NORTH AND EAST DEVON HEALTHCARE COMMUNITY
SHARED CARE PRESCRIBING GUIDELINE

Sulfasalazine Enteric Coated

Treatment of inflammatory bowel disease

Specialist: Please complete letter on page 5 before sending guideline to GP

GP: Please indicate whether you wish to share patient's care by completing letter on page 5 and return to specialist

Aim of treatment

Sulfasalazine is a long term treatment. The earliest initial response is at 6-12 weeks.
Indication: Treatment of adults with inflammatory bowel disease

A summary of prescribing information is provided on page 3.

Specialist responsibilities

- Decision to prescribe sulfasalazine.
- Discuss benefits and side effects of treatment with patient or patient's carers including where appropriate the risks associated with pregnancy and need for a reliable method of contraception.
- Refer patient to specialist nurse service where appropriate (eg. new patient) for advice on taking the drug, its cautions, side effects associated with treatment, monitoring requirements and the timing of re-assessment and by whom.
- Ascertain immune status by enquiring about history of chickenpox. Measurement of antibodies to varicella-zoster is not recommended.
- Issue a booklet for recording test results to patient
- Conduct baseline tests – full blood count, liver function tests, U&Es, serum creatinine, folate and vitamin B12. Copy test results to GP.
- Specify review dates.
- Prompt verbal communication followed up in writing to GP of changes in treatment or monitoring requirements, results of monitoring, assessment of adverse events or when to stop treatment. Urgent changes to treatment should be communicated by telephone to GP.
- Reporting adverse events to CHM.

General practitioner responsibilities

If GP has agreed to share care:

- Prescribing of oral sulfasalazine after communication with specialists regarding the need for treatment.
- Undertake monitoring of full blood count, liver function tests, U&Es, creatinine and CRP as specified. Review results and undertake any necessary action.
- Take appropriate action if patient reports sign(s) or symptom(s) specified under Monitoring.
- Be aware of criteria for referral to gastroenterology team.
- Respond to advice from secondary care on dose changes and frequency of monitoring.
- Report to and seek advice from specialist on any aspect of patient care of concern to GP which may affect treatment. Prompt referral to specialist if there is a change in patient's health status.
- Report adverse events to specialist.
- Stop treatment in case of a severe adverse event or as per shared care guideline.

Monitoring

1. Monitoring prior to starting therapy: gastroenterology team

- Measure baseline full blood count, LFTs, U&Es, creatinine, folate and vitamin B12.

2. Monitoring during treatment: general practice

Laboratory tests

Tests	Frequency of monitoring	Guidance	Action to be taken by GP
Full blood count	- Every two weeks for three months, then three monthly thereafter, then at discretion of specialist - If dose increase, repeat tests one month after dose increase; if stable revert to usual monitoring regime.	**If WCC** falls on three successive occasions **or** <3.5 x 10^9/l **If neutrophils** fall on 3 successive occasions **or** <2.0 x 10^9/l **If platelets** fall on 3 successive occasions **or** <150 x 10^9/l **If MCV** >105fl	If concerned about sequential drops in FBC indices (possibly still within the normal range) consider an early retest **If count(s) meet specified criteria, stop treatment and refer to Gastroenterology team** If an isolated MCV rise – check for other causes (B12, folate and alcohol consumption). **If results normal, refer to Gastroenterology team**
LFTs		**If AST or ALT** > 2 times ULN	If small rise in AST or ALT, early next test. **If >3 times ULN, stop treatment and refer to Gastroenterology team.**
U&Es and creatinine		If deterioration in renal function	Adjust dose or contact Gastroenterology team (see guidance for dose adjustment)
CRP	Every three months	If CRP high - consider infection	-

Signs and symptoms

Patients MUST report mouth ulcers, sore throat, fever, epistaxis, unexpected bruising or bleeding and any unexplained illness/infection.

Action to be taken by GP:

- **Review patient with any of the signs or symptoms listed above within 24 hours** for full blood count and liver function tests. Signpost patient to alternative provider if this is not possible e.g. weekend/bank holiday
- **Stop treatment and refer if:**
  - Rash – in cases of unexplained acute widespread rash, stop treatment and seek urgent advice (preferably from dermatology team)
  - Abnormal bruising
  - Severe sore throat
  - Severe oral ulceration
  - Unexplained illness including severe nausea, vomiting or diarrhoea

Do not stop treatment prior to surgery unless significant risk of infection.
Contact Microbiology if a patient, not known to be immune to chickenpox comes into contact with shingles or chickenpox, for advice on whether zoster immune globulin or other treatment is indicated.

Patient responsibilities

Patients:

- MUST report mouth ulcers, sore throat, fever, epistaxis, rash, unexpected bruising or bleeding, and any unexplained illness/infection to their GP and/or specialist.
- Report any other adverse effect to their GP and/or specialist whilst being treated with sulfasalazine.
- Ensure that they have a clear understanding of their treatment.
- Ensure they attend for monitoring requirements.
- Be aware that treatment will be stopped if patient does not attend for monitoring.

Back-up advice and support

Contact details	Telephone No	E-mail address
Dr T. Daneshmend	01392 402803	tawfique.daneshmend@nhs.net
Dr R. Ayres	01392 402818	reuben.ayres@nhs.net
Dr J. Christie	01392 402791	john.christie@nhs.net
Dr T. Shirazi	01392 406220	tarek.shirazi@nhs.net
Dr T. Ahmad	01392 406218	tariq.ahmad1@nhs.net
Dr A. Moran	01271 322734	alex.moran@ndevon.swest.nhs.uk
Dr A Davis	01271 322447	andrew.davis@ndevon.swest.nhs.uk
Nurse specialists (RD&E)		
Fiona Fry	01392 402728	F.fry@nhs.net
Clare Holding	01392 402728	Clare.holding@nhs.net
Laura. Strang	01392 402728	Laura.strang@nhs.net

Guideline updated by Clinical Effectiveness Team, NHS Devon in consultation with local specialists and GPs

For non-clinical enquiries: d-icb.devonformulary@nhs.net

Supporting Information

This guideline highlights significant prescribing issues, not all prescribing information and potential adverse effects are listed. Please refer to SPC/data sheet for full prescribing data.

Dose

Dose: Up to 4g/day.

Special patient groups: Use doses at the lower end of the range for patients with hepatic or renal impairment.

Contraindications

- Hypersensitivity to sulfasalazine, sulfonamides or salicylates
- Porphyria

Precautions

- Hepatic or renal impairment
- Adequate fluid intake is required as sulfasalazine causes crystalluria and kidney stone formation
- Limit alcohol intake to within national recommendations
- Patients with blood dyscrasias
- Patients with severe allergy or bronchial asthma.
- Patients with G-6-PD deficiency: caution as sulfasalazine may cause haemolytic anaemia
- Pregnancy: When planning a pregnancy, women of child bearing potential are advised to use a reliable method of contraception until discussion with the gastroenterology team about pregnancy planning. There is no evidence that sulfasalazine is teratogenic, but the possible risks and benefits to the mother and child should be discussed. Also, sulfasalazine may cause reversible oligospermia and infertility in men.
- Lactation: see SPC for further information.

Side effects

Common and uncommon:

- Leukopenia, thrombocytopenia
- Insomnia, depression, dizziness, headache, taste disorders, convulsions, tinnitus, vertigo
- Vasculitis, cough, dyspnoea, arthralgia
- Gastric distress, nausea, abdominal pain, diarrhoea, vomiting, stomatitis
- Elevation of liver enzymes, proteinuria
- Pruritus, alopecia, urticaria, fever, facial oedema
- (Epidermal necrolysis, Stevens-Johnson Syndrome and drug rash with eosinophilia and symptoms (DRESS) have been reported but less frequently)

Interactions

- Azathioprine and mercaptopurine: sulfasalazine inhibits TPMT enzyme. Risk of bone marrow suppression and leucopenia with concurrent use of azathioprine or mercaptopurine.
- Digoxin: concomitant use results in reduced absorption of digoxin
- Folates: sulfasalazine possibly reduces absorption of folic acid
- Hypoglycaemic agents: Hypoglycaemia has occurred in patients receiving sulfonamides. Patients receiving hypoglycaemic agents and sulfasalazine 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.

Pregnancy and lactation

See SPC for further information

Date ratified by Effective Practice Committee: April 2011
Review date: November 2013

Shared Care Agreement Letter - Consultant Request

To: Dr……

Practice Address: ……

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……

Patient Name:
Hospital number:
Date of birth:
Address:

DIAGNOSED CONDITION: **……**

I recommend treatment with the following drug: **……**

I request your agreement to sharing the care of this patient according to the North and East Devon Health Community Shared Care Prescribing Guidelines for this drug.

Principles of shared care:
GPs are invited to participate. If GP is not confident to undertake these roles, then they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If a specialist asks the GP to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient and accepted by them.

The doctor who prescribes the medication has the clinical and legal responsibility for the drug and the consequences of its use.

Signed:		**Date:**
Consultant name:		
Contact telephone number:		

GP RESPONSE
I agree/ do not agree* to share the care of this patient in accordance with the Shared Care Guideline.

Signed: …… Date: ……

GP name: …… *Delete as appropriate