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Coventry & Warwickshire Area Prescribing Committee

Shared Care Agreement

Mercaptopurine oral: *for the treatment of inflammatory bowel disease and auto immune hepatitis in adults*

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement (SCA) outlines suggested ways in which the responsibilities for managing the prescribing of oral **Mercaptopurine** can be shared between the specialist and general practitioner (GP). GPs are **invited** to participate. 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.
If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

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

Specialist Responsibilities
1. Discuss the benefits and side effects of treatment with the patient. 2. Initiate treatment with oral mercaptopurine. 3. Ask the GP whether he or she is willing to participate in shared care by emailing the shared care request letter, (continue to prescribe until GP has agreed to take over prescribing). 4. Monitor patients as described overleaf, or advise GP on which to monitor. Ensure copies of results are sent to the GP. 5. Communicate promptly with the GP when treatment is changed or needs to be changed by the GP, any results of the monitoring undertaken, and assessment of adverse events. 6. Have a mechanism in place to receive rapid referral of a patient from the GP in the event of adverse effects or deteriorating clinical condition. 7. Review the patient's condition & monitor response to treatment regularly where indicated, at least every 12 months. Report adverse events to the MHRA, on a Yellow Card (www.mhra.gov.uk/yellowcard) and to the GP and appropriate Medicines Optimisation team.

General Practitioner Responsibilities
1. Reply to the request for shared care as soon as practicable by emailing back the shared care letter. If declining the request please indicate the reason for declining. 2. Prescribe mercaptopurine at the dose/frequency recommended for a maximum of 1 month at a time. 3. Adjust the dose as advised by the specialist. 4. Prescribe and administer pneumococcal vaccine and annual influenza vaccine unless otherwise advised by the initiating specialist. 5. Monitor any parameters considered necessary as described overleaf, if agreed with the specialist to do so. 6. Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment. 7. Refer back to specialist if the patient's condition deteriorates, or if there are other concerns. 8. Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises. Report adverse events to the MHRA on a Yellow Card (www.mhra.gov.uk/yellowcard) and inform the specialist and appropriate Medicines Optimisation team.

Patient/carer's Role
1. Report to the specialist or GP if he or she does not have a clear understanding of the treatment. 2. Share any concerns in relation to treatment. 3. Inform specialist or GP of any other medication being taken, including over-the-counter, homeopathic, herbal or illicit products. 4. Report any adverse effects to the specialist or GP. The patient may also choose to report any adverse drug reaction direct to the MHRA on a Yellow Card, available at pharmacies, GP surgeries or from the Yellow Card hotline (freephone 0808 100 3352 during business hours). The form can also be downloaded from www.mhra.gov.uk/yellowcard

Back-up Advice and Support: See patient letter and/or other supporting information for contact details of clinician(s) initiating and stabilising patient prior to request for shared care.

SUPPORTING INFORMATION:

Licensed indications: **UNLICENSED FOR ULCERATIVE COLITIS, CROHNS & AUTO IMMUNE HEPATITIS**
Although unlicensed, mercaptopurine is widely used in ulcerative colitis and Crohn's disease as adjunctive therapy and as corticosteroid-sparing therapy. Mercaptopurine is an antimetabolite (cytotoxic purine analogue) drug that interferes with nucleic acid synthesis, thus is licensed to maintain and induce remission in leukaemia.

Dosage and administration: 1-1.5mg/kg daily, although some patients may respond to a lower starting dose of 0.75mg/kg daily.
Dosage may need to be reduced in renal or hepatic impairment.
Mercaptopurine is available as 50 mg scored tablets.

Monitoring:
Specialist baseline and annual: FBC, ESR, CRP, U&Es, creatinine, LFTs, TPMT (thiopurine methyltransferase) genetic testing or enzyme levels at discretion of specialist. Ask about oral ulceration/sore throat, unexplained rash or unusual bruising at every consultation.

GP: FBC & LFTs weekly for at least 8 weeks, or until stable. When stable monthly thereafter. When the disease, dose and blood monitoring is stable the FBC and LFT can be reduced to every 3 months.
U&E, creatinine at 4, 12 & 26 weeks, then annually. CRP & ESR every 3 months. Ask about oral ulceration/sore throat, unexplained rash or unusual bruising at every consultation.

Contraindications: previous hypersensitivity to azathioprine or mercaptopurine. TPMT deficiency - avoid if deficient or reduce dose if low levels**.**

Cautions: Pregnancy/contraception: women of childbearing potential and men receiving mercaptopurine should be advised to use effective contraception. Patients discovered or planning to become pregnant should be referred to the initiating specialist at the earliest opportunity without discontinuing mercaptopurine. Women being treated with mercaptopurine should not breastfeed.
Patients receiving mercaptopurine are at increased risk of lymphomas and malignancies of the skin: avoiding excessive exposure to the sun and use of high factor sunscreens are advised.
Live vaccines should be avoided, except on the advice of initiating specialist.

Side effects: Refer to SPCs for full list of adverse effects.
General signs of malaise such as headaches, dizziness, hair loss, diarrhoea, rash, myalgia and arthralgia occur infrequently. If severe or persistent refer to the initiating specialist.
Nausea can occur initially but can be reduced by taking the tablets after food.
Bone marrow suppression, leucopenia, anaemia and thrombocytopenia: GPs should be alert to any oral ulceration/sore throat, unexplained rash or abnormal bruising or bleeding.
Abnormal liver function can occur early in treatment leading to hepatotoxicity.
Biliary stasis, pancreatitis and cholestasis have been reported.

Mercaptopurine does not have black triangle (▼) status. All serious suspected adverse reactions (even well recognised or causal link uncertain) should be reported to the MHRA.

Drug interactions: The following drugs should not be initiated by a GP unless discussed with the initiating specialist:
warfarin: effect may be reduced requiring an increased dose of warfarin
aminosalicylates eg olsalazine, mesalazine, sulfasalazine: contribute to bone marrow toxicity – increased monitoring may be required
trimethoprim or co-trimoxazole: potential risk of haematological toxicity
clozapine – increased risk of agranulocytosis
Do not prescribe concomitant allopurinol due to risk of severe myelosuppression. If necessary to co-prescribe, the dose of mercaptopurine should be reduced to 25% of the usual dose. Febuxostat should also be avoided.
Mercaptopurine may reduce the absorption of phenytoin and digoxin.

Cost: At current prices, one year's treatment at a dose of 50 mg daily costs: £737 (Drug Tariff May 2015)

References:

1. Mowat C, Cole A, Windsor A, et al. On behalf of the IBD Section of the British Society of Gastroenterology Guidelines for the management of inflammatory bowel disease in adults Gut (2011). www.bsg.org.uk. Accessed 20.4.2011
2. Drug treatment for IBD patients. National association for Colitis and Crohn's. www.nacc.org.uk. Accessed 20.4.2011
3. BNF 60 September 2010
4. SPC. Puri –Nethol. www.emc.org.uk. Accessed 20.4.2011