BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Azathioprine for dermatological conditions and oral mucosal ulceration secondary to skin conditions
Amber *three months*	
Indication	Psoriasis, eczema and other skin conditions including pemphigus, pemphigoid and Lichen Planus. For the treatment of oral mucosal ulceration secondary to skin conditions including pemphigus, pemphigoid and Lichen Planus
Speciality / Department	Dermatology Oral Medicine
Trust(s)	North Bristol NHS Trust
	University Hospitals Bristol NHS Trust
	Weston Area Health NHS Trust

Section 2: Treatment Schedule

Usual dose and frequency of administration	A typical dose regimen is to commence 50-100mg daily and to increase by 50mg every 2 weeks to a maximum dose of 3.0mg per kg per day. Patient with reduced levels of TMPT activity (thioprine methyl transferase, the key enzyme metabolising azathioprine) usually need a dose reduction.
Route and formulation	Azathioprine is given daily by mouth and is available as 25mg, 50mg and 100mg tablets.
Duration of treatment	Azathioprine should be continued as long as clinically indicated unless there is a serious side effect or the drug becomes ineffective.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate
Secondary Care: Pre-treatment assessment with FBC, renal function, LFT, TPMT. HIV, Hepatitis B&C serology and Varicella serology testing and CXR are considered Secondary Care to monitor 1 weekly FBC and LFTs for the first 6 weeks of treatment, then every 2 weeks until dose stabilised for 6 weeks.

Subsequent tests - where appropriate

1. Primary Care to monitor FBC, & LFTs monthly. Renal function should be repeated 6 monthly. If dose, disease and monitoring stable, and TPMT normal, then, frequency of monitoring could be reduced to a minimum of 3-monthly based on clinical judgement.

Azathioprine should be withheld and the dermatology team contacted for discussion if any of the following occur. Falling or rising trends may also prompt discussion.

Problem	Action
Abnormal bruising or non-remitting sore throat	Stop drug and check FBC, contact team if abnormal
Hb <10g/dl WBC <3.5 x 10^9/L Neutrophils <1.8x10^9/l Platelets <100 x10^9/l	Stop drug and recheck weekly until stable
Elevation of liver enzymes (ALT/AST) >2 x normal	Reduce dose by 50% and recheck weekly until stable. Discuss with team
Severe rash or oral ulceration	Stop drug and inform team
Chicken pox/shingles infection	Stop and commence aciclovir.
New or increasing dry cough or dyspnoea	Stop drug. Consider CXR and discussions with team

Section 4: Side Effects

Please list the most common side effects and management. Please provide guidance on when the GP should refer back to the specialist.

Side effects and management	The most common side effects are nausea, vomiting and heartburn. These can be reduced by taking the drug with meals and an H_2-blocker or proton pump inhibitor may also be helpful. Rashes, hepatitis and alopecia may also occur. The most serious side effect is bone marrow suppression. -.
Referral back to specialist	Any serious side effect and common side effects if unmanageable.

Section 5: Drug Interactions

Please list clinically significant drug interactions (eMC link please click here)

Significant Drug Interactions	This is not a comprehensive list, for a full list of drug interactions please refer to the current edition of the British National Formulary (BNF) and the Summary of Product Characteristics (SPC). **Allopurinol:** azathioprine has increased toxicity. Therefore the azathioprine dose should be reduced to a quarter of the usual dose. **Aminosalicylates:** may increase the risk of leukopaenia when given with azathioprine. **Warfarin:** azathioprine reduces the effect of warfarin. **Co-trimoxazole** and trimethoprim: can cause life threatening haematotoxicity when co-prescribed with azathioprine. **ACE-inhibitors:** may cause anaemia **Febuxostat:** co-prescription of azathioprine with febuxostat is not recommended by the manufacturer.

	Immunisation with live vaccines is not recommended. Annual flu vaccinations are recommended.
Reminder to ask patient about specific problems	

Section 6: Contra-indications, Cautions and Special Recommendations

Please list

Cautions:

TPMT deficiency: may be associated with delayed haematotoxicity including bone marrow toxicity.
Sunscreens and protective covering should be encouraged to reduce sunlight exposure.
Localised or systemic infection (including **hepatitis B or C and tuberculosis**).

Pregnancy and breast feeding should be avoided in patients taking azathioprine. However azathioprine has been widely used as immunosuppression in pregnant patients when clinically indicated and a careful assessment of the risk versus benefit is advised.

Patients should avoid contact with people who have active chickenpox or shingles and report any contact to their GP and hospital specialist. If immunosuppressed patients are exposed to chickenpox or shingles, they will need to be assessed for susceptibility and the need for aciclovir post exposure prophylaxis, see: UKHSA guidance: Guidelines on post-exposure prophylaxis (PEP) for varicella/shingles and the Green Book Chapter 34.

Contra-indications:
TPMT deficiency
Lesch-Nyhan syndrome

Section 7: Advice to the patient

Advice for prescribing clinician to inform patient

1. Discuss potential benefits and side-effects of treatment with the Specialist and/or GP.
2. Share any concerns they have in relation to their treatment.
3. To report any side-effects to the Specialist and/or GP (see individual drug fact sheet for specific information).
4. To ensure that the patient held record if used is presented at every consultation (in primary or secondary care).
5. To agree to and attend for the monitoring of therapy (including having blood tests carried out at agreed intervals) and assessment of outcomes, to assist health professionals to provide safe, appropriate treatment.
6. To use adequate contraception, report any suspected pregnancy to the GP and/or Specialist and inform Specialist in a timely manner if plans to conceive.
7. To inform GP/Specialist/pharmacist of all medicines (including OTC preparations) that they are currently taking.

Section 8: Responsibilities for Secondary Care

Core responsibilities

1. Initiating treatment and prescribing for the first three months
2. Undertaking the clinical assessment and monitoring for the first three months.
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. blood test is due.

5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of Azathioprine.
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see section 5.

Other specific to drug

1.

Section 9: Responsibilities for Primary Care

Core responsibilities

1. Take on shared care proposal from the specialist to monitor and prescribe after the patient has been commenced on treatment. (The time from commencing treatment to agreeing shared care will vary between practices depending on prior agreement with the practices with the local rheumatology department and the practice ability and capacity to safely treat and monitor patients. Some practices may be unable to take on shared care until patient is stabilised on therapy)
2. If shared prescribing is declined, explain to the specialist in writing (fax preferred), the reason for this, copying in the pharmacy lead for the CCG.
3. To ensure that all relevant staff and patients are aware of the shared care arrangements. Blood test results, dosage adjustments, should be recorded in the patient held record and GP medical record. Any dosage adjustments should also be recorded in computer-based prescribing systems.
4. The dosage regimen should be clearly explained to the patient.
5. Contact the specialist to discuss any significant changes in the blood test results or patient's condition e.g. the medication becomes less effective.
6. Respond to dosage changes advised and prescribe appropriately. Receive copies of any blood test results carried out in secondary care for information and record in patient's record appropriately.
7. Monitor the patient for any side-effects to therapy and refer back to the Specialist should any serious side-effect occur. Side-effects / discontinuation of medication should be documented in the patient held record.

Other specific to drug

1.

Section 10: Contact Details

Name	Organisation	Telephone Number	E mail address
Dermatology Specialist Nurses	Bristol Dermatology Centre, BRI,UHBristol NHS Foundation Trust	0117 342 2640	Tracey.Wheeler@uhbristol.nhs.uk Tonia.Clarke@uhbristol.nhs.uk
Dermatology Consultants UHB and Weston	Bristol Dermatology Centre, BRI,UHBristol NHS Foundation Trust	0117 342 2234	DermatologySecretaries@uhbristol.nhs.uk

Dermatology Registrar on call	Bristol Dermatology Centre, BRI,UHBristol NHS Foundation Trust	**0117 923 0000 ask for on call registrar**	
Dermatology Consultant NBT	Bristol Dermatology Centre, BRI,UHBristol NHS Foundation Trust	0117 414 7596	
Consultant Oral Medicine Konrad S Staines	Oral Medicines Department Bristol Dental Hospital	01173429512	

Section 11: Document Details

Date prepared	May 2015 Change to information about PEP for varicella/shingles February 2023 added by BNSSG Formulary Team.
Prepared by	Dr Debbie Shipley
Date approved by JFG	April 2016
Date of review	April 2018
Document Identification: Version	Azathioprine Derm SCP V3.1

Section 12: Collaboration

Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Aligned as closely as possible to current azathioprine SCPs.
2. Sent to dermatology consultants UHB (includes Weston) and NBT and dermatology CNSs for comment and approval
3. Send to Consultant in Oral Medicines

Section 13: References

Please list references

1. British Association of Dermatologists' guidelines for the safe and effective prescribing of Azathioprine 2011. Meggitt SJ et al. BJD 20011 165, pp711-734