SHARED CARE GUIDELINE

Drug: Sodium Aurothiomalate (Gold injection)

Introduction	**Indications**: Licensed - Rheumatoid arthritis, progressive juvenile chronic arthritis especially if polyarticular or seropositive. **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
Dose & Administration	• Sodium aurothiomalate should only be administered by deep intramuscular (IM) injection followed by gentle massage of the area. • 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 or a total dose of 1000mg has been given. • A delay of up to two weeks between the test dose in secondary care and any subsequent doses in primary care is acceptable. • 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: FBC, LFTs, U&E's, serum creatinine/ eGFR, urinary dipstick for protein and chest x-ray

	• 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 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 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®) and make the necessary arrangements for administration of the injection. • Ensure that the patient understands their treatment and which warning symptoms to report (see adverse reactions below). • 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
Common Drug Interactions	• ACE inhibitors • Penicillamine This list is not exhaustive, please refer to SPCs and BNF
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.
Contra-indications	• 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	Urinalysis	ESR or CRP
Following initial injection	Prior to each injection	Prior to each injection	Every 3 months (for RA only)

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:

- WCC $< 3.5 \times 10^9$/L or less than the lower limit of reference range as per lab
- Neutrophils $< 2 \times 10^9$/L or less than the lower limit of reference range as per lab
- Eosinophilia $> 0.5 \times 10^9$/L
- Platelet $< 150 \times 10^9$/L or less than the lower limit of reference range as per lab
- 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.

Other adverse effects:

- Eosinophilia $> 0.5 \times 10^9$/L – seek advice from specialist team
- 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.