Central Manchester University Hospitals NHS
NHS Foundation Trust

Greater Manchester Interface Prescribing Group Shared Care Template

Shared Care Guideline for **Sulfasalazine in Rheumatological Conditions**		**Reference Number** **CMFT-SCG-008**
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Date approved by Commissioners: **January 2013**	**Review Date:** **January 2015**	

Please complete all sections

1. Licensed Indications	*It is licensed to treat rheumatoid arthritis which has failed to respond to non-steroidal anti-inflammatory drugs. Enteric coated tablets licensed only for rheumatoid arthritis.*
2. Therapeutic use & background	*Beneficial effect in suppressing the inflammatory activity of rheumatoid arthritis.*
3. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).	*Contraindications: Patients who have known sensitivity to sulfasalazine and other sulphonamides such as co-trimoxazole. Also sensitivity to salicylates i.e. aspirin.* *Cautions: G6PD deficiency as may cause haemolysis, mild/moderate renal impairment as may cause significant crystalluria, therefore ensure high fluid intake, should avoid in severe renal failure. Slow acetylator status as risk of haematological and hepatic toxicity. May impair folate absorption. Caution in severe allergy and bronchial asthma.* *Other side effects: Orange tears and urine- sulfasalazine is excreted in secretions and can stain some contact lenses.* Oligospermia and infertility may occur in men treated with sulfasalazine. Discontinuation of the drug appears to reverse these effects within 2 to 3 months.
4. Prescribing in pregnancy and lactation	*This drug can be prescribed in the pregnant/breastfeeding patient. Under these circumstances prescribing should be the responsibility of the Consultant.* *Sulfasalazine should be used with caution in pregnancy and not in doses > 2g/day unless specifically advised by consultant.* *Folic acid should be prescribed to those trying to conceive and during pregnancy. As sulfasalazine can impair folate absorption and metabolism.* *Small amounts of the drug may be excreted in breast milk, although these are not thought to be a risk to a healthy infant*

<table>
<tr><td rowspan="10">5. Dosage regimen for continuing care</td><td>Route of administration</td><td colspan="2">oral</td></tr>
<tr><td colspan="3">Preparations available (include in this section any necessary information relating to availability of special preparations for children or those with swallowing difficulties)
Enteric coated tablets only licensed for Rheumatoid Arthritis. Non EC tablets are available and suspension for swallowing difficulties.</td></tr>
<tr><td colspan="3">Please prescribe: Initially 500mg per day then increase by 500mg weekly until maintenance dose of 2-3 gram daily.</td></tr>
<tr><td>Is titration required</td><td>Yes (complete the following section) Yes</td><td></td></tr>
<tr><td colspan="3">Titrate dosage up by 500mg /week according to response.
Maintenance dosage up to a maximum 3gram/day.</td></tr>
<tr><td colspan="3">Adjunctive treatment regime

Folic acid may need to be prescribed as folate absorption and metabolism impaired.</td></tr>
<tr><td colspan="3">Conditions requiring dose reduction

Sulfasalazine should be used with caution in pregnancy and not in doses > 2g/day
In severe renal impairment eGFR<10ml/min start at very low dose and monitor see Renal Drug Handbook.</td></tr>
<tr><td colspan="3">Usual response time

Minimum 3 months</td></tr>
<tr><td colspan="3">Duration of treatment ongoing</td></tr>
<tr><td colspan="3">Treatment to be terminated by healthcare professional in consultation with Rheumatology Team.</td></tr>
<tr><td colspan="3">NB. All dose adjustments will be the responsibility of the initiating specialist care unless directions have been specified in the medical letter to the GP.</td></tr>
<tr><td>6.Drug Interactions

For a comprehensive list consult the BNF or Summary of Product Characteristics</td><td colspan="3">The following drugs must <u>not</u> be prescribed without consultation with the specialist:</td></tr>
<tr><td></td><td colspan="3">The following drugs may be prescribed with caution:
Digoxin- reduced absorption, resulting in non-therapeutic serum levels, has been reported when used concomitantly with oral sulfasalazine.

Azathioprine- Due to inhibition of thiopurine methyltransferase by sulfasalzine, bone marrow suppression and leucopenia have been reported when the thiopurine 6-mercaptopurine or it's prodrug, azathioprine, and oral sulfasalazine were used concomitantly.

Folates- Sulfasalazine possibly reduces absorption of folic acid.</td></tr>
<tr><td>7. Adverse drug reactions</td><td colspan="3">Specialist to detail below the action to be taken upon occurrence of a particular adverse event as appropriate. Most serious toxicity is seen with long-term use and may therefore present first to GPs.</td></tr>
</table>

For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult Summary of Product Characteristics or BNF	**Adverse event** System – symptom/sign	**Action to be taken** Include whether drug should be stopped prior to contacting secondary care specialist	**By whom**
	WBC<3.5 x 10^9/l Neutrophils<2.0 x 10^9/l Platelets<150 x 10^9/l AST, ALT> twice upper limit of reference range *MCV>105 fl*	*Withhold until discussion with Rheumatology Team.* *Check B12, folate and TSH. If abnormal treat any underlying abnormality. If normal, discuss with Rheumatology Team.*	*GP*
	Nausea/dizziness/headache	*If possible continue. May have to reduce dose or stop if symptoms severe. Discuss with Rheumatology Team*	*GP*
	Abnormal bruising or severe sore throat	*Check FBC immediately and withhold until results available. Discuss with Rheumatology Team if necessary as can cause blood disorders*	*GP*
	Unexplained acute widespread rash	*Withhold and seek urgent specialist advice.*	*GP*
	Oral Ulceration	*Withhold until discussion with Rheumatology Team*	*GP*
	The patient should be advised to report any of the following signs or symptoms to their GP without delay: *Advised to report any unexplained bleeding, bruising, purpura, sore throat, fever or malaise that occurs during treatment.*		
	Other important co morbidities (e.g. Chickenpox exposure). Include advice on management and prevention and who will be responsible for this in each case: *Annual 'flu vaccine should be given.*		
	Any adverse reaction to a black triangle drug or serious reaction to an established drug should be reported to the MHRA via the "Yellow Card" scheme.		
8.Baseline investigations	List of investigations / monitoring undertaken by secondary care *FBC* *U&Es* *LFTs*		
9. Ongoing monitoring requirements to be undertaken by GP	**Is monitoring required?**	**Yes or No (if yes complete following section)** Yes	

Monitoring	**Frequency**	**Results**	**Action**	**By whom**
FBC, U&E, LFT, (ESR desirable but not essential)	***During dose titration**: Monthly for 3 months* ***Maintenance dose**: Every 3 months thereafter for 2 years then can stop.*	*See Section 7: Adverse drug reactions above*		*GP*
Patient should be asked about presence of rash or oral ulceration at each visit				*GP*

10. Pharmaceutical aspects	e.g. special storage requirements, washout periods Or where there are "no special considerations" No special requirements
11. Secondary care contact information	**If stopping medication or needing advice please contact:**
	To contact The Kellgren Centre Rheumatology Manchester Royal Infirmary: **Enquiries regarding blood monitoring and results please contact the specialist nurses below:** **Specialist Nurse Jane Hawthorne 0161 276 4688** **Specialist Nurse Melissa Aris 0161 701 1454** **Specialist Nurse Carole Hill 0161 701 1454** **Fax number for GP blood results 0161 276 8690** **Consultant contact details below:** **Professor Ian Bruce 0161 276 4626** **Professor Ann Barton 0161 276 4626** **Dr Kimme Hyrich 0161 276 4627** **Dr Pauline Ho 0161 276 4397** **Dr Rachel Gorodkin 0161 276 4628** **To contact Rheumatology Department Trafford General Hospital:** **Trafford Rheumatology helpline number 0161 746 2162** **Consultant contact details below:** **Dr Frank McKenna 0161 746 2395** **Dr Preeti Shah 0161 746 2395**
12. Criteria for shared care	Prescribing responsibility will only be transferred when ▪ Treatment is for a specified indication and duration. ▪ Treatment has been recommended by the secondary care specialist. ▪ The patient's initial reaction to and progress on the drug is satisfactory. ▪ The GP has no objection in each individual case that shared care is appropriate. ▪ The patient's general physical, mental and social circumstances are such that he/she would benefit from shared care arrangements
13. Responsibilities of initiating specialist	Initiate treatment and prescribe for the 1st 3 months of treatment. Undertake baseline monitoring. Dose adjustments. Monitor patient's initial reaction to and progress on the drug. Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug, and agree to review the patient promptly if contacted by the GP. Provide GP with diagnosis, relevant clinical information and baseline results if abnormal, treatment to date and treatment plan and duration of treatment before consultant review.

14. Responsibilities of the GP	Provide GP with details of outpatient consultations, ideally within 14 days of seeing the patient or inform GP if the patient repeatedly does not attend appointment repeatedly. Provide GP with advice on when to stop this drug. Provide patient with relevant drug information to enable Informed consent to therapy Provide patient with relevant drug information to enable understanding of potential side effects and appropriate action. Provide patient with relevant drug information to enable understanding of the role of monitoring. Provide patient with monitoring booklet. Provide patient with rheumatology nurse helpline contact number. --- Continue treatment as directed by the specialist. Ensure no drug interactions with concomitant medicines. To monitor and prescribe in collaboration with the specialist according to this protocol. To ensure that the monitoring and dosage record is kept up to date in the shared care booklet. To ensure blood monitoring is carried out when responsibility is transferred from secondary care. To inform Rheumatology Team if patient repeatedly does not attend routine blood monitoring. To undertake vaccination as directed by the initiating consultant, the BNF or Green Book. Symptoms or results are appropriately actioned, recorded and communicated to secondary care when necessary.
15. Responsibilities of the patient	--- To take medication as directed by the prescriber, or to contact the GP if not taking medication. To attend hospital and GP clinic appointments and bring monitoring booklet. Failure to attend will result in medication being stopped (on specialist advice). To report adverse effects to their Specialist or GP.
17. Supporting documentation	The SCG must be accompanied by a patient information leaflet. *Patient Information Leaflet EMC Medicines Sulfasalazine* Arthritis Research UK Patient Information Leaflet Sulfasalazine
18. Patient monitoring booklet	The patient must receive a monitoring booklet from the specialist upon initiation of treatment. The patient must bring this booklet to all specialist and GP appointments where it will be updated by the health professional conducting the appointment. The patient must also produce the booklet to any health professional involved in other aspects of their care e.g. pharmacists and dentists. New monitoring books are available from Rheumatology Specialist nurses team.