SHARED CARE AGREEMENT FOR 6-MERCAPTOPURINE and AZATHIOPRINE in the treatment of Inflammatory Bowel Disease (Ulcerative Colitis, Crohn’s Disease) In Paediatric Patients

Sharing of care assumes communication between the specialist, GP and patient, and other members of the care team including specialist nurses and pharmacists. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

If a GP is invited by the specialist to participate in a shared care arrangement, the GP should reply to this request with in 10 working days. If the GP is not confident to undertake these roles, then he or she is 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.

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

Azathioprine is an immunomodulatory agent used in more severe inflammatory bowel disease, for maintenance therapy. It is metabolised to 6-mercaptopurine, which is therefore occasionally used if patients experience side effects with azathioprine.

Azathioprine is cytotoxic therefore the tablets should not be crushed by parents or carers; older children can usually take their own tablets (or can be given training by the specialists so that they can crush their own tablets).

The preferred product at UHL for children who cannot manage tablets is the 50mg/5ml oral solution manufactured by Nova and for safety reasons it is recommended that this strength is also prescribed in primary care as many parents/carers learn the doses in millilitres and so risk giving incorrect amounts if the strength changes.

### Specialist responsibilities

1. **Diagnosis of condition and ensuring other treatment options have been fully explored.**
   Patients/carers are provided with the patient information leaflet before commencing therapy.

2. **Discuss the benefits and side effects of treatment with the patient.** Ensure that the patient/carer understands that dosing of the medication is weight related and that they are aware of what symptoms to report. Record that information has been given and is understood by the patient in the notes.

3. **Perform baseline tests (FBC, LFTs, U&Es, amylase, TMPT and creatinine).**

4. **Prescribe initial course of Azathioprine and arrange testing and full monitoring during initial 3 months.** Bloods are done 2 weekly for the first 8 weeks, then 3 monthly or more often as clinically appropriate.

5. **Follow up of children including review of blood results.** Adjustment of dosing of Azathioprine as appropriate.

6. **Monitor for response and adverse drug reactions (ADRs) during initial course.**

7. **Liaison with the GP to share the patient’s care using the Shared Care Request Form: Shared Care Request Form.** Shared care should not be assumed until a written agreement has been received from the GP.

8. **If appropriate, outline to GP when therapy may be reduced and stopped assuming no relapse in patient’s condition.** Review periods to be agreed.

9. **Respond to issues raised by GP.**

10. **Advise GP on related issues such as drug interactions etc.**
GP responsibilities

1. Confirm or decline request to share patient’s care within 10 working days, using the shared care request form.
2. Monitor the patient’s overall health and well being and observing patient for evidence of ADRs/abnormalities and raising with secondary care clinician if necessary.
3. Prescription of drug after initial 3 months and review by secondary care.
4. Monitor blood counts, hepatic and renal function at recommended frequencies, and contact specialist if abnormal (see table below). The hospital team will also be reviewing all blood results regularly. Inform the specialist team if unable to perform bloods in primary care as in this case they can be done at the hospital. Check recent results are available not more than three months old before issuing a prescription. Seek advice from Paediatric Gastroenterologists in cases of concern.
5. GPs are NOT expected to adjust doses or stop treatment unless on the advice of the specialist.
6. Ensure compatibility with other concomitant medication.
7. Comply with terms of the Community Based Service and any national advice on azathioprine.
8. Ensuring advice is sought from the secondary care clinician if there is any significant change in the patient’s physical health status.
9. Reducing/stopping treatment in line with secondary care clinician’s original request.

Community pharmacist responsibilities

1. Check patient is taking the medicine as prescribed
2. Check the patient is attending for monitoring as outlined above
3. Report any side effects to the GP

Patient / carer 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 or GP of any other medication being taken, including over-the-counter products.
5. Report any adverse effects or warning symptoms to the specialist or GP whilst taking Azathioprine.
6. Inform other professionals of current treatment as necessary.
7. Azathioprine is currently considered safe in pregnancy. Discussions should take place between the patient and consultant / specialist nurse.

Further advice and support - this information is not inclusive of all prescribing information

British National Formulary via www.medicinescomplete.com


Paediatric Gastroenterologists (0116) 258 6794 or on-call consultant via UHL switchboard 0300 3031573

Trent Medicines Information Centre, Victoria Building, Leicester Royal Infirmary, LE1 5WW
Tel: 0116 258 6491 Fax: 0116 258 5680
Appendix – quick reference guide for monitoring azathioprine and 6-mercaptopurine in paediatric patients

<table>
<thead>
<tr>
<th>Dose</th>
<th>Pre-treatment</th>
<th>Routine</th>
<th>Discuss with specialist urgently</th>
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| Azathioprine: 2-2.5mg/kg body weight daily | FBC, LFTs, U&Es, amylase, TMPT and creatinine | FBC, LFTs, 2 weekly for 8 weeks then FBC, LFT and U&Es 3 monthly or as needed | ➢ WCC falls $<2.5 \times 10^9 /l$  
➢ Neutrophils $<1 \times 10^9 /l$  
➢ Platelets $<100 \times 10^9 /l$  
➢ LFTs (ALT/AST) $>2$ fold rise above upper limit reference range  
➢ Creatinine abnormal  
➢ Severe rash or bruising or ulceration of mucous membranes.  
➢ Any unexplained illness occurs including nausea or diarrhoea.  

If WCC $<3 \times 10^9 /l$ repeat bloods in 1 week and inform hospital specialist.  
If neutrophils $<1.5 \times 10^9 /l$ repeat in 1 week and inform hospital specialist. |