NHS LINCOLNSHIRE in association with
UNITED LINCOLNSHIRE HOSPITALS TRUST

SHARED CARE GUIDELINE: Management of Inflammatory Bowel Disease – azathioprine and mercaptopurine.

General Principles

Shared Care Responsibilities:
In its guidelines on responsibility for prescribing (circular EL (91) 127) between hospitals and general practitioners, the Department of Health has advised that legal responsibility for prescribing lies with the doctor who signs the prescription. (BNF, 76, September 18 - March 2019, p. 5)
Aims:
(1) The aim of shared care guidelines is to provide information and/or guidance to GPs and hospital staff relating to the potentially complex implications of sharing patient care for a specific drug between primary and secondary/tertiary care.
(2) Specific shared care guidance should be available for any high cost or high-risk drug therapy or device that may be prescribed for a patient following specialist referral. Such guidance will only be produced where shared care is considered an appropriate option.
(3) Each guideline will include a clear statement of the responsibilities of both the GP and the specialist unit within the overall provision of the treatment to the patient.
(4) Shared care guidelines will ensure that the GP has sufficient information available to undertake to prescribe a specialist treatment if s/he so wishes. It is not the intention of these guidelines to insist that GPs prescribe such treatment and any doctor who does not wish to accept clinical or legal responsibility to prescribe such a drug is under no obligation to do so. Nonetheless the development of a shared care guideline will only be undertaken within the context of a broad acceptance between Lincolnshire Prescribing and Clinical Effectiveness Forum (PACEF) and secondary/tertiary care that GP prescribing of such a treatment is appropriate within the constraints of formal shared care. Any drug approved for the development of a shared care guideline will automatically be classified as amber on the Lincolnshire Traffic Lights List and, if high-cost, will be supported financially through the High Cost Drugs Reserve. Thus there should be no financial reason why a GP should be deterred from prescribing a high cost drug under a shared care guideline.

Further copies

Further copies of any guideline in this series are available from members of the Optum Health System Support (HSS), Medicines Management and Optimisation (MMO) Team.
Optum MMO email - ohs.mmo.sharedservices@nhs.net

Date of Issue: September 2019
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Principles of shared care

NHS England published Guidance - Responsibility for prescribing between Primary, Secondary and Tertiary care – January 2018.

Extracts from guidance highlighting the key recommendations:
(Numbering kept from original document, for reference)

1.0 Introduction

1.1 Shared Care Prescribing guidelines are local policies to enable General Practitioners to accept responsibility for the prescribing and monitoring of medicines/ treatments in primary care in agreement with the initiating service.

1.4 Where possible shared care should be disease specific rather than medicine specific and link into complement local integrated care pathways and shared care policies. Medicines and conditions suitable for shared care will be identified by local medicines committees and will be classified as AMBER (AMBER 1 for Lincolnshire) through the traffic light system

. … However it should be remembered that the provision of shared care prescribing guidelines does not necessarily mean that the GP has to agree to accept clinical and legal responsibility for prescribing; that they should only do so if they feel clinically confident in managing that condition.

2.3 reasonable predictable clinical situation

2.3.1 Transfer of clinical responsibility to primary care should only be considered where the person's clinical condition is stale or predictable.

2.4 Agreement of shared care between consultant and GP

2.4.1 Referral to the GP should only take place once the GP has agreed in each individual case and the hospital or specialist will continue to provide prescriptions until a successful transfer of responsibilities. The GP should confirm the agreement and acceptance of the shared care prescribing arrangement and that the supply arrangements have been finalised. The secondary/ tertiary provider must supply an adequate amount of the medication to cover the transition period. The patient should then be informed to obtain further prescriptions from the GP.

2.7 Clear definition of responsibility

2.7.1 The areas of care for which each clinician has responsibility should be clearly defined.

2.8 Clinical responsibility

2.8.1 Clinical responsibility for prescribing is held by the person signing the prescription who must also ensure adequate monitoring.

2.9 Communication network & emergency support

2.9.1.Telephone details and (if appropriate) secure email addresses of both parties should be exchanged and recorded. This will enable the practice to access timely advice, guidance and information if problems arise, and will also enable secondary care clinicians to easily contact the GP if necessary. This should include out of hours contact numbers, how to access the on-call duty doctor. Patients and their carers should also be provided with contact details for support and help if required both in and out of hours.

2.9.2 People who are being treated on the advice of a secondary care team, but are no longer being seen in that setting, may still need a review should problems arise. The appropriate level of care or advice should be available from the secondary care team in a timely manner without necessarily requiring a new referral.

6.0 Monitoring

6.0.1 All appropriate monitoring arrangements must be fulfilled. The person delivering that aspect of the shared care agreement should ensure that the resources to do this are in place in the clinical setting in which they are delivered.

Drugs covered by this agreement

Azathioprine(AZA) and Mercaptopurine (MP)
Indications to use in IBD:
In Crohn's disease:
For induction and maintenance of remission, as steroid sparing agent, to maintain surgically induced remission, to prevent recurrence of complicated disease following surgery, as adjunct treatment with biologics such as infliximab and Adalimumab to induce or maintain remission
In Ulcerative colitis:
For induction and maintenance remission in mild to moderately severe colitis. In acute severe colitis, AZA/MP should not be used but once induction is achieved with cyclosporine, AZA/MP is started to maintain remission.

Specialist Responsibilities

The specialist secondary/tertiary care service will:

1. Confirm the diagnosis of IBD and rationale for starting azathioprine (AZA) /mercaptopurine (MP).
2. Exclude underlying active/occult infections with screening blood tests.
3. Discuss the benefits and side effects of the treatment with the patient. Ensure that the patient understands the warning signs and symptoms to report.
4. Patient signs treatment agreement
5. Undertake pre-treatment screening Full Blood Count (FBC) U&Es, Liver Function Tests (LFTs) and TMPT assay.
6. Check viral serology (hepatitis B and C, HIV, Varicella zoster and Epstein Barr)
7. Assess co-morbidities, including respiratory, renal and liver disease
8. Initiate AZA/MP treatment and monitor blood tests as per protocol.
9. When treatment is stabilized (patient is tolerating the drug well and initial blood test monitoring is satisfactory), send share care agreement request to GP.
10. Ensure that the patient continues to receive supplies of medication and the required level of monitoring until the GP formally agrees to share care.
11. Communicate promptly any changes in blood test monitoring and modification of dose to the GP, if applicable.
12. Periodically review patient's clinical condition in Consultant or IBD CNS clinic.
13. Have a mechanism in place to receive rapid referral/review request from the GP in the event of deteriorating clinical condition or other concern.
14. Follow up any adverse drug reactions reported by the GP and report back to the GP.
15. Advise the GP on continuing or stopping AZA/MP therapy following medical review of the patient and associated drug therapy.

GP Responsibilities

The GP will:

1. Notify the consultant/specialist service provider in writing, within two weeks, if they accept share care.
2. Prescribe AZA/MP for the patient once the dose has been stabilized and blood test monitoring is satisfactory.
3. Undertake the ongoing monitoring as detailed on pages 4 & 5 of this protocol.
4. Report any adverse events to the consultant or specialist nurse and stop/modify treatment on their advice immediately if an urgent need arises.
5. Remain vigilant to the risk of potential drug interactions.
6. Report symptoms of disease flare to the consultant or specialist nurse.
7. Carry out any investigations that are communicated and deemed appropriate
8. Follow recommended immunization schedule:
   a) Annual flu vaccination in recommended.
   b) Pneumococcal vaccination is recommended once (check antibody titre every 5 -10 years)
9. In patients exposed to chicken pox or shingles, passive immunisation should be considered for varicella. Refer to the Green Book – Immunisation against infectious disease. (https://www.gov.uk/government/publications/shingles-herpes-zoster-the-green-book-chapter-28a
10. Live vaccine should be avoided with AZA/MP treatment.

Referral Criteria

1. The specialist service will continue to monitor blood tests and supply treatment until the GP has accepted responsibility for shared care.
2. Patients will have been stabilized on AZA / MP and will have received at least 3 months treatment prior to transfer of care.

Licensed Indications

AZA and MP are widely used in the treatment of Inflammatory Bowel Disease (IBD) (Ulcerative Colitis and Crohn's disease) as steroid sparing agents as well to maintain steroid free remission. They are however unlicensed for use in IBD.
In Crohn's disease, they are effective in inducing and maintaining long term remission. Thiopurines are also co-prescribed with biologic treatment (such as infliximab or Adalimumab).
Thiopurine is also used to maintain long term remission of ulcerative colitis.
Decision as to whether patient is initiated on AZA /MP rests with the treating consultant.

Recommended Dosage and Administration

Azathioprine – 1.5 mg/kg/day increasing to 2- 2.5mg/kg/day after 4-6 weeks adjusted within these limits depending on clinical response and haematological/biochemical tolerance. Start with a lower dose of 1 - 1.5mg/kg, or less if TPMT level is low.
Mercaptopurine – 1-1.5mg/kg/day. Mercaptopurine may be taken with food or on an empty stomach, but patients should standardize the method of administration. The drug should not be taken with milk or dairy products. Mercaptopurine should be taken at least 1 hour before or 2 hours after ingestion of milk or dairy products.

Preparations Available

Azathioprine tablets 25mg & 50mg
Mercaptopurine 50mg scored tablets

Adverse Effects

For further information on adverse effects please refer to the online BNF which can be accessed via https://bnf.nice.org.uk/
or from the Summary of Product Characteristics which can be accessed via: www.medicines.org.uk

Azathioprine

Common or very common – bone marrow depression (dose related0 increased risk of infection, leucopenia, thrombocytopenia.
Uncommon – anaemia, hepatic disorders, hypersensitivity, pancreatitis.
Rare or very rare – agranulocytosis, alopecia, bone marrow disorders, diarrhea, gastrointestinal disorders, neoplasms, photosensitivity reaction, pneumonitis, severe cutaneous adverse reactions (SCARc).
Frequency not known – nodular regenerative hyperplasia, sinusoidal obstruction syndrome.

Specific adverse effects – further information

Nausea – May occur, usually starting early during the course of treatment, and usually resolves after a few weeks without any alteration to dose. Moderate nausea may be managed by using divided daily dose, taking doses after food, prescribing concurrent antiemetics or temporarily reducing the dose.
Hypersensitivity reactions (including malaise, dizziness, vomiting, diarrhoea, fever, rigors, myalgia, arthralgia, rash , hypotension and renal dysfunction). **Immediately withdraw treatment and contact specialist for advice.**
Red cell aplasia – cases have been reported. If occur consider reducing dose or discontinuing treatment – contact specialist (Haematology) for advice.
Neutropenia and thrombocytopenia –neutropenia is dose dependent. Management of neutropenia and thrombocytopenia requires careful monitoring and dose adjustment. Contact specialist for advice.

Mercaptopurine

Common or very common – anaemia, appetite decreased, bone-marrow depression, diarrhoea, hepatic disorders, hepatotoxicity (more common at high doses), leucopenia, nausea, oral disorders, thrombocytopenia, vomiting.
Uncommon - arthralgia, fever increased risk of infections, neutropenia, pancreatitis, rash.
Rare or very rare - alopecia, face oedema, intestinal ulcer, neoplasms, oligozoospermia.
Frequency not known – photosensitivity reaction.

There is slight increased rates of viral, fungal, parasitic, bacterial, and mycobacterial infections in patients exposed to thiopurine therapy. Viral infections are of particular concern with a predisposition to cytomegalovirus, varicella zoster virus and Epstein-Barr virus (EBV) infections. Risk is higher when combined with corticosteroid therapy. Risk of therapy should therefore be balanced with benefits and it would need appropriate prevention (such as vaccination), vigilance, prompt diagnosis and effective treatment.

For further information refer to Summary of Product Characteristics.

Drug Interactions

For detailed information on drug interactions, please refer to the online BNF which can be accessed via https://bnf.nice.org.uk/
or from the Summary of Product Characteristics which can be accessed via: www.medicines.org.uk
Below is a summary of some of the key interactions.

Azathioprine

ACE inhibitors
Increased risk of anaemia and leucopenia. Consider alternatives to ACEI.
Allopurinol
Avoid concomitant use. Enhances effects and risk of myelosuppression. Reduce azathioprine to 25% of original dose if concomitant use can't be avoided.
Aminosalicylates (mesalazine, olasalazine, balazide, sulfasalazine).
Caution. Increased risk of haematological toxicity.
Anticonvulsants (phenytoin, carbamazepine, sodium valproate)
Caution. Possible reduced absorption of these anticonvulsants.
Co-trimoxazole
Avoid. Increased risk of serious haematological toxicity.
Febuxostat
Avoid. Increased risk of toxicity.
Trimethoprim
Avoid. Increased risk of serious haematological toxicity.
Warfarin
Caution. Possible reduced anticoagulant effect. May need to reduce azathioprine dose or increased warfarin dose.
Live vaccines
Avoid immunisation with live vaccines. BCG vaccine, influenza (live), MMR (live), rotavirus, typhoid (oral), varicella –zoster, yellow fever (live) increases risk of generalised, potentially life threatening infection

Mercaptopurine

Ribavirin
Severe myelosuppression has been reported following concomitant administration of ribavirin and 6-mercaptopurine, therefore concomitant administration is not advised.
Myelosuppressive agents
When mercaptopurine used with other myelosuppressive agents caution should be used and dose reductions may be needed based on haematological monitoring.
Allopurinol (& other xanthine oxidase inhibitors)
Avoid concomitant use. Enhances effects and risk of myelosuppression. Reduce mercaptopurine to 25% of original dose if concomitant use can't be avoided. Other xanthine oxidase inhibitors such as febuxostat may decrease the metabolism of mercaptopurine. Concomitant administration is not recommended, as data are insufficient to determine an adequate dose reduction.
Aminosalicylates (mesalazine, olasalazine, balazide, sulfasalazine).
Caution. Increased risk of haematological toxicity. Lower doses of mercaptopurine may need to be considered.
Methotrexate
If used concomitantly risk of increased toxicity – monitor full blood count. Dose adjustment may be required.
Infliximab
Interactions have been observed between azathioprine (a pro-drug of 6-mercaptopurine and infliximab). Closed monitoring is required if used concomitantly.
Anticoagulants
Inhibition of the anticoagulant effect of warfarin and acenocoumarol have been reported when co-administered with mercaptopurine. Higher doses of anticoagulants may be required. It is recommended there is increased monitoring of anticoagulants.

Precautions and Contraindications

For further information on contraindications and cautions in use, please refer to the online BNF which can be accessed via https://bnf.nice.org.uk/
or from the Summary of Product Characteristics which can be accessed via: www.medicines.org.uk

Azathioprine
Contraindications
Hypersensitivity to azathioprine or mercaptopurine or any of the excipients of the medication.
Moderate/severe renal or liver impairment
Significant haematological impairment including bone-marrow function.
Pancreatitis
Thiopurine Methyl Transferase (TPMT) deficiency – homozygous state: **serious and fatal toxicity may occur.**
Pregnancy- treatment should not generally be initiated during pregnancy but see caution section.
Breast feeding – present in milk in low concentration, no evidence of harm in small studies – use if potential benefit outweighs risk.
Severe infections
Cautions
Patients who have not previously had chicken pox should be advised to seek medical attention if they come into contact with this or shingles. Consider temporary withdrawal of azathioprine. BAD guidance recommends prompt use of oral antivirals acyclovir, valaciclovir in all patients. Patients receiving azathioprine exposed to chickenpox or shingles, passive immunisation should be carried out using varicella-zoster immunoglobulin.

The administration of live vaccines is contra-indicated on theoretical grounds. Patients with a deficiency in the enzyme thiopurine methyltransferase (TPMT) as these patients may have a higher risk of bone marrow toxicity. This can be exacerbated by co-administration with drugs that inhibit TPMT such as sulfasalazine, mesalazine, balsalazide or olsalazine.
Use with caution in patients with renal failure, hepatic disease and frail elderly: dosages used should be at the lower end of the range.
Hepatitis B&C infection or a history of tuberculosis.
Use with caution in patients with confirmed or suspected alcoholism.
Patients prescribed azathioprine should be advised to limit exposure to sunlight by wearing protective clothing and using high factor sunscreens.
Patients should be advised to report any signs of bone marrow suppression or hypersensitivity i.e. infection, fever, cough, unexplained bruising or bleeding, fatigue, hypotension, myalgia, dizziness to their GP and this should be reported to the hospital clinician or specialist nurse.

Use in pregnancy

As both ulcerative colitis and Crohn's disease occur in young adults, managing IBD in pregnancy is not uncommon. Maintaining adequate disease control during pregnancy is essential for both maternal and foetal health.
If planning to conceive patients should be advised to contact their gastroenterologist.
If an unplanned pregnancy occurs drug treatment should not be discontinued but advice should be sought from the specialist service on the future management of the patient.
It is important that the risk benefit ratio of continuing treatment is discussed with the patient and this is the responsibility of the specialist service.
Within the current guidelines on the management of inflammatory bowel disease in adults from the British Society of Gastroenterology the advice is to continue use of azathioprine during pregnancy as the risks to the foetus from disease activity appears to be greater than continued therapy.
The current edition of the BNF states:
There is no evidence that azathioprine is teratogenic, however there have been reports of low birth weight babies and premature births

Mercaptopurine

Contraindications

Hypersensitivity to mercaptopurine or azathioprine or any of the excipients of the medication.
Thiopurine Methyl Transferase (TPMT) deficiency – homozygous state: serious and fatal toxicity may occur.
Pregnancy – avoid as teratogenic.
Breast feeding - discontinue breast feeding.
Lactose – those with rare hereditary problems with galactose intolerance , complete lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Cautions

Hepatic impairment – may need dose reduction
Renal impairment - reduce dose
Bone marrow depression - treatment with mercaptopurine known to cause bone marrow suppression leading to leukopenia and thrombocytopenia and less frequently anaemia. Monitor full blood counts frequently (see monitoring section)
Hepatotoxicity – mercaptopurine is hepatotoxic and liver function tests should be monitored (see monitoring section). Gamma Glutamyl transferase (GGT) levels in plasma may be particularly predictive of withdrawal due to hepatotoxicity. More frequent monitoring may be advisable in those with pre-existing liver disease or those receiving other potentially hepatotoxic therapy.

TPMT Deficiency – those with inherited deficiency of TPMT are unusually sensitive to the myelosuppressive effect of mercaptopurine. This problem can be exacerbated by co-administration with medicines that inhibit TMPT such as olsalazine, mesalazine or sulfasalazine. TPMT levels will be monitored before start of and during therapy with mercaptopurine.
Infections – As mercaptopurine is immunosuppressive patients have increased susceptibility to viral, fungal and bacterial infections, including severe or atypical infection and viral reactivation. The infectious disease and complications may be more severe in these patients than in non- treated patients.
UV exposure – patients treated with mercaptopurine are more susceptible to the sun. Exposure to sunlight and UV light should be limited and patients should be recommended to wear protective clothing and to use sunscreen with a high protection factor.

Monitoring

Baseline:
Baseline monitoring FBC, U&E's, LFTs, Albumin and creatinine/calculated GFR.
TPMT level should be checked
Check Varicella status - check serology in patients where there is an unclear history of chicken pox or shingles.
Check hepatitis B, C, E, HIV and Epstein Barr virus status.
Following initiation of treatment, monitor FBC and LFT at weeks 2, 4, 6, 8 and 12. Thereafter monitor every 3 months.
Following dose increases FBC, LFTs and U/Es should be monitored every 2 weeks until on a stable dose for 8 weeks Thereafter monitor every 3 months.
Seek specialist advice and stop treatment:

Laboratory results	
Value	**Action**
WBC >3 x 10^9/L	Continue with the same dose
WBC <3 x 10^9/L	Continue treatment, check vitamin B12 and folate levels if this has not been done in last 6 months and discuss result with specialist. Low levels of vitamin B12 and folate can be indicative of bone marrow dysfunction which can result in leucopenia. Specialist may request thiopurine metabolite levels.
WBC <2.5 x 10^9/L	Stop drug for a week and contact specialist for advice. Specialist may request additional tests as above. Repeat FBC test as instructed by specialist. Specialist may request treatment is started at a lower dose, with frequent (weekly) monitoring of FBC.
WBC <1.5 x 10^9/L	Stop treatment immediately. Contact specialist for advice.
Neutrophil 1-1.5 x 10^9/L	Contact specialist for advice. Repeat FBC as instructed by specialist Specialist may request thiopurine metabolite levels.
Neutrophil <1.0 x 10^9/L	Stop treatment immediately. Contact specialist for advice. If the patient is unwell or febrile, admit to hospital.

Value	Action
Lymphocyte <0.5 x 10^9/L	Stop treatment immediately. Contact specialist for advice. If the patient is unwell or febrile, admit to hospital.
Platelet <150 x 10^9/L	Contact specialist for advice Repeat FBC as instructed by specialist
LFT > 2 times normal range of parameters (AST/ALT/alkaline phosphatase, GGT, serum bilirubin)	LFT's twice the normal range or greater Stop treatment and seek specialist advice LFTs Abnormal but not twice normal range, Seek specialist advice. Recheck LFTs after a week. If still abnormal or worsening stop treatment.

Expected results
MCV increase above normal range
Lymphocytes reduce below normal range

Clinical condition
Acute abdominal symptoms of pancreatitis – stop drug immediately and seek specialist advice
Fever, arthralgia, myalgia on starting - stop drug and seek specialist advice
Skin reactions significant and new – stop drug and check FBC. If FBC abnormal contact specialist for advice. Wait until rash resolves and consider restarting at reduced dose, providing no blood dyscrasias.
Sore throat, oral ulceration or abnormal bruising – withhold drug until FBC results known. Contact hospital specialist
Nausea or anorexia – may be self-limiting, reduce dose or contact specialist for advice. If dose increases required, increase dose slowly. Stop drug if persistent
If patient is systemically unwell and/or suspicion significant infection - **stop drug and seek specialist advice or admit in hospital.**
Varicella –if in contact with the virus, contact hospital specialist clinician.

Information Given to the Patient

Patient information leaflet supplied to patient during initial clinic visit when treatment first discussed. Benefit and side effects of treatment with thiopurine should be discussed with patient.

All patients are encouraged by the gastroenterology team to contact Crohn's and Colitis UK. Their website provides a wide range of advice/information for patients and carers which includes patient information leaflets on treatment with azathioprine.
www.crohnsandcolitis.org.uk
British Society for Gastroenterology has produced an information sheet for patients on the use of azathioprine and mercaptopurine which also may be a useful reference for prescribers. A copy of this sheet can be downloaded from their website.
http://www.bsg.org.uk/pdfworddocs/azaibdpt.doc

Contact Details

Nurse specialists
For Lincoln, Louth and Grantham
Clinical Nurse Specialist – Inflammatory Bowel Disease
Tel no 01522 512512 Ext 582006 or Bleep 2138
For Boston
Clinical Nurse Specialist – Inflammatory Bowel Disease
Tel 01205 446549 Bleep 621

References

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Date:

NHS No:

Dear Dr

Re :

Diagnosis :

Current Medication :

You may be aware that the trust has adopted a shared care protocol for the monitoring and prescribing of Azathioprine (or Mercaptopurine).

We have identified the above patient who would be suitable for shared care monitoring.

I would be grateful if you would FAX or post the enclosed pro forma confirming your acceptance of these arrangements over the monitoring and prescribing of Azathioprine, as soon as possible. We can then update our records and inform the patient accordingly.

If you have any questions please don't hesitate to contact me on Tel: 01522 512512 Ext 582006 or Fax: 01522 573101

Yours Sincerely,

Caroline Hayhurst
Lead Inflammatory Bowel Disease
Clinical Nurse Specialist

Section A: to be completed by Secondary Care

Consultant:

Indication for prescription:

Drug Prescribed:

Date started:

Current Dose:

Monitoring variations:

Date next blood test due:

Next Clinic review due: ……..…… months' time

Section B: to be completed by Practice – to be returned back to IBD CNS team

The above patient has/has not (please delate as appropriate) been accepted into our monitoring service as per the shared care guidelines.

Practice date for next blood test:

Practice Stamp:

Signed:

Return date: