

Shared Care Guideline Stepping Hill Hospital and North Derbyshire CCG

Shared Care Guideline for Leflunomide in Rheumatological Conditions in Adults		Reference Number
Version: 1	Replaces:	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	Leflunomide 10mg and 20mg tablets
2. Licensed Indications <i>(state if this is an unlicensed indication)</i>	Leflunomide is indicated for treatment of adult patients with active rheumatoid arthritis as a disease-modifying anti-rheumatic drug and active psoriatic arthritis.
3. Criteria for shared care	Prescribing responsibility will only be transferred when <ul style="list-style-type: none"> 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 shared care	<ul style="list-style-type: none"> Patient does not consent to shared care. Patient does not meet criteria for shared care.
5. Therapeutic use & background	Leflunomide is a disease-modifying anti-rheumatic agent with antiproliferative properties. It has immunomodulating/ immunosuppressive characteristics, acts as an antiproliferative agent, and

	displays anti-inflammatory properties. A771726, the active metabolite of leflunomide, inhibits the human enzyme dihydroorotate dehydrogenase (DHODH) and exhibits antiproliferative activity.	
6. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).	<p>Contraindications: Severe immunodeficiency, serious infections, impaired liver function due to any cause, severe unexplained hypoproteinaemia, renal impairment (moderate to severe).</p> <p>Cautions: Localised or systemic infection including hepatitis B or C and history of tuberculosis. Drug potentiation- haematotoxic or hepatotoxic drugs such as methotrexate, caution if used together. Impaired bone marrow function including anaemia, leucopenia or thrombocytopenia (avoid if significant and due to causes other than rheumatoid arthritis). Interstitial lung disease.</p>	
7. Prescribing in pregnancy and lactation	<p>This drug should not be prescribed during pregnancy and or while breastfeeding.</p> <p>It is important that women of childbearing potential do not start leflunomide until pregnancy has been excluded and both men and women must use reliable contraception. If, during treatment, there is a delay in onset of menstruation or other reason to suspect pregnancy then the patient must notify their GP and Consultant as soon as possible. Pregnancy is not recommended during treatment and for 2 years after stopping leflunomide. If the patient wants to conceive then blood metabolite levels need to be checked and a wash out organised if necessary.</p> <p>Men should use effective contraception. For men wishing to father a child, contact rheumatology specialist for advice.</p> <p>Women must not breastfeed while they are taking leflunomide.</p>	
8. Dosage regimen for continuing care	Route of administration:	Oral
	Preparations available: Leflunomide 10mg and 20mg tablets	
	Tablets can be dispersed in water for swallowing difficulties and enteral feeding.	
	Please prescribe: 10mg-20mg per day depending on disease severity.	
	Is titration required	Yes
	Titrate dosage up by 10mg according to response. Maintenance dosage up to a maximum 20mg/day	
	Adjunctive treatment regime: Annual flu vaccinations are safe and recommended. Pneumococcal vaccination is safe and recommended. 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: e.g. impaired renal/ liver function Not to be used in impaired liver function, moderate/severe renal impairment.	
	Usual response time : 8-12 weeks	
	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	<p>The following drugs must <u>not</u> be prescribed without consultation with the specialist:</p> <ul style="list-style-type: none"> Live vaccines (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever, varicella zoster) are contraindicated. 	

<p>comprehensive list consult the BNF or Summary of Product Characteristics</p>	<p>The following drugs may be prescribed with caution:</p> <ul style="list-style-type: none"> Leflunomide may inhibit the metabolism of warfarin, phenytoin and tolbutamide. It has an extremely long elimination half life and interactions with these drugs and with other DMARDs may occur even after leflunomide has been discontinued. Alcohol should be avoided (or limited to max. 8 units weekly) due to an increased risk of hepatotoxicity. The effect of leflunomide is significantly decreased by colestyramine (enhanced elimination), avoid unless drug elimination desired. 		
<p>10. Adverse drug reactions</p> <p><i>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</i></p>	<p>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.</p>		
	<p>Adverse event System – symptom/sign</p>	<p>Action to be taken <small>Include whether drug should be stopped prior to contacting secondary care specialist</small></p>	<p>By whom</p>
	<p>WCC < 3.5 x 10⁹/l Neutrophils < 1.6 x 10⁹/l Platelets < 140 x 10⁹/l Unexplained eosinophilia > 0.5 x 10⁹/L Unexplained fall in serum albumin < 30g/l</p>	<p>Withhold until discussion with Rheumatology Team</p>	<p>GP</p>
	<p>ALT and/or AST > 100 units/L OR Any sudden increases (e.g. double of baseline ALT)</p>	<p>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</p>	<p>GP</p>
	<p>Rash or Itch</p>	<p>Consider dosage reduction with or without antihistamines if severe, withhold until discussion with Rheumatology Team</p>	<p>GP</p>
	<p>MCV > 105 fl</p>	<p>Check serum folate, B12, alcohol history and TSH. Treat any underlying abnormality. If results normal discuss with Rheumatology Team</p>	<p>GP</p>
	<p>Abnormal bruising or severe sore throat</p>	<p>Withhold until urgent FBC results available and discuss with Rheumatology Team as can cause bone marrow suppression.</p>	<p>GP</p>
	<p>Creatinine > 30% above baseline and/or calculated GFR < 60</p>	<p>Use clinical judgement. Repeat in 1 week and if still > 30% above baseline withhold until discussed with the Rheumatology Team</p>	<p>GP</p>
	<p>Hair Loss</p>	<p>Consider dosage reduction if severe, withhold until discussion with Rheumatology Team as risk of alopecia</p>	<p>GP</p>
	<p>Hypertension</p>	<p>If BP > 140/90 treat in line with NICE guidance. If BP remains uncontrolled, withhold until discussion with Rheumatology Team</p>	<p>GP</p>
	<p>Headache</p>	<p>If severe, discuss reducing dose with Rheumatology Team. If headaches persist, withhold until discussion with Rheumatology Team</p>	<p>GP</p>
	<p>Weight Loss</p>	<p>If > 10% weight loss with no other cause identified reduce dosage or withhold until discussion with Rheumatology Team as risk of anorexia</p>	<p>GP</p>
	<p>Breathlessness</p>	<p>If increasing shortness of breath occurs withhold until discussion with Rheumatology Team as risk of interstitial lung disease</p>	<p>GP</p>

	GI Upset	Give symptomatic treatment and consider dosage reduction. If symptoms are severe or persistent, stop and consider washout.	GP	
	<p>The patient should be advised to report any of the following signs or symptoms to their GP without delay: Severe skin rash that causing blistering Jaundice Blood dyscrasias e..g sore throat, infection, unexplained or abnormal bruising or bleeding</p> <p>Leflunomide may also cause mouth ulcers, skin rash (including Stevens–Johnson syndrome and toxic epidermal necrolysis), gastrointestinal upset, headaches, dizziness, tenosynovitis and hair loss.</p> <p>If a severe undesirable side effect of leflunomide occurs or for any other reason rapid removal of its active metabolite is required a washout procedure with cholestyramine 8 grams three times a day or activated charcoal 50 grams four times a day, each for 11 days is available. Washout should be discussed with specialist.</p> <p>Leflunomide increases susceptibility to infections which should be treated promptly.</p> <p>Other important co morbidities (e.g. Chickenpox exposure):</p> <ul style="list-style-type: none"> • 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). • 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 leflunomide should be temporarily discontinued until the patient has recovered from the infection. 			
	<p>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.</p>			
11. Baseline investigations	<p><i>List of investigations / monitoring undertaken by secondary care</i> FBC U&Es incl GFR LFT (ALT, AST and albumin) Height Pre-viral screen in high risk patients: HIV, HBV (surface antigen, core antibody), HCV (antibody test) and consider herpes zoster status (if appropriate) BP: If >140/90 on two consecutive readings 2 weeks apart treat hypertension before commencing the drug Weight: To allow assessment of weight loss, this may be attributable to leflunomide Screening for lung disease should be undertaken at clinician discretion on a case by case basis.</p>			
12. Ongoing monitoring requirements to be undertaken by GP (Local commissioning arrangements may vary).	Is monitoring required?	<p>Yes (N.B. Bolton DAWN monitoring based on BSR guidelines 2008/2017 for initiation/dose increases/parenterals; subsequent shared care as per GMMM)</p>		
	Monitoring	Frequency	Results	Action
	FBC, U&E, LFTs with albumin, (ESR desirable but not essential)	<p>During dose titration: Every 2 weeks until achieve a stable dose for 6 weeks.</p> <p>Maintenance dose: Monthly for 3 months then at least every 3 months. More frequent monitoring</p>	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

		is appropriate in patients at higher risk of toxicity. Dose Increases/Starting an additional DMARD: Every 2 weeks until on stable dose for 6 weeks then revert back to previous schedule.	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
			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
	Blood pressure	Every monitoring visit	If BP > 140/90 treat in line with NICE guidance. If BP remains uncontrolled, withhold until discussion with Rheumatology Team		GP
	Weight	Every monitoring visit	If >10% weight loss with no other cause identified reduce dosage or withhold until discussion with Rheumatology Team as risk of anorexia		GP
*Patients at higher risk of toxicity include: <ul style="list-style-type: none"> Use in combination with methotrexate 					
13. Pharmaceutical aspects	No special requirements.				
14. Responsibilities of initiating specialist	<ul style="list-style-type: none"> 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. 				

	<ul style="list-style-type: none"> • 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 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 consultant 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: <ul style="list-style-type: none"> ○ Patients should report all symptoms and signs suggestive of blood disorders (e.g. sore throat, bruising and mouth ulcers) ○ Patients should report all symptoms and signs suggestive of liver toxicity (e.g. nausea, vomiting, abdominal discomfort, dark urine and jaundice) • 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.
<p>15. Responsibilities of the GP</p>	<ul style="list-style-type: none"> • 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 specialist, 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: <ul style="list-style-type: none"> ○ Only issue a 28 day prescription and send them the next available appointment for a blood test ○ If they fail to attend a second blood test then contact the consultant 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: <ul style="list-style-type: none"> ○ Signs or symptoms indicating blood dyscrasias eg sore throat, infection,

	<ul style="list-style-type: none"> ○ unexplained or abnormal bruising or bleeding. ○ Any signs of bone marrow suppression (ie infection, fever, unexplained bruising or bleeding) ○ Jaundice ○ The patient becomes pregnant ○ Non compliance is suspected ○ 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 <ul style="list-style-type: none"> ● The shared care agreement will cease to exist, and prescribing responsibility will return to secondary care, where: <ul style="list-style-type: none"> ○ 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 specialist 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. 								
16. Responsibilities of the patient	<ul style="list-style-type: none"> ● 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. 								
17. Additional Responsibilities e.g. Failure of patient to attend for monitoring, Intolerance of drugs, Monitoring parameters outside acceptable range, Treatment failure, Communication failure	<table border="1"> <thead> <tr> <th>List any special considerations</th> <th>Action required</th> <th>By whom</th> <th>Date</th> </tr> </thead> <tbody> <tr> <td>[insert]</td> <td>[insert]</td> <td>[insert]</td> <td>[insert]</td> </tr> </tbody> </table>	List any special considerations	Action required	By whom	Date	[insert]	[insert]	[insert]	[insert]
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[insert]	[insert]	[insert]	[insert]						
18. Supporting documentation	<p>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/)</p> <p>Arthritis Research UK Patient Information Leaflet Leflunomide</p>								
19. Patient monitoring booklet	<p>The patient may receive a monitoring booklet from the specialist upon initiation of treatment if that is the local practice. 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.</p>								
20. Shared care agreement form	Attached below								
21. Contact details	See Appendix 1								

Appendix 1 – Local Contact Details

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Secondary care contact information	If stopping medication or needing advice please contact:
	Dr <i>[insert text here]</i>
	Contact number: <i>[insert text here]</i>
	Hospital: <i>[insert text here]</i>
	To contact Rheumatology Department Stepping Hill Hospital: <i>Consultants:</i> 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:**
Leflunomide for the treatment of Rheumatological Conditions

Drug	Leflunomide 10mg and 20mg tablets																
Indication	Leflunomide is indicated for treatment of adult patients with active rheumatoid arthritis as a disease-modifying anti-rheumatic drug and active psoriatic arthritis.																
Overview	Leflunomide is a disease-modifying anti-rheumatic agent with antiproliferative properties. It has immunomodulating/ immunosuppressive characteristics, acts as an antiproliferative agent, and displays anti-inflammatory properties.																
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)	<p>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.</p> <p>Initial regimen: 10mg-20mg per day depending on disease severity.</p> <p>Clinical monitoring: Specialist review to ensure continued benefit</p> <p>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.</p> <p>Safety monitoring: BP, Weight, FBC, U&E and LFTs.</p> <p>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.</p> <p>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.</p> <p>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.</p>																
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)	<p>Maintenance prescription: prescribe and monitor leflunomide 3 months after initiation in accordance with the specialist's recommendations OR as per local commissioning arrangements.</p> <p>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.</p> <p>Safety monitoring:</p> <table border="1"> <tr> <td rowspan="4">FBC, U&E, LFTs with albumin, (CRP desirable but not essential)</td> <td rowspan="4"> <p>During dose titration: Every 2 weeks until achieve a stable dose for 6 weeks.</p> <p>Maintenance dose: Monthly for 3 months then at least every 3 months. More frequent monitoring is appropriate in patients at higher risk of toxicity.</p> <p>Dose Increases/Starting an additional DMARD: Every 2 weeks until on stable dose for 6 weeks then revert back to previous schedule.</p> </td> <td>WCC < 3.5 x 10⁹/l Neutrophils < 1.6 x 10⁹/l Platelets < 140 x 10⁹/l Unexplained eosinophilia > 0.5 x 10⁹/L Unexplained fall in serum albumin < 30g/l</td> <td>Withhold until discussion with Rheumatology Team</td> </tr> <tr> <td>ALT and/or AST > 100 units/L OR Any sudden increases (e.g. double of baseline ALT)</td> <td>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</td> </tr> <tr> <td>MCV > 105 fl</td> <td>Check serum folate, B12 and TSH. Treat any underlying abnormality. If results normal discuss with Rheumatology Team</td> </tr> <tr> <td>Creatinine > 30% above baseline and/or calculated GFR < 60</td> <td>Use clinical judgement. Repeat in 1 week and if still > 30% above baseline withhold until discussed with the Rheumatology Team</td> </tr> <tr> <td>Blood pressure</td> <td>Every monitoring visit</td> <td colspan="2">If BP > 140/90 treat in line with NICE guidance. If BP remains uncontrolled, withhold until discussion with Rheumatology Team</td> </tr> </table>			FBC, U&E, LFTs with albumin, (CRP desirable but not essential)	<p>During dose titration: Every 2 weeks until achieve a stable dose for 6 weeks.</p> <p>Maintenance dose: Monthly for 3 months then at least every 3 months. More frequent monitoring is appropriate in patients at higher risk of toxicity.</p> <p>Dose Increases/Starting an additional DMARD: Every 2 weeks until on stable dose for 6 weeks then revert back to previous schedule.</p>	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	Blood pressure	Every monitoring visit	If BP > 140/90 treat in line with NICE guidance. If BP remains uncontrolled, withhold until discussion with Rheumatology Team	
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	Weight	Every monitoring visit	If >10% weight loss with no other cause identified reduce dosage or withhold until discussion with Rheumatology Team as risk of anorexia
	*Patients at higher risk of toxicity include: Use in combination with methotrexate		
Duration of treatment: Stop treatment on advice of specialist.			
Re-referral criteria: Seek urgent advice from secondary care if:			
<ul style="list-style-type: none"> ➤ 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 ➤ Non compliance is suspected ➤ 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 			
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 Itch		Consider dosage reduction with or without antihistamines if severe, 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
	Hair Loss		Consider dosage reduction if severe, withhold until discussion with Rheumatology Team as risk of alopecia
	Hypertension		If BP > 140/90 treat in line with NICE guidance. If BP remains uncontrolled, withhold until discussion with Rheumatology Team
	Headache		If severe, consider dosage reduction. If headaches persist, withhold until discussion with Rheumatology Team
	Weight Loss		If > 10% weight loss with no other cause identified reduce dosage or withhold until discussion with Rheumatology Team as risk of anorexia
	Breathlessness		If increasing shortness of breath occurs withhold until discussion with Rheumatology Team as risk of interstitial lung disease
	GI Upset		Give symptomatic treatment and consider dosage reduction. If symptoms are severe or persistent, stop and consider washout.
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. During infection requiring antibiotics leflunomide should be temporarily discontinued until the patient has recovered from the infection.		
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