Western Locality Shared care information on the prescribing of Sulfasalazine

April 2013

Specialist: Please complete the Shared Care letter sending a request to GP

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

Aim of treatment

Treatment of mild to moderate active ulcerative colitis and to maintain remission; active Crohn's disease

Specialist responsibilities

1. To assess full blood count and renal and liver function before staring treatment. Continue monitoring FBC fortnightly and LFTs (including AST or ALT) 4 weekly for the first 12 weeks. Ask about the presence of a rash / oral ulceration at each visit.
2. To initiate treatment. Patients will have received at least 3 months of treatment, and have been stabilised on a suitable dose.
3. To send a Shared Care Agreement letter to the GP requesting Shared care for a particular patient.
4. The following information will also need to be sent:
    a. Results of blood tests
    b. Results of any other appropriate investigations
    c. Advice on dose alterations where appropriate
5. To periodically review the patient.
6. Evaluation of adverse effects / monitoring results reported by the GP.
7. Deciding when it is appropriate to withdraw therapy in the case of no response.
8. Advising on dosage reduction once remission has been sustained for 6 months.
9. Ensuring the patient is aware of the signs of bone marrow depression.

General practitioner responsibilities

If GP has agreed to share care:

1. To respond to the Shared Care Agreement letter without delay. To state whether they agree or do not agree to share the care of the patient in accordance with this Shared Care Guidelines.
2. To monitor the patient's overall health and well being
3. To carry out appropriate monitoring (see below)
4. To prescribe treatment
5. To monitor side effects of treatment, and seek urgent advice as necessary
6. To contact the appropriate secondary care physician as appropriate

Monitoring

Monitoring during treatment: general practice

Laboratory tests

Full Blood count	3 monthly
Liver Function Tests (including ALT or AST)	3 monthly
Ask about the presence of rash / oral ulceration at each visit If during the first year of treatment blood results have been stable, 6 monthly tests will suffice for the second year and, thereafter, monitoring of blood toxicity could be discarded.	

Results/symptoms and actions to be taken:		
Test/symptom	**Result**	**Action**
WBC	<3.5x10^9/L	Withhold drug, discuss with specialist
Neutrophils	<2x10^9/L	Withhold drug, discuss with specialist
Platelets	<150x10^9/L	Withhold drug, discuss with specialist
AST, ALT or Alk. Phos	>2 fold rise (from upper limit or reference range)	Withhold drug, discuss with specialist
Rash or oral ulceration		Withhold drug, discuss with specialist
MCV	>108fl *	Investigate and if B12 or folate low, start appropriate supplementation
Nausea / dizziness / headache		If possible continue, may have to reduce dose or stop if symptoms severe.
Abnormal bruising or sore throat		Withhold until FBC result available

* MCV threshold updated due to change in local lab reported normal values; if blood samples are not being analysed by Derriford Hospital lab, confirm threshold for action with specialist. (February 2018)

Signs and symptoms

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

At each visit, ask patient about the presence of rash or oral ulceration.

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 – late rashes are more serious than early ones.
- 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/patient carer responsibilities

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

Back-up advice and support

Gastroenterology

- Dr C Hayward 01752 792112
- Dr S Lewis 01752 517611
- Dr S Cochrane 01752 431286
- Dr S Dunlop 0845 1558155
- Dr A Latchford 01752 792687
- Dr M Metzner 01752 792765

Derriford Medicines Information: 01752 439976

Medicines Optimisation Teams

- NEW Devon CCG, Western Locality 01752 398800
- Kernow CCG 01726 627953

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

- Ulcerative colitis (maintenance dose): 500mg four times daily
- Sulfasalazine is available as tablets or film coated tablets in strength of 500mg

Contraindications

- Hypersensitivity to sulfasalazine, sulfonamides or salicylates
- Infants under the age of 2 years
- 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 rheumatology 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

(Refer to SPC for further information)

Common and uncommon

- Leucopenia, 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

Shared Care Agreement Letter – Consultant Request

To: Dr……

Practice Address……

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Patient Name:	
NHS Number:	
Date of birth:	
Address:	

Diagnosed condition: …….

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

At the following dosage: …….

I request your agreement to sharing the care of this patient according to the Western Locality Shared Care Information guidelines for this drug. The patient has been initiated on treatment and stabilised in accordance with the appropriate Shared Care Information.

Principles of shared care:

GPs are invited to participate, but **if the GP is not confident to undertake these roles then they are under no obligation to do so.** If so, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. If asked 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.

Remember: 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:			
Telephone number:		**Fax number**	
Email address			

Please sign below and return promptly. Remember to keep a copy of this letter for the patient's records. If this letter is not returned shared care for this patient will not commence.

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.