Northern Lincolnshire and Goole NHS
NHS Foundation Trust

Prescribing Framework for Methotrexate Tablets in Rheumatic Diseases

Patient's Name:…… Unit Number: ……

Patient's Address:……(Use addressograph sticker)

GP's Name:……..

Communication

We agree to treat this patient within this Prescribing Framework.

Consultant's Signature:……..

GP's Signature:…….

If the General Practitioner is unable to accept prescribing responsibility for the above patient the consultant should be informed within one week of receipt of this framework and consultant's / nurse specialist's letter. In such cases the GP are requested to update the consultant, by letter, of any relevant changes in the patient's medication / medical condition.

APPROVAL PROCESS

Written by:	**Dr Tim Gillott, Consultant Rheumatologist**
Monitoring Guidance:	**Yorkshire DMARD monitoring guidelines 2014**
Approved by:	**Northern Lincolnshire and Goole Medicines and Therapeutics Committee**
Ratified By:	**Northern Lincolnshire Area Prescribing Committee**
Review date:	**May 2021**

1. Background

DMARDs are fundamental to arresting the disease process in Rheumatoid Arthritis and other inflammatory arthritides. While early initiation of therapy is essential to arrest the disease process, sustained use is vital if disease suppression is to be maintained. Prolonged therapy requires long-term monitoring for toxicity and safety profile

Methotrexate is a DMARD that may be used for rheumatoid arthritis (NICE Clinical Guideline 79, www.nice.org.uk/cg79) and other rheumatic diseases.

Methotrexate is usually used orally, however a proportion of patients are unable to tolerate a potentially effective therapy due to gastrointestinal intolerance. This group of patients often benefit from subcutaneous methotrexate given on a weekly basis.

Currently **subcutaneous** methotrexate prescription and supplies are coordinated by the hospital. The specialist remains responsible for doses and checking blood results in patients on **subcutaneous** methotrexate. Although subcutaneous methotrexate is now licenced, the prescribing and continuation responsibility lies within secondary care

These guidelines aim to provide a framework for

-Prescribing and monitoring of oral methotrexate by GPs

-Set out the associated responsibilities of GPs and hospital specialists who enter into the shared care arrangements.

METHOTREXATE	
Dose:	Treatment may begin at a dose of 10-20mg WEEKLY using 2.5mg tablets and increased to 20mg after 2-4 weeks. Folic acid should be co-prescribed, but patients should be advised not to take it on the day they take their methotrexate. The day of administration plus strength of tablet should be specified. Maximum recommended dose oral = 30mg weekly.
Baseline Tests:	FBC/U&E/LFT + consider pregnancy test. All patients should have a pre-treatment CXR and consider PFT (in RA). Where TLCO less than 70% or clinical concern a baseline HRCT chest may be advisable (lung toxicity is increased when fibrosis is present).
Routine Monitoring:	Repeat FBC/LFT/U&Es 2 weekly for 2 months (0-2), then monthly for 4 months (2-6) and then 3 monthly unless dose changes. NPSA MTX monitoring books for all patients remain recommended (Consider increasing the frequency of monitoring if psoriatic arthritis, diabetes, obesity, uncertain alcohol intake or concomitant medication which may reduce the renal excretion of methotrexate). Patients could be guided to have a blood test (e.g. for CRP) just prior to their secondary care appointment.

Indications for Stopping Therapy:	**Stop medication and contact local rheumatology service if:** WCC <3.5 10^9/L or below local normal range Neutrophils < 2.0 10^9/L or below local normal range Platelets <150 10^9/L or below local normal range AST or ALT > 3 times normal range (iu/L) Oral ulceration/Unusual bruising/Rash/Nausea/Alopecia Any new respiratory symptoms including cough Fever **Consider the need for folic acid rescue - refer to BNF for dosage recommendations and discuss with Rheumatology Service.**
Assessment of Response:	Clinical effect usually within 2 to 4 months.
Additional information:	**Warnings/Caution:** Avoid in significant hepatic impairment Not recommended in severe renal impairment (creatinine clearance <10ml/min) the dose should be reduced by 50% if the CrCl is between 10-20ml/min. Also consider dose reduction if CrCl 20-50ml/min. Caution when pre-existing haematological condition Caution - underlying chest disease/smoker Where history of excessive alcohol intake **Drug interactions:** Avoid live vaccines (zoster safe if weekly MTX dose 20mg or less) Concomitant administration of folate antagonists such as trimethoprim, cotrimoxazole and nitrous oxide should be avoided Penicillins may potentiate levels of methotrexate (Patients should stop taking methotrexate if they have any infection/require antibiotics and restart once the antibiotic course is completed and the infection has resolved) Acitretin - severe hepatitis reported when combined with MTX Vitamin preparations containing folic acid
Pregnancy & Breastfeeding:	Adequate contraception should be used by women and continued for at least 3 months after stopping treatment with methotrexate. Contra-indicated in breast feeding. **If pregnancy occurs during treatment with methotrexate immediately contact the Rheumatology Service for appropriate advice.**
Please refer to licensed datasheet for more comprehensive prescribing information: http://www.medicines.org.uk/EMC/medicine/6005/SPC/Maxtrex+Tablets+10+mg/	

Information to patient

Explain current dose of ONCE WEEKLY methotrexate and dose of folic acid.
Inform patient of expected response to treatment and possible side effects.

Patients should be told to go to their GP immediately if they experience any fever, rash, bruising, bleeding, sore throat, oral ulceration, shortness of breath, dry cough, jaundice or infection.

As per NPSA recommendations patients should be given a pre-treatment patient information leaflet and a patient held monitoring booklet.

Responsibilities of clinicians involved

ORAL Methotrexate:

Stage of Treatment	Hospital Specialist	General Practitioner
Initiation	Assess the patient following referral by GP Recommend appropriate treatment to the GP Carry out baseline full blood count, differential WCC, platelets, U&Es and LFTs Perform baseline chest x-ray (where not performed within last 6 months). Give patient NPSA Methotrexate booklet and fill in. Prescribe first month of treatment	Prescribe on FP10 after the first month of treatment
Maintenance	Assess clinical response to treatment Provide adequate advice and support for the GP Provide information to GP on frequency of monitoring if doses are changed Fill in patient NPSA Methotrexate booklet where relevant.	FBC (including platelets, differential white cell), U&E, LFTs & CRP should be checked every 2 weeks for the first 2 months, and provided the dose and blood results remain stable, monthly thereafter. The monitoring interval may be increased to 3 monthly if the patient's condition has been stable after 4-6 months. Fill in patient NPSA Methotrexate booklet, **including any dose changes and results.**

Contact Details:

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