Title: Shared care guideline for Azathioprine use in renal patients with autoimmune conditions	Salford Royal NHS NHS Foundation Trust University Teaching Trust safe • clean • personal
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Authors Division: Clinical and support services	
Departments/Groups This Document Applies to: Renal	
Scope: Trust Wide	**Classification:** Shared care protocol
Keywords: azathioprine, Renal, autoimmune	**Replaces Issue No:** New

To be read in conjunction with the following documents:
Medicines policy, renal lupus and vasculitis guidelines, http://intranet/policies-resources/trust-policy-documents/trust-wide-clinical/gen/tc1410/?locale=en

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Authorised by: Exec Medicines Management Group	**Authorisation Date:** March 2014	

Document for Public Display: yes

Required NHSLA Evidence **N**
If this policy is required for NHSLA evidence, then this document must have been checked against the current standards for compliance. If this is not known by the author, confirmation should be sought from the Risk and Health and Safety Department.

Contents

Shared Care Protocol for azathioprine in renal patients

Introduction

Azathioprine is prescribed for renal patients for a range of indications. This document relates specifically to the shared care between primary and secondary care of renal patients with autoimmune conditions that affect the kidney.

Purpose and Scope

Shared care is an agreement between the GP and the consultant.

This shared care document has been developed to facilitate the safe and appropriate prescribing, supply and monitoring of azathioprine in primary and secondary care. It is aimed at all healthcare professionals involved in prescribing, dispensing and monitoring azathioprine.

This document must be agreed by SRFT and the patients CCG.

Policy statement

This shared care protocol must be adhered to by all medical, nursing, pharmacy and other staff who are involved in the care of patients who are suitable for shared care, as agreed by both the GP and hospital specialist caring for the patient.

Monitoring and review
This shared care protocol will be reviewed on a two yearly basis or in the intervening period if new research is published, there are changes to the drug license or funding arrangements that necessitate an update before the two years have passed.

Drug Name & Formulation:	
1. Relevant Licensed Indications	Azathioprine is indicated in severe cases of the following diseases in patients who are intolerant to steroids or who are dependent on steroids and in whom the therapeutic response is inadequate despite treatment with high doses of steroids: - Systemic lupus erythematosus;
2. Therapeutic use & background	Off label use as a steroid sparing agent in glomerulonephritis therapy during both the induction and maintenance phase of treatment.
3a. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).	a) Hypersensitivity to azathioprine, 6-mercaptopurine (metabolite of azathioprine) or to any of the excipients. b) Severe infections. c) Severely impaired hepatic or bone-marrow function. d) Pancreatitis. e) Any live vaccine especially BCG, smallpox, yellow fever.
3b With caution:	Pregnancy and lactation, where the risks of teratogenicity are outweighed by the benefits
4. Prescribing in pregnancy and lactation	Can be given with caution if benefits outweigh the risks.
5. Dosage regimen for continuing care	Route of administration: Oral Starting dose 1-2.5mg/kg/day
	Is titration required? — Not in primary care
	Titration guidance: Titration will be undertaken in secondary care.
	Adjunctive treatment regime: *n/a*
	Conditions which might require dose reduction depending on clinical

<table>
<tr><td></td><td>judgment:
Low white cell count
Raised liver enzymes</td></tr>
<tr><td></td><td>Usual response time:
At least 4 weeks</td></tr>
<tr><td></td><td>Duration of treatment:
From 1 year to lifelong</td></tr>
<tr><td></td><td>Treatment to be terminated by:
Primary care at end of designated treatment period where specified or if prolonged periods of white cell count less than 4.</td></tr>
<tr><td>6.Drug Interactions

For a comprehensive list consult the BNF or Summary of Product Characteristics</td><td>The following drugs must <u>not</u> be prescribed without consultation with the specialist:
Allopurinol,
Mycophenolate mofetil,
Sulfasalazine, 6-mercaptopurine,
Other immunosuppressant/ cytotoxic chemotherapeutic agents</td></tr>
<tr><td></td><td>The following drugs may be prescribed with caution:
n/a</td></tr>
<tr><td>7. Adverse drug reactions

For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult Summary of Product Characteristics or BNF</td><td>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.
<table>
<tr><th>Adverse Event</th><th>Action to be taken</th><th>By whom</th></tr>
<tr><td>Infections</td><td>Consider dose reduction during period of infection
Check FBC
Refer to secondary care</td><td>Secondary care</td></tr>
<tr><td>Rash</td><td>Stop azathioprine
Check FBC
Check LFTs
Refer to secondary care</td><td>Primary care</td></tr>
<tr><td>Temperature >38.5</td><td>Stop azathioprine
Check FBC
Refer to secondary care</td><td>Primary care</td></tr>
<tr><td>Neoplasm</td><td>Refer to appropriate specialty
Notifiy renal team</td><td>Primary care

Primary care</td></tr>
<tr><td>Bone marrow suppression</td><td>Stop azathioprine
Check FBC
Check LFTs</td><td>Primary care</td></tr>
</table></td></tr>
</table>

		Refer to secondary care			
	Additional guidance / warnings: About 10 % of patients have a thiopurine methyltransferase deficiency due to genetic polymorphism. They may therefore be unable to metabolise azathioprine completely. Consequently they may be exposed to an increased myelotoxic effect. Phenotyping or genotyping of the patient is desirable before administration of the medicinal product in order to investigate a possible thiopurine transferase deficiency. Such tests will be carried out in secondary care prior to or on initiation of therapy.				
8.Baseline investigations	Full blood count to include, white cell count, neutrophil count, platelets and haemoglobin Liver function tests, Renal Function tests, Immunology if required, TPMT				
9. Ongoing monitoring requirements to be undertaken by GP	**Is monitoring required?**		**Yes (if yes complete following section)**		
	Monitoring	**Frequency**	**Results**	**Action**	**By whom**
	FBC Us and Es LFTs	Monthly from week 12-26 then every 3/12	Lymphocytes <0.5x 109/L Neutrophils <2 x 109/L <1.5x 109/L Platelets <150 x 109/L Liver function tests >2 fold rise in AST, ALT from upper limit of normal) >4 fold rise in AST, ALT	Discuss with renal team Discuss with renal team Stop and discuss with renal team Discuss with renal team Discuss with renal team Stop and discuss	Primary care
10. Pharmaceutical aspects	Available as a tablet formulation only. Patients with swallowing difficulties should be discussed with secondary care pharmacist.				

11. Secondary care contact information	**If advice is required please contact: Renal consultant or renal baton bleep holder at Salford Royal Hospital through switch board 0161 789 7373** **Azathioprine should not be permantently stopped without seeking advice. Temporary suspension**
	Complete details for local distribution
12. Criteria for shared care	Patients should have completed the initial 8 weeks under the care of the secondary care team and have white cell count greater than 4, LFTs less than 2 x the upper limit of normal.
13. Responsibilities of initiating specialist team:	Initiate treatment and prescribe until the GP formally agrtees to shared care. Request shared care in the clinical letter. Routine follow up no less than annually Send a written letter after each out-patient attendance to confirm on-going dose and blood tests. Inform GP of any patients who fail to attend out-patient follow up Provide back up advice including out of hours.
14. Responsibilities of the GP	Monitor patients overall health and well being and perform routine health screens. Ensure vaccinations are offered as required eg pneumococcal vaccine, seasonal influenza. Prescribe the drug treatment as described in the clinic letter/ letter to GP. Monitor blood results (FBC, renal function, LFTs and CRP) in line with recommendations from secondary care Report any adverse events to secondary care Assist where required in the on-going monitoring of disease
15. Responsibilities of District Nurses	none
16. Responsibilities of the patient	To attend all appointments with the clinical teams and for blood test monitoring in primary and secondary care, or to contact the relevant team and made alternative arrangements if unable to attend. To take medicines are prescribed To contact GP or hospital team if any severe side effects are encountered including any rashes, high temperature or increased bruising. To avoid exposure to sun and use high factor sun screen.
17. Supporting	Patient information leaflet

documentation	http://intranet/policies-resources/leaflets/ren/med2712/?locale=en
18. Patient monitoring booklet	none
19. Shared care agreement form	Attached below

Appendix 1- PLEASE ADAPT LETTERS AS APPROPRIATE TO DRUG

Shared Care Agreement to be added to clinic letter as required

Shared care is an agreement between the GP and the hospital consultant. This form is a request by the consultant to share the suggested pathway of your patient. If you are unable to agree to the sharing of care and continued prescription of the suggested medication, please make this known to the Consultant within 14 days, stating the nature of your concern.

Please contact the consultant within 14 days to discuss any concerns. If we do not hear otherwise, implied consent will be assumed.

(Insert patients name and identifier such as DOB) is being considered for treatment with azathiopine.

If this treatment should prove to be successful, the continuing supply of azathioprine would need to be prescribed by yourself.

If you have any queries regarding this medication and its administration or if there is any reason why you do not wish this treatment to be undertaken, could you please contact myself, Dr ([insert Dr's Name) or Dr (insert Dr's name)'s secretary within the next fourteen days.

I will be happy to respond to any questions.

Please find enclosed the Salford Royal NHS Foundation Trust Shared Care Protocol.

Kind regards

Yours sincerely,

Appendix 2- *PLEASE ADAPT LETTERS AS APPROPRIATE TO DRUG*

Patient Information Letter

Dear (Insert patients name & hospital number),

As you are aware your Consultant has recommended continueing treatment with azathioprine.

We have asked your GP to prescribe azathioprine for you. He/She has agreed to prescribe this for you and you should request your prescriptions from your GP surgery.

If you have any queries please contact (insert contact name and details),

Kind regards

Yours sincerely

(Insert Consultant's signature)	(Insert signature of specialist nurse)
Dr (insert Dr's Name) Consultant (Insert Dr's role)	(Insert name of specialist nurse) (Print role of specilised nurse)

Endorsed by:		
Name of Lead Clinician/Manager or Committee Chair	**Position of Endorser or Name of Endorsing Committee**	**Date**
Aladdin Shurrab	Clinical Director Renal Medicine	November 2013
Dr John MacDonald	Chair of Medicines Management Group	March 2014
Lindsay Harper	Director of Pharmacy	March 2014

Record of Changes to Document - Issue number:				
Changes approved in this document by - Corporate Governance and Risk Management			Date:	
Section Number	Amendment (***shown in bold italics)***	Deletion	Addition	Reason
	New			

Screening Equality Analysis Outcomes (Policies/Procedures)

The Trust is required to ensure that all our policies/procedures meet the requirements of its service users, that it is accessible to all relevant groups and **furthers the aims of the Equality Duty for all protected groups by age, religion/belief, race, disability, sex, sexual orientation, marital status/civil partnership, pregnancy/maternity, gender re-assignment. Due consideration may also be given to carers & socio/economic.**

Have you been trained to carry out this assessment? YES **If 'no' contact Equality Team 62598 for details.**	
Name of policy or document : Shared Care guideline for azathioprine in renal patients **Key aims/objectives of policy/document (impact on both staff & service users):** To outline the key responsibilities of primary and secondary care in the administration and monitoring of azathioprine for patients with renal auto-immune conditions.	
1) a) Whom is this document or policy aimed at?	1a) Trust wide, primary and secondary care health teams responsible for the care of patients with renal autoimmune conditions who require azathioprine.
2) a) Is there any evidence to suggest that your 'end users' have different <u>needs</u> in relation to this policy or document; (e.g.health/employment inequality outcomes) (**NB If you do not have any evidence you should put in section 8 how you will start to review this data)**	2a) no
3) a) Does the document require any decision to be made which could result in some individuals receiving different treatment, care, outcomes to other groups/individuals?	3a) no
b) If yes, on what basis would this decision be made? **(It must be objectively justified)**	3b) no
4) a) Have you included where you may need to make reasonable adjustments for disabled users or staff to ensure they receive the same outcomes to other groups ?	4a) n/a

5) a) Have you undertaken any consultation/involvement with service users or other groups in relation to this document?	5a) n/a
b) If yes, what format did this take? face/face or questionnaire? (please provide details of this)	5b)
c)Has any amendments been made as a result?	5c)
6) a) Are you aware of any complaints from service users in relation to this policy?	6a) n/a
b) If yes, how was the issue resolved? Has this policy been amended as a result?	6b)

7) a) To summarise; is there any evidence to indicate that any groups listed below receive different outcomes in relation to this document?

	Yes		No	unsure
	Positive	Negative*		
Age			x	
Disability	x			
Sex			x	
Race			x	
Religion & Belief			x	
Sexual orientation			x	
Pregnancy & Maternity				x
Marital status/civil partnership			x	
Gender Reassignment			x	
Carers *1			x	
Socio/economic2**			x	

1: That these two categories are not classed as protected groups under the Equality Act.

2: Care must be taken when giving due consideration to socio/economic group that we do not inadvertently discriminate against groups with protected characteristics

Negative Impacts

*If any negative impacts have been identified you must either a) state below how you have eliminated these within the policy or b) conduct a full impact assessment:

Patients with disability may be less able to attend for frequent blood tests. Ensuring as much as possible can be done by primary care should be easier for patients.

Providing prescription from primary care facilities collection and delivery from local pharmacies which may benefit patients.

Pregnant patients would only receive azathioprine if the benefits have been shown to outweigh the risks on an individual patient basis.

8) How will the future outcomes of this policy be monitored?

Bi-annual audit

9) **If any negative impact has been highlighted by this assessment, you will need to undertake a full equality impact assessment:**

Will this policy require a full impact assessment? No
(if yes please Contact Equality Officer on 206 7204, for further guidance)

Low Type/sign_____Elizabeth Lamerton _____
date: November 2013