Central Manchester University Hospitals NHS
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NHS

Greater Manchester Interface Prescribing Group Shared Care Template

Shared Care Guideline for **Sodium Aurothiomalate (Gold) for Rheumatological Conditions**	**Reference Number** **CMFT-SCG-003**
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Date approved by Commissioners: **January 2013**	**Review Date:** **January 2015**

Please complete all sections

1. Licensed Indications	*Sodium Aurothiomalate is used in the management of active progressive rheumatoid arthritis.*
2. Therapeutic use & background	*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 sulphydryl 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.*
3. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).	*Contraindications: severe renal or hepatic impairment, history of blood disorders or marrow aplasia, exfoliative dermatitis, systemic lupus erythematosus, necrotising endocarditis, significant pulmonary fibrosis, porphyria, pregnancy and breastfeeding.* *Cautions: elderly, caution in mild to moderate renal and hepatic impairment, history of urticaria, eczema or inflammatory bowel disease.*
4. Prescribing in pregnancy and lactation	*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.*

<table>
<tr><td rowspan="8">5. Dosage regimen for continuing care</td><td colspan="2">Route of administration</td><td>IM injection</td></tr>
<tr><td colspan="3">Preparations available (include in this section any necessary information relating to availability of special preparations for children or those with swallowing difficulties)

Preparation is an IM injection.</td></tr>
<tr><td colspan="3">Dose to be prescribed including units, frequency and duration of treatment.

Please prescribe: 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 increased by stages from 50mg per week to 50mg every 4 weeks.</td></tr>
<tr><td>Is titration required</td><td>Yes (complete the following section) Yes</td><td></td></tr>
<tr><td colspan="3">Titrate dosage up to a total dose of 1000mg
Maintenance dosage up to a maximum 50mg weekly then decrease dosage interval according to response</td></tr>
<tr><td colspan="3">Adjunctive treatment regime

No adjunctive treatment</td></tr>
<tr><td colspan="3">Conditions requiring dose reduction

No dosage reduction required</td></tr>
<tr><td colspan="3">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.</td></tr>
<tr><td colspan="3">Duration of treatment ongoing</td></tr>
<tr><td colspan="3">Treatment to be terminated by healthcare professional in consultation with Rheumatology Team.</td></tr>
<tr><td colspan="3">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.</td></tr>
<tr><td>6.Drug Interactions

For a comprehensive list consult the BNF or Summary of Product Characteristics</td><td colspan="3">The following drugs must <u>not</u> be prescribed without consultation with the specialist:

Live vaccines (e.g. oral polio, oral typhoid, MMR, BCG, yellow fever, varicella zoster) are contraindicated.
Penicillamine- avoidance of sodium aurothiomalate advised by manufacturer increased risk of toxicity</td></tr>
<tr><td></td><td colspan="3">The following drugs may be prescribed with caution:

ACE inhibitors- flushing and hypotension reported when sodium aurothiomalate</td></tr>
</table>

7. Adverse drug reactions

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

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.

Adverse event System – symptom/sign	**Action to be taken** Include whether drug should be stopped prior to contacting secondary care specialist	**By whom**
WBC<3.5 x 10^9/l Neutrophils< 2.0 x 10^9/l Platelets<150 x 10^9/l	*Withhold until discussed with Rheumatology Team*	*GP*
Eosinophilia > 0.5 x 10^9/l	*Caution and increased vigilance required*	*GP*
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*	*GP*
Rash (usually itchy) or oral ulceration	*Withhold until discussion with Rheumatology Team*	*GP*
Abnormal bruising or severe sore throat	*Check FBC immediately and withhold until results are available as risk of blood disorders*	*GP*

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

Other important co morbidities (e.g. Chickenpox exposure). Include advice on management and prevention and who will be responsible for this in each case:

Annual flu vaccine should be recommended

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.

8.Baseline investigations

List of investigations / monitoring undertaken by secondary care
FBC
U&E
LFT
Chest X-Ray

9. Ongoing monitoring requirements to be undertaken by GP

Is monitoring required? **Yes or No (if yes complete following section)** *Yes*

Monitoring	**Frequency**	**Results**	**Action**	**By whom**
FBC, LFT, U&E	*FBC and urinalysis at the time of each injection*	*See Section 7: Adverse drug reactions above*		*GP*

	The patient should be asked about presence of rash or mouth ulcers before each injection	*GP*
10. Pharmaceutical aspects	*e.g. special storage requirements, washout periods Or where there are "no special considerations"* *store below 25C and protect from light*	
11. Secondary care contact information	**If stopping medication or needing advice please contact:**	
	To contact The Kellgren Centre Rheumatology Manchester Royal Infirmary: **Enquiries regarding blood monitoring and results please contact the specialist nurses below:** **Specialist Nurse Jane Hawthorne 0161 276 4688** **Specialist Nurse Melissa Aris 0161 701 1454** **Specialist Nurse Carole Hill 0161 701 1454** **Fax number for GP blood results 0161 276 8690** **Consultant contact details below:** **Professor Ian Bruce 0161 276 4626** **Professor Ann Barton 0161 276 4626** **Dr Kimme Hyrich 0161 276 4627** **Dr Pauline Ho 0161 276 4397** **Dr Rachel Gorodkin 0161 276 4628** **To contact Rheumatology Department Trafford General Hospital:** **Trafford Rheumatology helpline number 0161 746 2162** **Consultant contact details below:** **Dr Frank McKenna 0161 746 2395** **Dr Preeti Shah 0161 746 2395**	
12. Criteria for shared care	Prescribing responsibility will only be transferred when ▪ Treatment is for a specified indication and duration. ▪ Treatment has been initiated and established by the secondary care specialist. ▪ The patient's initial reaction to and progress on the drug is satisfactory. ▪ The GP has no objection 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	
13. Responsibilities of initiating specialist	Initiate treatment and prescribe until dose is stable. Undertake baseline monitoring. Advice GP of any 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.	

	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 repeatedly does not attend appointment. Provide GP with advice on when to stop this drug. 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. Provide patient with relevant drug information to enable understanding of the role of monitoring. Provide patient with monitoring booklet. Provide patient with rheumatology nurse helpline contact number. ----------
14. Responsibilities of the GP	Continue treatment as directed by the specialist. Ensure no drug interactions with concomitant medicines. To monitor and prescribe in collaboration with the specialist according to this protocol. To ensure that the monitoring and dosage record is kept up to date in the shared care booklet. To ensure blood monitoring is carried out once dose stable and responsibility transferred from secondary care. To inform Rheumatology Team if patient repeatedly does not attend routine blood monitoring. 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. ----------
15. Responsibilities of the patient	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. Failure to attend will result in medication being stopped (on specialist advice). To report adverse effects to their Specialist or GP.
17. Supporting documentation	The SCG must be accompanied by a patient information leaflet. Patient Information Leaflet EMC medicines Sodium Aurothiomalate Arthritis Research UK Patient Information Leaflet Sodium Aurothiomalate

18. Patient monitoring booklet	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.