SY ICB Shared Care Protocol
For
Hydroxychloroquine use in Adults

Note – This protocol is based on the
National Hydroxychloroquine Shared Care Protocol
developed 4 July 2022

It is intended for use exclusively within Sheffield & Rotherham places.

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Version 1

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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). Dermatologist or rheumatologist to organise baseline retinal monitoring at ophthalmology department within 1 year of commencement of hydroxychloroquine.
- 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 after a minimum of 12 weeks, including where there are unforeseen delays to transfer of care.
- Once treatment is optimised, request that primary care take over prescribing via shared care in a letter 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 five years, dermatologist or rheumatologist to refer for retinal monitoring. Patients who are at higher risk of retinal toxicity will need to be referred earlier (see section 9). Ophthalmology will recall patients annually thereafter, whilst patient continues on hydroxychloroquine.
- Ophthalmologist to write to patient, rheumatologist / dermatologist and primary care if patient defaults annual retinal monitoring appointment

Primary care responsibilities

- Respond to the request from the specialist for shared care in writing. It is asked that this be undertaken within 14 days of the request being received by the GP practice, where possible.
- If accepted, prescribe ongoing treatment as detailed in the specialist's 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.
- 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.
- As part of patient's annual medication review discuss retinal monitoring to ensure patient is being monitored by dermatologist / rheumatologist in accordance with section 8.
- On receipt of retinal monitoring results, add the Snomed code 1104901000000103 for hydroxychloroquine retinopathy monitoring, to the patient's clinical record, which will aid future audit.

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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To be agreed and completed locally (include supporting information)

No added indications.

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

- 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 regimen

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- Transfer of monitoring and prescribing to primary care is normally after at least 12 weeks, and when the patient's dose has been optimised and with satisfactory investigation results for at least 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 stabilisation:

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 (following initial stabilisation):

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 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.

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	Hydroxychloroquine sulfate 200 mg tablets Hydroxychloroquine sulfate 300 mg tablets The 300 mg strength given once daily is an alternative to prescribing as alternate day dosing with 200 mg and 400 mg but please note that the 300 mg strength is currently more expensive.
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.
- **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.
- **Tamoxifen**: increased risk of retinal toxicity, necessitates annual 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
- **Topiramate** – increased risk of toxicity when co-administered with valproate, monitor for signs and symptoms of encephalopathy or hyperammonaemia
- **Systemic azithromycin or other systemic macrolide antibiotics** (erythromycin or clarithromycin) is associated with an increased risk of cardiovascular events (including angina or chest pain and heart failure) and cardiovascular mortality

8. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

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Retinal monitoring at baseline and throughout treatment with hydroxychloroquine is the responsibility of the specialist, ie dermatologist, rheumatologist and ophthalmologist with oversight from primary care.

Baseline investigations:

- Urea and electrolytes (U&Es) & eGFR
- 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/ 1.73 m2)
- Electrocardiogram (ECG), if concerns exist regarding the QT-interval, see section 4 and section 7.
- Dermatologist / rheumatologist to arrange baseline retinal monitoring with ophthalmology department within 1 year of commencement on hydroxychloroquine. **N.B. Baseline retinal**

monitoring is a local requirement in Sheffield and is not in line with RCOphth guideline.

- If high risk (ie concomitant tamoxifen, renal impairment with eGFR< 60ml/min/1.73 m2 or dose > 5mg/kg/day) dermatologist / rheumatologist to refer to ophthalmology, stating patient is high risk, so that ophthalmologist can arrange for annual retinal monitoring recalls after baseline retinal monitoring.
- N.B. The community Diabetic Screening programme does not involve the same imaging as recommended for the hydroxychloroquine programme and such patients would therefore require a referral into the hydroxychloroquine clinic for retinal monitoring. This will normally be organised by the rheumatologist/dermatologist.
- Contrary to the SPC, annual eye checks at a high street optometrist is NOT considered essential for patients taking hydroxychloroquine.
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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, confirm the ongoing dose, and whether the ongoing monitoring outlined in section 9 remains appropriate.
- After the patient has been on hydroxychloroquine for five years, dermatologist / rheumatologist to refer patient to ophthalmology (or other commissioned service as appropriate) for annual monitoring for retinopathy. Patients who are at higher risk of retinal toxicity will need to be referred earlier. See section 9 below for risk factors.
- Ophthalmology will recall patients annually thereafter for retinal monitoring, whilst patient continues on hydroxychloroquine
- N.B retinal monitoring follows that recommended by the RCOpth and replaces the recommendation for annual ophthalmic examination detailed in the SmPC.

9. Ongoing monitoring requirements to be undertaken by primary care

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See section 10 for further guidance on management of adverse effects/responding to monitoring results.

Monitoring	Frequency

As part of patient's annual medication review, which may include annual check of renal function, dependent upon individual patient's risk factors, discuss retinal monitoring to ensure patient is being monitored by dermatologist / rheumatologist in accordance with section 8. of the shared care protocol.
 	
Risk factors may change over time; primary care should discuss with specialist if new risk factors that are 'high risk' are identified before the five-year mark.
	• Annually after 5 years of treatment, **or**
	• After 1 year if additional risk factors are present. Risk factors include:
	  ○ concomitant tamoxifen use
	  ○ impaired renal function (eGFR <60mL/min/1.73m^2)
	  ○ hydroxychloroquine dose (>5mg/kg/day)

Vaccines are safe and recommended for this patient group and should be offered in line with the standard schedule. Refer to Green Book Chapter 6 and Green book Chapter 28 a Shingles for further details. • **Annual** influenza (The Green Book, Chapter 19) vaccinations are recommended. • COVID-19 vaccination is safe and recommended (see The Green Book, Chapter 14a).	• Shingles vaccination: one-off course when eligible under the national schedule. • Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list. • COVID-19 vaccination as per national schedule.

(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending, to inform action to be taken by secondary care.

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 for primary care
Retinopathy monitoring: possible or definite retinal toxicity	**Possible retinopathy:** Dermatologist or rheumatologist to take necessary action arising from retinal monitoring following discussion with ophthalmologist, primary care and patient. **Definite retinopathy:** Dermatologist or rheumatologist to take necessary action arising from retinal monitoring following discussion with ophthalmologist, primary care and patient. Primary care clinician will be advised by dermatologist or rheumatologist when to stop repeat prescriptions.
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.
Psychiatric reactions, including reports of depression, anxiety, hallucinations, and psychosis.	Occurs especially in the first month of treatment; events have been reported in patients with no prior history of psychiatric disorders. 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

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) 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.
- Patients should be advised to contact a doctor immediately if they experience new or worsening mental health problems (such as irrational thoughts, anxiety, hallucinations, and feeling confused or feeling depressed, including thoughts of self-harm or suicide). Family members or caregivers may also be advised to be vigilant for these reactions and the need to seek medical advice if they occur.

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/pils/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.

The BSR guideline on prescribing DMARDs in pregnancy and breast feeding 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.

Paternal exposure:

Hydroxychloroquine is compatible with paternal exposure.

13. Specialist contact information

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Sheffield Teaching Hospitals

Rheumatology

Rheumatology Daytime telephone number: 0114 2713086

Email addresses: For routine primary care queries not covered by the SCP please email : sth.rheumatologygpcorrespondence@nhs.net – usual response time is within two working days.

If patient acutely unwell and this is thought related to hydroxychloroquine, **GP** only, to contact Rheumatology on call, hours 9 am to 5 pm only - via STH switchboard

For patient queries: sth.ropd@nhs.net

Dermatology

Email address: Sth.alldermsecteam@nhs.net / or individual consultants secretary phone number via STH switchboard.

Ophthalmology

Daytime telephone number: 0114 226 8862

Email address: sth.medretinauveitis@nhs.net

Out of hours contact details: On call ophthalmologist via hospital switchboard

The Rotherham NHS Foundation Trust

Rheumatology

Nurses telephone helpline: 01709424739

Consultant: Dr. Leticia Garcia (working days Mon-Wed) 01709 425171

Nurse Specialists: Sisters Sue Elsey, Louise Hale, Kerry Hopewell and Mandy Hademan
- Bleep 079 via switchboard (01709 820000)

Specialist Registrar: Bleep 101 via switchboard (01709 820000)

For individual patient enquiries- clinicians are advised to use the Advice & guidance from eReferrals.

For general enquiries (not patient specific)- rgh-tr.rheumatologysecretaries@nhs.net

Dermatology

Nurses telephone helpline: 01709 424436

Consultants

Dr Saurabh Mittal	(Mon- Friday)	01709 424161
Dr Samanthi Paranavithane	(Mon-Friday)	01709 424161

Email address: rgh-tr.dermatologysecretaries@nhs.net

Ophthalmology

Secretaries telephone:

01709 423987
01709 423983
01709 423985

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 by the specialist. 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. Zentiva. Date of revision of the text: 03/07/2023. Accessed via https://www.medicines.org.uk/emc/product/1764/smpc on 13/05/2025Hydroxychloroquine sulfate 200 mg film-coated tablets. Blackrock Pharmaceuticals. Date of revision of the text: 27/01/2023. Accessed via https://www.medicines.org.uk/emc/product/11540/smpc on 09/06/2025
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rheumatic drugs. Accessed via https://academic.oup.com/rheumatology/article/56/6/865/3053478#97289292 on 19/05/2025.
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- Royal College of Ophthalmologists. 2020. Hydroxychloroquine and Chloroquine Retinopathy: Recommendations on Monitoring. Accessed via Hydroxychloroquine and Chloroquine Retinopathy Monitoring Guideline and Recommendations 2020 | The Royal College of Ophthalmologists on 20/05/2025.
- Immunisation against infectious diseases (The Green Book). Accessed via https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book on 20/05/2025.
- NICE Clinical Knowledge Summary. DMARDS: Hydroxychloroquine. Last revised April 2020. Accessed via https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/ on 9/6/2025
- Stockley's Drug Interactions. Accessed via www.medicinescomplete.com on 20/05/2025
- NEWT Guidelines. Hydroxychloroquine. Last updated November 2012. Accessed via https://access.newtguidelines.com/H/Hydroxychloroquine.html on 18/01/2021.
- RMOC Advice on the monitoring requirements for HCQ: *final draft pending publication*.
- MHRA drug safety update Feb 2022- Hydroxychloroquine: increased risk of cardiovascular events when used with macrolide antibiotics; reminder of psychiatric reactions

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. Accessed via https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/ on 20/05/2025

- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Accessed via https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care on 20/05/2025
- NICE NG197: Shared decision making. Last updated June 2021. https://www.nice.org.uk/guidance/ng197/.

17. Local arrangements for referral

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Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

Each speciality may have different criteria for referral. Seek advice where necessary. Each directorate has their own arrangements / paperwork for transferring care to primary care, but please note that Transfer forms are not considered necessary for hydroxychloroquine and instead a clinic letter asking primary care to take over prescribing as per responsibilities set out in the shared care protocol will suffice. If primary care clinicians are unhappy to accept shared care a sample rejection letter can be found here.