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National shared care protocol:

Hydroxychloroquine for patients within adult services

4 July 2022, Version 1

Review date – January 2025

The content of this shared care protocol was correct as of January 2022. As well these protocols, please ensure that summaries of product characteristics (SPCs), British national formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites are reviewed for up-to-date information on any medicine.

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 five years, refer for ophthalmology monitoring. 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. It is asked that this be undertaken within 14 days of the request being made, where possible.
- 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.
- Remind the specialist when the patient is approaching five years on hydroxychloroquine and will require referral to ophthalmology for retinal toxicity monitoring. Patients who are at higher risk of retinal toxicity will need to be referred earlier (see section 9).

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)

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 • 300mg 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.
- **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

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

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Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to primary care.

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, 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, refer 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.

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

Refer the patient to the specialist when the patient is approaching **5 years of treatment** (or **1 year** in patients with additional risk factors).
These patients will be referral from the specialist to ophthalmology (or other
	• 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)

commissioned service as appropriate) for annual retinopathy monitoring. See RCOphth guidelines. 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.	hydroxychloroquine dose (>5mg/kg/day)
• Patients aged 70-79 years old could be eligible for the shingles vaccine (herpes zoster). For patients who are immunosuppressed (e.g. those taking prednisolone at a dose of 10 mg or more for more than 4 weeks in the prior 3 months, or 20 mg or more for more than 10 days in the prior month) a non-live vaccine should be used. Specialist input may be required. If patient is taking additional DMARDs, check advice for all drugs. For more information see The Green Book, Chapter 28a. • **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. • 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

As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance	
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:** primary care to ensure **withheld** 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.

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.

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.

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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Speciality	Contact name	Contact Details
Neurology	**ESNEFT Ipswich Site**	
	Dr Simon Kerrigan Dr Petr Pokorny Dr Mortada Elyas Dr Clare Galton Dr Andrew Graham	Email Secretaries: neurologyipswich@esneft.nhs.uk Tel: 01473 704044 / 01473 704041
	ESNEFT Colchester Site	
	Dr Imtiaz Ahmed Dr Dr Natalia Salari Dr Mohammed Sharief Epilepsy Nurse Specialist	Telephone Secretaries: 01206 742243 Email Secretaries: ch.neurology@esneft.nhs.uk Tel Epilepsy Nurse Specialist: 01206 746472
Dermatology	**ESNEFT Ipswich Site**	
	Shuk Yates, Clinical Nurse Specialist Dermatology Jodie Newman, Clinical Nurse Specialist Dermatology Dr Liberta Labinoti	Consultant (via secretaries): 01473 704042 Specialist nurse: 01473 706877 Email: IPS.derm@esneft.nhs.uk Advice and guidance on NHS e-referrals

	ESNEFT Colchester Site	
	Dr Farooq Dr Asfar Dr Galahitiyawa, Kerry Penfold, Clinical Nurse Specialist Dermatology Soumya Sunny, Clinical Nurse Specialist Dermatology Dr Khalid Mahmood Susan Robertson, Clinical Nurse Specialist Dermatology	Email: dermatologycolchester@esneft.nhs.uk Specalist Nurse: 01206 487 216
	WSFT	
Dermatology	Dr Lis Andrews-Fraser Dr Jacqui Hawkins Dr Rachel Jenkins Dr Aruni Ranasinghe Dr Kun Chen Dr Abbas Al-Shammari Nurse Specialist Dermatology	Email: dermatology@wsh.nhs.uk
	ESNEFT Ipswich Site	
	Dr Lane / Dr Watts: Dr Weerakoon / Dr Shand Dr Abdulkader/Dr Ntatsaki	Tel: 01473 702362 Tel: 01473 702039 Tel: 01473 707324 Email: ihn-tr.rheum-sharedcare@nhs.net Advice and guidance on NHS e-referrals
	ESNEFT Colchester Site	
Rheumatology	Dr Paul Byrne Dr Tom Walton Dr Rachel Davies Dr Lauren Steel Clinical Nurse Specialist May Clark Clinical Nurse Specialist Lucy Mascurine	Tel Department: (01206) 742165/742279 Email Nurses: rheumatology.nurseadvice@esneft.nhs.uk
	WSFT	
	Dr Katerina Achilleos Dr Catherine Bevington Dr Shweta Bhagat Dr Vivek Rajagopal	Tel: 01284 713484 Tel: 01284 712907 Tel: 01284 712977 Tel: 01284 712590 Email Nurses: RheumatologyNurses2@wsh.nhs.uk Tel: 01284713707 Email Secretary: RheumatologySecretaries@wsh.nhs.uk
Respiratory	**ESNEFT Ipswich Site**	

Dr Matthew Burton Dr Jonathan Douse Dr Nicholas Innes Dr Rana Rabbani Dr Yu Hon Man Dr Md Erfanur Shuvo	Email Secretaries : respsecretaries@esneft.nhs.uk Tel Secretaries: 01473 703779 / 01473 703508
ESNEFT Colchester Site	
Respiratory Dr Rekha Badiger Dr Samantha Cooper Dr Peter Hawkins Dr Misha Sidhu Dr Mphatso Wirima Dr Emma Boynton Dr Safin Rahman	Email Secretaries: respsecretaries@esneft.nhs.uk Tel: 01206 742612

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
- Hydroxychloroquine sulfate 200 mg film-coated tablets. Zentiva. Date of revision of the text: 17/07/21. Accessed via https://www.medicines.org.uk/emc/product/1764/smpc on 26/01/22
- Hydroxychloroquine sulfate 200 mg film-coated tablets. Accord. Date of revision of the text: 31/08/2021. Accessed via https://www.medicines.org.uk/emc/product/11326/smpc on 26/01/22
- Hydroxychloroquine sulfate 200 mg film-coated tablets. Blackrock Pharmaceuticals. Date of revision of the text: 11/11/2020. Accessed via https://www.medicines.org.uk/emc/product/11540/smpc on 08/04/2021
- Hydroxychloroquine sulfate 200 mg film-coated tablets. Ipca Laboratories. Date of revision of the text: 07/04/2020. Accessed via https://www.medicines.org.uk/emc/product/11516/smpc accessed 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.
- Immunisation against infectious diseases (The Green Book). Accessed via https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book on 03/02/2021.
- 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
- 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*.

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/.

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.

To be agreed and completed locally

SNEE Integrated Medicines Optimisation Committee approved 13/08/2024 ESNEFT MGG approved 27/08/2024 D&Tc 11/24

Appendix 1: Shared Care Request letter (Specialist to Primary Care Prescriber)

Dear *[insert Primary Care Prescriber's name]*

Patient name: *[insert patient's name]*
Date of birth: *[insert date of birth]*
NHS Number*:* *[insert NHS Number]*
Diagnosis: *[insert diagnosis]*

As per the agreed *[insert APC name]*shared care protocol for *[insert medicine name]* for the treatment of *[insert indication],* this patient is now suitable for prescribing to move to primary care.

The patient fulfils criteria for shared care and I am therefore requesting your agreement to participate in shared care. Where baseline investigations are set out in the shared care protocol, I have carried these out.

I can confirm that the following has happened with regard to this treatment:

	Specialist to complete
The patient has been initiated on this therapy and has been on an optimised dose for the following period of time:	
Baseline investigation and monitoring as set out in the shared care documents have been completed and were satisfactory	*Yes / No*
The condition being treated has a predictable course of progression and the patient can be suitably maintained by primary care	*Yes / No*
The risks and benefits of treatment have been explained to the patient	*Yes / No*
The roles of the specialist/specialist team/ Primary Care Prescriber / Patient and pharmacist have been explained and agreed	*Yes / No*
The patient has agreed to this shared care arrangement, understands the need for ongoing monitoring, and has agreed to attend all necessary appointments	*Yes / No*
I have enclosed a copy of the shared care protocol which covers this treatment/the SCP can be found here (insert electronic/ web link)	*Yes / No*
I have included with the letter copies of the information the patient has received	*Yes / No*
I have provided the patient with sufficient medication to last until	
I have arranged a follow up with this patient in the following timescale	

Treatment was started on *[insert date started]* and the current dose is *[insert dose and frequency]*.

If you are in agreement, please undertake monitoring and treatment from *[insert date]*
NB: date must be at least 1 month from initiation of treatment.

The next blood monitoring is due on *[insert date]* and should be continued in line with the shared care guideline.

Please respond to this request for shared care, in writing, within 14 days of the request being made where possible.

Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist) *[NOTE THAT THIS WILL BE ELECRONICALLY MANAGED]*

Primary Care Prescriber Response

Dear *[insert Doctor's name]*
Patient *[insert Patient's name]*
NHS Number *[insert NHS Number]*
Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & frequency

I can confirm that I am willing to take on this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: _____Date: _____

Primary Care Prescriber address/practice stamp

Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist) *[NOTE THAT THIS WILL BE ELECRONICALLY MANAGED]*

Re:

Patient	*[insert Patient's name]*
NHS Number	*[insert NHS Number]*
Identifier	*[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS *[insert CCG name]***,** in conjunction with local acute trusts have classified *[insert medicine name]*as a Shared Care drug, and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

		Tick which apply
1.	**The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care** As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	
2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	

3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	
5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed***.*** For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	
6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England ‘Responsibility for prescribing between Primary & Secondary/Tertiary care’ guidance (2018) states that “when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and

the dissemination of sufficient, up-to-date information to individual GPs.” In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Yours sincerely

Primary Care Prescriber signature: _____
Date: _____

Primary Care Prescriber address/practice stamp