Yeovil District Hospital NHS
NHS Foundation Trust

ORAL METHOTREXATE POLICY
(excluding use in cancer care)

Version Number	3	Version Date	September 2018
Policy Owner	Chief Pharmacist		
Author	Clinical Pharmacy Manager		
First approval or date last reviewed	December 2010 (first approved) July 2014 (last reviewed)		
Staff/Groups Consulted	Consultant Rheumatologists Rheumatology CNS Consultant Dermatologists Dermatology CNS		
Draft agreed by Policy Owner	Chief Pharmacist September 2018		
Discussed by Policy Group	Medicines Committee September 2018		
Approved by Medicines Committee	September 2018		
Next Review Due	September 2021		
Policy Audited			
Equality Impact Assessment Completed	September 2018 Clinical Pharmacy Manager		

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1. RATIONALE

Oral methotrexate is a safe and effective medication at the right dose and with appropriate monitoring. In July 2004 the National Patient Safety Agency (NPSA) published 'Patient Safety Alert 03: Reducing the harm caused by oral methotrexate'. However, between 2004 and 2006, the NPSA received 165 reports of patient safety incidents involving oral methotrexate. Of these, 14 happened before the launch of the patient safety alert and the remaining 151 happened after this date. The NPSA issued a subsequent alert 'Patient Safety Alert 13: Improving compliance with oral methotrexate guidelines' in June 2006 to remind all NHS organisations of the actions they need to take to prevent such incidents occurring. This policy ensures the implementation of the NPSA action points.

2. AIM

To ensure all prescribing, dispensing and administration of oral methotrexate within Yeovil District Hospital NHS Foundation Trust is in accordance with NPSA Patient Safety Alerts 03 and 13 thereby enhancing patient safety.

3. DEFINITIONS

Methotrexate

Low-dose oral methotrexate (up to 25mg taken weekly) is an antineoplastic agent used to treat a range of inflammatory conditions such as psoriasis, rheumatoid arthritis and inflammatory bowel disease. It has immunosuppressant properties and is used in large doses to treat some cancers.

4. ROLES AND RESPONSIBILITIES

4.1. Consultants

The consultant is responsible for ensuring compliance with this policy.

4.2. Prescribers

It is the prescriber's responsibility to ensure that all action points covered under section 5 of this policy are followed.

4.3. Pharmacy Staff

It is the responsibility of pharmacy staff to ensure that all action points covered under section 6 of this policy are followed.

4.4 Nursing Staff

It is the responsibility of nursing staff to ensure that all action points covered under section 7 of this policy are followed.

5. THE PRESCRIBING OF ORAL METHOTREXATE

Oral methotrexate therapy may only be initiated by a Consultant specialist or Specialist Registrar (usually a Rheumatologist or Dermatologist). Junior doctors may prescribe continuation methotrexate therapy for patients. Rheumatology Clinical Nurse Specialists qualified as independent prescribers may also prescribe methotrexate.

Information on the risks and benefits of oral methotrexate must be given to the patient before treatment is initiated. Confirmation of the patient's understanding and consent should be sought, baseline tests conducted and the monitoring schedule explained. At the point of initiation on oral methotrexate therapy, all patients must be issued with a methotrexate pre-treatment information leaflet and a patient-held monitoring and dosage record.

Responsibility for monitoring therapy remains with the Consultant specialist or Specialist Registrar until arrangements are made for responsibility to be shared with the patient's GP. The Shared Care Protocol for oral methotrexate contains all the relevant information required for care to be shared between Consultant and GP, and to inform all relevant parties about common methotrexate side effects. It is the responsibility of the GP to inform the Consultant within 14 days if they are not willing to prescribe and monitor methotrexate as per the Shared Care Protocol with Somerset CCG.

All staff involved in the care of patients prescribed methotrexate must be aware of patients who present with symptoms such as breathlessness, dry persistent cough, vomiting or diarrhoea, as these can be signs of oral methotrexate toxicity or intolerance.

Prescribers must be satisfied that there are no contra-indications to methotrexate therapy and prior to prescribing all patients should have a full blood count, U&Es, creatinine and liver function tests performed. Any excessive abnormalities in test results should be discussed with the relevant Consultant specialist or Specialist Registrar before treatment is continued.

Prescribers must be aware of the potential for drug interactions with methotrexate and in particular the need to avoid trimethoprim and co-trimoxazole for patients prescribed methotrexate.

Prescribing of methotrexate should be delayed until discussion with the patient's specialist in the following circumstances:

- acute infection
- acute respiratory disease
- acute renal insufficiency
- oral ulceration/sore throat
- unexplained rash
- unusual bruising

All prescribers must avoid the use of "as directed" in prescribing – a specific dose must be applied to each prescription.

For inpatients, the prescriber must record the correct dosage and frequency on the hospital drug administration record and strike out the six days of the week when a dose must not be administered. For frequency, the term 'once weekly' must always be written in full and never abbreviated.

Prescriptions must be complete, legible and include the form, strength, dose and directions in full.

If the clinical condition of a patient prescribed methotrexate deteriorates the continued need for methotrexate prescribing should be carefully considered and fully documented in patient's notes. If treatment is discontinued this should be fully documented in the medical notes and a date set for potential re-introduction of treatment. The methotrexate prescription should be cancelled on the prescription chart in such a way that it is clear that the patient was prescribed methotrexate but that it is not possible to administer any further doses unless the prescription is rewritten.

6. THE DISPENSING OF ORAL METHOTREXATE

On presentation of a methotrexate outpatient prescription, pharmacy staff should ask to see the patient's methotrexate booklet, if available, and check if any dose changes have been made since the last prescription issue. Clinical pharmacists should ask to see the methotrexate booklets of all inpatients prescribed methotrexate on admission to hospital. This should be part of the medicines reconciliation process. Pharmacy should supply a methotrexate booklet to any patient who has not already received one.

Pharmacists should assess the needs of individual patients. Patients with reduced manual dexterity must be assessed for the suitability of the medication containers used for methotrexate and folic acid tablets. Patients should also be asked about any difficulties they may have reading the printed instructions on the labels.

The strength of methotrexate tablet supplied to the patient must stay consistent to prevent any confusion. The patient's methotrexate booklet should be checked, if available, to confirm the previous supply.

Yeovil District Hospital NHS Foundation Trust dispenses only 2.5mg methotrexate tablets (the only exception is for the management of paediatric oncology patients).

Patients should be informed of their dose in terms of quantity of tablets and weekly frequency.

Patients prescribed both oral methotrexate and folic acid should be asked if they are able to easily distinguish between them. Pharmacy are able to supply loose tablets for methotrexate 2.5mg tablets and foil packed tablets for folic acid 5mg tablets for those patients who are unable to differentiate between the two medications.

All pharmacy staff must be aware of patients presenting with symptoms such as breathlessness, dry persistent cough, vomiting or diarrhoea, as these can be signs of oral methotrexate toxicity or intolerance.

Pharmacists must be aware of the potential for drug interactions with methotrexate and inform the prescriber if there are any concerns with the combination of therapy prescribed.

All inpatient prescriptions for oral methotrexate must be clinically checked by a pharmacist. The prescription must clearly indicate the day of the week when methotrexate should be given and the other days of the week must be crossed through. When the clinical check is complete, the prescription must be signed and dated by the pharmacist to indicate that the prescription is correct for that patient.

Normal dispensing procedures should be followed. Any label for methotrexate tablets must contain the additional automatic warnings "take this medication only once each week" and "caution: cytotoxic agent".

7. THE ADMINISTRATION OF ORAL METHOTREXATE TO INPATIENTS

Nursing staff must be aware that methotrexate must only be administered once weekly. All relevant sections of the medication administration record must be checked to ensure methotrexate has not been prescribed more frequently. Nursing staff should be aware that doses for methotrexate usually range between 7.5mg and 25mg once weekly.

Nursing staff must check the patient's wristband against the medication administration record and the pharmacy labels attached to the medicine's container. The patient's name, the medicine, the strength of the tablet, the dose and the timing must also be checked.

Nursing staff must ensure that any prescription for methotrexate has been clinically checked by a pharmacist and that the prescription is signed and dated by that pharmacist. If this is not the case, nursing staff should refer to pharmacy as soon as possible during normal working hours.

Nursing staff must ask the patient to confirm that the methotrexate is required.

Nursing staff must be aware of patients who report symptoms such as breathlessness, dry persistent cough, vomiting or diarrhoea, as these can be signs of methotrexate toxicity or intolerance. Patients reporting these symptoms must be referred back to the prescriber.

Nursing staff must record the medication given on the medication administration record at the time of administration.

8. LIMITATIONS

This is a Trust-wide policy and applies to all staff involved in the prescribing, dispensing and administration of methotrexate.

9. IMPLEMENTATION, MONITORING AND EVALUATION

With the implementation of the above policy, the Trust is fully compliant with the NPSA's Patient Safety Alerts 03 and 13. Audits should be undertaken to establish continuing compliance with these alerts and the co-ordination of such audits should be managed by the Clinical Governance department and the Pharmacy department. An audit to monitor for compliance with the NPSA's Patient Safety Alerts 03 and 13 is included in the Trust's Medicines Optimisation Programme and Audit Plan.

All staff involved in the process of prescribing, dispensing or the administration of methotrexate must report any untoward incidents/errors involving this medication via Safeguard. All reported methotrexate incidents will be discussed by the Medicines Committee.

10. REFERENCES

10.1. Reducing the harm caused by oral methotrexate. Patient Safety Alert 03. National Patient Safety Agency. July 2004.

10.2. Improving compliance with oral methotrexate guidelines. Patient Safety Alert 13. National Patient Safety Agency. June 2006.

11. ANNEX A – EQUALITY IMPACT ASSESSMENT TOOL

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

		Yes / No / N/A	Comments
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
	• Disability	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	No	
4.	Is the impact of the policy/guidance likely to be negative?	No	
5.	If so can the impact be avoided?	N/A	
6.	What alternatives are there to achieving the policy/guidance without the impact?	N/A	
7.	Can we reduce the impact by taking different action?	N/A	

If you have identified a potential discriminatory impact of this procedural document, please refer it to the Trust's lead for Equality & Diversity, together with any suggestions as to the action required to avoid / reduce this impact.

For advice in respect of answering the above questions, please contact the Trust's lead for Equality & Diversity.

Signed – Sharon Hodges, Clinical Pharmacy Manager **Date –** 19th September 2018