

## Prescribing Framework for Sulfasalazine for Immunosuppression

Patient's Name:..... NHS Number: .....

Patient's Address:.....(Use addressograph sticker)

GP's Name:.....

### Communication

We agree to treat this patient within this Prescribing Framework	
Specialist Prescriber's Name.....	Prof Reg. No. ....
Specialist Prescriber's Signature.....	Date:.....
<i>Where prescriber is <u>not</u> a consultant:</i>	
Consultant's Name: .....	GMC No .....
Consultant's Signature .....	Date:.....
GP's Signature:.....	Date:.....
GP's Name (if different from listed above).....	

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.

The patient's GP should sign and **send back to specialist**, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **unwilling** to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

Full copy of framework can also be found at : <http://www.hey.nhs.uk/amber.htm>

## 1. Background

DMARDs are fundamental to arresting the disease process in Rheumatoid Arthritis and other inflammatory arthritides. While early initiation of therapy is essential to arrest the disease process, sustained use is vital if disease suppression is to be maintained. Prolonged therapy requires long-term monitoring for toxicity and safety profile

Sulfasalazine is a DMARD which may be used for treatment of rheumatoid arthritis (NICE Clinical Guideline 79, [www.nice.org.uk/cg79](http://www.nice.org.uk/cg79)) and other rheumatic diseases.

These guidelines aim to provide a framework for the prescribing of sulfasalazine by GPs and to set out the associated responsibilities of GPs and hospital specialists who enter into the shared care arrangements.

This document should be read in conjunction with the guidance "Responsibility for prescribing between Primary & Secondary/Tertiary Care" <https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf>

## 2. Indication

Rheumatic disease: Rheumatoid arthritis, seronegative ankylosing spondylitis and other inflammatory arthropathy

Immunological disease: Urticaria or angioedema unresponsive to standard medication particularly pressure induced urticaria

Gastric disease: Active Crohn's disease, maintenance of remission of mild to moderate and severe ulcerative colitis

## 3. Dose

Rheumatic disease:

Initially 500mg twice daily for 2 weeks, increased to 1g twice daily thereafter.

In some circumstances up to 1g three times daily may be given, following specific advice from rheumatologists

Immunological disease:

Initially 500mg daily for 1 month increasing to 1g daily to control urticaria or angioedema if required

Further increase should be in discussion with immunologists.

Gastric disease:

Acute exacerbation of IBD: 1 gm four times daily until remission is induced after which the dose is reduced to 500 mg four times a day

Long term maintenance: 500 mg four times daily

Doses may vary for individual patients and will be documented in specialist letter.

## 4. Duration of treatment

Advice will be given to the GP on duration of treatment and dose changes for each individual patient.

## 5. Contraindications and cautions

Sulfasalazine is contraindicated in patients with a history of sensitivity to sulphonamides or salicylates, with G6PD deficiency and severe renal impairment.

Use with caution in moderate renal impairment and hepatic impairment.

Sulfasalazine suspension is contraindicated in those sensitive to sodium benzoate.

Pregnancy – may be used in pregnancy – refer to specialist (folic acid may be prescribed in first trimester)

Breast-feeding – avoid

## 6. Adverse effects

Adverse effects include:

**Haematological:** Neutropenia, thrombocytopenia, rarely haemolytic anaemia and aplastic anaemia.

**Gastrointestinal:** Nausea, vomiting, allergic hepatitis.

**Other:** Severe but short lived headache, peripheral neuropathy, reversible oligospermia, orange / yellow discolouration of urine and permanent staining of extended wear contact lenses. (daily-wear soft contact lenses and gas permeable lenses respond to standard cleaning).

## 7. Interactions

Possible increased risk of leukopenia when given with azathioprine, mercaptopurine. May reduce absorption of digoxin and folic acid.

**Details of contraindications, cautions, drug interactions and adverse effects listed above are not exhaustive. For further information always check with BNF [www.bnf.org.uk](http://www.bnf.org.uk) or SPC ([www.medicines.org.uk](http://www.medicines.org.uk)).**

## 8. Monitoring

**Disease monitoring:** Clinical response to therapy

**Drug monitoring** (see also table below):

Full blood count, LFTs and U&Es should be checked as a baseline prior to initiating therapy.

Full blood count and LFTs should be checked every month for 3 months and then every 3 months thereafter. Frequency of monitoring may be reduced further once dose is stabilised, as advised by specialist.

Patients should be asked about the presence of rash or oral ulceration at each visit. A gradual downward trend of either platelets and/or neutrophils would be an indication that they should be checked more regularly. Similarly if the LFTs fall outside the normal range they should be checked more frequently.

Monitoring parameter	Recommended response
WBC < 4.0 x 10 <sup>9</sup> /l	withhold <b>until discussed</b> with specialist team
Neutrophils <2.0 x 10 <sup>9</sup> /l	withhold <b>until discussed</b> with specialist team
Platelets <150 x 10 <sup>9</sup> /l	withhold <b>until discussed</b> with specialist team
>2 fold rise in AST, ALT (from upper limit reference range)	withhold <b>until discussed</b> with specialist team
MCV > 105 fl	Withhold & check B12 & folate, TSH. If normal <b>discuss with the specialist</b> or his / her team. If folate is low sulfasalazine may be restarted with appropriate folate supplementation and close monitoring.
Unexplained acute widespread rash	Withhold seek <b>urgent advice from specialist team</b>
Oral ulceration	Withhold <b>until discussed</b> with specialist team.
Abnormal bruising or <b>severe sore</b> throat	Check FBC <b>immediately</b> and withhold until results are available. <b>Discuss</b> with the specialist team, if necessary.

### 9. Information to patient

Patients should be informed about benefits and risks of treatment and need for monitoring.

Patients should be told to go to their GP immediately if they experience any fever, rash, bruising, bleeding, sore throat, oral ulceration, jaundice or infection.

Patients should also be told that orange / yellow discolouration of urine and permanent staining of extended wear contact lenses may occur. (daily-wear soft contact lenses and gas permeable lenses respond to standard cleaning).

### 10. Responsibilities of clinicians involved

Stage of Treatment	Hospital Specialist	General Practitioner
Initiation	Assess the patient following referral by GP Carry out baseline full blood count, differential WCC, platelets, U&Es and LFTs Prescribe initial first month supply Recommend appropriate treatment to the GP by approved DMARDs clinic letter	Prescribe on FP10
Maintenance	Assess clinical response to treatment Provide adequate advice and support for the GP. Provide information to GP on frequency of monitoring if doses are changed	Monitor for adverse effects, refer to consultant where necessary. Full blood count and LFTs should be checked every month for 3 months and then every 3 months thereafter. Patients should be asked about the presence of rash or oral ulceration at each visit.

### Contact Details:

During Office hours:

Number for patients and non urgent enquiries for staff tel: 01482 675683.  
(The helpline number is an answering machine service in which messages are taken at midday Mon - Fri.)

For urgent or staff enquiries only contact consultant secretary via switchboard (01482 875875)

Specialist pharmacists

Interface Pharmacist – Antonio Ramirez 0148) 674306  
Rheumatology – Emily Hardaker 01482 674043

Out of hours: Contact On-call Registrar for Medicine via Switchboard: tel 01482 875875

### APPROVAL PROCESS for Shared Care Framework

Written by:	<b>Marie Miller, Interface Pharmacist</b>
Consultation process:	<b>Rheumatology, Immunology, Gastroenterology</b>
Approved by:	<b>MMIG</b>
Ratified by:	<b>HERPC March 2014 Update June 2018</b>
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