Prescribing Clinical Network

Surrey (East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG & Surrey Heath), Crawley CCG and Horsham & Mid-Sussex CCG

Application for change in colour classification

GREEN - Non-Specialist Drugs
GPs (or non-medical prescribers in primary care) are able to take full responsibility for initiation and continuation of prescribing

BLUE - Specialist Input WITHOUT Formal Shared Care Agreement
Prescribing initiated and stabilised by specialist but has potential to transfer to primary care WITHOUT a formal shared care agreement

AMBER - Specialist Initiation WITH Shared Care Guidelines
Prescribing initiated and stabilised by specialist but has potential to transfer to primary care under a formal shared care agreement

RED - Specialist ONLY drugs
Treatment initiated and continued by specialist clinicians

BLACK – NOT recommended
Not recommended for use in any health setting across Surrey and NW Sussex health economy

Medicine details[1,2]

Name, brand name	Sodium aurothiomalate Myocrisin Injection 2%® Myocrisin 100mg/ml Solution for Injection®
Manufacturer	Sanofi
Licensed indication	Myocrisin® is used in the management of active progressive rheumatoid arthritis and progressive juvenile chronic arthritis especially if polyarticular or seropositive.
Formulation	Myocrisin 20mg/ml Solution for Injection® Each 0.5ml of solution for injection contains 10mg of Sodium aurothiomalate (20mg/ml). Myocrisin 100mg/ml Solution for Injection® Each 0.5ml of solution for injection contains 50mg of Sodium aurothiomalate (100mg/ml). 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.
Usual dosage	**Adults** An initial test dose of 10 mg should be given in the first week followed by weekly doses of 50 mg until signs of remission occur. At this point 50 mg doses should be given at two week intervals until full remission occurs. With full remission the interval between injections should be increased progressively to three, four and then, after 18 months to 2 years, to six weeks. If after reaching a total dose of 1 g (excluding the test dose), no major improvement has occurred and the patient has not shown any signs of gold toxicity, six 100 mg injections may be administered at weekly intervals. If no sign of remission occurs after this time other forms of treatment are to be considered.

	Current status	Proposed status
Traffic Light Status	AMBER	For NEW patients only. RED - **Specialist ONLY drugs** Treatment initiated and continued by specialist clinicians.

Reason for requested change

As part of the review of expired documents on the PAD, the shared care guideline for the use of sodium aurothiomalate in rheumatoid arthritis was identified as requiring revision.

Sodium aurothiomalate was given an AMBER status in August 2013 by the Prescribing Clinical Network and shared care guidelines are available on the PAD. The PAD states that 'It was noted that this shared care is requested for maintenance therapy once a therapeutic response is reached which is usually at 10-20 weeks'. The PCN supported the shared care document.

In the interim:

1. The British Society for Rheumatology (BSR) and the British Healthcare Professionals in Rheumatology (BHPR) guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs, published in 2017, continues to include the use of sodium aurothiomalate and recommends that 'patients receiving gold therapy should have urinalysis for blood and protein prior to each dose'[3].

2. No prescribing of sodium aurothiomalate has been identified across the PCN affiliated CCGs (see appendix 1).

3. Locally, when asked for their views and usage of sodium aurothiomalate:

    a. The consultant rheumatologists at the Rheumatology Network responded in February 2018 that shared care guidelines for sodium aurothiomalate were no longer required.

    b. GPs felt that due to extremely limited patient numbers their experience of monitoring had much reduced and they were no longer in a strong position to take on shared care and recommended that a red status be awarded.

<u>Proposed changes:</u>

1. The traffic light status for sodium aurothiomalate is changed from AMBER to RED for NEW patients - treatment initiated and continued by specialist clinicians.

2. For any new patients initiated on sodium aurothiomalate, prescribing should be retained by the specialist.

3. For any patients currently taking sodium aurothiomalate in primary care, monitoring should be retained in primary care and requirements should be as described in the current BNF and SPC. Primary care monitoring requirements for people on sodium aurothiomalate are available from CKS at: https://cks.nice.org.uk/dmards#!scenario:7

Key Considerations

Cost implications to the local health economy

Cost of product[2]:
Myocrisin 10mg/0.5ml solution for injection ampoules (Sanofi) - Sodium aurothiomalate 20 mg per 1 ml, 10 ampoule - NHS indicative price = £45.55

Myocrisin 50mg/0.5ml solution for injection ampoules (Sanofi) - Sodium aurothiomalate 100 mg per 1 ml, 10 ampoule - NHS indicative price = £134.80

Annual cost per patient:
Variable depending on dosing interval. Each ampoule of the usual maintenance dose of 50mg is £13.48.

Impact to current prescriber or medication initiator

- The current initiator is the consultant/specialist rheumatologist, which will not change as a result of this proposed change in traffic light status. Consultant/specialist rheumatologists will now continue to prescribe for NEW patients – there is no shared care.
- Local consultant rheumatologists have confirmed that they no longer require shared care guidelines.
- GPs felt that due to extremely limited patient numbers their experience of monitoring had much reduced and they were no longer in a strong position to take on shared care and recommended that a red status be awarded.
- There is no prescribing of sodium aurothiomalate across the CCGs affiliated to the PCN at this time.
- For any new patients initiated on sodium aurothiomalate, prescribing should be retained by the specialist.
- For any patients currently taking sodium aurothiomalate in primary care, monitoring should be retained in primary care and requirements should be as described in the current BNF and SPC. Primary care monitoring requirements for people on sodium aurothiomalate are available from CKS at: https://cks.nice.org.uk/dmards#!scenario:7

Impact to proposed prescriber or medication initiator

See above.

Impact to patients

- Sodium aurothiomalate remains as an option for prescribing by specialists in those patients where it is appropriate.
- Any established patients may continue to receive sodium aurothiomalate from their primary care prescribers.

Additional comments

PCN is asked to:

1. Agree that the traffic light status for sodium aurothiomalate for NEW patients should change to RED – specialist ONLY drugs. Treatment initiated and continued by specialist clinicians.
2. Review the draft policy statement and agree any amendments.
3. Agree that the entry on the PAD for sodium aurothiomalate is updated and the outdated shared care

guidelines currently available on the PAD are removed.
Identified lead for development of necessary documents e.g. shared care agreement
Name: **Designation:** **Organisation:** **Estimated date of preparation:**

Appendix 1: Number of items and cost for sodium aurothiomalate prescribing (ePACT).

	CCG	ePACT items	ePACT cost
March 16 – Feb 17	NWS, ES, G&W, SD and SH	8	£271.93
	CHMS	0	0
March 17 – Feb 18	NWS, ES, G&W, SD and SH	0	0
April 17- Feb 18	CHMS	0	0

References:

1. Summary of Product Characteristics. eMC. Myocrisin injection 2%. Available at: https://www.medicines.org.uk/emc/product/234/smpc <accessed 10.5.18>
2. BNF. Sodium aurothiomalate. Medicines Complete. Available at: https://www.new.medicinescomplete.com/#/content/bnf/_463714444?hspl=gold <accessed 15.5.18
3. BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs. Available at: https://academic.oup.com/rheumatology/article/56/6/865/3053478 <accessed 16.5.18>

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Declaration of Interest: None

Date: 15.5.18

Reviewed by:

Declaration of Interest:

Date:

VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
v1	17.5.18	T. Bahra	Draft	Out for consultation
v2	31.7.18	T. Bahra	Draft	Change of traffic light to RED
v3	16.8.18	T. Bahra	Final	Add clinician comment (RN)