SHARED CARE GUIDELINE

Lancashire & South Cumbria Medicines Management Group

Drug: Sodium Aurothiomalate (Gold injection)

Introduction	**Indications**: Licensed – Active, progressive rheumatoid arthritis, progressive juvenile chronic arthritis especially if polyarticular or seropositive. Unlicensed – skin diseases including pemphigus **Background:** The mechanism of action of Sodium aurothiomalate is not known. Benefit should not be expected until a cumulative dose of at least 300- 500mg has been given. If there is no response after a cumulative dose of 1000mg has been given, alternative DMARD therapy will be considered. **Definitions:** Stable dose – the dose will be titrated to achieve efficacy at the lowest dose. Once efficacy achieved and provided the patient can tolerate the dose, this will be termed "stable dose" Stable bloods – results of blood tests remain below the "alert" thresholds as set by national guidelines and have stayed at similar levels for at least two consecutive tests. N.B. The patient can continue to have active disease despite being on a stable dose or having stable bloods, so the "patient" is not referred to as "stable"
Form	Myocrisin 100mg/ml solution for injection, 0.5ml ampoules[1]
Dose & Administration	• Sodium aurothiomalate should only be administered by deep intramuscular (IM) injection followed by gentle massage of the area. The patient should remain under medical observation for a period of 30 minutes after drug administration. • Typical dose: An initial 10mg test dose (administered in secondary care) in the first week, followed by 50mg doses weekly until signs of remission occur. • In patients showing signs of remission, 50mg doses should be given at two weekly intervals until full remission occurs. • With full remission, the interval between injections should be increased progressively to three and then four weeks. • After 18 months to 2 years, the interval between injections is to be increased to six weeks. • If after reaching a total dose of 1000mg (excluding the test dose), no major improvement has occurred other forms of treatment are to be considered. N.B. Do not use a darkened solution (more than pale yellow).
Secondary Care Responsibilities	• Confirm the diagnosis. • Check for absence of pregnancy in women of child-bearing age and ensure the patient understands the importance of contraception. • Discuss the benefits and side effects of treatment with the patient. Ensure that the patient understands which warning signs and symptoms to report. • Perform pre-treatment screening[2]: height, weight, blood pressure, FBC, LFT, albumin and, creatinine/ calculated GFR, urinalysis for blood and protein and chest x-ray • Patients should be assessed for co-morbidities, including evaluation for respiratory disease and screening for occult viral infection • Administer a 10mg test dose and observe the patient for 30minutes for signs of allergic reaction. • Ensure that the patient understands not to expect improvement for the first few injections. • Provide the patient with prescriptions for Sodium Aurothiomalate (Myocrisin®) injection until on stable dose and undergoing 3 monthly monitoring. Provide the patient with a monitoring and dosage record booklet and ensure that the patient knows when and where to attend for monitoring. Encourage the patient to take responsibility for ensuring that results of tests are entered in the monitoring booklet. • Make arrangements for shared care with the patient's GP.

	• Review the patient regularly to monitor the patient's response to therapy. • Advise the GP on frequency of monitoring, frequency of injections and when to stop treatment. • Ensure that clear backup arrangements exist for GPs to obtain advice.
Primary Care Responsibilities	• Provide the patient with prescriptions for Sodium aurothiomalate (Myocrisin®) once on stable dose and undergoing 3 monthly monitoring and make the necessary arrangements for administration of the injection. • Monitor at the recommended frequencies (see MONITORING below) and ensure that test results are recorded in the monitoring booklet. • Report any adverse events to the consultant or specialist nurse and stop treatment on their advice or immediately if an urgent need arises (see MONITORING below). • Report any worsening of control of the condition to the consultant or the specialist nurse. • Follow recommended immunisation programme.
Immunisations	Annual flu vaccine is recommended Pneumococcal vaccination recommended In patients exposed to chicken pox or shingles, if required, passive immunisation should be considered for varicella. Refer to Green book: Varicella: the green book, chapter 34 - Publications - GOV.UK
Common Drug Interactions	This list is not exhaustive, please refer to SPCs and BNF • ACE inhibitors • Penicillamine
Cautions	• Elderly • Moderate renal or hepatic impairment • History of urticaria or eczema • History of colitis • If phenylbutazone or oxyphenbutazone are administered concurrently • Irreversible skin pigmentation (chrysiasis) can occur in sun-exposed areas after prolonged treatment with sodium aurothiomalate. Patients should be advised to limit exposure to the sun by wearing protective clothing and using high factor sunscreens.
Contraindications	• Severe renal or hepatic impairment • History of blood disorders or marrow aplasia • Exfoliative dermatitis • Systemic lupus erythematosus • Necrotising enterocolitis • Pulmonary fibrosis • Acute Porphyria • Pregnancy and breastfeeding • Co-prescribing of penicillamine
This guidance does not replace the SPC's, which should be read in conjunction with this guidance.	

MONITORING AND ADVERSE EFFECTS

Treatment Status	FBC	LFT	Albumin	Creatinine / calculated GFR	Urinalysis (blood and protein)
Initial monitoring until on stable dose for 6 weeks	Every 2 weeks	Every 2 weeks	Every 2 weeks	Every 2 weeks	Prior to each dose
For next three months	Monthly	Monthly	Monthly	Monthly	Prior to each dose
Thereafter	Every 3 months	Every 3 months	Every 3 months	Every 3 months	Prior to each dose

***Please note:** If the patient is also being treated with **leflunomide**, increased monthly monitoring is required, as specified in the leflunomide shared care guidance. (Where other biologic/DMARDs are used in combination with sodium aurothiomalate, the standard monitoring requirements, as outlined above, continue to apply).

As per secondary care responsibilities, for clarity the frequency of monitoring should be specified in the initial shared care request.

Dose increases should be monitored by FBC, creatinine / calculated GFR, albumin and LFTs every 2 weeks until on stable dose for 6 weeks and then revert to previous schedule.

The team responsible for prescribing the medication should also hold responsibility or monitoring
i.e. prescribing to be carried out in Primary care only once patient on stable dose and undergoing 3 monthly monitoring

- The patient should be asked about the presence of rash, unusual bruising or mouth ulcers, unexplained breathlessness or cough. If present, withhold until discussed with specialist team.
- Results of FBC, including numerical platelet count, at the time of each injection need not be available before the injection is given, but must be available before the next injection. However urinalysis must precede monthly administration.

If 2+ proteinuria or more check MSSU. If infection present treat appropriately. If sterile and 2+ proteinuria or more persists on two consecutive occasions, STOP sodium aurothiomalate and discuss with the specialist team.

In the event of the following adverse laboratory results or patient reported symptoms, withhold sodium aurothiomalate injections until discussed with specialist team and repeat the test after two weeks:

- WCC < 3.5 x 10 9/L or less than the lower limit of reference range as per lab
- Neutrophils < 1.6 x 10 9/L or less than the lower limit of reference range as per lab
- Platelets < 140 x 10 9/L or less than the lower limit of reference range as per lab
- AST/ALT > 100U/l
- MCV > 105Fl
- Creatinine increase >30% over 12 months and / or calculated GFR <60ml/min
- Unexplained eosinophilia >0.5 x 109/l
- Unexplained reduction in albumin <30g/l
- Rash or oral ulceration
- Abnormal bruising or **severe** sore throat: Check FBC immediately
- New or increasing dyspnoea or dry cough **STOP** sodium aurothiomalate as a precaution and discuss urgently with specialist team.

	As well as responding to absolute values in laboratory tests, it is also relevant to observe trends in results (e.g. gradual decreases in white blood cells or albumin, or increasing liver enzymes). If urgent clinical abnormalities arise emergency access to specialist rheumatology advice should be sought. **Other adverse effects:** • Haematuria - requires investigation • Anaphylactoid reactions are rare but may occur a few minutes after the injection. Advise the specialist team and do not give any further doses. • Blood dyscrasias, hepatotoxicity, peripheral neuropathy and Guillain-Barre syndrome. • Colitis This list is not exhaustive; please refer to SPCs and BNF.

References

1. https://www.medicines.org.uk/emc/medicine/18613 SPC Myocrisin 100mg/ml Solution for Injection
2. BSR/BHPR Non-Biologic DMARD Guidelines 2017

RELEVANT CONTACT LIST

Speciality	
Name and Title	Tel. No.

Appendix 1

Optional Shared Care Agreement form

Request by Specialist Clinician for the patient's GP to enter into a shared care agreement

PLEASE NOTE: The use of this form is not compulsory, but the same information must be communicated between the specialist service and primary care in advance of entering into a shared-care agreement.

Part 1 - To be signed by Consultant / Associate Specialist / Speciality Trainee or Specialist Nurse (who must be a prescriber)

Dear Doctor:	Click or tap here to enter text.
Name of Patient:	Click or tap here to enter text.
Address:	Click or tap here to enter text.
	Click or tap here to enter text.
	Click or tap here to enter text.
Date:	Click or tap to enter a date.
Patient NHS Number:	Click or tap here to enter text.
Patient Hospital Number:	Click or tap here to enter text.
Diagnosed Condition:	Click or tap here to enter text.

I request that you prescribe:

(1) Click or tap here to enter text.
(2) Click or tap here to enter text.
(3) Click or tap here to enter text.
(4) Click or tap here to enter text.

for the above patient in accordance with the LMMG shared care guideline(s) (Available on the LMMG website).

Last Prescription Issued:	Click or tap to enter a date.
Next Supply Due:	Click or tap to enter a date.
Date of last blood test (if applicable):	Click or tap to enter a date.
Date of next blood test (if applicable:	Click or tap to enter a date.
Frequency of blood test (if applicable:	Click or tap here to enter text.

I confirm that the patient has been stabilised and reviewed on the above regime in accordance with the Shared Care guideline.

If this is a Shared Care Agreement for a drug indication which is unlicensed or off label, I confirm that informed consent has been received from the patient.

I will accept referral for reassessment at your request. The medical staff of the department are available if required to give you advice.

Details of Specialist Clinicians

Name:	Click or tap here to enter text.
Date:	Click or tap to enter a date.
Position:	Choose an item.
Signature:	Click or tap here to enter text.

(An email from the specialist clinician will be taken as the authorised signature)
In all cases, please also provide the name and contact details of the Consultant.

When the request for shared care is made by a Specialist Nurse, it is the supervising consultant who takes medicolegal responsibility for the agreement.

Consultant	Click or tap here to enter text.

Contact Details	
Telephone Number	Click or tap here to enter text.
Extension	Click or tap here to enter text.
Email Address	Click or tap here to enter text.

Part 2 - To be completed by Primary Care Clinician (GP)

I agree to prescribe and monitor Click or tap here to enter text. for the above patient in accordance with the LMMG shared care guideline(s) commencing from the date of next supply / monitoring (as stated in Part 1 of the agreement form).

Name:	Click or tap here to enter text.
Date:	Click or tap to enter a date.
Signature:	Click or tap here to enter text.

*Please sign and return a copy **within 14 calendar days** to the address above* **OR**

If you **do not** agree to prescribe, please sign below and provide any supporting information as appropriate:

I **DO NOT** agree to enter in to a shared care agreement on this occasion.

Name:	Click or tap here to enter text.
Date:	Click or tap to enter a date.
Signature:	Click or tap here to enter text.
Further information:	Click or tap here to enter text.