North of Tyne, Gateshead and North Cumbria Area Prescribing Committee

Hydroxychloroquine
Shared Care Guidance for patients within adult services

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol (section 2) and communicated to primary care.
- Use a shared decision making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see section 11), to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Assess for contraindications and cautions (see section 4) and interactions (see section 7).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in section 5.
- Prescribe the maintenance treatment for at least 4 weeks. Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, and baseline test results. Include contact information (section 13).
- Conduct the required reviews in section 8 and communicate the results to primary care. After each review, advise primary care whether treatment should be continued and confirm the ongoing dose.
- Give advice to primary care on continuing treatment if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.
- After the patient has been on hydroxychloroquine for ten years, refer for ophthalmology monitoring using the attached proforma (Appendix 2). Patients who are at higher risk of retinal toxicity will need to be referred earlier (see section 9).

Primary care responsibilities

- Respond to the request from the specialist for shared care in writing within 14 days.
- If accepted, prescribe ongoing treatment as detailed in the specialists request and as per section 5 taking into any account potential drug interactions in section 7.
- Adjust the dose of hydroxychloroquine prescribed as advised by the specialist.
- Assess for possible interactions with hydroxychloroquine when starting new medicines (see section 7).
- Manage any adverse effects as detailed in section 10 and discuss with specialist team when required.
- Stop hydroxychloroquine and discuss urgently with the specialist if retinopathy or cardiomyopathy are confirmed.
- Discuss other adverse effects with the specialist team as clinically appropriate (see section 10).
- Contact the specialist team for advice if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.
- Refer back to the specialist any patients identified who appear to have become lost to follow up, particularly if they may be approaching ten years on hydroxychloroquine. These patients will require a specialist decision re either deprescribing of hydroxychloroquine or onward referral to ophthalmology for retinal toxicity monitoring. Patients who are at higher risk of retinal toxicity will need to be referred after three years (see section 9).
- Referral to Ophthalmology is **not** a Primary care responsibility; this is the responsibility of the specialist team.

Patient and/or carer responsibilities

- Take hydroxychloroquine as prescribed and do not stop taking it without speaking to their primary care prescriber or specialist. Tell anyone who prescribes them a medicine that they are taking hydroxychloroquine.
- Attend regularly for monitoring and review appointments with primary care, specialist, and ophthalmology. Be aware that medicines may be stopped if they do not attend appointments.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed in section 11.
- Report the use of any over the counter medications to their prescriber and be aware they should discuss the use of hydroxychloroquine with their pharmacist before purchasing any OTC medicines.
- Inform the specialist or primary care prescriber immediately if they become pregnant or wish to become pregnant.

1. Background

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Hydroxychloroquine is an antimalarial and a disease modifying anti-rheumatic drug (DMARD) with several pharmacological actions which may be involved in its therapeutic effect.

Hydroxychloroquine is not licensed for all indications included in this shared care protocol. Its use for the indications below is however supported by various sources and bodies including the BNF, NICE, British Society for Rheumatology (BSR) and British Health Professionals in Rheumatology (BHPR), British Association of Dermatologists (BAD) and British Thoracic Society (BTS).

2. Indications

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Hydroxychloroquine is licensed for treatment of:

- Active rheumatoid arthritis
- Systemic and discoid lupus erythematosus
- Dermatological conditions caused or aggravated by sunlight

This shared care protocol also includes treatment of chronic inflammatory conditions where off-label use of hydroxychloroquine is appropriate, including but not limited to the following specialities and conditions:

- Rheumatology (e.g. inflammatory arthritis, connective tissue disease, Sjögren's syndrome, myositis)
- Dermatology (e.g. urticaria, other inflammatory skin diseases)
- Respiratory disease (e.g. interstitial lung disease, sarcoidosis).
- Renal medicine

These additional indications are off-label. The initiating specialist must specify the indication for each patient when initiating shared care and clearly state when use is off-label.

This shared care protocol applies to adults aged 18 and over.

3. Locally agreed off-label use

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Not applicable

4. Contraindications and cautions

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This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Hypersensitivity to hydroxychloroquine or 4-aminoquinoline compounds
- Pre-existing maculopathy

Cautions:

- Concurrent use of medicines which may cause adverse ocular or skin reactions
- Concurrent use of drugs which may prolong the QT interval (see section 7 interactions)
- Diabetes mellitus, and those taking anti-diabetic drugs (including SGLT-2 inhibitors) for any indication (hydroxychloroquine treatment may lower blood glucose)
- Glucose-6-phosphate dehydrogenase deficiency
- Increased risk of retinopathy with high doses (>5 mg/kg/day), long-term treatment (>5 years), eGFR <60 mL/min/1.73m^2 or concurrent tamoxifen use.
- Myasthenia gravis or psoriasis (may exacerbate)
- Porphyria cutanea tarda, and other acute porphyrias
- Renal or hepatic disease and concurrent use of drugs known to affect these organs
- Sensitivity to quinine
- Severe gastrointestinal, neurological (especially for those with a history of epilepsy – may lower the seizure threshold), or blood disorders
- Significant cardiac arrhythmias due to the risk of QT interval prolongation

5. Initiation and ongoing dose regime

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- Transfer of prescribing to primary care is normally after 4 weeks
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician
- Termination of treatment will be the responsibility of the specialist.

Initial therapy:

200mg to 400 mg daily. Dose should not exceed 6.5 mg/kg/day (based on actual body weight).

The initial period must be prescribed by the initiating specialist.

Maintenance dose:

200mg to 400 mg daily. The risk of significant toxicity increases with doses above 5 mg/kg/day (based on actual body weight).

The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

In patients taking 400mg daily, the dose can be reduced to 200mg daily when no further improvement is evident. The maintenance dose may be increased to 400mg daily if the response lessens.

Dose adjustment and caution are recommended in renal or hepatic impairment.

Deprescibing hydroxychloroquine:

Decisions around deprescribing rest with the initiating specialist. As the risk of toxicity increases with duration of therapy, ongoing use needs to be regularly reviewed in patients on long term therapy. If it is not clearly effective then discontinuation and switch to alternative therapy should be considered.

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	Hydroxychloroquine sulfate 200 mg tablets 150mg tablets are available but do not offer a clinical advantage and are not preferred. As an alternative, alternate day dosing with 200 mg and 400 mg may be used.
Administration details:	Each dose should be taken with food. If necessary, tablets may be crushed and dispersed in water (unlicensed).
Other important information:	Antacids may reduce absorption of hydroxychloroquine. Oral antacids should be avoided for 4 hours before and after the dose.

7. Significant medicine interactions

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The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

The following drugs must not be prescribed without consultation with the specialist:

- **Drugs that can prolong the QT interval: for example, amiodarone, moxifloxacin, quinine, citalopram**. Avoid concomitant use; possible increased risk of QT prolongation/ventricular arrhythmias.
- Systemic oral (or iv) **Azithromycin, erythromycin, clarithromycin** and other macrolide antibiotics: increased risk of cardiovascular events
- **Antidiabetic drugs and/or insulin**: hypoglycaemic effect may be enhanced, may need dose adjustment of antidiabetic medication.
- **Cimetidine**: possible increase in plasma concentration of hydroxychloroquine.
- **Ciclosporin**: possible increase in plasma concentration of ciclosporin (combination used by some specialists).
- **Digoxin**: possible increase in plasma concentration of digoxin.
- **Mefloquine and other drugs known to lower the convulsion threshold**: possible increased risk of convulsions.
- **Penicillamine**: possible increased risk of haematological toxicity.
- **Rifampicin**: possible reduction in hydroxychloroquine efficacy.
- **Tamoxifen**: increased risk of retinal toxicity, necessitates earlier ophthalmic monitoring (see section 4).

The following drugs may be prescribed with caution:

- **Antacids and calcium carbonate-containing supplements**: may reduce absorption of hydroxychloroquine; separate administration by at least four hours. Other calcium salts do not appear to interact.
- **Antiepileptics**: activity of antiepileptic drugs may be impaired with hydroxychloroquine. Additionally, hydroxychloroquine may lower the seizure threshold.
- **Neostigmine and pyridostigmine**: effects may be antagonised by hydroxychloroquine.
- **Intra-dermal rabies vaccine**: possible reduced antibody response

8. Baseline investigations to be undertaken by specialist

Baseline blood tests are the responsibility of the specialist; once the patient is established on hydroxychloroquine with no anticipated further dose changes then prescribing can transferred to primary care.

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Baseline investigations:

- Urea and electrolytes (U&Es) & creatinine clearance (CrCl)
- Alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST), & albumin
- Full blood count (FBC)

- Weight
- Height and blood pressure (if indicated)
- Assess for co-morbidities which may influence DMARD choice, including risk factors for retinopathy (e.g. concomitant tamoxifen use, eGFR <60 mL/min)
- Electrocardiogram (ECG), if concerns exist regarding the QT-interval, see section 4 and section 7.

Ongoing monitoring:

- No routine ongoing laboratory monitoring is required for hydroxychloroquine. Monitoring may be required if the patient is prescribed an additional DMARD.
- The specialist will retain the responsibility for monitoring the patient's ongoing response to treatment, and advise if a dose change or treatment cessation is appropriate. This should be undertaken annually.
- After each review, advise primary care whether treatment should be continued and confirm the ongoing dose.
- The specialist is responsible for referring the patient for ophthalmological monitoring for retinopathy once the patient has been on treatment for ten years, or sooner if risk factors for retinal toxicity are present. Referral should be made using the attached proforma (Appendix 2).

9. Ophthalmological monitoring for retinal toxicity

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See section 10 for further guidance on management of adverse effects.

Monitoring	Frequency
Because of capacity constraints within the Newcastle ophthalmology service, it is not possible to screen patients as frequently as suggested by the RCOphth guidelines. After pragmatic discussions between the ophthalmology and rheumatology departments, it is proposed to screen only those patients at the highest risk of retinopathy at this time. This decision will be reviewed in 2024. Patients should only be referred if they meet either of the following criteria: • No risk factors for retinopathy but have been on HCQ for more than 10 years • Any risk factors for retinopathy and on treatment for 3 years or more Risk factors may change over time; primary care should notify the specialist if new risk factors are identified.	• Annually after 10 years of treatment, **or** • After 3 years if additional risk factors are present. The **risk factors for retinopathy** are: • High dose use (>5mg/kg actual body weight) • Use of chloroquine rather than Hydroxychloroquine • Chronic kidney disease: eGFR <60 ml/min/1.73m^2 • Tamoxifen use • Asian ethnicity (although not included in the RCOphth guideline there is evidence of a different pattern of retinopathy in this group and an increased overall risk)

10. Adverse effects and other management

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Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

Result	Action

Retinopathy monitoring: possible or definite retinal toxicity	• **Possible retinopathy:** Consider whether withholding is in the best interests of the patient (See RCOphth guidelines for recommendations on managing possible retinopathy), specialist to be informed and to determine follow-up plan. • **Definite retinopathy: withhold drug** pending urgent discussion between patient and specialist.
Vision disturbances including blurred vision, changes in visual acuity or abnormal colour vision	Refer to optometrist/ ophthalmologist; discuss with specialist team
Symptoms or signs of cardiomyopathy e.g. breathlessness, swelling in the abdomen and ankles, palpitations, cardiac conduction disorders and ECG changes.	Review for reversible causes. Discuss with specialist team urgently and consider withholding. If cardiomyopathy occurs due to hydroxychloroquine treatment, hydroxychloroquine must be withheld.
Headache, gastrointestinal disturbances e.g. abdominal pain, nausea, diarrhoea, vomiting	Review for reversible causes; discuss with specialist team if persistent or severe
Skin and subcutaneous tissue disorders e.g. pruritic erythematous macular rash occurring soon after treatment commenced, blue-black pigmentation of the skin, bleaching of skin & hair	Withhold and discuss with specialist team
Skeletal muscle myopathy or neuromyopathy	Review for reversible causes; withhold and discuss with specialist team
Signs and symptoms of bone marrow suppression e.g. sore throat, oral ulceration, abnormal bleeding/bruising, signs of infection	Review for reversible causes. Be aware that the underlying condition may contribute to bone marrow suppression. Although the risk is low, if bone marrow suppression is suspected, discontinue treatment and obtain an urgent FBC and other bloods as appropriate. Discuss with specialist team.
New/ worsening mental health problems after starting hydroxychloroquine (such as irrational thoughts, anxiety, hallucinations, confusion, depression, suicidal ideation)	Withhold and discuss with specialist team

11. Advice to patients and carers

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The specialist will counsel the patient with regard to the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines.

The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

- Vision disturbances including blurred vision, changes in visual acuity or abnormal colour vision.
- Signs or symptoms of bone marrow suppression, such as a sore throat, oral ulceration, abnormal bleeding or bruising, or other signs of infection.
- Rash
- Muscle weakness

- Symptoms of hypoglycaemia, including dizziness, weakness, or hunger
- Actual or planned pregnancy or breastfeeding
- New / worsening mental health problems, irrational thoughts or thoughts of self-harm or suicide

The patient should be advised:

- Avoid over-the-counter and prescribed antacids for four hours before and after doses of hydroxychloroquine.
- A number of patients who take hydroxychloroquine may experience some loss of their peripheral and central vision. Patients who drive must inform the DVLA if their eyesight is affected. For further information see: https://www.gov.uk/driving-eyesight-rules
- That vaccination in line with current national advice (e.g. for COVID-19, influenza and shingles) is safe and recommended.
- Tell anyone who prescribes them a medicine that they are taking hydroxychloroquine. Always ask a pharmacist before purchasing any medicines over the counter, including herbal remedies, and ask if they are safe.
- Inform the specialist or primary care prescriber immediately if they become pregnant or wish to become pregnant.

Patient information:

- General information: https://patient.info/medicine/hydroxychloroquine-tablets-quinoric
- Rheumatology: https://www.versusarthritis.org/about-arthritis/treatments/drugs/hydroxychloroquine/
- Dermatology: https://www.bad.org.uk/for-the-public/patient-information-leaflets/hydroxychloroquine
- Patient information leaflets are also available from https://www.medicines.org.uk/emc/search?q=hydroxychloroquine

12. Pregnancy, paternal exposure and breast feeding

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It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.

All patients should be informed of the risks and benefits of taking this medicine during pregnancy and breastfeeding. The specialist team should be contacted if a patient becomes pregnant or is planning to become pregnant or breastfeed.

The BSR and BHPR guideline on prescribing DMARDs in pregnancy and breastfeeding advises the following:

Pregnancy:

Hydroxychloroquine can be continued throughout pregnancy.

Information for patients and carers: https://www.medicinesinpregnancy.org/Medicine--pregnancy/Hydroxychloroquine/.

Breastfeeding:

Hydroxychloroquine is compatible with breastfeeding, though does pass into breast milk in small quantities.

Information for healthcare professionals: https://www.sps.nhs.uk/medicines/hydroxychloroquine/.

Paternal exposure:

Hydroxychloroquine is compatible with paternal exposure.

13. Specialist contact information

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Northumbria Rheumatology Specialist Nurses: North Tyneside: 0191 293 4159 Wansbeck: 01670 529 448

Newcastle Rheumatology - Advice line number 0191 2137967

Newcastle Dermatology – 0191 2824485

Gateshead Rheumatology – 0191 4452857

North Cumbria Rheumatology – 01228 814732

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

15. References

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- Hydroxychloroquine sulfate 200 mg film-coated tablets (Quinoric®). Bristol Laboratories. Date of revision of the text: 13/10/2020. Accessed via https://www.medicines.org.uk/emc/product/477/smpc on 08/04/2021
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- Royal College of Ophthalmologists. 2020. Hydroxychloroquine and Chloroquine Retinopathy: Recommendations on Monitoring. Accessed via https://www.rcophth.ac.uk/standards-publications-research/clinical-guidelines/ on 03/02/2021.

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- NICE Clinical Knowledge Summary. DMARDS: Hydroxychloroquine. Last revised April 2020. Accessed via https://cks.nice.org.uk/topics/dmards/management/hydroxychloroquine/ on 03/02/2021.
- Stockley's Drug Interactions. Accessed via www.medicinescomplete.com on 08/04/2021
- Hydroxychloroquine – increased risk of cardiovascular events when used with macrolide antibiotics; reminder of psychiatric reactions. MHRA Drug Safety Update 15/2/2022, accessed via https://www.gov.uk/drug-safety-update/hydroxychloroquine-chloroquine-increased-risk-of-cardiovascular-events-when-used-with-macrolide-antibiotics-reminder-of-psychiatric-reactions
- RMOC Advice on the monitoring requirements for HCQ: *final draft pending publication, link to be added*.
- Guideline for Hydroxychloroquine (HCQ) Retinal Monitoring, Newcastle Hospitals. Dr Ben Thompson, Mr James Talks, Claire Pinder (December 2021)

16. Other relevant national guidance

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- Shared Care for Medicines Guidance – A Standard Approach (RMOC). Available from https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/
- NHSE guidance – Responsibility for prescribing between primary & secondary/tertiary care. Available from https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

APC board date:
Last updated:

Appendix 1: Simplified Shared Care Request letter

Shared Care Request/ Confirmation

- Specialist to complete first section of form and send to patient's GP.
- GP to complete second section of form and return to specialist within 14 days.

Consultant: ……

Speciality: ……

Hospital: ……..

Affix Patient label if available

Name:…… DOB: ……..

Address: ……..

NHS No: …… Hospital No: ……..

Treatment Requested for Prescribing in Accordance with an Approved Shared Care Arrangement:

As per the agreed North of Tyne, Gateshead and North Cumbria shared care protocol for **Hydroxychloroquine**, this patient is now suitable for prescribing to move to primary care.

The indication for Hydroxychloroquine for this patient is: ……

and this Is not an off-label indication. The current dose is ……

The patient fulfils criteria for shared care and I am therefore requesting your agreement to participate in shared care

Signed (speciality team) …… **Name (print)** ……

Role: …….. **Date** ……

To be completed by GP Please tick one box

I ACCEPT the proposed shared care arrangement for this patient ☐

Or

I DO NOT ACCEPT the proposed shared care arrangement for this patient ☐

My reason(s) for not accepting include:

Signed …… **Name (print) ……. Date ……..**
(Patients GP)

N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the hospital consultant and the patient's GP

Appendix 2: Referral Proforma: Hydroxychloroquine Retinal Monitoring

This pro forma must be included with any referral for this service. Please read the associated referral guidelines *(reference / hyperlink TBC);* referrals not meeting these will be returned.

Referrals should only be made by the secondary care team responsible for the decision to continue hydroxychloroquine. Monitoring tests will not be repeated more frequently than every 2 years

Patient Details (attach sticker)

Name: _____

Address: _____

Date of Birth: _____

NHS Number: _____

Hospital Number: _____

Referrer Details

Name: _____

Specialty: _____

Hospital: _____

Address for result: _____

_____

Indication for Hydroxychloroquine

Diagnosis _____ Current dose: _____

Patient weight (kg): _____ Daily dose/kg: _____

Start date: _____ Total duration of treatment if not continuous: _____

Previous retinal screening for HCQ?: No If yes, date and details

Risk factors for retinopathy

(1) ❒ Renal impairment (eGFR <60)

Latest eGFR: _____ Date: _____

(2) ❒ Tamoxifen use (please give details): _____

(3) ❒ Chloroquine use

(4) ❒ Daily dose >5mg/kg

(5) ❒ Asian ethnicity

Only refer if:

❒ **No risk factors and on treatment for 10 years or more**

❒ **One or more risk factors** [(1)-(5) above] **and on treatment for 3 years or more**

Hydroxychloroquine retinal monitoring referral proforma Version 1, December 2021