NHS
Telford and Wrekin
Clinical Commissioning Group

Methotrexate
Dermatology and Rheumatology Effective Shared Care Agreement

Patient details

Name: _____

Address: _____

Date of Birth: _____

NHS number: _____

Contact details
Specialist:
Address:

Email:

Contact number:

GP

Address:

Email:

Contact number:

Patient

Name:

Contact number:

Agreement to shared care, to be signed by GP and Specialist before prescribing is transferred to GP

Specialist Signature: _____

Date: _____

GP Signature: _____

Date: _____

Patient Signature: _____

Date: _____

This Effective Shared Care Agreement outlines suggested ways in which the prescribing responsibilities can be shared between the specialist and 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's health remains with the specialist.
If a specialist asks the GP to prescribe, the GP should reply to this request within 2 weeks

The prescriber of the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Responsibilities of the specialist initiating treatment

- Discuss with the patient options for treatment and the suitability of methotrexate
- Discuss the potential benefits and side effects of treatment with the patient
- Undertake baseline tests: **FBC, LFTs, U&Es, Chest X-ray**, if not done within 6 months (Full pulmonary function tests should be considered in selected patients), **CRP +ESR** (Rheumatology & Gastroenterology only), **P111NP** (Dermatology only: baseline test and at hospital review).
- Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient. Consultant attaches copy of Shared Care Agreement (SCA) from the trust intranet to printed letter.
- Titrate methotrexate to an effective dose. If both GP and Consultant feel it is appropriate, shared care may be initiated before the patient is stabilised on the effective dose, as long as the dose is stable until the next Consultant appointment.
- Or commence treatment with methotrexate and once patient is on a stable dose between visits, consider transfer of prescribing and monitoring to GP.
- When prescribing, ensure the exact day of the week for the dose to be taken, is clearly specified.
- Provide patient with methotrexate treatment booklet. Ensure initial baseline test results are recorded and also the dose and the day of the week, the dose should be taken, is recorded
- Ensure agreed signed shared care form has been received back from GP to indicate that the GP is in agreement with prescribing and monitoring.
- Ensure this has been discussed with patient, and that patient has signed SCA form
- Regular follow-up of patient (at least annually)
- Communicate promptly with the GP when treatment is changed
- Advise GP on dosage adjustment and when and how to stop treatment
- Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition and ensure that clear backup arrangements exist for GPs to obtain advice and support
- Check and document that the patient is using effective contraception.
- Report adverse events to the MHRA (via Yellow Card)

Responsibilities of the General Practitioner

- Notify the specialist in writing within 2 weeks if they agree with this Shared Care Agreement.
- Prescribe methotrexate (2.5mg tablets only) once each week (specify day); "as required" or "as directed" are unsuitable dosage instructions for oral methotrexate) and folic acid 5mg.
- When prescribing, ensure that the exact day of the week for the dose of methotrexate is clearly specified. Ensure dose prescribed as xx mg (xx tablets of 2.5mg)
- Arrange and record on-going monitoring as agreed with specialist: **FBC, U&Es & LFTs: every 2 weeks until dose of methotrexate and monitoring stable for 6 weeks, thereafter monthly**. Thereafter, in the absence of risk factors (e.g. age, comorbidity, renal impairment) and following discussion with the specialist team, it may be appropriate to reduce frequency of monitoring to every 2-3 months. Any dosage increase should be followed by an FBC one week later. **CRP + ESR** (Rheumatology & Gastroenterology only) may be required every 3 months.
- Ensure patient has a methotrexate booklet, if not provide patient with a booklet. Record bloods results in patient's booklet and ensure both the day of the week and the dose are also recorded in the booklet.
- Ensure and document drug interactions with other medicines
- Check patient is using adequate contraception
- Continued prescribing is appropriate for patients attending regular review. Ensure dose is clearly stated on the prescription.

- Report adverse events to the MHRA (via Yellow Card)
- Administer influenza vaccine annually unless otherwise advised by the initiating specialist
- Check patient has had ONE DOSE of pneumococcal vaccine (revaccination is not recommended except every five years in patients whose antibody levels are likely to have declined more rapidly e.g. asplenia.) - see BNF or Green Book
- Passive immunisation using Varicella immunoglobulin (VZIG) should be considered in non-immune patients if exposed to chickenpox or shingles.
- Ask about oral ulceration/sore throat, unexplained rash or unusual bruising at every consultation

Withhold treatment with methotrexate until discussed with specialist

- WBC < 3.5 x 109/L
- Neutrophils < 2 x 109/L
- Platelets < 150 x 109/L
- AST / ALT > 2-3 times the upper limit of normal (minor elevations of AST/ALT are common)
- MCV>105fl- Withhold and check serum B12, folate and TSH and discuss with specialist if necessary.
- Albumin-unexplained fall (in absence of liver disease)
- Oral ulceration / sore throat/ nausea and vomiting/ diarrhoea
- New or increasing dyspnoea or cough.
- Mild to moderate renal impairment
- Unexplained rash / abnormal bruising

Please note: A rapidly increasing or decreasing trend in any values should prompt caution and extra vigilance. Some patients may have abnormal baseline values, specialist will advise

General information on methotrexate

Licensed Indication

- Rheumatoid arthritis
- Psoriasis

Unlicensed Indication

- Psoriatic Arthritis
- Connective Tissue Disease
- Systemic lupus erythematosus
- Vasculitis
- Scleroderma

Dosage and administration

A typical dose regimen may be - 7.5-10mg once weekly increasing by 2.5-5 mg every 4-6 weeks to a usual maximum of 25mg. (NB Although the maximum licensed dose of methotrexate when used in the treatment of rheumatoid arthritis is 20mg once weekly, doses of up to 25mg/30mg[1 2] once weekly are supported by national guidance and are covered by this Shared Care Agreement.)

Lower doses should be used in the frail elderly or if there is significant renal impairment.

Regular folic acid supplements are thought to reduce toxicity and a dose of 5mg once a week should be prescribed (folic acid can be taken any day as long as it's not on the same day as the methotrexate).

Subcutaneous route can be considered if patient is poor responder or gastro-intestinal side effects

Methotrexate is available in 2.5mg and 10mg tablets – to minimise the chance of drug overdose occurring if the two strengths are confused it is recommended that only 2.5mg tablets are used and this should be specified on the prescription.

Contraindications

Severe renal or hepatic impairment

Chronic or recurrent infections especially respiratory or urinary tract

Severe anaemia, leucopenia or thrombocytopenia

Untreated folate deficiency

History of alcohol abuse/cirrhosis

Pregnancy: female patients must be advised not to conceive whilst receiving methotrexate. A reliable form of contraception should be used by men and women whilst on methotrexate and for at least 6 months after discontinuing it. Discontinue methotrexate and refer immediately if a patient or partner discovers they are pregnant whilst taking methotrexate.

Breast Feeding: Women being treated with methotrexate should not breastfeed.

Side effects

Myelosuppression & decreased resistance to infection: especially respiratory/urinary tract or shingles/chickenpox. Temporarily withhold methotrexate if patient is systemically unwell with significant infection requiring anti-infective intervention.

Hepatotoxicity: methotrexate may be hepatotoxic, particularly at high cumulative dosages.

Nausea: commonly encountered, may resolve with dose reduction and/or addition of anti-emetic medication.

Alopecia, stomatitis, diarrhoea: contact the initiating specialist if severe or persistent.

Respiratory function: infrequently, methotrexate can cause interstitial pneumonitis, pulmonary oedema and fibrosis. Patients complaining of unexplained dyspnoea or unexplained non-productive cough should be referred immediately to the initiating specialist

Drug Interactions[3]

Co-trimoxazole or trimethoprim must be avoided in patients taking methotrexate (increased antifolate effect).

NSAIDs reduce tubular excretion of methotrexate and thereby enhance toxicity. However, NSAIDs in addition to the above doses of methotrexate are not contraindicated.

Live vaccines (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever, varicella zoster) should be avoided in patients taking methotrexate.

Clozapine may cause increased risk of agranulocytosis.

Excess alcohol should be avoided (more than 4-6 units per week)

There are numerous drug interactions and the Summary of Product Characteristics (www.medicines.org.uk) should be consulted both before treatment and when new drugs are introduced.

[1] BSR/BHPR guideline for disease-modifying anti-rheumatic drug (DMARD) therapy in consultation with the British Association of Dermatologists :Rheumatology 2008 available at http://www.rheumatology.org.uk/includes/documents/cm_docs/2009/d/diseasemodifying_antirheumatic_drug_dmard_therapy.pdf

[2] EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2013 update Ann Rheum Dis doi:10.1136/annrheumdis-2013-204573

[3] BNF 66 September 2013-March 2014