FULL SHARED CARE AGREEMENT FOR

Aminosalicylates

In the treatment of

Inflammatory Bowel Disease

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On behalf of:
East Leicestershire and Rutland Clinical Commissioning Group
Leicester City Clinical Commissioning Group
West Leicestershire Clinical Commissioning Group
Leicestershire Partnership NHS Trust
University Hospitals of Leicester NHS Trust

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Additional medicines information is available from:
Trent Medicines Information Centre
Victoria Building, Leicester Royal Infirmary, LE1 5WW
Tel: 0116 255 5779 / 0116 258 6491
Fax: 0116 258 5680
e-mail: medicines.info@uhl-tr.nhs.uk
**Full Shared Care Agreement for the prescribing of 6-mercaptopurine, aminosalicylates, azathioprine and methotrexate in the treatment of gastroenterological disease**

**Introduction and purpose**

This shared care agreement has been produced following classification of aminosalicylates, in the Leicestershire drug traffic light scheme. See website at [www.lmsg.nhs.uk](http://www.lmsg.nhs.uk)

Shared care has been defined as the mechanism of sharing patient care between primary and secondary care providers. This document sets out these responsibilities from initial diagnosis to ongoing support.

**Disease Background**

- Inflammatory bowel disease is a chronic lifelong condition.
  - Ulcerative colitis is a non-transmural condition involving the colon. Patients are classified as follows: Proctitis, Left sided disease or Pancolitis.
  - Crohn’s disease is a patchy transmural condition and can affect the whole gastrointestinal tract.
- Autoimmune hepatitis is a chronic inflammatory liver condition causing abnormal transaminases.

Diffuse inflammatory bowel disease or disease that does not respond to local therapy requires oral treatment with an aminosalicylate with or without an adjunctive corticosteroid.

All these conditions are characterised by episodes of relapse and remission. Relapses are not predictable and patients with frequent relapses will require intervention with corticosteroids. Dose changes do not require a new shared care agreement.

Patients requiring repeated courses of corticosteroids will require immunomodulating agents for maintaining remission and treatment of active disease i.e. 6-mercaptopurine, azathioprine or methotrexate.

**Drugs covered by the agreement**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
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<tbody>
<tr>
<td>Balsalazide</td>
<td>Ulcerative colitis</td>
</tr>
<tr>
<td>Mesalazine oral</td>
<td>Ulcerative colitis</td>
</tr>
<tr>
<td>Rectal mesalazine does not require a shared care agreement.</td>
<td>Crohn’s disease</td>
</tr>
<tr>
<td>Sulfasalazine EC tablets and suppositories</td>
<td>Ulcerative colitis</td>
</tr>
<tr>
<td></td>
<td>Crohn’s disease</td>
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</tbody>
</table>

The manufactures’ of sulfasalazine advise that preparations that lower stool pH such as lactulose might prevent the release of sulfasalazine.

Blood dyscrasias can occur with aminosalicylates.

**Further information regarding contraindications, cautions, side effects and interactions are available in the BNF and the relevant summary of product characteristics [https://www.medicines.org.uk/emc](https://www.medicines.org.uk/emc)**

**Secondary Care Clinician Responsibilities**

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing and monitoring of these drugs in the conditions named above can be shared between the specialist and general practitioner (GP). GPs are asked to participate.
Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

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

**Hospital clinician responsibilities:**
1. Perform baseline tests (see Appendix). Discuss the benefits and side effects of treatment with the patient. Ensure that the patient is aware of what symptoms and side effects to report. Record that information has been given and is understood by the patient in the notes.
2. Prescribe initial course of treatment and arrange testing and full monitoring of blood tests as outlined in the Appendix.
3. Return to follow up where bloods and the patient are reviewed. Adjust treatment as appropriate for the individual patient.
4. Ask the GP, using the shared care agreement form, to continue prescribing the Shared Care Request Form.
5. Periodically review the patient’s condition and communicate promptly with the GP when treatment is changed.
6. Communicate promptly with the GP in writing when to adjust the dose, stop or change treatment, and when to consult with specialist. A further shared care is not required for alterations in dosing.
7. Report adverse events to the MHRA as appropriate and GP.
8. Ensure that clear backup arrangements exist for GPs to obtain advice and support.

**GP responsibilities:**
1. Confirm the request for shared care within 10 working days, using the shared care request form.
2. Prescribe and titrate the dose dependant on symptoms.
3. Arrange full monitoring and follow up of regular blood tests once care is transferred (see Appendix). Check recent results are available (see Appendix for recommended maximum interval) before issuing a prescription. Seek advice from Inflammatory Bowel Disease Helpline in all cases of concern.
4. Ensure compatibility with other concomitant medication.
5. Adjust the dose as advised by the specialist See clinic letter with treatment plan.
6. Stop treatment on the advice of the specialist, or immediately if an urgent need to stop treatment arises.
7. Report adverse events to the specialist and MHRA where appropriate.

**Community pharmacist responsibilities**

1. Support the patient to take the medication as prescribed.
2. Advise patient about the importance of the required blood tests (see Appendix).
3. Ensure compatibility with other concomitant medication, including over the counter medicines.
4. Seek advice from GP in cases of concern.

**Patient’s role/responsibilities:**

1. Attend all blood tests and appointments with GP and specialist.
2. Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
4. Inform specialist, GP or pharmacist of any other medication being taken, including over-the-counter products.
5. Report any adverse effects or warning symptoms to the specialist or GP such as unexplained bleeding, bruising, sore throat, fever or malaise.
6. Inform other professionals of current treatment as necessary.

The responsibility for arranging and taking action on blood test results where necessary remains with the prescribing clinician

Contact for support and advice

Inflammatory Bowel Disease Helpline 0116 2584352

LGH Consultants - Richard Robinson 0116 2584797
Adrian Gelsthorpe 0116 2584796
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LRI Consultants - Barrie Rathbone 0116 2586630
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Supporting Information

Summary of Product Characteristics (SPC): http://emc.medicines.org.uk/


<table>
<thead>
<tr>
<th>Version</th>
<th>Section</th>
<th>Description of amendments</th>
<th>Date</th>
<th>Author / amended by</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0</td>
<td>2.0</td>
<td>New document with aminosalicylates now having their separate shared care</td>
<td>July 18</td>
<td>SG</td>
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</table>
## Appendix Drug Monitoring

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Pre-treatment</th>
<th>Routine</th>
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<tbody>
<tr>
<td><strong>Aminosalicylates</strong></td>
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<tr>
<td>Mesalazine oral - IBD</td>
<td>Dose and licensing depends on brand prescribed (see BNF)</td>
<td>U&amp;Es, creatinine</td>
<td>U&amp;Es and creatinine at 3 months then annually (more frequently in renal impairment).</td>
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<tr>
<td>Balsalazide - UC</td>
<td>Acute attack: 2.25g three times daily.</td>
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<td></td>
<td>Maintenance: 1.5g twice daily</td>
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<tr>
<td>Sulfasalazine EC tablets - IBD</td>
<td>Acute attack: 1-2g four times daily.</td>
<td>FBC, U&amp;E, LFT, Creatinine, CRP</td>
<td>FBC and LFTs every 2 weeks for 8 weeks then monthly for 3 months. If dose and bloods stable for 3 months, then test FBC, LFT &amp; CRP 3 monthly. After dose increase repeat bloods one month after; if stable revert to usual monitoring regime. If after first year, dose and bloods stable then bloods can be reduced to 6 monthly.</td>
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<tr>
<td></td>
<td>Maintenance: 500mg four times a day</td>
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