and sulfapyridine are found in low levels in breast milk. Patients should avoid breastfeeding while taking this medicine. Seek advice from Specialist Team

Monitoring Standards for Sulfasalazine based on BSR BHPR Standards 2017

The following standards have been agreed for the monitoring of sulfasalazine in all patients at Princess Alexandra Hospital NHS Trust.

Pre-treatment by Specialist	Height, weight, blood pressure, FBC, U&Es, LFTs, calculated GFR and albumin	
Initial monitoring by Specialist	FBC Creatinine / calculated GFR ALT +/- AST Albumin	Every 2 weeks until on stable dose for 6 weeks.
Ongoing monitoring by GP	FBC Creatinine / calculated GFR ALT +/- AST Albumin	Then once on stable dose monitor monthly for 3 months.
	FBC Creatinine / calculated GFR ALT +/- AST Albumin	At least every 12 weeks. **No routine monitoring needed after 12 months of standard monitoring schedule**
Dose increase	FBC Creatinine / calculated GFR ALT +/- AST Albumin	Every 2 weeks until on stable dose for 6 weeks, then revert to previous schedule
Specialist and GP at every visit	Rash/Oral ulceration	Patient should be asked about these symptoms at each visit.

Action and Advice

If a GP has taken blood tests for the general medical management of a patient and blood test results fall into the categories below or the patient reports one of the adverse events below, these are recommendations for considering the withdrawal of Sulfasalazine therapy:

Blood Test Results	
WBC < 3.5 x 10^9/l	Withhold until discussed with specialist team
Neutrophils < 2.0 x 10^9/l	Withhold until discussed with specialist team
Platelets < 150 x 10^9/l	Withhold until discussed with specialist team
> 2-fold rise in AST, ALT (from upper limit of reference range)	Withhold until discussed with specialist team
MCV > 105fl	Check B12, serum folate and TSH. Treat any underlying abnormality. If results normal, discuss with specialist team

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Unexplained reduction in albumin <30 g/l	Discuss with specialist team
Creatinine increase >30% over 12 months and/or calculated GFR <60 ml/min	Withhold until discussed with specialist team
Symptoms	
Unexplained acute widespread rash	Withhold and seek urgent specialist (preferably dermatological) advice.
Abnormal bruising or sever sore throat	Withhold until FBC results available & discuss with specialist team
Oral ulceration – adverse effect or disease flare	Discuss with specialist team
Nausea/dizziness/headache	If possible continue, may have to reduce dose or stop if symptoms are severe. Discuss with specialist team, if necessary.

Clinically relevant Drug interactions

- Azathioprine: may contribute to bone marrow toxicity, may be co-prescribed with sulfasalazine with
- additional blood monitoring, Specialist to advise.
  Cardiac glycosides: absorption of digoxin possibly reduced.
- Sulfonamides bear certain chemical similarities to some oral hypoglycemic agents. Hypoglycemia has occurred in patients receiving sulfonamides. Patients receiving sulfasalazine and hypoglycemic agents should be closely monitored.

Further Information and references

1. Psoriasis, psoriatic arthritis, and rheumatoid arthritis: Is all inflammation the same Seminars in Arthritis and Rheumatism Volume 46, Issue 3, December 2016, Pages 291-304 http://www.sciencedirect.com/science/article/pii/S0049017216300646

2. Psoriatic arthritis: latest treatments and their place in therapy Ther Adv Chronic Dis. 2015 Jul; 6(4): 194–203. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4480547/

This document does not replace the SPC and BNF and should be read in conjunction with it.

BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs 2017 https://academic.oup.com/rheumatology/article/3053478/BSR-and-BHPR-guideline-for-the-prescription-and?searchresult=1

BSG guidelines for management of inflammatory bowel disease in adults:
https://www.bsg.org.uk/clinical/bsg-guidelines.html?section=inflammatory-bowel-disease

West Essex Shared Care Guidelines
Shared Care Medicines - West Essex CCG

CKS
http://cks.nice.org.uk/dmards#!scenario:11

Arthritis Research UK
http://www.arthritisresearchuk.org/arthritis-information/drugs/sulfasalazine.aspx

GMC Prescribing Guidance: Shared Care
https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/shared-care

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GP response to Shared Care Agreement

(only complete & send if NOT participating in shared care)

This shared care agreement has been approved by the Medicines Management Optimisation Programme Board

Patient Name:	NHS No:
Consultant:	Medicine requested for shared care: **Sulfasalazine**

I will **NOT** be undertaking the GP responsibilities as described in the agreed shared care agreement. 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. **ANONYMISED COPY OF THIS FORM ONLY** to the E-MAIL: **tpa-tr.ClinicalPharmacy@nhs.net**

(sending a copy of this form to the PAH pharmacy 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 Medicines Optimisation Team of the reasons shared care is not being undertaken by GPs allowing for changes to be made in future updates to improve patient safety)

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The Prlncess Alexandra Hospltal NHS
NHS Trust

Hamstel Road
Harlow, Essex
CM20 1QX

Tel: 01279 444455

Information for patients:

SHARED CARE: Agreement information and confirmation

Patient name:

.....

Medicine:

.....

We would be grateful if you would take time to read this information as it will help us work with you to manage your condition and ensure safe prescribing of the specific medicine listed above.

What is a Shared Care Agreement (SCA)?

A Shared Care Agreement (SCA) enables the care you have for a specific condition to be shared between the hospital and your GP.

The agreement means that the medicine the hospital has started, can be continued by your GP, so you won't have to visit the hospital to collect your medicine.

The SCA gives information on your medicine, guidance on the prescribing and monitoring responsibilities for your consultant (in the hospital), your GP and you. For an SCA, to work everyone involved must understand it and communicate effectively.

Your consultant and your GP will need to sign the agreement and if you agree to this approach, we would ask you to sign this letter, to indicate your agreement to have your care managed in this way.

How does shared care work?

Your consultant and GP share responsibility for your care.

The consultant is a specialist in your condition and will start prescribing your medicine, making sure it is suitable for you. There will come a point in your treatment when you may not need to be monitored by the consultant as often and this monitoring can be done by your GP.

Once your GP has agreed to the SCA, they will be able to prescribe the same medicine for you at the dose recommended by the consultant.

The organisation which regulates GPs, the General Medical Council, says that 'when a GP prescribes a medicine, the GP needs to satisfy themselves that the prescription is needed, appropriate for the patient and within the limits of their competence'.

So, your GP can only issue a prescription if the consultant and you keep to the responsibilities you have agreed (see below). If responsibilities are not kept or if the GP no longer feels it is safe to prescribe the medicine, he/she will explain the reasons to you and your consultant, then prescribing responsibilities will be transferred back to the hospital.

What do I need to do to ensure the SCA can continue?

- **Attend hospital outpatients**
  You must still attend the hospital for regular reviews as directed by your consultant (these may be less frequent than before and you may be seen by a specialist pharmacist or a specialist nurse). If you do not attend your hospital appointments, your GP will not be able to continue issuing prescriptions for this medication.

- **Attend GP appointments**
  You must attend any appointments you have with your GP in relation to this medicine, so they can look after you effectively

- **Have blood tests as you have been advised to:** Your consultant should have informed you if and how often you need to have blood monitoring tests. You can usually have your blood taken at an appropriate clinic and not need to go to the hospital.

- If you do not have the blood monitoring tests as advised by your consultant, your GP will no longer be able to issue you with prescriptions as it would not be safe to do so.

What do I do if I am having side-effects to the medicine?

Your consultant should have informed you of the common side-effects to expect and what to do if you experience them. If you think you may be having side-effects from a medicine report these directly to your consultant. Your GP may need to seek advice from your consultant before issuing you with another prescription; this is to ensure it is safe for you to continue on the medication.

What if my disease symptoms change or get worse?

Report any changes in disease symptoms or circumstances that could affect management of your disease to your consultant.

What about the other medicines I take?

Inform your GP and the consultant of all other medicines you are taking, including those you may have bought yourself. Do not take new medicines (including those you could buy) until you have discussed this with your pharmacist, GP or consultant.

If you would like to go ahead with a shared care agreement for the specific medication identified on page 1, please sign below to confirm that you:

- Understand the shared care agreement.
- Are happy to have your care for this aspect of your health managed by a shared care agreement.
- You agree to attend regular review appointments as requested.
- You agree to have blood tests as required.

What happens if I change GP Practice?

If you register at a new GP Practice a new agreement needs to be put in place between your new GP and the specialist team.

The specialist team can start this process if you provide them with information before you move to make sure there is a smooth handover.

Patient's signature .....

Date .....

Print name .....

If at any point in time you would like this shared care agreement to stop, please talk to your GP.