The Princess Alexandra Hospital NHS NHS Trust

NHS West Essex Clinical Commissioning Group

Shared Care Agreement

AZATHIOPRINE / MERCAPTOPURINE (MP)

For up to date version of Shared Care Agreement contact specialist team or latest version on website https://westessexccg.nhs.uk/your-health/medicines-optimisation-and-pharmacy/shared-care-medicines

Referral Criteria

These guidelines are for patients over 16 years of age.
Shared Care is only appropriate if it provides the optimum solution for the patient.
Prescribing responsibility will only be transferred when it is agreed by the Consultant and the patients' GP
Safe prescribing must be accompanied by effective monitoring
When transfer is agreed, the patient will be given a supply of azathioprine/mercaptopurine (MP) sufficient for 4 week maintenance therapy
The doctor who prescribes the medication has the clinical responsibility for the drug and the consequences of its use.
From April 2019 West Essex patients under the care of Princess Alexandra Hospital Rheumatology Consultant will be assessed and those patients with stable disease markers and DAS<3.2 after 6 months of consultant led care will be transferred for ongoing case management to a West Essex General Practitioner with Specialist Interest (GPSI) in Rheumatology. Thereafter shared care for the management of DMARD will be between the Consultant/GPSI (further referred to as Specialist) and the GP.

SHARED CARE RESPONSIBILITIES

Consultant
Undertake the necessary testing to confirm a diagnosis for which azathioprine / MP treatment is recommended.
Ensure the patient's concurrent drug therapy is stabilised and there are no contra-indications to treatment with azathioprine / MP
Ensure that patient is aware of risks and benefits of medication and has read appropriate information leaflet.
Ensure the patient understands the shared care agreement and has signed the Patient Agreement Letter (page 9-10)
Perform baseline tests (see Monitoring section) including TPMT and provide results to GP
Initiate treatment and prescribe until the patient has been on a stable dose for minimum of SIX weeks
Send a letter to the GP requesting shared care for this patient.
Review the patient in outpatients as clinically appropriate and advise the GP promptly after these reviews on when to adjust the dose, stop treatment or consult with the Specialist.
Inform GP, by letter, of each clinic attendance and action taken for the management of the patient ensuring current dose, most recent blood results and frequency of monitoring are stated.
Evaluate any reported adverse effects by GP or patient.
Inform GP of patients who do not attend clinic appointments, admin to contact patient to rearrange.
Ensure that backup advice is available at all times. (see Contacts section) and respond to any GP queries as soon as practicable.
12. To report any adverse events to the CHM and GP (see link)
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
For patients under the care of Princess Alexandra Hospital Rheumatology Consultant refer patients with stable disease markers and DAS<3.2 for ongoing case management after 6 months of consultant led care to General Practitioner with Specialist Interest in Rheumatology; inform the GP.

General Practitioner with Specialist Interest in Rheumatology (for West Essex patients under the care of Princess Alexandra Hospital)
Accept patients with stable disease markers and DAS<3.2 for ongoing case management after 6 months of consultant led care.
Provide ongoing patient education
Annual review of all patients as per NICE guidance
Review the patient annually or as clinically appropriate and advise the GP promptly after these reviews on when to adjust the dose, stop treatment or consult with the Specialist.
Inform GP, by letter, of each clinic attendance and action taken for the management of the patient ensuring current dose, most recent blood results and frequency of monitoring are stated.

Written by: Clare Macpherson, Senior Pharmacist
References: Draft SCG for Azathioprine in Gastroenterology by Dr Lakshmana Kumar, Consultant, Rheumatology Department guidelines for prescribing Azathioprine
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Evaluate any reported adverse effects by GP or patient.
Inform GP of patients who do not attend clinic appointments and contact patient to rearrange.
To report any adverse events to the CHM and GP (see link)
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

General Practitioner

Monitor patient's overall health and well-being.
Consider request to prescribe under shared care arrangements and reply only if you **do not agree** to share care, in a timely manner within 14 days as outlined on page 7 with clinical reasons and return to Consultant and Pharmacy department.
Ensure compatibility with other concomitant medication.
Prescribe at the dose recommended.
Monitor U&E, creatinine, FBC and LFTs at recommended frequencies (see monitoring section) and refer if abnormal.
Adjust the dose as advised by the Specialist.
Stop treatment on advice of Specialist or immediately if any urgent need to stop treatment arises (see monitoring section).
Report any adverse events to the Specialist and CHM.
https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
Inform Specialist of any change in the medical condition of patient which may have effect on disease / medications.
Ensure patient is offered an annual flu vaccination and a one off pneumococcal vaccination

Patient

Report to Specialist or GP if there is not a clear understanding of their treatment and discuss any concerns in relation to treatment
Report any adverse effects to their Specialist whilst taking Azathioprine / MP, especially unexplained bruising/bleeding, fever, infections or mouth ulcers which should be reported immediately.
Report any changes in disease symptoms to Specialist whilst taking Azathioprine / MP.
Alert GP and/or Specialist of any changes of circumstance which could affect management of disease e.g. plans for pregnancy whilst taking Azathioprine / MP.
Inform GP or Specialist of any other medicines being taken including over-the-counter products.
Do not use sunbeds, and avoid strong sunlight or use a sun cream with a high sun protection factor (SPF of at least 15).
Attend for regular reviews and blood monitoring tests.

CONTACT NUMBERS FOR ADVICE AND SUPPORT

Advice and guidance: Access Advice & Guidance tool via e-RS referral system selecting the relevant specialty for non-urgent queries

Princess Alexandra Hospital NHS Trust - Gastroenterology	
Consultant	**For GPs only**: contact Gastroenterologist of the week via switchboard if urgent **Email for GPs only**: tpa-tr.gastroadminclinicalcorrespondence@nhs.net
Specialist Gastroenterology Pharmacist: Clare Macpherson	Bleep 272 Direct dial: 01279 278224 (voicemail if not answered) Claremacpherson@nhs.net for medication issues
IBD Specialist Nurse	Direct dial:01279 278223 (voice mail only) usual response within 48 hours Paht.ibd@nhs.net

Princess Alexandra Hospital NHS Trust - Rheumatology

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Consultant:	**For GPs only**: contact Rheumatologist via switchboard if urgent tpa-tr.rheumatologyadminclinicalcorrespondence@nhs.net for non-urgent queries.
Rheumatology Specialist Nurse DMARDs	01279827434 helpline (voice mail only) for non-urgent queries only Lily Robinson
Rheumatology Specialist Nurse / Pharmacist - Biologics	01279827819 helpline (voice mail only) for non-urgent queries only Mona Kamal Zou / Sachini Amarasekera
	Patients can email tpa-tr.rheumatologyadminclinicalcorrespondence@nhs.net for non-urgent queries.

Princess Alexandra Hospital NHS Trust - Dermatology	
Consultant:	**For GPs only**: contact Dermatologist via switchboard if urgent 01279 444455 Ext 7431 / 7421 for non-urgent queries only tpa-tr.dermatologyclinicalcorrespondence@nhs.net
Specialist Pharmacist Dermatology	Noemi.corrao@nhs.net

Princess Alexandra Hospital NHS Trust - Neurology	
Consultant:	**For GPs only:** contact Neurologist via switchboard if urgent 01279 444455 Ext 7422 for non-urgent queries only

Princess Alexandra Hospital NHS Trust - Haematology	
Consultant:	**For GPs only:** contact Haematologist via switchboard if urgent 01279 444455 Ext 7035 for non-urgent queries only

Princess Alexandra Hospital NHS Trust - Pharmacy	
Medicines Information (for medicines related queries)	01279 827054

CLINICAL INFORMATION

Prescribed Indications covered by this Shared Care Agreement

Azathioprine

All licensed indications:

Severe rheumatoid arthritis
Systemic lupus erythematosus
Dermatomyositis and polymyositis
Auto-immune chronic active hepatitis
Pemphigus vulgaris
Polyarteritis nodosa
Auto -immune haemolytic anaemia
Chronic refractory idiopathic thrombocytopenic purpura

and the following unlicensed autoimmune disorders:

Severe eczema[1]
Vasculitis[1]
Crohn's Disease and Ulcerative Colitis[2]
Psoriatic arthritis[3]
Myasthenia gravis[4]
Chronic inflammatory demyelinating polyneuropathy[4]
Autoimmune mediated neurological disorders[4]

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6-Mercaptopurine
Unlicensed Indications - Crohn's Disease and Ulcerative Colitis[2]

Therapeutic Summary

Azathioprine is used as a disease-modifying agent to induce and maintain remission in several inflammatory and autoimmune conditions. Azathioprine is a pro-drug, which is cleaved rapidly in the liver to MP. The predominant toxic effect is myelosuppression, although hepatotoxicity is also well recognised. Azathioprine is metabolised by the enzyme thiopurine methyl transferase (TPMT). It has been established that approximately 90% of the population have a Normal TPMT activity and may require standard doses of azathioprine, 11% have intermediate TPMT activity and are at a higher risk of adverse drug reactions on standard doses of azathioprine and 0.3% are deficient or have no detectable TPMT activity and are at risk of suffering life-threatening complications even when treated with low doses of azathioprine. TPMT activity can be measured phenotypically and genotypically.
For rheumatoid diseases improvement may take 2 to 3 months to occur.

Note: Mercaptopurine is the active metabolite of Azathioprine, with the same mechanism of action, the same risk/benefit profile and the same monitoring requirements. However, MP may be better tolerated than Azathioprine**. The dose of MP is approximately half that of Azathioprine.**

Dose and Route of Administration

Azathioprine

In general, the dosage range is 1 to 3 mg/kg bodyweight/day orally, and should be adjusted according to the clinical response (which may be evident only after weeks or months) and haematological tolerance. For the treatment of chronic active hepatitis the dosage is usually between 1**.**0 and 1**.**5 mg/kg bodyweight/day and for IBD up to 2**.**5mg/kg body weight/day.

Starting typically at 1mg/kg and increasing after 4 to 6 weeks to 2 to 3 mg/kg/day according to response.

When the therapeutic response is evident, consideration should be given to reducing the maintenance dosage to the lowest level compatible with maintenance of the response.

Mercaptopurine

0**.**75 to 1**.**5 mg/kg daily by mouth.
See SPC for more details
http://www.medicines.org.uk/emc/medicine/2882 azathioprine
http://www.medicines.org.uk/emc/medicine/24688 mercaptopurine

Duration of Treatment

Indefinite but may be withdrawn after a prolonged period of remission in selected cases.
It is also used as a rotational treatment in eczema.

Adverse Effects and Management

Undesirable effects may vary in their incidence depending on the indication.
Bone marrow suppression (leucopenia, thrombocytopenia)
Hypersensitivity reactions including malaise, rash, dizziness, vomiting, diarrhoea, fever, rigors, nephritis requires immediate withdrawal.
Hepatotoxicity (hepatic necrosis, biliary stasis, hepatic veno-occulsive disease)
Anorexia, nausea, vomiting
Oral ulceration, rarely gastrointestinal ulceration
Rarely pancreatitis
CNS disturbances (headache, drowsiness, blurred vision)
Alopecia
Increased susceptibility to infection

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Oligospermia
See BNF and SPC for comprehensive list and details

Skin Care: There is an increased risk of skin cancer. Patients should be aware of the need for adequate sun protection measures. This risk is greater in patients who have a history of previous treatment with PUVA

IMMUNOSUPRESSION
For patients who have not had chicken pox and are in contact with anyone with the virus follow guidance from Public Health England June 2019 https://www.gov.uk/government/publications/varicella-zoster-immunoglobulin

TPMT Assay:
Individuals with severely reduced TPMT activity **(homozygous) should not be prescribed AZATHIOPRINE** as serious and fatal toxicity may occur within 6 weeks of starting the drug. For mild/moderate (heterozygous) deficiency serious adverse events may occur anytime and as late as 6 months after treatment commences. Serious Adverse Events can be exacerbated by minor infections or drug interactions (See Drug Interactions & contra-indications**). Heterozygous individuals should be prescribed Azathioprine/MP with caution and reduced drug dosage.**

Cautions

Patients should try to avoid contact with people who have active chickenpox or shingles and should report any such contact urgently to their GP or Specialist. Passive immunisation should be carried out using Varicella zoster immunoglobulin (VZIG) in non-immune patients if exposed to chickenpox or shingles.
Anticoagulant effect of warfarin possibly reduced by Azathioprine / MP.
Sunscreens and protective covering should be encouraged to reduce sunlight exposure.
Infection with hepatitis B or C and history of TB

Contraindications

Moderate/severe renal or liver impairment
Hypersensitivity to azathioprine, MP (metabolite of azathioprine) or to any of the excipients.
Severe infection
Severely impaired hepatic or bone-marrow function.
Pancreatitis
Pregnancy unless the benefits outweigh the risks (see below)
Lactation
Low or marginal TPMT levels.
Patients should avoid 'live' vaccines such as oral polio, MMR, BCG and yellow fever. An inactivated form of polio is readily available.
Increased risk of haematological toxicity with co-trimoxazole/trimethoprim. Avoid concomitant use.

Pregnancy and Lactation

The risk benefit discussion for continuing treatment in pregnant/breastfeeding patients or those considering pregnancy/breastfeeding will be undertaken by secondary care
The manufacturer advises that azathioprine is contra-indicated in pregnancy, although many specialists consider it to be a low risk.[5] Women of child bearing potential should be advised to use effective contraception. In most cases Azathioprine/MP should not be prescribed if there is a risk of pregnancy although there may be some circumstances where continuing treatment for the safety of the individual outweighs the possible risks related to the unborn child. Dose reduction at 32 weeks of gestation may prevent neonatal leucopenia. Women treated with Azathioprine/MP should not breast feed, contact Specialist for advice

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Monitoring Standards for Azathioprine and Mercaptopurine based on BSR BHPR Standards 2017

The following standards have been agreed for the monitoring of Azathioprine and Mercaptopurine in all patients at Princess Alexandra Hospital NHS Trust.

Pre-treatment by Specialist	Height, weight, blood pressure, FBC, U&Es, LFTs, TPMT phenotype, creatinine, varicella status, hepatitis B&C status	
Initial monitoring by Specialist	FBC Creatinine / calculated GFR ALT +/- AST Albumin	Every 2 weeks until on stable dose for 6 weeks.
Ongoing monitoring by GP	FBC Creatinine / calculated GFR ALT +/- AST Albumin	Then once on stable dose monitor monthly for 3 months.
	FBC Creatinine / calculated GFR ALT +/- AST Albumin	At least every 12 weeks
Dose increase	FBC Creatinine / calculated GFR ALT +/- AST Albumin	Every 2 weeks until on stable dose for 6 weeks, then revert to previous schedule
	Heterozygotes for TPMT	Continue monitoring FBC and LFTs monthly. GP will be informed of this by secondary care when shared care is initiated.

Action and Advice

If a GP has taken blood tests for the general medical management of a patient and blood test results fall into the categories below or the patient reports one of the adverse events below, these are recommendations for considering the withdrawal of Azathioprine / MP therapy:

Blood Test Results	
WBC < 3.5 x 10^9/l	Withhold until discussed with specialist team
Neutrophils < 2.0 x 10^9/l	Withhold until discussed with specialist team
Platelets < 150 x 10^9/l	Withhold until discussed with specialist team
> 2-fold rise in AST, ALT (from upper limit of reference range)	Withhold until discussed with specialist team
MCV > 105fl	Check B12, serum folate and TSH. Treat any underlying abnormality. If results normal, discuss with specialist team
U&Es	Abnormal result discuss with specialist team
Unexplained reduction in albumin <30 g/l	Discuss with specialist team
Creatinine increase >30% over 12 months and/or calculated GFR <60 ml/min	Withhold until discussed with specialist team
Symptoms	
Abnormal bruising or bleeding	Withhold until FBC results available & discuss with specialist team
Severe sore throat	Withhold until FBC results available & discuss with specialist team

Clinically relevant Drug interactions – see SPC for complete listing

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Allopurinol: Dose of Azathioprine/MP should be reduced to 25% of original dose.
Warfarin: Azathioprine/MP inhibits the anti-coagulant effect of warfarin
Carbamazepine, Phenytoin, Sodium Valproate: Azathioprine/MP reduces the absorption of these drugs
Angiotensin-converting enzyme (ACE) inhibitors: Co-prescription of azathioprine may cause anaemia (if significant, consider alternative to ACE inhibitor or different DMARD).
Aminosalicylates i.e. mesalazine, olsalazine, balsalazide or sulfasalazine: may contribute to bone marrow toxicity.
Co-trimoxazole and trimethoprim can cause life threatening haematoxicity

References

BAD guidelines for prescribing Azathioprine in Dermatology:

BSG guidelines for management of inflammatory bowel disease in adults:

BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs 2017 https://academic.oup.com/rheumatology/article/3053478/BSR-and-BHPR-guideline-for-the-prescription-and?searchresult=1

Azathioprine prescribing in neurology J Neurol (2008) 255:791–795

Azathioprine in Neurology.pdf

5). The Second European Evidenced-Based Consensus on Reproduction and Pregnancy in Inflammatory Bowel Disease Journal of Crohn's and Colitis, Volume 9, Issue 2, 1 February 2015, Pages 107–124, https://doi.org/10.1093/ecco-jcc/jju006

Useful information

This document does not replace the SPC and BNF and should be read in conjunction with it.

West Essex CCG webpage for Shared Cared Guidelines –
https://westessexccg.nhs.uk/your-health/medicines-optimisation-and-pharmacy/shared-care-medicines/255-shared-care-letter/file

Arthritis Research UK Patient Information Leaflet - Azathioprine
http://www.arthritisresearchuk.org/arthritis-information/drugs/azathioprine.aspx

Patient.co.uk Patient Information Leaflet - Mercaptopurine
http://www.patient.co.uk/medicine/mercaptopurine-xaluprine

CKS DMARDs
http://cks.nice.org.uk/dmards#!scenario:1

GMC Prescribing Guidance: Shared Care
https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/prescribing-and-managing-medicines-and-devices/shared-care

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GP response to Shared Care Agreement

(only complete & send if NOT participating in shared care)

This shared care agreement has been approved by the Medicines Management Optimisation Programme Board June 2016

Patient Name:	NHS No:
Consultant:	Medicine requested for shared care: **Azathioprine / Mercaptopurine** delete as appropriate

I will **NOT** be undertaking the GP responsibilities as described in the agreed shared care agreement. My clinical reasons for declining shared care for this patient are listed in the box below:

Yours sincerely

{GP name}

{Surgery}

Please send a copy of this response to:
1. The Consultant requesting shared care
2. **ANONYMISED COPY OF THIS FORM ONLY** to the E-MAIL: **tpa-tr.ClinicalPharmacy@nhs.net**

(sending a copy of this form to the PAH pharmacy will help to identify any inappropriate requests for shared care e.g. indication not covered, hospital monitoring requirements not fulfilled. It will also help to inform the CCG Medicines Optimisation Team of the reasons shared care is not being undertaken by GPs allowing for changes to be made in future updates to improve patient safety)

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The Prlncess Alexandra Hospltal NHS
NHS Trust

Information for patients:

SHARED CARE:
Agreement information and confirmation

Hamstel Road
Harlow, Essex
CM20 1QX

Tel: 01279 444455

Patient name:

.....

Medicine:

.....

We would be grateful if you would take time to read this information as it will help us work with you to manage your condition and ensure safe prescribing of the specific medicine listed above.

What is a Shared Care Agreement (SCA)?

A Shared Care Agreement (SCA) enables the care you have for a specific condition to be shared between the hospital and your GP.

The agreement means that the medicine the hospital has started, can be continued by your GP, so you won't have to visit the hospital to collect your medicine.

The SCA gives information on your medicine, guidance on the prescribing and monitoring responsibilities for your consultant (in the hospital), your GP and you. For an SCA, to work everyone involved must understand it and communicate effectively.

Your consultant and your GP will need to sign the agreement and if you agree to this approach, we would ask you to sign this letter, to indicate your agreement to have your care managed in this way.

How does shared care work?

Your consultant and GP share responsibility for your care.

The consultant is a specialist in your condition and will start prescribing your medicine, making sure it is suitable for you. There will come a point in your treatment when you may not need to be monitored by the consultant as often and this monitoring can be done by your GP.

Once your GP has agreed to the SCA, they will be able to prescribe the same medicine for you at the dose recommended by the consultant.

The organisation which regulates GPs, the General Medical Council, says that 'when a GP prescribes a medicine, the GP needs to satisfy themselves that the prescription is needed, appropriate for the patient and within the limits of their competence'.

So, your GP can only issue a prescription if the consultant and you keep to the responsibilities you have agreed (see below). If responsibilities are not kept or if the GP no longer feels it is safe to prescribe the medicine, he/she will explain the reasons to you and your consultant, then prescribing responsibilities will be transferred back to the hospital.

What do I need to do to ensure the SCA can continue?

- **Attend hospital outpatients**

You must still attend the hospital for regular reviews as directed by your consultant (these may be less frequent than before and you may be seen by a specialist pharmacist or a specialist nurse). If you do not attend your hospital appointments, your GP will not be able to continue issuing prescriptions for this medication.

- **Attend GP appointments**

You must attend any appointments you have with your GP in relation to this medicine, so they can look after you effectively

continued overleaf

- **Have blood tests as you have been advised to:** Your consultant should have informed you if and how often you need to have blood monitoring tests. You can usually have your blood taken at an appropriate clinic and not need to go to the hospital.
- If you do not have the blood monitoring tests as advised by your consultant, your GP will no longer be able to issue you with prescriptions as it would not be safe to do so.

What do I do if I am having side-effects to the medicine?

Your consultant should have informed you of the common side-effects to expect and what to do if you experience them. If you think you may be having side-effects from a medicine report these directly to your consultant. Your GP may need to seek advice from your consultant before issuing you with another prescription; this is to ensure it is safe for you to continue on the medication.

What if my disease symptoms change or get worse?

Report any changes in disease symptoms or circumstances that could affect management of your disease to your consultant.

What about the other medicines I take?

Inform your GP and the consultant of all other medicines you are taking, including those you may have bought yourself. Do not take new medicines (including those you could buy) until you have discussed this with your pharmacist, GP or consultant.

If you would like to go ahead with a shared care agreement for the specific medication identified on page 1, please sign below to confirm that you:

- Understand the shared care agreement.
- Are happy to have your care for this aspect of your health managed by a shared care agreement.
- You agree to attend regular review appointments as requested.
- You agree to have blood tests as required.

What happens if I change GP Practice?

If you register at a new GP Practice a new agreement needs to be put in place between your new GP and the specialist team.

The specialist team can start this process if you provide them with information before you move to make sure there is a smooth handover.

Patient's signature ..... Date

.....

Print name .....

If at any point in time you would like this shared care agreement to stop, please talk to your GP.