PATHWAYS AND GUIDELINES DEVELOPMENT SUBGROUP

Shared Care Protocol

GMMMG NHS

Shared Care Protocol for **Sulfasalazine for inflammatory bowel disease in adults**		Reference Number
Version: Final draft – 15.2.2018	**Replaces:** non-applicable	**Issue date:** *dd/mm/yyyy*
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Date approved by Pathways & Guidelines Development Subgroup: *dd/mm/yyyy*	**Date approved by Greater Manchester Medicines Management Group:** *dd/mm/yyyy*	
Date approved by Commissioners: *dd/mm/yyyy*	**Review Date:** *dd/mm/yyyy*	

Please complete all sections

1. Name of Drug, Brand Name, Form and Strength	Sulfasalazine 500mg tablets Sulfasalazine 500mg enteric coated tablets Sulfasalazine 250mg/5ml suspension
2. Licensed Indications	Induction and maintenance of remission in ulcerative colitis and treatment of Crohn's disease.

3. Criteria for shared care	Prescribing responsibility will only be transferred when
	• Treatment is for a specified indication.
	• Depending upon local commissioning arrangements there are two models for DMARD shared care across the conurbation:
	  ○ Model a) Hospital prescribes and monitors until patient on stable dose (usually 3 months) then prescription/ monitoring shifts to primary care with support/ guidance from secondary care.
	  ○ Model b) Primary care prescribes and monitors from the beginning with support/ guidance from secondary care.
	• The GP has agreed in writing 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

4. Patients excluded from shared care	• Patient does not consent to shared care. • Patient does not meet criteria for shared care.
5. Therapeutic use & background	Sulfasalazine is an aminosalicylate anti-inflammatory. Following oral administration around 90% of the dose reaches the colon where it is split by bacteria into sulfapyridine and mesalazine. Overall the drug and its metabolites exert immunomodulatory effects, antibacterial effects, effects on the arachidonic acid cascade and alteration of activity of certain enzymes. The net result clinically is a reduction in activity of the inflammatory bowel disease. The sulfapyridine moiety acts as a carrier to the site of action but is also responsible for the majority of the side-effects associated with sulfasalazine.
6. 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. Patients with porphyria. *Cautions:* Use in caution in patients with G6PD deficiency, as may cause haemolysis. Use in caution with mild/moderate renal impairment as may cause significant crystalluria, therefore ensure high fluid intake, and avoid in severe renal failure. Slow acetylator status as risk of haematological and hepatic toxicity. May impair folate absorption. Should be used in caution where patients have severe allergy and bronchial asthma. Other side effects: Orange tears and urine as 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.
7. 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. It is important to consult the specialist consultant if the patient is trying to conceive or becomes pregnant whilst taking sulfasalazine. 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 folic acid 5mg per day 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 full-term infant.
8. Dosage regimen for continuing care	***Route of administration*** Oral ***Preparations available:*** Sulfasalazine 500mg tablets Sulfasalazine 500mg enteric coated tablets Sulfsalazine 250mg/5ml suspension

	Please prescribe: Acute attack 1-2g 4 times daily until remission occurs, reducing to maintenance dose of 500mg 4 times daily.		
	Is titration required		**No**
	Adjunctive treatment regime: Annual flu vaccinations are safe and recommended. Pneumococcal vaccination is safe and recommended. Shingles vaccine (varicella-zoster) – currently recommended in people over the age of 69 years. To date the JCVI recommendations have not been extended to younger age groups in the rheumatic disease population. Low levels of immunosuppression are not considered an absolute contraindication, and the JCVI Green Book addresses this, recommending that low-dose CSs (prednisolone<20mg daily) and oral DMARD therapy at standard doses are not a contraindication in most patients, although clinician discretion is advised. In non-immune patients exposed to chickenpox or shingles, passive immunisation should be carried out using Varicella zoster immunoglobulin (VZIG). It is the specialist's responsibility to make the recommendation for vaccination at the appropriate time. Folic acid may need to be prescribed as folate absorption and metabolism impaired.		
	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. Refer to Renal Drug Handbook for most up to date guidance.		
	Usual response time : Up to 3 months		
	Duration of treatment: Ongoing		
	Treatment to be terminated by: GP in consultant with gastroenterologist.		
	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.		
9.Drug Interactions ***For a comprehensive list consult the BNF or Summary of Product Characteristics***	Note the following list is not complete, and the SPC and current BNF remain authoritative. 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. • Sulfonamides bear certain chemical similarities to some oral hypoglycaemic agents. Hypoglycaemia has occurred in patients receiving sulfonamides. Patients receiving sulfasalazine and hypoglycaemic agents should be closely monitored. • Methotrexate: increased incidence of gastrointestinal adverse events with concurrent use of sulfasalazine. Pharmacokinetics of either drug not affected by concurrent use.		
10. Adverse drug reactions *For a comprehensive list (including rare and very rare adverse effects), or if*	**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.**		
	Adverse event System – symptom/sign	**Action to be taken** Include whether drug should be stopped prior to contacting secondary care specialist	**By whom**

significance of possible adverse event uncertain, consult Summary of Product Characteristics or BNF	WCC<3.5 x 10^9/l Neutrophils <1.6 x 10^9/l Platelets <140 x 10^9/l Unexplained eosinophilia >0.5 x 109/L Unexplained fall in serum albumin <30g/L	Withhold until discussion with Gastroenterology Team	GP
	ALT and/or AST > 100 units/L OR Any sudden increases (e.g. double of baseline ALT)	Withhold until discussed with the Gastroenterology Team. Check any other reason such as alcohol, drug interaction including over the counter medication as risk of hepatic dysfunction	GP
	Rash or oral ulceration	Withhold until discussion with Gastroenterology Team	GP
	MCV>105 fl	Check serum folate, B12, alcohol history and TSH. Treat any underlying abnormality. If results normal discuss with Gastroenterology Team	*GP*
	Abnormal bruising or severe sore throat	Withhold until urgent FBC results available and discuss with Gastroenterology Team as can cause bone marrow suppression.	GP
	Creatinine >30% above baseline and/or calculated GFR <60	Use clinical judgement Repeat in 1 week and if still >30% above baseline withhold until discussed with the Gastroenterology Team	GP
	Nausea/dizziness/headache	If possible continue. May have to reduce dose or stop if symptoms severe. Discuss with Gastroenterology Team	GP
	Unexplained acute widespread rash	Withhold and seek urgent specialist advice.	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 vaccinations are safe and recommended (due to suppressed immune system with these drugs). • Pneumococcal vaccination is safe and recommended (due to suppressed immune system with these drugs). • Shingles vaccine (varicella-zoster) – currently recommended in people over the age of 69 years. To date the JCVI recommendations have not been extended to younger age groups in the rheumatic disease population. Low levels of immunosuppression are not considered an absolute contraindication, and the JCVI Green Book addresses this, recommending that low-dose CSs (prednisolone<20mg daily) and oral DMARD therapy at standard doses are not a contraindication in most patients, although clinician discretion is advised. • In non-immune patients exposed to chickenpox or shingles, passive immunization should be carried out using varicella zoster immunoglobulin (VZIG).		

	• Patients should try to avoid contact with people who have active chickenpox or shingles and should report any such contact urgently to their GP or specialist. • During infection requiring antibiotics sulfasalazine should be temporarily discontinued until the patient has recovered from the infection.
	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.
11.Baseline investigations	*List of investigations / monitoring undertaken by secondary care* FBC U&Es incl GFR LFT (ALT, AST and albumin) Height and weight Blood pressure Pre-viral screen in high risk patients: HIV, HBV (surface antigen, core antibody), HCV (antibody test) and consider herpes zoster status (if appropriate) Screening for lung disease should be undertaken at clinician discretion on a case by case basis.

12. Ongoing monitoring requirements to be undertaken by GP

Is monitoring required? **Yes**

Monitoring	Frequency	Results	Action	By whom
FBC, U&E, LFTs with albumin, (ESR desirable but not essential)	**During dose titration**: Every 2 weeks until achieve a stable dose for 6 weeks. **Maintenance dose**: Monthly for 3 months then at least every 3 months. More frequent monitoring is appropriate in patients at higher risk of toxicity. If dose and monitoring is stable after 12 months no routine monitoring required. **Dose Increases/Starting an additional DMARD:** Every 2 weeks until on stable dose for 6 weeks then revert back to previous schedule. If dose and monitoring is stable after 12 months no routine monitoring	WCC<3.5 x 10^9/l Neutrophils <1.6 x 10^9/l Platelets <140 x 10^9/l Unexplained eosinophilia >0.5 x 10^9/L Unexplained fall in serum albumin <30g/l	Withhold until discussion with Gastroenterology Team	GP
		ALT and/or AST > 100 units/L OR Any sudden increases (e.g. double of baseline ALT)	Withhold until discussed with the Gastroenterology Team. Check any other reason such as alcohol, drug interaction including over the counter medication as risk of hepatic dysfunction	GP
		MCV>105 fl	Check serum folate, B12, alcohol history and TSH. Treat any underlying abnormality. If results normal discuss with Gastroenterology Team	GP
		Creatinine >30% above baseline and/or calculated	Use clinical judgement. Repeat in 1 week	GP

		required.	GFR <60	and if still >30% above baseline withhold until discussed with the Gastroenterology Team	
	Patient should be asked about presence of rash or oral ulceration at each visit				*GP*
13. Pharmaceutical aspects	No special requirements.				

14. Responsibilities of initiating specialist	• Depending upon local commissioning arrangements there are two models for DMARD shared care across the conurbation:
	  ○ Model a) Hospital prescribes and monitors until patient on stable dose (usually 3 months) then prescription/ monitoring shifts to primary care with support/ guidance from secondary care.
	  ○ Model b) Primary care prescribes and monitors from the beginning with support/ guidance from secondary care.
	• Undertake baseline monitoring.
	• Advise GP on dose adjustments.
	• Monitor patient's initial reaction to and progress on the drug.
	• Ensure that the patient has an adequate supply of medication until GP supply can be arranged.
	• Patients will be considered suitable for transfer to GP prescribing ONLY when they meet the criteria listed in section 3 above.
	• The initiating specialist prescriber will write formally to the GP to request shared care using the GMMMG agreed process. Failure to supply all the required information will result in the refusal of the request until all information has been supplied
	• Patients will only be transferred to the GP once the GP has agreed.
	• 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, treatment to date and treatment plan, duration of treatment before consultant review.
	• Provide GP with details of outpatient consultations, ideally within 14 days of seeing the patient or inform GP if the patient does not attend appointment.
	• Act upon communication from the GP in a timely manner.
	• 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.
	• Patients should be advised to seek medical attention for the following:
	  ○ Patients should report all symptoms and signs suggestive of blood disorders (e.g. sore throat, bruising and mouth ulcers)
	  ○ Patients should report all symptoms and signs suggestive of liver toxicity (e.g. nausea, vomiting, abdominal discomfort, dark urine and jaundice)
	• Provide patient with relevant drug information to enable understanding of the role of monitoring.
	• Be available to provide patient specific advice and support to GPs as necessary.
	• Provide GP with advice on when to stop this drug.				

15. Responsibilities of the GP	• Continue treatment as directed by the specialist.
	• Act upon communication from the specialist in a timely manner.
	• Ensure no drug interactions with concomitant medicines.
	• To monitor and prescribe in collaboration with the specialist according to this protocol.
	• 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.
	• GPs should reply to request for shared care to either accept or decline within 14 days. A form is available on the GMMMG website to facilitate this, if you so wish.
	• If the GP does not feel it is appropriate to take on the prescribing then the prescribing responsibilities will remain with the specialist. The GP should indicate the reason for declining.
	• Enter a READ code (e.g. 8BM5.00) on to the patient record to highlight the existence of shared care for the patient.
	• Undertake more frequent tests if there is evidence of clinical deterioration, abnormal results, or other risk factors. Contact consultant team for advice on monitoring in these circumstances if required.
	• Check all monitoring results prior to issuing a repeat prescription to ensure it is safe to do so.
	• If a patient fails to attend for monitoring:
	  ○ Only issue a 28 day prescription and send them the next available appointment for a blood test
	  ○ If they fail to attend a second blood test then contact the consultant team for advice and to discuss suitability for continued shared care before supplying further prescriptions
	• Monitor the patient's general wellbeing.
	• Seek urgent advice from secondary care if:
	  ○ Signs or symptoms indicating blood dyscrasias eg sore throat, infection, unexplained or abnormal bruising or bleeding.
	  ○ Any signs of bone marrow suppression (ie infection, fever, unexplained bruising or bleeding)
	  ○ Jaundice
	  ○ The patient becomes pregnant
	  ○ Non compliance is suspected
	  ○ The GP feels a dose change is required
	  ○ There is marked deterioration renal function
	  ○ The GP feels the patient is not benefiting from the treatment
	• The shared care agreement will cease to exist, and prescribing responsibility will return to secondary care, where:
	  ○ The clinical situation deteriorates such that the shared care criterion of stability is not achieved.
	  ○ The clinical situation requires a major change in therapy.
	  ○ GP feels it to be in the best stated clinical interest of the patient for prescribing responsibility to transfer back to the consultant team. The consultant team will accept such a transfer within a timeframe appropriate to the clinical circumstances.
	There must be discussion between the consultant team and GP on this matter and agreement from the consultant team to take back full prescribing responsibility for the treatment of the patient. The consultant team should be given 14 days' notice in which to take back prescribing responsibilities from primary care.

16. 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, bring monitoring booklet (if issued) • Note that failure to attend will result in medication being stopped (on specialist advice). • To report adverse effects to their Specialist or GP. • Inform the specialist, GP or pharmacist dispensing their prescriptions of any other medication being taken, including over-the-counter medication			
17.Additional Responsibilities e.g. Failure of patient to attend for monitoring, Intolerance of drugs, Monitoring parameters outside acceptable range, Treatment failure, Communication failure	**List any special considerations**	**Action required**	**By whom**	**Date**
	[insert]	***[insert]***	***[insert]***	***[insert]***
18. Supporting documentation	The SCG must be accompanied by a patient information leaflet. (Available from http://www.medicines.org.uk/emc OR http://www.mhra.gov.uk/spc-pil/)			
19. Patient monitoring booklet (may not be applicable for all drugs)	The patient may 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.			
20. Contact details	See Appendix 1			

Appendix 1 – Local Contact Details

Lead author contact information	**Name:** *[insert text here]*
	Email: *[insert text here]*
	Contact number: *[insert text here]*
	Organisation: *[insert text here]*

Commissioner contact information	**Name:** *[insert text here]*
	Email: *[insert text here]*
	Contact number: *[insert text here]*
	Organisation: *[insert text here]*

Secondary care contact information	**If stopping medication or needing advice please contact:**
	Dr *[insert text here]*
	Contact number: *[insert text here]*
	Fax:*[insert text here]*
	Hospital: *[insert text here]*

Shared Care Protocol Summary:
Sulfsalazine for the treatment of inflammatory bowel disease in adults

Drug	Sulfasalazine 500mg tablets Sulfasalazine 500mg enteric coated tablets Sulfsalazine 250mg/5ml suspension
Indication	Induction and maintenance of remission in ulcerative colitis and treatment of Crohn's disease.
Overview	Sulfasalazine is an aminosalicylate anti-inflammatory. Overall the drugs and its metabolites exert immunomodulatory effects, antibacterial effects, effects on the arachidonic acid cascade and alteration of activity of certain enzymes. The net results clinically is a reduction in activity of the inflammatory bowel disease.
Specialist's Responsibilities	**Initial investigations:** Assessment and diagnosis. Discuss the benefits and side effects of treatment with the patient. Baseline FBC, U&Es, LFTs, GFR, Height, Weight, Blood pressure and Pre-viral screen in high risk patients: HIV, HBV, HCV. Screening for lung disease and Herpes Zoster status should be undertaken at clinician discretion on a case by case basis. **Initial regimen:** 1mg/kg/day increasing after 4-6 weeks to 2-3mg/kg/day **Clinical monitoring:** Initially 500mg per day then increase by 500mg weekly until maintenance dose of 2-3 grams daily. **Frequency of Monitoring:** During dose titration: every 2 weeks until achieve maintenance dose. Maintenance dose: Monthly for 3 months then 3-monthly thereafter. Initial monitoring for the first 3 months will be carried out by the specialist OR as per local commissioning arrangements. **Safety monitoring:** FBC, U&E and LFTs **Prescribing duration:** Started by Hospital and supplied by hospital for the initial 3 months of treatment, thereafter transferred to GP OR as per local commissioning arrangements. **Prescribing details:** Initiated by specialist, prescribed and monitored by the specialist for the first 3 months and then care transferred over to the GP OR as per local commissioning arrangements. To stop the drug or provide information to the GP on when to stop the drug. **Documentation:** The specialist team will write formally to the GP to request shared care using the GMMMG agreed process. Patients will only be transferred to the GP once the GP has agreed. Provide GP with diagnosis, relevant clinical information, treatment plan, duration of treatment with 14 days of seeing the patient or inform GP if the patient does not attend appointment.
GP's Responsibilities	**Maintenance prescription:** Prescribe and monitor sulfasalazine 3 months after initiation in accordance with the specialist's recommendations OR as per local commissioning arrangements. Acute attack 1-2g 4 times daily until remission occurs, reducing to maintenance dose of 500mg 4 times daily. **Clinical monitoring:** To report to and seek advice from the specialist on any aspect of patient care which is of concern to the GP and may affect treatment. **Safety monitoring:**

FBC, U&E, LFTs with albumin, (CRP desirable but not essential)	**During dose titration**: Every 2 weeks until achieve a stable dose for 6 weeks. **Maintenance dose**: Monthly for 3 months then at least every 3 months. More frequent monitoring is appropriate in patients at higher risk of toxicity. After 12 months no routine monitoring required. The decision to discontinue monitoring should be personalised to each individual patient. **Dose**	WCC<3.5 x 10^9/l Neutrophils <1.6 x 10^9/l Platelets <140 x 10^9/l Unexplained eosinophilia >0.5 x 10^9/L Unexplained fall in serum albumin <30g/l	Withhold until discussion with Gastroenterology Team
		ALT and/or AST > 100 units/L OR Any sudden increases (e.g. double of baseline ALT)	Withhold until discussed with the Gastroenterology Team. Check any other reason such as alcohol, drug interaction including over the counter medication as risk of hepatic dysfunction
		MCV>105 fl	Check serum folate, B12 and TSH. Treat any underlying abnormality. If results normal discuss with Gastroenterology Team
		Creatinine >30% above	Use clinical judgement. Repeat in

	Increases/Starting an additional DMARD: Every 2 weeks until on stable dose for 6 weeks then revert back to previous schedule.	baseline and/or calculated GFR <60	1 week and if still >30% above baseline withhold until discussed with the Gastroenterology Team
Oral ulceration	Patient should be asked about presence of rash or oral ulceration at each visit		

Duration of treatment: Stop treatment on advice of specialist.

Re-referral criteria: Seek urgent advice from secondary care if:

- Signs or symptoms indicating blood dyscrasias e.g. sore throat, infection, unexplained or abnormal bruising or bleeding.
- Any signs of bone marrow suppression (i.e. infection, fever, unexplained bruising or bleeding)
- Jaundice
- The patient becomes pregnant
- Non compliance is suspected
- The GP feels a dose change is required
- There is marked deterioration renal function
- The GP feels the patient is not benefiting from the treatment
- Patient fails to attend for monitoring on two consecutive occasions

Documentation: GPs should reply to request for shared care to either accept or decline within 14 days. A form is available on the GMMMG website to facilitate this, if you so wish.

Adverse Events

Adverse events	Action
WCC<3.5 x 10^9/l Neutrophils <1.6 x 10^9/l Platelets <140 x 10^9/l Unexplained eosinophilia >0.5 x 109/L Unexplained fall in serum albumin <30g/L	Withhold until discussion with Gastroenterology Team
ALT and/or AST > 100 units/L OR Any sudden increases (e.g. double of baseline ALT)	Withhold until discussed with the Gastrenterology Team. Check any other reason such as alcohol, drug interaction including over the counter medication as risk of hepatic dysfunction
Rash or oral ulceration	Withhold until discussion with Gastroenterology Team
MCV>105 fl	Check serum folate, B12 and TSH. Treat any underlying abnormality. If results normal discuss with Gastroenterology Team
Abnormal bruising or severe sore throat	Withhold until urgent FBC results available and discuss with Rheumatology Team as can cause bone marrow suppression.
Creatinine >30% above baseline and/or calculated GFR <60	Repeat in 1 week and if still >30% above baseline withhold until discussed with the Gastroenterology Team
Nausea/dizziness/headache	If possible continue. May have to reduce dose or stop if symptoms severe. Discuss with Gastroenterology Team
Unexplained acute widespread rash	Withhold and seek urgent specialist advice.

Contra-indications Cautions Drug Interactions

Please refer to the BNF and/or SPC for information.

In non-immune patients exposed to chickenpox or shingles, passive immunisation should be carried out using Varicella zoster immunoglobulin (VZIG). It is the specialist's responsibility to make the recommendation for vaccination at the appropriate time.

Other Information

Annual flu vaccinations are safe and recommended.
Pneumococcal vaccination is safe and recommended.
During infection sulfasalazine should be temporarily discontinued until the patient has recovered from the infection.
May colour urine, soft contact lenses or skin an orange/yellow colour.

Contact Details

Name:
Address:
Telephone: