SHARED CARE PROTOCOL AND INFORMATION FOR GPs	NHS Lothian
Methotrexate	
Clinical indication: For the treatment of rheumatological inflammatory diseases	
Version 3.0: September 2009	Due for review: **September 2011**

Introduction
With the exception of sulfasalazine, DMARDs are usually started after assessment by a rheumatologist. Methotrexate is a cytotoxic agent and should be prescribed, supplied and administered in accordance with local guidelines.
'Rheumatological Management and Shared Care Guidelines' available on website: *www.refhelp.scot.nhs.uk*

Shared Care
A shared care protocol is used to **facilitate the sharing of care and transfer of prescribing.** This would usually take place once the patient's condition is stable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects. GPs should only take on the prescribing when they are confident in the use of the drug, in the context of the protocol. Contingency plans must be in place to enable the patient to receive the recommended treatment, should the GP decline to prescribe.

Indication for Therapy
Indications – active joint inflammation usually supported by indices of inflammation.
Duration – most drugs require up to 3 to 4 months trial to assess efficacy. Therapy is continued providing the drug is working and there are no side effects.
Relapse is common after withdrawal of therapy.

Preparations Available
Only prescribe 2.5mg tablet formulation

Recommended Dosage and Administration
Most patients commenced on 7.5mg – 10mg **orally once weekly**. Usually titrated by 2.5mg – 5mg fortnightly to target dose (usually 15mg – 20mg once weekly but may be titrated higher at the discretion of the rheumatologist).
Folic acid 5mg (orally) to be taken the day after methotrexate.
May be switched to s/c self-administration for greater efficacy or to minimise some side-effects (switch supervised by CNS in rheumatology clinic).

Cost
28 x 2.5mg tablets = £3.27..

Adverse Effects and Drug Interactions
The incidence and severity of side effects are considered to be dose related.
Common: nausea, diarrhoea, mouth ulcers, rash, haematological abnormalities (leucopenia) and raised LFTs (> 2-3 times upper limit of normal).
Uraemia (though usually only at higher doses), headaches, drowsiness, blurred vision.

Pneumonitis is a rare, but potentially fatal side effect of methotrexate use. This may present initially as a dry, non-productive cough and/or dyspnoea. If pneumonitis is suspected, methotrexate should be discontinued and the patient admitted to hospital urgently.

For a complete list of drug interactions please see the BNF / Summary of Product Characteristics.
New prescription of NSAIDs and aspirin can reduce the excretion of methotrexate, increasing the risk of toxicity. NSAIDs are commonly used in conjunction with methotrexate in inflammatory diseases, therefore, monitoring is essential.
Co-trimoxazole and trimethoprim should not be co-administered with methotrexate (rare reports of acute megloblastic pancytopenia). Folic acid or its derivatives may alter the response to methotrexate (folic acid must not be administered on the same day as methotrexate).

Precautions and Contra-Indications
Cautioned in renal failure and in the elderly; contra-indicated in suspected/actual local or systemic infection and bone marrow failure.

Pregnancy and Lactation
Contraindicated in pregnancy and during breastfeeding. Reliable contraception should be used by males or females during treatment and for at least 3 months after treatment discontinued.

Contact Points
Rheumatology Clinical Nurse Specialists (CNS):
0131 537 1405
Rheumatology SpR (via switchboard):
0131 537 1000
Rheumatology Clinical Pharmacist:
0131 537 1000 (bleep 8461)
Rheumatic Diseases Unit (WGH):
0131 537 1798
Rheumatology Secretary (St John's Hospital):
01506 52 3824

Approved for use by the General Practice Prescribing Committee, LPCD and the Drug & Therapeutics Committee, LUHD.

Shared Care Responsibilities

Aspects of Care for which the Consultant is responsible

- Assessing the need for DMARD.
- Arranging for the patient to receive counselling in verbal and written form.
- Providing relevant baseline investigations.
- Following the patient's response to treatment at the out- patient clinic.
- Communicating advice to the patient's GP re monitoring requirements.
- Decision to switch to s/c self-administration.
- At any stage of treatment, advising GP of concerns re monitoring or potential adverse effects of treatment.

Aspects of Care for which the General Practitioner is responsible

- Prescribing DMARD under the guidance of the consultant.
- Reporting any suspected adverse reactions to the patient's consultant and complete a yellow card if appropriate. Discuss any significant abnormalities with consultant.
- Liaising with the consultant regarding any complications of treatment.
- Monitoring the general health of the patient.
- Monitoring for specific side effects as detailed in "Monitoring" section.
- Provision of pneumococcal and annual influenza vaccination.

Aspects of Care for which the Clinical Nurse Specialist is responsible

- Counselling all patients who are to commence on methotrexate on both the agent itself and its safe administration. Patients are counselled both verbally and are provided with patient information, which provides details on safe handling.

Monitoring

Test	Frequency	Abnormal result	Action if abnormal result
FBC	Fortnightly from initiation of therapy until the dose and tests have been stable for 6 weeks. Then monthly until the dose and disease has been stable for one year. Thereafter, the frequency of monitoring may be reduced based on clinical judgement based on due consideration for risk factors including age, co-morbidity, renal impairment etc, when monthly monitoring is to continue.	WBC <3.5 x 10^9/l. neutrophils <2.0 x 10^9/l. platelets <150 x 10^9/l.	Withhold methotrexate and discuss with specialist team.
		MCV >105 fl.	Check B12, folate and TSH. If abnormal, treat underlying abnormality; if normal, discuss with specialist team.
LFTs and albumin		AST > twice upper limit of normal reference range. ALT > twice upper limit of normal reference range. Unexplained fall in albumin (in absence of active disease).	Withhold methotrexate and discuss with specialist team.
U&Es and creatinine		Mild/moderate renal impairment.	Withhold methotrexate and discuss with specialist team.

- Abnormal trends should prompt extra vigilance.
- Withhold and discuss urgently with specialist team if new or increasing dyspnoea or dry cough develops.
- Temporarily withdraw if the patient reports sore throat, unexplained bleeding or bruising, mouth ulcers or other signs of blood dyscrasia or evidence of infection. Perform repeat blood monitoring.
- In the event of an unexplained acute widespread rash, withhold methotrexate and inform rheumatologist.
- Trends in ESR are useful in decision-making.

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This information was prepared by the Rheumatic Diseases Unit and Pharmacy Department, Western General Hospital, NHS Lothian through liaison with the General practice Prescribing Committee and LUHD Drug and Therapeutics Committee