BNSSG Shared Care Guidance

Section 1: Heading

Drug	Methotrexate for dermatological conditions
Amber *three months*	
Indication	Psoriasis, eczema and other skin conditions
Speciality / Department	Dermatology
Trust(s)	North Bristol NHS Trust
	University Hospitals Bristol NHS Trust
	Weston Area Health NHS Trust

Section 2: Treatment Schedule

Usual dose and frequency of administration	5-30mg ONCE WEEKLY Methotrexate is usually started at a dose between 5mg-15mg ONCE WEEKLY orally increasing by 2.5mg-5mg on a 1-2 weekly basis. The starting dose will vary depending on the severity of the condition, age, renal function and other co-morbid conditions. Target dose ranges between 10-20mg once per week, but doses may go up to 30mg per week. It is available in an oral or injectable form. Patients may be switched to a subcutaneous preparation if inefficacy or GI intolerance of oral methotrexate. The decision to increase the dose will be taken by the dermatology team. Methotrexate should be continued as long as clinically indicated unless there is a serious side effect or the drug becomes ineffective. We recommend folic acid supplementation 5mg once weekly, usually to be taken the day before methotrexate. We will have discussed the benefits and possible risks of methotrexate in the clinic, given them a written drug information sheet, made them aware that they must have regular blood monitoring tests and given them a shared care record card.
Route and formulation	Oral tablets Subcutaneous injection

Duration of treatment	Methotrexate should be continued as long as clinically indicated unless there is a serious side effect or the drug becomes ineffective.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests - where appropriate

Secondary Care : Pre-treatment assessment with FBC, renal function, LFT, CXR (unless done within the previous 6 months),Procollagen3peptide levels(in adult patients with no active psoriatic arthritis).

HIV, Hepatitis B&C serology and Varicella serology testing are considered

Secondary Care to monitor 2 weekly FBC and LFTs until dose stabilised for 6 weeks.

Subsequent tests - where appropriate

1. Primary Care to monitor FBC, renal function & LFTs monthly for 12 months. Thereafter, if dose, disease and monitoring stable, frequency of monitoring could be reduced to a minimum of 3-monthly based on clinical judgement.
   It is helpful if the patient's shared care monitoring card is filled in for clinic appointments

2. Secondary Care- Pro Collagen 3 peptide levels are monitored every 3-12 months.

Methotrexate should be withheld and the dermatology team contacted for discussion if any of the following occur. Falling or rising trends may also prompt discussion.

Problem	**Action**
Abnormal bruising or non-remitting sore throat	Stop drug and check FBC, contact team if abnormal
Hb <10g/dl WBC <3.5 x 10^9/L Neutrophils <1.8x10^9/l Lymphocytes < 0.5x 10/l Platelets <100 x10^9/l	Stop drug and recheck weekly until stable
Elevation of liver enzymes (ALT/AST) >2 x normal	Stop drug and recheck weekly until stable. Discuss resuming drug with team
Increasing renal impairment eg GFR <50	Stop drug if change is acute, discuss with team if dose reduction needed.
Severe rash or oral ulceration	Stop drug and inform team
Chickenpox or shingles	Chicken pox/shingles infection - stop and commence aciclovir.
New or increasing dry cough or dyspnoea	Stop drug. Consider CXR and discussions with team

Section 4: Side Effects

Please list the most common side effects and management. Please provide guidance on when the GP should refer back to the specialist.

Side effects and management	Common side effects include nausea, diarrhoea and dyspepsia.

	These may respond to: increasing dose of folic acid to 5mg 3-6 days per week and/or adding in an anti emetic eg Metoclopramide 10mg before methotrexate dose. Occasionally folic acid can cause nausea. Serious but rare side effects include neutropaenia, other myelosupression, pneumonitis and hepatic fibrosis.
Referral back to specialist	Any serious side effect and common side effects if unmanageable.

Section 5: Drug Interactions

Please list clinically significant drug interactions (eMC link please click here)

Significant Drug Interactions	This is not a comprehensive list, for a full list of drug interactions please refer to the current edition of the British National Formulary (BNF) and the Summary of Product Characteristics (SPC). Patients on methotrexate should not take co-trimoxazole (Septrin®) or trimethoprim. Penicillin, phenytoin and antimalarial agents can also interact with methotrexate; however at the doses of methotrexate used this is rarely a problem. Caution should be used with concomitant use of NSAIDs and salicylates as toxicity of methotrexate can occur. However patients using constant dosage regimens of NSAIDs have received concurrent doses of methotrexate with no problems. The use of high dose salicylates should be avoided. Low dose salicylates (up to 150mg aspirin/day is considered acceptable) Drugs with nephrotoxic, myelotoxic or hepatic potential should be used with caution. Immunisations involving live vaccines should be avoided e.g. Rubella, BCG, Yellow Fever. Oral Polio Vaccine should not be given to the patient or household contacts. Annual flu vaccines (except FLUENZ the nasal flu vaccine which is a live attenuated virus) are safe and recommended. Pneumovax is safe and recommended. Zostervax if indicated should be discussed with the team. Potential toxicity of methotrexate should be monitored when starting potential interacting drugs
Reminder to ask patient about specific problems	

Section 6: Contra-indications, Cautions and Special Recommendations

Please list

Contra-indications:

1. Methotrexate is contraindicated in pregnancy. It is strongly recommended that methotrexate should be stopped by both male and female users 3 months before any planned pregnancy. In cases of accidental pregnancy, methotrexate should be stopped immediately. (For further details see SPC and BNF). If methotrexate is stopped, effective contraception will need to continue for a further 3 months.
2. Due to the potential for serious adverse reactions from methotrexate in breast fed infants, breastfeeding is contra-indicated in women taking methotrexate.
3. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucosegalactose malabsorption should not take this medicine.

Cautions:

4. Significantly impaired renal function (eGFR <50 reduces clearance. If eGFR 20-50: 50-100% of normal dose; if eGFR 10-20: 50% of normal dose; if eGFR <10: contra-indicated). (Renal Drug Handbook Second Edt)
5. Significantly impaired hepatic function
6. Localised or systemic infection (including hepatitis B or C and TB). Withhold temporarily during infection and treat with appropriate antibiotics.
7. Unexplained anaemia / cytopaenia associated with marrow failure
8. Pre-existing lung disease
9. Excessive alcohol consumption. Patients should be advised to limit their alcohol intake to well within national recommendations, and those at particular risk of liver disease may be advised to avoid alcohol completely.
10. Avoid live vaccine. Discuss with team if Zostervax indicated.
11. Patients should avoid contact with people who have active chickenpox or shingles and report any contact to their GP and hospital specialist. If immunosuppressed patients are exposed to chickenpox or shingles, they will need to be assessed for susceptibility and the need for aciclovir post exposure prophylaxis, see: UKHSA guidance: Guidelines on post-exposure prophylaxis (PEP) for varicella/shingles and the Green Book Chapter 34.

Section 7: Advice to the patient

Advice for prescribing clinician to inform patient

1. Discuss potential benefits and side-effects of treatment with the Specialist and/or GP.
2. Share any concerns they have in relation to their treatment.
3. To report any side-effects to the Specialist and/or GP (see individual drug fact sheet for specific information).
4. To ensure that the patient held record is presented at every consultation (in primary or secondary care).
5. To agree to and attend for the monitoring of therapy (including having blood tests carried out at agreed intervals) and assessment of outcomes, to assist health professionals to provide safe, appropriate treatment.
6. To avoid excessive alcohol intake and stay well within national recommendations or avoid if advised to do so.
7. To use adequate contraception (both male and females), report any suspected pregnancy to the GP and/or Specialist and inform Specialist in a timely manner if plans to conceive.
8. To inform GP/Specialist/pharmacist of all medicines (including OTC preparations) that they are currently taking.

Section 8: Responsibilities for Secondary Care

Core responsibilities

1. Initiating treatment and prescribing for the first three months
2. Undertaking the clinical assessment and monitoring for the first three months.
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. blood test is due.
5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of Methotrexate.
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see section 5.

Other specific to drug

1. Supply patient held record

Section 9: Responsibilities for Primary Care

Core responsibilities 1. Take on shared care proposal from the specialist to monitor and prescribe after the patient has been commenced on treatment. (The time from commencing treatment to agreeing shared care will vary between practices depending on prior agreement with the practices with the local rheumatology department and the practice ability and capacity to safely treat and monitor patients. Some practices may be unable to take on shared care until patient is stabilised on therapy) 2. If shared prescribing is declined, explain to the specialist in writing (fax preferred), the reason for this, copying in the pharmacy lead for the CCG. 3. To ensure that all relevant staff and patients are aware of the shared care arrangements. Blood test results, dosage adjustments, should be recorded in the patient held record and GP medical record. Any dosage adjustments should also be recorded in computer-based prescribing systems. 4. The dosage regimen should be clearly explained to the patient. 5. Contact the specialist to discuss any significant changes in the blood test results or patient's condition e.g; the medication becomes less effective. 6. Respond to dosage changes advised and prescribe appropriately. Receive copies of any blood test results carried out in secondary care for information and record in patient's record appropriately. 7. Monitor the patient for any side-effects to therapy and refer back to the Specialist should any serious side-effect occur. Side-effects / discontinuation of medication should be documented in the patient held record.
Other specific to drug
1.

Section 10: Contact Details

Name	Organisation	Telephone Number	E mail address
Medical Dermatology CNS Team	UHBW NHS Foundation Trust	0117 342 2640	DermMedCNS@uhbw.nhs.uk
BRI Medical Secretaries	UHBW NHS Foundation Trust	0117 342 9767	DermatologySecretaries@uhbristol.nhs.uk
BRI Dermatology On Call Mon-Fri 9am-5pm	UHBW NHS Foundation Trust	Click here to enter details	bridermatologyoncall@uhbw.nhs.uk
Dermatology Consultant NBT	Southmead Hospital, North Bristol NHS Trust	0117 414 7596	

Section 11: Document Details

Date prepared	May 2015
Prepared by	Dr Debbie Shipley Change to information about PEP for varicella/shingles February 2023 added by BNSSG Formulary Team. UHBW contact details updated September 2024.
Date approved by JFG	April 2016
Date of review	April 2018
Document Identification: Version	Methotrexate Derm SCP April16 v1.3

Section 12: Collaboration

Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. Aligned as closely as possible to current rheumatology Methotrexate SCP.
2. Sent to dermatology consultants UHB (includes Weston) and NBT and dermatology CNSs for comment and approval

Section 13: References

Please list references

1. K. Chakravarty, H. McDonald, et al. BSR/BHPR guideline for disease-modifying anti-rheumatic drug (DMARD) therapy in consultation with the British Association of Dermatologists. Rheumatology. 2008; 47(6): 924-5
2. British National Formulary 68