Shared Care Guideline
Stepping Hill Hospital and North Derbyshire CCG

Shared Care Guideline for Methotrexate in Rheumatological Conditions in Adults		Reference Number
Version: 1.1	**Replaces: 1**	**Issue date: November 2017**
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Date noted by JAPC: June 2018	**Review Date: October 2019**	

Please complete all sections

1. Name of Drug, Brand Name, Form and Strength	Methotrexate 2.5mg tablets
2. Licensed Indications	Oral methotrexate is licensed to treat adults with rheumatoid arthritis and is also widely used to treat other inflammatory arthritides and connective tissue diseases including adults with juvenile inflammatory arthritis.
3. Criteria for shared care	Prescribing responsibility will only be transferred when • Treatment is for a specified indication. • Patient has completed three months treatment (prescribed and monitored by Rheumatology Team), has reached the target dose and blood test results are stable • The GP has agreed in writing in each individual case that shared care is appropriate. • The patient's general physical, mental and social circumstances are such that he/she would benefit from shared care arrangements
4. Patients excluded from	• Patient does not consent to shared care. • Patient does not meet criteria for shared care.

shared care	
5. Therapeutic use & background	Methotrexate is an anti-metabolite cytotoxic drug which inhibits DNA synthesis and cellular replication. It belongs to the group of DMARDs alongside gold, penicillamine, hydroxychloroquine, azathioprine, leflunomide, and sulfasalazine.
6. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).	Contraindications: Pregnancy and breast feeding, suspected local or systemic infection, bone marrow failure with unexplained anaemia and cytopenia. Following administration to a man or woman, conception should be avoided by using an effective contraception method for at least three months after finished course. Hypersensitivity to methotrexate or any excipients. Cautions: Significant renal impairment from any cause, hepatitis B or C, history of TB, lung fibrosis
7. Prescribing in pregnancy and lactation	This drug cannot be prescribed in the pregnant or breastfeeding patient. Following administration to woman, conception should be avoided by using an effective contraception method for at least 3 months after finished course. Although paternal exposure to methotrexate is not a definite contra-indication to fathering a child, as data is limited, many men taking methotrexate may wish to continue using contraception for a least 3 months following methotrexate exposure. Methotrexate cannot be recommended in breastfeeding because of theoretical risks and insufficient outcome data
8. Dosage regimen for continuing care	***Route of administration:*** Oral ***Preparations available:*** Methotrexate 2.5mg tablets CSM warning with methotrexate that doses are weekly and attention should be paid to the strength of methotrexate tablets prescribed and the frequency of dosing. 2.5mg tablets are recommended in Greater Manchester however, patients should be made aware of other strengths and to question possible discrepancies. ***Please prescribe:*** 7.5-25mg ONCE weekly according to hospital instructions (the initial dose may be 5-15mg once weekly, increasing by 2.5mg-5mg every 2-6 weeks until the disease is stabilized) Only prescribe 2.5mg tablets to avoid dosing errors. ***Is titration required*** Titrate dosage up by 2.5mg-5mg every 2-6 weeks according to response. Maintenance dosage up to a maximum licensed dose of 20mg / week. Rarely the maximum dose can be 25mg/week. ***Adjunctive treatment regime:*** • Folic acid 5mg a minimum of ONCE weekly also given but may be given more frequently if necessary (usually 3 days after methotrexate). Folic acid reduces the toxic effects of methotrexate. Folic acid can be given any day as long as it is not on the same day as methotrexate. If nausea or GI effects persist despite folic acid then increase dose or switch to folinic acid 15mg ONCE weekly can be used as an alternative. • Annual flu vaccinations are safe and recommended. • Pneumococcal vaccination is safe and recommended. • Shingles vaccine (varicella-zoster) – currently recommended in people over the age of 69

	years. To date the JCVI recommendations have not been extended to younger age groups in the rheumatic disease population. Low levels of immunosuppression are not considered an absolute contraindication, and the JCVI Green Book addresses this, recommending that low-dose CSs (prednisolone<20mg daily) and methotrexate <0.4mg/kg/week are compatible with the shingles vaccine. • In non-immune patients exposed to chickenpox or shingles, passive immunisation should be carried out using Varicella zoster immunoglobulin (VZIG). It is the specialist's responsibility to make the recommendation for vaccination at the appropriate time.
	Conditions requiring dose reduction: Lower doses should be considered for frail elderly patients and those with poor renal function. Methotrexate is contra-indicated in severe renal failure. If maximum oral dose is not effective or causes intolerance consider referral to the rheumatology team to consider switch to subcutaneous route of administration before discontinuation of the drug.
	Usual response time: 6 weeks to 3 months
	Duration of treatment: Ongoing
	Treatment to be terminated by: Healthcare professional in consultation with Rheumatology team
	NB. All dose adjustments will be the responsibility of the initiating specialist care unless directions have been specified in the medical letter to the GP.
9.Drug Interactions ***For a comprehensive list consult the BNF or Summary of Product Characteristics***	The following drugs must <u>not</u> be prescribed without consultation with the specialist: • **<u>Trimethoprim or co-trimoxazole</u> must be avoided in patients taking methotrexate due to increased risk of pancytopenia (increased antifolate effect) and for three months after stopping methotrexate.** • Live vaccines e.g. oral polio, oral typhoid, MMR, BCG, yellow fever should be avoided in patients taking methotrexate. • Avoid concomitant use of cytotoxics and clozapine as increased risk of agranulocyctosis. • Retinoids as increased risk of hepatotoxicity and increased plasma levels. • Ciclosporin or leflunomide- risk of toxicity • Levetiradetam - plasma concentration of methotrexate possibly increased by levetiracetam • Nitrous oxide and pyrimethamine - antifolate effect of methotrexate increased • Acitretin (a treatment for psoriasis) is metabolised to eretinate. Methotrexate levels may be increased by eretinate and severe hepatitis has been reported following concomitant use.
	The following drugs may be prescribed with caution: • Caution with phenytoin potential to increase antifolate effect • NSAIDs, aspirin and penicllin all reduce the tubular excretion of methotrexate and thereby enhance toxicity. Risk with NSAIDs is less in those given low doses of methotrexate (5 to 25 mg weekly) for psoriasis or rheumatoid arthritis and with normal renal function. The manufacturers of methotrexate and the CSM in the UK do not advise the avoidance of NSAIDs (except azapropazone and non-prescription aspirin and ibuprofen), even though their use is a recognised additional risk factor for toxicity. Instead their advice is that the methotrexate dose should be well monitored • Aminoiphylline - methotrexate possibly increases plasma concentration of aminophylline • Ciprofloxacin - excretion of methotrexate possibly reduced by ciprofloxacin • Excess alcohol should be avoided (or limit to max. 14 units per week). • Caution with drugs with potential hepatotoxic or nephrotoxic effects
10. Adverse drug reactions	**Specialist to detail below the action to be taken upon occurrence of a particular adverse event as appropriate. Most serious toxicity is seen with long-term use and may therefore present first to GPs.**

For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult Summary of Product Characteristics or BNF

Adverse event System – symptom/sign	**Action to be taken** Include whether drug should be stopped prior to contacting secondary care specialist	**By whom**
WCC<3.5 x 10^9/l Neutrophils <1.6 x 10^9/l Platelets <140 x 10^9/l Unexplained eosinophilia >0.5 x 10^9/L Unexplained fall in serum albumin <30g/l	Withhold until discussion with Rheumatology Team	GP
ALT and/or AST > 100 units/L OR Any sudden increases (e.g. double of baseline ALT)	Withhold until discussed with the Rheumatology Team. Check any other reason such as alcohol, drug interaction including over the counter medication as risk of hepatic dysfunction	GP
Rash or oral ulceration	Withhold until discussion with Rheumatology Team	GP
MCV>105 fl	Check serum folate, B12, alcohol history, and TSH. Treat any underlying abnormality. If results normal discuss with Rheumatology Team	*GP*
Abnormal bruising or severe sore throat	Withhold until urgent FBC results available and discuss with Rheumatology Team as can cause bone marrow suppression.	GP
Creatinine >30% above baseline and/or calculated GFR <60	Use clinical judgement. Repeat in 1 week and if still >30% above baseline withhold until discussed with the Rheumatology Team	GP
New or increasing dyspnoea and/or dry cough	Withhold and discuss urgently with rheumatology team as risk of interstitial pneumonitis	GP
Nausea, vomiting, diarrhoea	Withhold until discussion with Rheumatology team	GP
Suspected infection requiring antibiotics	Withhold temporarily until infection cleared	GP

The patient should be advised to report any of the following signs or symptoms to their GP without delay:

Severe skin rash that causes blistering,
Persistent cough, pain or difficulty breathing or become breathless
Skin rash and fever with swollen glands
Sore throat, fever, chills or achiness
Severe allergic reaction (anaphylactic reaction)

These may suggest bone marrow suppression. Stop the drug and obtain an urgent FBC / other bloods as appropriate.

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.

If the patient has not previously had chicken pox and they come into contact with someone who has chicken pox or shingles or the patient develops chicken pox or shingles.

Other important co morbidities (e.g. Chickenpox exposure):

- Live vaccines should not be given concurrently with these treatments.
- Annual flu vaccinations are safe and recommended (due to suppressed immune system with these drugs).
- Pneumococcal vaccination is safe and recommended (due to suppressed immune system with these drugs).
- Shingles vaccine (varicella-zoster) – currently recommended in people over the age of 69 years. To date the JCVI recommendations have not been extended to younger age groups in the rheumatic disease population. Low levels of immunosuppression are not considered an absolute contraindication, and the JCVI Green Book addresses this, recommending that low-dose CSs (prednisolone<20mg daily) and methotrexate <0.4mg/kg/week are compatible with the shingles vaccine.
- In non-immune patients exposed to chickenpox or shingles, passive immunization should be carried out using varicella zoster immunoglobulin (VZIG).
- Patients should try to avoid contact with people who have active chickenpox or shingles and should report any such contact urgently to their GP or specialist.
- During infection requiring antibiotics methotrexate should be temporarily discontinued until the patient has recovered from the infection.

Any adverse reaction to a black triangle drug or serious reaction to an established drug should be reported to the MHRA via the "Yellow Card" scheme.

11.Baseline investigations

List of investigations / monitoring undertaken by secondary care

FBC
U&Es incl GFR
LFT (ALT, AST and albumin)
Height and weight
Blood Pressure
Pre-viral screen in high risk patients: HIV, HBV (surface antigen, core antibody), HCV (antibody test) and consider herpes zoster status (if appropriate)
Screening for lung disease should be undertaken at clinician discretion on a case by case basis

12. Ongoing monitoring requirements to be undertaken by GP

(Local commissioning arrangements may vary).

Is monitoring required?	**Yes** (N.B. Bolton DAWN monitoring based on BSR guidelines 2008/2017 for initiation/dose increases/parenterals; subsequent shared care as per GMMMG)

Monitoring	Frequency	Results	Action	By whom
FBC, U&E, LFTs with albumin, (ESR desirable but not essential)	**During dose titration**: Every 2 weeks until achieve a stable dose for 6 weeks. **Maintenance dose**: Monthly for 3 months then at least every 3 months. More frequent monitoring is appropriate in patients at higher risk of Toxicity* e.g. if combined with leflunomide	WCC<3.5 x 10^9/l Neutrophils <1.6 x 10^9/l Platelets <140 x 10^9/l Unexplained eosinophilia >0.5 x 10^9/L Unexplained fall in serum albumin <30g/l	Withhold until discussion with Rheumatology Team	GP
		ALT and/or AST > 100 units/L OR Any sudden increases (e.g. double of baseline ALT)	Withhold until discussed with the Rheumatology Team. Check any other reason such as alcohol, drug interaction including over the counter medication as risk of hepatic dysfunction	GP

		Dose Increases/Starting an additional DMARD: Every 2 weeks until on stable dose for 6 weeks then revert back to previous schedule.	MCV>105 fl	Check serum folate, B12, alcohol history and TSH. Treat any underlying abnormality. If results normal discuss with Rheumatology Team	GP
			Creatinine >30% above baseline and/or calculated GFR <60	Use clinical judgement. Repeat in 1 week and if still >30% above baseline withhold until discussed with the Rheumatology Team	**GP**
	*Patients at higher risk of toxicity include: • BMI<18 or >30 • Renal impairment CKD3+ • Pre-existing liver disease • Age >80 • Previous DMARD toxicity • Significant other morbidity • Use in combination with leflunomide				
13. Pharmaceutical aspects	Only supply 2.5mg tablets to avoid dosing errors as per NPSA alert and CSM warning.				
14. Responsibilities of initiating specialist **(Local commissioning arrangements may vary).**	• Undertake baseline monitoring. • Supply the first three months of medication (and additional two weeks to cover transition between Secondary to Primary care prescribing responsibility). • Supply blood forms for three months at the time of prescribing (patient to use these at their GP or local phlebotomy service during the initiation period. • Monitor blood test results during the first three months initiation period. • Advise GP on dose adjustments. • Monitor patient's initial reaction to and progress on the drug. • Ensure that the patient has an adequate supply of medication until GP supply can be arranged. • Patients will be considered suitable for transfer to GP prescribing ONLY when they meet the criteria listed in section 3 above. • The initiating specialist prescriber team will write formally to the GP to request shared care using the GMMMG agreed process. Failure to supply all the required information will result in the refusal of the request until all information has been supplied • Patients will only be transferred to the GP once the GP has agreed. • Continue to monitor and supervise the patient according to this protocol, while the patient remains on this drug, and agree to review the patient promptly if contacted by the GP. • Provide GP with diagnosis, relevant clinical information and baseline results, treatment to date and treatment plan, duration of treatment before specialist review. • Provide GP with details of outpatient consultations, ideally within 14 days of seeing the patient or inform GP if the patient does not attend appointment. • Provide GP with advice on when to stop this drug. • When and additional anti-rheumatology medication is added (either a biologic or a DMARD) the specialist should inform the GP and confirm if any changes to or additional				

	monitoring is required. If no extra monitoring is needed, this should also be stated.
	• Act upon communication from the GP in a timely manner.
	• Provide patient with relevant drug information to enable Informed consent to therapy.
	• Provide patient with relevant drug information to enable understanding of potential side effects and appropriate action.
	• Patients should be advised to seek medical attention for the following:
	  o Patients should report all symptoms and signs suggestive of blood disorders (e.g. sore throat, bruising and mouth ulcers)
	  o Patients should report all symptoms and signs suggestive of liver toxicity (e.g. nausea, vomiting, abdominal discomfort, dark urine and jaundice)
	  o Patient should report any upper abdominal pain as this is an indicator of development of pancreatitis.
	• Provide patient with relevant drug information to enable understanding of the role of monitoring.
	• Be available to provide patient specific advice and support to GPs as necessary.
	• Provide patient with specialist nurse helpline contact number e.g. rheumatology helpline.

15. Responsibilities of the GP
 	
(Local commissioning arrangements may vary).
	• Facilitate blood tests at surgery during the initial three months of treatment. Blood forms will be provided by the referring consultant and results will therefore be sent back to the appropriate consultant.
	• Continue treatment as directed by the specialist.
	• Act upon communication from the specialist in a timely manner.
	• Ensure no drug interactions with concomitant medicines.
	• To monitor and prescribe in collaboration with the specialist according to this protocol.
	• To undertake vaccination as directed by the initiating specialistt, the BNF or Green Book.
	• Symptoms or results are appropriately actioned, recorded and communicated to secondary care when necessary.
	• GPs should reply to request for shared care to either accept or decline within 14 days. A form is available on the GMMMG website to facilitate this, if you so wish.
	• If the GP does not feel it is appropriate to take on the prescribing then the prescribing responsibilities will remain with the specialist. The GP should indicate the reason for declining.
	• Enter a READ code (e.g. 8BM5.00) on to the patient record to highlight the existence of shared care for the patient.
	• Undertake more frequent tests if there is evidence of clinical deterioration, abnormal results, or other risk factors. Contact specialist team for advice on monitoring in these circumstances if required.
	• Check all monitoring results prior to issuing a repeat prescription to ensure it is safe to do so.
	• If a patient fails to attend for monitoring:
	  o Only issue a 28 day prescription and send them the next available appointment for a blood test
	  o If they fail to attend a second blood test then contact the specialist team for advice and to discuss suitability for continued shared care before supplying further prescriptions
	• Monitor the patient's general wellbeing.
	• Seek urgent advice from secondary care if:
	  o Signs or symptoms indicating blood dyscrasias eg sore throat, infection, unexplained or abnormal bruising or bleeding.
	  o Any signs of bone marrow suppression (ie infection, fever, unexplained bruising or bleeding)
	  o Jaundice
	  o The patient becomes pregnant
	  o Non compliance is suspected
	  o The GP feels a dose change is required
	  o There is marked deterioration renal function
	  o The GP feels the patient is not benefiting from the treatment

<table>
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The shared care agreement will cease to exist, and prescribing responsibility will return to secondary care, where:

The clinical situation deteriorates such that the shared care criterion of stability is not achieved.
The clinical situation requires a major change in therapy.
GP feels it to be in the best stated clinical interest of the patient for prescribing responsibility to transfer back to the specialist team. The specialist team will accept such a transfer within a timeframe appropriate to the clinical circumstances.

There must be discussion between the consultant team and GP on this matter and agreement from the specialist team to take back full prescribing responsibility for the treatment of the patient. The specialist team should be given 14 days' notice in which to take back prescribing responsibilities from primary care.

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<tr><td>16. Responsibilities of the patient</td><td colspan="4">

To take medication as directed by the prescriber, or to contact the GP if not taking medication
To attend hospital and GP clinic appointments, bring monitoring booklet (if issued)
Failure to attend will result in medication being stopped (on specialist advice).
To report adverse effects to their Specialist or GP.

</td></tr>
<tr><td rowspan="2">17.Additional Responsibilities e.g. Failure of patient to attend for monitoring, Intolerance of drugs, Monitoring parameters outside acceptable range, Treatment failure, Communication failure</td><td>List any special considerations</td><td>Action required</td><td>By whom</td><td>Date</td></tr>
<tr><td>[insert]</td><td>[insert]</td><td>[insert]</td><td>[insert]</td></tr>
<tr><td>18. Supporting documentation</td><td colspan="4">The SCG must be accompanied by a patient information leaflet. (Available from http://www.medicines.org.uk/emc OR http://www.mhra.gov.uk/spc-pil/)</td></tr>
<tr><td>19. Patient monitoring booklet</td><td colspan="4">The patient must receive a monitoring booklet from the specialist upon initiation of treatment. The patient must bring this booklet to all specialist and GP appointments where it will be updated by the health professional conducting the appointment. The patient must also produce the booklet to any health professional involved in other aspects of their care e.g. pharmacists and dentists.</td></tr>
<tr><td>20. Contact details</td><td colspan="4">See Appendix 1</td></tr>
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Appendix 1 – Local Contact Details

Secondary care contact information	**If stopping medication or needing advice please contact:**
	Dr *[insert text here]*
	Contact number: *[insert text here]*
	Hospital: *[insert text here]*
	To contact Rheumatology Department Stepping Hill Hospital: *Consultants:* Dr C. Filer Dr A. Ismail Dr L. Mercer Rheumatology Nurse Helpline 0161 419 4250 Rheumatology Medication Helpline 0161 419 5202 Rheumatology Secretaries 0161 419 5069

Appendix 2 - **Shared Care Guideline Summary:**
***Oral Methotrexate* for the treatment of *Rheumatological Conditions* in Adults**

Drug	Methotrexate 2.5mg tablets
Indication	Oral methotrexate is licensed to treat adults with rheumatoid arthritis and is also widely used to treat other inflammatory arthritides and connective tissue diseases including adults with juvenile inflammatory arthritis.
Overview	Methotrexate is an anti-metabolite cytotoxic drug which inhibits DNA synthesis and cellular replication.
Specialist's Responsibilities N.B. Bolton DAWN monitoring based on BSR guidelines 2008/2017 for initiation/dose increases/parenterals; subsequent shared care as per GMMMG)	**Initial investigations:** Assessment and diagnosis. Discuss the benefits and side effects of treatment with the patient. Baseline FBC, U&E, LFT, BP, GFR, height, weight, and Pre-viral screen in high risk patients: HIV, HBV, HCV. Screening for lung disease and Herpes Zoster status should be undertaken at clinician discretion on a case by case basis. **Initial regimen**: 7.5-25mg ONCE weekly according to hospital instructions (the initial dose may be 5-15mg once weekly, increasing by 2.5mg-5mg every 2-6 weeks until the disease is stabilized) **Clinical monitoring:** Specialist review to ensure continued benefit **Frequency of Monitoring:** During dose titration: every 2 weeks until achieve maintenance dose. Maintenance dose: Monthly for 3 months then 3-monthly thereafter. Initial monitoring for the first 3 months will be carried out by the specialist OR as per local commissioning arrangements. **Safety monitoring:** FBC, U&E and LFTs **Prescribing duration:** Started by Hospital and supplied by hospital for the initial 3 months of treatment, thereafter transferred to GP OR as per local commissioning arrangements. **Prescribing details:** Initiated by specialist, prescribed and monitored by the specialist for the first 3 months and then care transferred over to the GP OR as per local commissioning arrangements. To stop the drug or provide information to the GP on when to stop the drug. **Documentation:** The specialist team will write formally to the GP to request shared care using the GMMMG agreed process. Patients will only be transferred to the GP once the GP has agreed. Provide GP with diagnosis, relevant clinical information, treatment plan, duration of treatment with 14 days of seeing the patient or inform GP if the patient does not attend appointment.
GP's Responsibilities N.B. Bolton DAWN monitoring based on BSR guidelines 2008/2017 for initiation/dose increases/parenterals; subsequent shared care as per GMMMG)	**Maintenance prescription:** prescribe and monitor oral methotrexate 3 months after initiation in accordance with the specialist's recommendations OR as per local commissioning arrangements. Maintenance dosage up to a maximum licensed dose of 20mg / week. Rarely the maximum dose can be 25mg/week. **Clinical monitoring:** To report to and seek advice from the specialist on any aspect of patient care which is of concern to the GP and may affect treatment. **Safety monitoring:**

FBC, U&E, LFTs with albumin, (CRP desirable but not essential)	**During dose titration**: Every 2 weeks until achieve a stable dose for 6 weeks. **Maintenance dose**: Monthly for 3 months then at least every 3 months. More frequent monitoring is appropriate in patients at higher risk of toxicity e.g. also on leflunomide **Dose Increases/Starting an additional DMARD:** Every 2 weeks until on stable dose for 6 weeks then revert back to previous schedule.	WCC<3.5 x 10^9/l Neutrophils <1.6 x 10^9/l Platelets <140 x 10^9/l Unexplained eosinophilia >0.5 x 10^9/L Unexplained fall in serum albumin <30g/l	Withhold until discussion with Rheumatology Team
		ALT and/or AST > 100 units/L OR Any sudden increases (e.g. double of baseline ALT)	Withhold until discussed with the Rheumatology Team. Check any other reason such as alcohol, drug interaction including over the counter medication as risk of hepatic dysfunction
		MCV>105 fl	Check serum folate, B12 and TSH. Treat any underlying abnormality. If results normal discuss with Rheumatology Team
		Creatinine >30% above baseline and/or calculated GFR <60	Use clinical judgement. Repeat in 1 week and if still >30% above baseline withhold until discussed with the

			Rheumatology Team

*Patients at higher risk of toxicity include:

- BMI<18 or >30
- Renal impairment CKD3+
- Pre-existing liver disease
- Age >80
- Previous DMARD toxicity
- Significant other morbidity
- Use in combination with lefluonmide

Duration of treatment: Stop treatment on advice of specialist.

Re-referral criteria: Seek urgent advice from secondary care if:

- Signs or symptoms indicating blood dyscrasias e.g. sore throat, infection, unexplained or abnormal bruising or bleeding.
- Any signs of bone marrow suppression (i.e. infection, fever, unexplained bruising or bleeding)
- Jaundice
- The patient becomes pregnant
- The GP feels a dose change is required
- There is marked deterioration renal function
- The GP feels the patient is not benefiting from the treatment
- Patient fails to attend for monitoring on two consecutive occasions OR none compliance is suspected.

Documentation: GPs should reply to request for shared care to either accept or decline within 14 days. A form is available on the GMMMG website to facilitate this, if you so wish.

Adverse Events

Adverse events	Action
WCC<3.5 x 10^9/l Neutrophils <1.6 x 10^9/l Platelets <140 x 10^9/l Unexplained eosinophilia >0.5 x 10^9/L Unexplained fall in serum albumin <30g/l	Withhold until discussion with Rheumatology Team
ALT and/or AST > 100 units/L OR Any sudden increases (e.g. double of baseline ALT)	Withhold until discussed with the Rheumatology Team. Check any other reason such as alcohol, drug interaction including over the counter medication as risk of hepatic dysfunction
Rash or oral ulceration	Withhold until discussion with Rheumatology Team
MCV>105 fl	Check serum folate, B12 and TSH. Treat any underlying abnormality. If results normal discuss with Rheumatology Team
Abnormal bruising or severe sore throat	Withhold until urgent FBC results available and discuss with Rheumatology Team as can cause bone marrow suppression.
Creatinine >30% above baseline and/or calculated GFR <60	Use clinical judgement. Repeat in 1 week and if still >30% above baseline withhold until discussed with the Rheumatology Team
New or increasing dyspnoea and/or dry cough	Withhold and discuss urgently with rheumatology team as risk of interstitial pneumonitis
Nausea, vomiting, diarrhoea	Withhold until discussion with Rheumatology team
Suspected infection requiring antibiotics	Withhold temporarily until infection cleared

Contra-indications Cautions Drug Interactions

Please refer to the BNF and/or SPC for information.

In non-immune patients exposed to chickenpox or shingles, passive immunisation should be carried out using Varicella zoster immunoglobulin (VZIG). It is the specialist's responsibility to make the recommendation for vaccination at the appropriate time.

Other Information

- Annual flu vaccinations are safe and recommended.
- Pneumococcal vaccination is safe and recommended.
- Only prescribe 2.5mg tablets to avoid dosing errors.
- CSM warning with methotrexate that doses are ONCE WEEKLY.
- During infection requiring antibiotics methotrexate should be temporarily discontinued until the patient has recovered from the infection.
- Also prescribe Folic acid 5mg a minimum of ONCE weekly also given but may be given more frequently if necessary (usually 3 days after methotrexate). Folic acid reduces the toxic effects of methotrexate.

Contact Details

Name: *[insert text here]*
Address: *[insert text here]*
Telephone: *[insert text here]*

Appendix 3 - Shared Care Referral

Sent electronically by Stepping Hill (if available) when appropriate to transfer prescribing and monitoring responsibilities to GP

Dear Dr,

This patient is suitable for treatment with a medication which has been accepted for shared care according to the Derbyshire Joint Area Prescribing Committee and Stockport NHS Foundation Trust shared care protocol.

I am therefore requesting your agreement to share the care of this patient. Please see the corresponding letter (sent on the same date as this agreement request) for details of the medication. Pre-treatment investigations have been undertaken as per the shared care agreement and the patient has received the first three months of medication, is tolerating the treatment well and all blood tests have remained within the acceptable ranges.

Please return the response form within the next 14 days via fax to 0161 419 5548.

For further information please refer to the Shared Care Protocol which can be accessed below: http://www.derbyshiremedicinesmanagement.nhs.uk/clinical_guidelines/out_of_area_shared_care_guidelines

Thank you

The Rheumatology Team,

Response Form (to be completed by the GP and returned to the fax number above)

Dear Dr_____,

I have received your request for shared care of the above patient who has been receiving treatment for the past 3 months with _____ as prescribed by their rheumatology consultant.

A: I am willing to accept the shared care for this patient, to continue to prescribe and monitor as set out in the protocol
B: I wish to discuss this request with you
C: I am unable to undertake shared care of this patient.
If unable to undertake shared care, please state why:
GP Signature:
Date:
GP address/practice stamp
Yours sincerely