Shared Care Guideline
Stepping Hill Hospital and North Derbyshire CCG

Shared Care Guideline for Hydroxychloroquine in Rheumatological Conditions in Adults		Reference Number
Version: 1	**Replaces:**	**Issue date: November 2017**
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Date noted by JAPC: June 2018	**Review Date: October 2019**	

Please complete all sections

1. Name of Drug, Brand Name, Form and Strength	Hydroxychloroquine 200mg tablets
2. Licensed Indications	Licensed for use as a disease modifying anti-rheumatic drug in rheumatoid arthritis, discoid, systemic lupus erythematosus, and other rheumatic conditions e.g. connective tissue disorder, Sjogren's syndrome.
3. Criteria for shared care	Prescribing responsibility will only be transferred when • 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

<table>
<tr><td></td><td>appropriate.
The patient's general physical, mental and social circumstances are such that he/she would benefit from shared care arrangements</td></tr>
<tr><td>4. Patients excluded from shared care</td><td>• Patient does not consent to shared care.
• Patient does not meet criteria for shared care.</td></tr>
<tr><td>5. Therapeutic use & background</td><td>Hydroxychloroquine is considered a disease-modifying anti-rheumatic drug (DMARD) because it can decrease the pain and swelling of arthritis, and it may prevent joint damage and reduce the risk of long-term disability. It is believed that hydroxychloroquine interferes with communication of cells in the immune system.</td></tr>
<tr><td>6. Contraindications (please note this does not replace the SPC or BNF and should be read in conjunction with it).</td><td>Hypersensitivity to 4-aminoquinolone compounds.
Hydroxychloroquine is contraindicated in patients with moderate to severe hepatic or renal impairment, and in those with pre-existing maculopathy. An eye test should be carried out if there is visual disturbance, and for those over 60 years.
It is also contraindicated in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Caution with the following:
• Psoriasis
• Epilepsy
• G6PD deficiency
• Porphyria
• Myasthenia gravis
• Elderly
• Patients with severe gastrointestinal, neurological or blood disorders.
• Sensitivity to quinine</td></tr>
<tr><td>7. Prescribing in pregnancy and lactation</td><td>This drug can be prescribed in the pregnant however it is not recommended by the manufacturer. Use in pregnancy is supported by BSR Guidelines and under these circumstances prescribing should be the responsibility of the Specialist.
Use in breastfeeding is supported by BSR Guidelines.</td></tr>
<tr><td>8. Dosage regimen for continuing care</td><td>
<table>
<tr><td>Route of administration:</td><td colspan="2">Oral</td></tr>
<tr><td colspan="3">Preparations available:
Hydroxychloroquine sulphate 200mg tablets</td></tr>
<tr><td colspan="3">Please prescribe:
200-400 mg daily</td></tr>
<tr><td>Is titration required:</td><td>No – usually started at 200mg BD</td><td></td></tr>
<tr><td colspan="3">Typical regime 200mg-400mg
Maintenance dosage up to a maximum 6.5mg/kg ideal body weight per day. Dosage may be reduced to 200mg daily depending on clinical response. To avoid excessive dosage in obese patients the doses should be calculated on the basis of ideal body weight.</td></tr>
<tr><td colspan="3">Adjunctive treatment regime:
Hydroxychloroquine used as an adjunctive treatment to Methotrexate as well as other DMARDs.
Pneumovax and annual "flu vaccine" should be given.</td></tr>
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</td></tr>
</table>

	Conditions requiring dose reduction: e.g. impaired renal/ liver function Use lower doses if there is significant renal or hepatic impairment.
	Usual response time : 2-3 months
	Duration of treatment: Ongoing, risk of ocular toxicity increased over time, important patient maintains under rheumatology follow up.
	Treatment to be terminated by: Healthcare professional in consultation with Rheumatology Team.
	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.
9.Drug Interactions ***For a comprehensive list consult the BNF or Summary of Product Characteristics***	The following drugs must <u>not</u> be prescribed without consultation with the specialist: • **Amiodarone**, **bosutinib, droperidol** and **moxifloxacin**: increased risk of ventricular arrhythmias: avoid concomitant use. • **Ciclosporin**: possible increase in plasma concentration of ciclosporin. • **Digoxin**: possible increase in plasma concentration of digoxin. • **Mefloquine**: increased risk of convulsions. • May enhance the effect of hypoglycaemic agents.
	The following drugs may be prescribed with caution: **Antacids**: reduce absorption of hydroxychloroquine. Avoid administration within 4 hours of dose
10. 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**
Development of blurred vision or changes in visual acuity	Stop medication and refer to optometrist and then if appropriate to an ophthalmologist. Also refer to Rheumatology team	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 report any visual disturbances.
	Other important co morbidities (e.g. Chickenpox exposure): If exposed to chickenpox or shingles contact rheumatology specialist for advice. Sunscreens should be encouraged to reduce sunlight exposure.
	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.
11.Baseline investigations	*List of investigations / monitoring undertaken by secondary care* FBC U&Es incl GFR LFT (ALT, AST and albumin) Height and weight Blood pressure

<table>
<tr><td></td><td colspan="5">Pre-viral screen in high risk patients: HIV, HBV (surface antigen, core antibody), HCV (antibody test) and consider herpes zoster status (if appropriate)
Formal ophthalmic examination, ideally including objective retinal assessment for example using optical coherence tomography, within 1 year of commencing hydroxchloroquine. Screening for lung disease should be undertaken at clinician discretion on a case by case basis.</td></tr>
<tr><td rowspan="3">12. Ongoing monitoring requirements to be undertaken by GP

(Local commissioning arrangements may vary).</td><td colspan="2">Is monitoring required?</td><td colspan="3">Yes

(N.B. Bolton DAWN monitoring based on BSR guidelines 2008/2017 for initiation/dose increases/parenterals; subsequent shared care as per GMMMG)</td></tr>
<tr><td>Monitoring</td><td>Frequency</td><td>Results</td><td>Action</td><td>By whom</td></tr>
<tr><td>Annual eye test if continued >5 years (ideally including optical coherence tomography)</td><td>Development of blurred vision or changes in visual acuity</td><td>Stop medication and refer to Rheumatology team</td><td>GP to refer to opthalomology/ optometrist</td></tr>
<tr><td>13. Pharmaceutical aspects</td><td colspan="5">No special considerations</td></tr>
<tr><td>14. Responsibilities of initiating specialist</td><td colspan="5">• 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 specialist 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</td></tr>
</table>

	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. • 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	• 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. • To ensure that the monitoring and dosage record is kept up to date (if applicable). • To undertake vaccination as directed by the initiating specialist, 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 (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. • Monitor the patient's general wellbeing. • Inform the specialist team immediately if a patient has become pregnant or is planning to become pregnant for treatment options to be considered. • Notify the specialist team of any circumstances that may preclude the use of *Hydroxychloroquine* for example, the use of illicit drugs or contraindications to treatment. • Seek urgent advice from secondary care if: ▪ Toxicity is suspected ▪ Non-compliance is suspected ▪ The GP feels a dose change is required ▪ There is marked deterioration in the patient's condition ▪ 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: • The clinical situation deteriorates such that the shared care criterion of stability is not achieved. • The clinical situation requires a major change in therapy. • The patient is a risk to self or others • 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

<table>
<tr><td></td><td colspan="4">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.</td></tr>
<tr><td>16. Responsibilities of the patient</td><td colspan="4">• 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.</td></tr>
<tr><td rowspan="2">17.Additional Responsibilities
e.g. Failure of patient to attend for monitoring, Intolerance of drugs, Monitoring parameters outside acceptable range, Treatment failure, Communication failure</td><td>List any special considerations</td><td>Action required</td><td>By whom</td><td>Date</td></tr>
<tr><td>[insert]</td><td>[insert]</td><td>[insert]</td><td>[insert]</td></tr>
<tr><td>18. Supporting documentation</td><td colspan="4">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/)</td></tr>
<tr><td>19. Patient monitoring booklet</td><td colspan="4">Non-applicable</td></tr>
<tr><td>20. Contact details</td><td colspan="4">See Appendix 1</td></tr>
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Appendix 1 – Local Contact Details

Secondary care contact information	**If stopping medication or needing advice please contact:**
	Dr *[insert text here]*
	Contact number: *[insert text here]*
	Hospital: *[insert text here]*
	To contact Rheumatology Department Stepping Hill Hospital: *Consultants:* 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:**
***Hydrochloroquine* for the treatment of *Rheumatological Conditions* in adults**

Drug	Hydroxychloroquine
Indication	Rheumatological conditions
Overview	Hydroxychloroquine is considered a disease-modifying anti-rheumatic drug (DMARD) because it can decrease the pain and swelling of arthritis, and it may prevent joint damage and reduce the risk of long-term disability. It is believed that hydroxychloroquine interferes with communication of cells in the immune system.
Specialist's Responsibilities (N.B. Bolton DAWN monitoring based on BSR guidelines 2008/2017 for initiation/dose increases/parenterals; subsequent shared care as per GMMMG)	**Initial investigations:** Assessment and diagnosis. Discuss the benefits and side effects of treatment with the patient. Baseline opthalomogical assessment within 1 year of commencing hydroxchloroquine , FBC, U&Es, LFTs, GFR, Height, Weight, Blood pressure and 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. **Initial regimen:** 200mg -400mg per day **Clinical monitoring:** Specialist review to ensure continued benefit **Safety monitoring:** Annual eye test if continued >5 years (ideally including optical coherence tomography) **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. **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. **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.
GP's Responsibilities (N.B. Bolton DAWN monitoring based on BSR guidelines 2008/2017 for initiation/dose increases/parenterals; subsequent shared care as per GMMMG)	**Maintenance prescription:** prescribe and monitor hydroxychloroquine 3 months after initiation in accordance with the specialist's recommendations OR as per local commissioning arrangements. **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. **Safety monitoring:**

Annual eye test if continued >5 years (ideally including optical coherence tomography)	Refer to opthalomology/ optometrist	GP

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
- 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

	➢ Patient fails to attend for monitoring on two consecutive occasions **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	<table><tr><th>Adverse events</th><th>Action</th></tr><tr><td>Development of blurred vision or changes in visual acuity</td><td>Stop medication and refer to optometrist and then if appropriate to an ophthalmologist. Also refer to Rheumatology team .</td></tr></table>
Contra-indications **Cautions** **Drug Interactions**	Please refer to the BNF and/or SPC for information. • Hydroxychloroquine is contraindicated in patients with significant hepatic or renal impairment, and in those with pre-existing maculopathy. • Caution with the following: ➢ Psoriasis ➢ Epilepsy ➢ G6PD deficiency ➢ Porphyria ➢ Myasthenia gravis ➢ Elderly ➢ Sensitivity to quinine ➢ Patients with severe gastrointestinal, neurological or blood disorders. • Use lower doses if there is renal or hepatic impairment. • If exposed to chickenpox or shingles contact rheumatology specialist for advice • Amiodarone, bosutinib, droperidol and moxifloxacin: increased risk of ventricular arrhythmias: avoid concomitant use. • Ciclosporin: possible increase in plasma concentration of ciclosporin. • Digoxin: possible increase in plasma concentration of digoxin. • Mefloquine: increased risk of convulsions. • May enhance the effect of hypoglycaemic agents. • Antacids: reduce absorption of hydroxychloroquine. Avoid administration within 4 hours of dose. NB. Very toxic in overdose – seek advice from National poisons Information
Other Information	Annual flu vaccinations are safe and recommended. Pneumococcal vaccination is safe and recommended.
Contact Details	**Name:** *[insert text here]* **Address:** *[insert text here]* **Telephone:** *[insert text here]*

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