Name: Attach Banda Label here
Address:

Date of Birth:
NHS number:

Coventry & Warwickshire
Area Prescribing Committee

SHARED CARE AGREEMENT

Methotrexate [Maxtrex] oral / Metoject subcutaneous injection

ESCA: *For treatment of Rheumatoid arthritis and psoriasis*

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of methotrexate 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 specialist 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.

RESPONSIBILITIES and ROLES

Specialist responsibilities

1. To discuss the benefits, side effects and expected outcomes of treatment with the patient.
2. To supply the departmental drug information leaflet, counsel the patient and obtain informed consent.
3. To ensure that the patient understands the WEEKLY dosing regime.
4. To undertake appropriate baseline tests (i.e. FBC, LFTs, U&Es, creatinine, EGFR, chest X-ray and VZV) and provide results of baseline blood tests and recommend frequency of monitoring to the GP.
5. To monitor FBC, hepatic and renal function at recommended frequencies, and take action if abnormal.
6. When considering subcutaneous methotrexate the initial dose will be administered in clinic with the rheumatology nurse specialist. All patients will be asked to sign a competency sheet for self-injection and a copy will be kept in the patient's case notes.
7. To recommend the dose and timing of any concomitant folic acid.
8. To obtain patient consent to shared care arrangement and to hold personal and treatment details on computerised blood monitoring database.
9. Initiate initial prescription outlining dose and timing of any concomitant medications.
10. To ensure that for both oral and subcutaneous methotrexate, dosages on all correspondence between secondary and primary care will be written in milligram (mg) and for patients on oral methotrexate will include the number of 2.5mg tablets to be taken. Dosage changes will be recorded within methotrexate dosage alert card in mg and number of 2.5mg tablets to be taken.
11. Written request to GP inviting to participate in shared care.
12. To periodically review the patient's condition and communicate promptly with the GP when treatment is changed, providing a copy of most up to date blood tests with clinical letter.
13. To report adverse events to the MHRA and GP.
14. To ensure that clear backup arrangements exist for GPs to obtain advice and support weekdays.

General Practitioner responsibilities

1. To reply in writing to the request for shared care as soon as practicable.
2. To prescribe oral/ sc methotrexate at the recommended dose. **For oral form prescribe only 2.5mg tablets**.
3. Agree to use blood forms advised by specialist to monitor and take appropriate action in the case of abnormal bloods
4. Patients living 'out of area' will have their blood results faxed by their GP surgery to the specialist team.
5. To ensure compatibility with other concomitant medication and adjust the dose as advised by the specialist.
6. To stop treatment on the advice of the specialist, or immediately if an urgent need to stop treatment arises.
7. To report adverse events to the specialist and MHRA.
8. GPs should develop processes which ensure that all prescriptions for methotrexate are dealt with separately and prescribers are alerted to the need for vigilance

Patient/carer's role

1. To attend all appointments with GP and specialist.
2. To attend for bloods as discussed/ advised by rheumatology team.
3. To report to the specialist or GP if he or she does not have a clear understanding of the treatment.
4. To keep the patient–held monitoring and dosage record booklet safe and bring to all clinic and GP appointments.
5. To share any concerns in relation to treatment.
6. To inform specialist or GP of any other medication being taken, including over-the-counter products.
7. To report any adverse effects or warning symptoms to the specialist or GP whilst taking methotrexate

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 (see SPC for complete details/specific guidance http://emc.medicines.org.uk)

Licensed indications:
Oral Methotrexate - rheumatoid arthritis and psoriasis
SC Metoject – rheumatoid arthritis
Time to response 8-12 weeks.Used in the treatment of adults with severe, active, classical or definite rheumatoid arthritis who are unresponsive or intolerant to conventional therapy.

Dosage and administration:

Adults:

Starting dose usually 15mg weekly [6 x 2.5mg tablets]. Only 2.5mg tablets should be used. The dosing schedule may be adjusted gradually to achieve an optimal response and will not exceed a total weekly dose of 30mg The patient-held methotrexate alert card details the patient's dose.
Prescribing records must state: dose and number of methotrexate tablets to be taken.[NPSA 2010]
Folic acid 5mg day after methotrexate- should be co-prescribed to minimise the risk of side effects.
Methotrexate should be swallowed whole, not crushed or chewed and taken with food. Some patients take methotrexate once a week by subcutaneous injection.[sc] All practitioners must adhere to the Arden Cancer Network policy on SC cytotoxic chemotherapy disposal.
When changing patients from oral to sc methotrexate there may be a dose reduction.
In view of current security restrictions patients may need a flight certificate to carry injections for air travel. A pre printed certificate in several languages is available at
www.metoject.com/data

Elderly: Methotrexate should be used with extreme caution in elderly patients, a reduction in dosage should be considered.

Monitoring:
Bloods (FBC, U&E Liver), e-GFR and CXR before starting treatment (pulmonary function tests may be required in some patients)
Single therapy
. FBC,U&E,LFTs every 2 weeks until dose and monitoring stable for 6 weeks, then once every month for a year. Can consider reducing frequency of monitoring to every 2-3 months after 1 year if no risk factors.

Combination therapy: Maintain monthly bloods

During treatment Action to be taken:

- **WBC<3.5_10^9/l** Withhold until discussed with specialist team.
- **Neutrophils<2.0_10^9/l** Withhold until discussed with specialist team.
- **Platelets<150_10^9/l** Withhold until discussed with specialist team.
- **AST, ALT>twice upper limit of reference range** Withhold until discussed with specialist team.
- **Albumin-unexplained fall (in absence of active disease)** Withhold until discussed with specialist team.
- **Rash or oral ulceration,nausea and vomiting, diarrhoea** Withhold until discussed with specialist team.
- **New or increasing dyspnoea or dry cough** Withhold and discuss urgently with specialist team.
- **MCV>105 fl** Withhold and check serum B12, Folate and TFT and discuss with specialist team if necessary.
- **Mild to moderate renal impairment** Withhold until discussed with specialist team (refer BNF).
- **Severe sore throat, abnormal bruising** Immediate FBC and withhold until the result of FBC is available

Please note that in addition to absolute values for haematological indices a rapid fall or a consistent downward trend in any value should prompt caution and extra vigilance.

Cautions/Contra-indications:

- Profound impairment of renal or hepatic function or haematological impairment.
- Liver disease including fibrosis, cirrhosis, recent or active hepatitis, active infectious disease and overt or laboratory evidence of immunodeficiency syndrome[s]
- Unexplained anaemia, leucopenia or thrombocytopenia
- Pregnancy or breast feeding.
- Patients with known allergic hypersensitivity to methotrexate
- Suspected local or systemic infection

Therapeutic use: **Refer to MTRAC VS 97/15** The NPSA has published actions to reduce the risks associated with oral methotrexate. See www.npsa.nhs.uk

Side effects:

Low-dose methotrexate may be associated with a number of serious adverse effects, including:

- hepatotoxicity
- pulmonary toxicity
- bone-marrow toxicity

Other common non-life-threatening adverse effects of low-dose methotrexate are those affecting the gastrointestinal system (nausea, diarrhoea and stomatitis), and the central nervous system (headaches, drowsiness, blurred vision). The risk of minor adverse effects may be reduced by giving regular folic acid. An annual influenza vaccination is recommended.

Methotrexate was launched in 1989 and no longer has black triangle (▼) *status. Serious suspected reactions (even if well recognised or causal link uncertain) should be reported to the CSM.*

Drug interactions (see also above under cautions):

Methotrexate is extensively protein-bound and may be displaced by other protein-bound drugs (e.g. diuretics, salicylates, hypoglycaemics), with a potential for increased toxicity. Concomitant use of other drugs with nephrotoxic or hepatotoxic potential (including alcohol) should be avoided. Folate antagonists such as trimethoprim and co-trimoxazole should not be given concomitantly. Methotrexate excretion is reduced by probenecid, penicillin, NSAIDs. The British Society for Rheumatology Guidelines state that NSAIDs are not contraindicated with the above doses of methotrexate. .Live vaccines should not be administered to patients receiving methotrexate. Antifolate effect of methotrexate increased by phenytoin.

References:

1. National Guidelines for the Monitoring of Second Line Drugs. British Society for Rheumatology. July 2000.
2. MTRAC guidance VS97/15.
3. National Patient Safety Agency. www.npsa.nhs.uk
4. Wyeth Pharmaceuticals. Methotrexate sodium tablets 2.5 mg. Summary of Product Characteristics 2003.
5. **BSR/BHPR guideline for disease-modifying anti-rheumatic drug (DMARD) therapy 2008**