

Shared Care Guideline Stepping Hill Hospital and North Derbyshire CCG

Shared Care Guideline for Sodium Aurothiomalate in Rheumatological Conditions in Adults		Reference Number
Version: 1	Replaces:	Issue date: November 2017
Author(s)/Originator(s): (please state author name and department) Dr. C. Filer (Consultant Rheumatologist) Stepping Hill Hospital Dr. A. Ismail (Consultant Rheumatologist) Stepping Hill Hospital Dr. L. Mercer (Consultant Rheumatologist) Stepping Hill Hospital Rebecca Heaton (Specialist Pharmacist) Stepping Hill Hospital <i>Based on the previous shared care guidelines from GMMMG</i>		To be read in conjunction with the following documents: Current Summary of Product characteristics (http://www.medicines.org.uk) BNF BSR and BHPR Guideline for the Prescription and Monitoring of Non-Biologic Disease-Modifying Anti-Rheumatic Drugs 2017 BSR and BHPR Guideline on Prescribing Drugs in Pregnancy and Breast-Feeding – Part 1: standard and biologic disease modifying anti-rheumatic drugs and corticosteroids 2015
Date noted by JAPC: June 2018		Review Date: October 2019

Please complete all sections

1. Name of Drug, Brand Name, Form and Strength	Sodium aurothiomalate (Myocrisin®)20mg/ml injection, 10mg ampoules. Sodium aurothiomalate (Myocrisin®)100mg/ml injection, 50mg ampoules
2. Licensed Indications	Sodium Aurothiomalate is used in the management of active progressive rheumatoid arthritis and other rheumatological conditions.
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	<p>The precise mode of action of sodium aurothiomalate is not yet known. Treatment with gold has been shown to be accompanied by a fall in ESR and CRP, an increase in serum histidine and sulphhydryl levels and a reduction in serum immunoglobulins, rheumatoid factor titres and Clq-binding activity. Numerous experimental observations have been recorded including physico-chemical changes in collagen and interference with complement activation, gammaglobulin aggregation, prostaglandin biosynthesis, inhibition of cathepsin and production of superoxide radicals by activated polymorphonuclear leucocytes.</p>	
6. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).	<p>Contraindications: severe renal or hepatic impairment, history of blood disorders or marrow aplasia, exfoliative dermatitis, systemic lupus erythematosus, necrotising enterocolitis, significant pulmonary fibrosis, porphyria, pregnancy and breastfeeding. Hypersensitivity to Sodium aurothiomalate or any excipients.</p> <p>Cautions: elderly, caution in mild to moderate renal and hepatic impairment, history of urticaria, eczema or inflammatory bowel disease.</p>	
7. Prescribing in pregnancy and lactation	<p>This drug should not be prescribed during pregnancy and/or while breastfeeding. The safety of sodium aurothiomalate in the foetus and the newborn has not been established. Female patients receiving sodium aurothiomalate should be instructed to avoid pregnancy. Pregnancy patients should not be treated with sodium aurothiomalate. Lactating mothers under treatment with sodium aurothiomalate excrete significant amounts of gold in their breast milk and should not breast feed their infants.</p>	
8. Dosage regimen for continuing care	Route of administration:	IM injection
<p>Preparations available: Sodium aurothiomalate (Myocrisin®)20mg/ml injection, 10mg ampoules. Sodium aurothiomalate (Myocrisin®)100mg/ml injection, 50mg ampoules Preparation is an intramuscular injection.</p>		
<p>Myocrisin® should be administered only by deep intramuscular injection followed by gentle massage of the area. The patient should remain under medical observation for a period of 30 minutes after drug administration.</p>		
<p>Please prescribe: 10mg test dose may be used (which should be given in secondary care followed by 30min observation to look for signs of allergic reaction) followed by 50mg weekly until there is a significant response or a total dose of 1000mg has been given. In patients who respond, the interval between doses may be increased in stages from 50mg per week to 50mg every 4 to 6 weeks.</p>		
Is titration required	Yes	
<p>Titrate dosage up to a total dose of 1000mg. Maintenance dosage up to a maximum 50mg weekly then decrease dosage interval according to response.</p>		
<p>Adjunctive treatment regime:</p> <ul style="list-style-type: none"> • Annual flu vaccinations are safe and recommended. • Pneumococcal vaccination is safe and recommended. 		
<p>Conditions requiring dose reduction: e.g. impaired renal/ liver function No dosage reduction required</p>		
<p>Usual response time: Benefit should not be expected until a cumulative dose of at least 500mg has been given. If there is no response after a cumulative dose of 1000mg has been given, consider alternative DMARD therapy.</p>		

	<p>Duration of treatment: Ongoing.</p> <p>If there is no response after a cumulative dose of 1000mg has been given, consider alternative DMARD therapy.</p> <p>Treatment to be terminated by: Healthcare professional in consultation with Rheumatology Team.</p> <p>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.</p>																				
<p>9. Drug Interactions</p> <p><i>For a comprehensive list consult the BNF or Summary of Product Characteristics</i></p>	<p>The following drugs must <u>not</u> be prescribed without consultation with the specialist:</p> <ul style="list-style-type: none"> • Penicillamine- avoidance of sodium aurothiomalate advised by manufacturer increased risk of toxicity • Concurrent gold administration may exacerbate aspirin-induced hepatic dysfunction. • Caution should be exercised if phenylbutazone or oxyphenbutazone are administered concurrently. <p>The following drugs may be prescribed with caution:</p> <ul style="list-style-type: none"> • ACE inhibitors- flushing and hypotension reported when sodium aurothiomalate 																				
<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> <table border="1" data-bbox="418 842 1521 1799"> <thead> <tr> <th data-bbox="418 842 802 926"> Adverse event <small>System – symptom/sign</small> </th> <th data-bbox="802 842 1187 926"> Action to be taken <small>Include whether drug should be stopped prior to contacting secondary care specialist</small> </th> <th data-bbox="1187 842 1521 926"> By whom </th> </tr> </thead> <tbody> <tr> <td data-bbox="418 926 802 1150"> 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 data-bbox="802 926 1187 1150"> Withhold until discussion with Rheumatology Team </td> <td data-bbox="1187 926 1521 1150"> GP </td> </tr> <tr> <td data-bbox="418 1150 802 1375"> ALT and/or AST > 100 units/L OR Any sudden increases (e.g. double of baseline ALT) </td> <td data-bbox="802 1150 1187 1375"> 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> <td data-bbox="1187 1150 1521 1375"> GP </td> </tr> <tr> <td data-bbox="418 1375 802 1455"> Rash (usually itchy) or oral ulceration </td> <td data-bbox="802 1375 1187 1455"> Withhold until discussion with Rheumatology Team </td> <td data-bbox="1187 1375 1521 1455"> GP </td> </tr> <tr> <td data-bbox="418 1455 802 1642"> MCV > 105 fl </td> <td data-bbox="802 1455 1187 1642"> Check serum folate, B12, alcohol history and TSH. Treat any underlying abnormality. If results normal discuss with Rheumatology Team </td> <td data-bbox="1187 1455 1521 1642"> GP </td> </tr> <tr> <td data-bbox="418 1642 802 1799"> Abnormal bruising or severe sore throat </td> <td data-bbox="802 1642 1187 1799"> Withhold until urgent FBC results available and discuss with Rheumatology Team as can cause bone marrow suppression. </td> <td data-bbox="1187 1642 1521 1799"> GP </td> </tr> </tbody> </table>			Adverse event <small>System – symptom/sign</small>	Action to be taken <small>Include whether drug should be stopped prior to contacting secondary care specialist</small>	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 (usually itchy) 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
Adverse event <small>System – symptom/sign</small>	Action to be taken <small>Include whether drug should be stopped prior to contacting secondary care specialist</small>	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 (usually itchy) 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																			

	<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>2 + proteinuria or more</p>	<p>Check MSSU and protein/creatinine ratio: If infection present treat appropriately. If no infection present and proteinuria confirmed, withhold until discussed with Rheumatology Team</p>	<p>GP</p>		
<p>The patient should be advised to report any of the following signs or symptoms to their GP without delay: Patients should be advised to seek prompt medical attention if diarrhoea, sore throat, fever, infection, non-specific illness, unexplained bleeding and bruising, purpura, mouth ulcers, metallic taste, rash, breathlessness, or cough develop.</p>					
<p>Other important co morbidities: Annual flu vaccine should be recommended. Pneumococcal vaccination is safe and recommended (due to suppressed immune system with these drugs).</p>					
<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>					
<p>11. Baseline investigations</p>	<p><i>List of investigations / monitoring undertaken by secondary care</i> Chest X-Ray Urinary dipstick for protein 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.</p>				
<p>12. Ongoing monitoring requirements to be undertaken by GP (Local commissioning arrangements may vary).</p>	<p>Is monitoring required?</p>	<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>			
	<p>Monitoring</p>	<p>Frequency</p>	<p>Results</p>	<p>Action</p>	<p>By whom</p>
	<p>FBC, U&E, LFTs with albumin, (ESR desirable but not essential)</p>	<p>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.</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>

		More frequent monitoring is appropriate in patients at higher risk of toxicity.	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
		<p>Dose Increases/Starting an additional DMARD: Every 2 weeks until on stable dose for 6 weeks then revert back to previous schedule.</p>	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
			Urinalysis for blood and protein	Prior to each dose	Check MSSU and protein/creatinine ratio: If infection present treat appropriately. If no infection present and proteinuria confirmed, withhold until discussed with Rheumatology Team
The patient should be asked about presence of rash or mouth ulcers before each injection				GP	

13. Pharmaceutical aspects	Store below 25C and protect from light
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. • 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.
15. Responsibilities of the GP (Local commissioning arrangements may vary).	<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.

	<ul style="list-style-type: none"> • To undertake vaccination as directed by the initiating consultant, 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 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: <ul style="list-style-type: none"> ○ Signs or symptoms indicating blood dyscrasias eg sore throat, infection, 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 • 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	List any special considerations	Action required	By whom	Date

e.g. Failure of patient to attend for monitoring, Intolerance of drugs, Monitoring parameters outside acceptable range, Treatment failure, Communication failure	<i>[insert]</i>	<i>[insert]</i>	<i>[insert]</i>	<i>[insert]</i>
18. Supporting documentation	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/)			
19. Patient monitoring booklet	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.			
20. Contact details	See Appendix 1			

Appendix 1 – Local Contact Details

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:**
Sodium Aurothiomalate (Gold) for the treatment of Rheumatological Conditions in adults

Drug	Sodium aurothiomalate (Myocrisin®)20mg/ml injection, 10mg ampoules. Sodium aurothiomalate (Myocrisin®)100mg/ml injection, 50mg ampoules												
Indication	Sodium Aurothiomalate is used in the management of active progressive rheumatoid arthritis and other rheumatological conditions.												
Overview	Treatment with gold has been shown to be accompanied by a fall in ESR and CRP, an increase in serum histidine and sulphhydryl levels and a reduction in serum immunoglobulins, rheumatoid factor titres and Clq-binding activity.												
Specialist's Responsibilities	<p>Initial investigations: Assessment and diagnosis. Discuss the benefits and side effects of treatment with the patient. Baseline FBC, U&E, LFT, Chest X-Ray, Urinary dipstick for protein, Blood pressure, 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 test dose may be used (which should be given in clinic followed by 30min observation to look for signs of allergic reaction) followed by 50mg weekly until there is a significant response or a total dose of 1000mg has been given. In patients who respond, the interval between doses may be decreased in stages from 50mg per week to 50mg every 4 to 6 weeks.</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: FBC, U&E and LFTs, Urinalysis for blood and protein</p> <p>Prescribing duration: Started by specialist and supplied by specialist 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	<p>Maintenance prescription: prescribe and monitor sodium aurothiomalate 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</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
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
Urinalysis for blood and protein	Prior to each dose	2 + proteinuria or more	Check MSSU and protein/creatinine ratio: If infection present treat appropriately. If no infection present and proteinuria confirmed, withhold until discussed with Rheumatology Team
The patient should be asked about presence of rash or mouth ulcers before each injection			See Adverse Events section

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 or feels the patient is not benefiting from treatment
- There is marked deterioration renal function
- Patient fails to attend for monitoring on two consecutive occasions or non-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	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
	2 + proteinuria or more	Check MSSU and protein/creatinine ratio: If infection present treat appropriately. If no infection present and proteinuria confirmed, withhold until discussed with Rheumatology Team

Contra-indications Cautions Drug Interactions	Please refer to the BNF and/or SPC for information.
--	---

Other Information	<ul style="list-style-type: none"> • Annual flu vaccinations are safe and recommended. • Pneumococcal vaccination is safe and recommended. • Myocrisin® should be administered only by deep intramuscular injection followed by gentle massage of the area. The patient should remain under medical observation for a period of 30 minutes after drug administration. • During infection requiring antibiotics Sodium aurothiomalate (Myocrisin®) should be temporarily discontinued until the patient has recovered from the infection
--------------------------	---

Contact Details	<p>Name: [insert text here] Address: [insert text here] Telephone: [insert text here]</p>
------------------------	--

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