National shared care protocol adapted for local use:

Rheumatological Conditions: Hydroxychloroquine for patients within adult services.

The content of this shared care protocol was correct as of November 2023. 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 the 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 (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 (section 4) and interactions (section 7).
- Conduct required baseline investigations and initial monitoring (section 8).
- Initiate and optimise treatment as outlined in section 5. Once the patient is known to be tolerating the medicine, transfer to shared care would normally take place. Before transfer to shared care, the patient is expected to have had at least one specialist review and be stable (no increase in medication dose for at least 6 weeks alongside satisfactory investigation results). On transferring shared care, the specialist will provide at least 4 weeks medication to enable the practice to receive and process the shared care agreement and set up prescribing and ongoing monitoring. Any bloods required within the 4 weeks should be requested/organised and followed up by the specialist.
- If shared care is considered appropriate, and once treatment is optimised, write to the patient's GP practice, and request shared care; detailing the diagnosis, the current and ongoing dose, baseline, and most recent test results, confirm the monitoring schedule and when the next monitoring is required. Include the specialist service contact information (section 13).
- The specialist should also provide the details of the treatment to be undertaken by the GP. Including the reasons for the choice of treatment, medicine combination, frequency of treatment, and the next review date by the specialist.
- Prescribe sufficient medication to enable transfer to primary care (usually 42 days). Further prescriptions will be issued where there are unforeseen delays to the transfer of care. The patient should not be put in a position where they are unsure where to obtain medication supplies. The specialist team will be responsible for monitoring and prescribing the medicine during this initial period.
- Conduct the required reviews in section 8 and communicate the results in writing to primary care within 14 days where possible. After each review, provide primary care with a written

summary within 14 days, advising whether treatment should be continued confirming 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.
- Review patients annually. Review once every two years for patients under a Patient Initiated Follow-ups (PIFU) pathway.
- Provide the patient with a patient information sheet and details of their treatment, including any dosage changes made, follow-up appointments, monitoring requirements, and specialist team contact details. Highlight the importance of monitoring the patient and explain the potential withdrawal of treatment if monitoring appointments are not attended.
- Contact details for primary care prescribers will be made available.
- Details for fast-track referral will be supplied.
- After the patient has been on hydroxychloroquine for **five years**, refer for ophthalmology monitoring. Patients who are at higher risk of retinal toxicity **(on concomitant tamoxifen, impaired renal function, high hydroxychloroquine dose)** will need to be referred earlier (section 9).

Primary care responsibilities

- If shared care is not accepted, inform the specialist of the decision in writing within 14 days with reasons as to why shared care cannot be entered into. If shared care is accepted, ensure knowledge and understanding of the therapeutic issues relating to the patient's clinical condition. Undergo any additional training necessary to carry out the prescribing and monitoring requirements.
- Agree that, in their opinion, the patient should receive shared care for the diagnosed condition unless good reasons exist for the management to remain within the secondary care.
- If accepted, prescribe ongoing treatment as detailed in the specialist's request and as per section 5 taking into account any potential drug interactions in section 7.
- Adjust the dose of hydroxychloroquine prescribed as advised by the specialist and communicate any changes made to the patient.
- Conduct the required monitoring as outlined in section 9. Communicate any abnormal results to the specialist.
- Ensure the patient is given the appropriate follow-up and monitoring appointments. If a patient fails to attend, contact the patient in a timely manner to arrange alternative appointments. It is the GP's responsibility to decide whether to continue treatment in a patient who does not attend follow-up and monitoring appointments. If the patient regularly fails to attend the monitoring appointment, the GP may withhold the prescription and inform the consultant responsible for the patient's care.
- Assess for possible interactions with hydroxychloroquine when starting new medicines (section 7).
- Manage any adverse effects as detailed in section 10 and discuss them with the specialist team when required. Refer the patient back to the specialist team if further investigation is 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 (section 10).
- Contact the specialist team for advice if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.
- Discuss with and remind patients that they need to attend annual optician reviews and that they will require referral to ophthalmology for retinal toxicity monitoring when they have been on hydroxychloroquine for five years. Patients who are at higher risk of retinal toxicity (on concomitant tamoxifen, impaired renal function, high hydroxychloroquine dose) will need to be referred earlier (see section 9). If patients have not been referred to ophthalmology at 5 years, the specialist team must be contacted to organise the referral.
- Offer patients vaccination in line with the current Joint Committee on Vaccination and Immunisation advice. (Immunisation against infectious disease).

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. If unable to attend, inform the relevant practitioner as soon as possible and arrange and alternative appointment. 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 (OTC) medications to their prescriber and be aware they should discuss the use of hydroxychloroquine with their pharmacist before purchasing any OTC medicines.
- Store the medication securely away from children.
- Read the information supplied by the GP, specialist, and pharmacist, and contact the relevant practitioner if they do not understand any of the information given.
- Inform the specialist or primary care prescriber as soon as possible if they become pregnant or wish to become pregnant.

Community pharmacist responsibilities

- Professionally check prescriptions to ensure they are safe for the patient and contact the GP if necessary to clarify their intentions.
- Fulfil the legal prescriptions unless they are considered unsafe.
- Counsel the patient on the proper use of their medication.
- Advise patients suspected of experiencing an adverse reaction with their medicines to contact their GP.

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. Clinical benefit may take up to 3 months. NSAIDs and simple analgesics may need to be continued.

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),

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

2. Indications

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The licensed indications for hydroxychloroquine include:

- Active rheumatoid arthritis
- Systemic and discoid lupus erythematosus

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 conditions:

- Licensed: Active rheumatoid arthritis, systemic and discoid lupus erythematosus
- Unlicensed: Inflammatory arthritis, connective tissue disease, Sjögren's syndrome, myositis.

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

3. Locally agreed off-label use

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Inflammatory arthritis, connective tissue disease, Sjögren's syndrome, myositis

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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- Once the patient is known to be tolerating the medicine, transfer to shared care would normally take place. Before transfer to shared care, the patient is expected to have had at least one specialist review and be stable (no increase in medication dose for at least 6 weeks alongside satisfactory investigation results). On transferring shared care, the specialist will provide at least 4 weeks medication to enable the practice to receive and process the shared care agreement and set up prescribing and ongoing monitoring. Any bloods required within the 4 weeks should be requested/organised and followed up by the specialist.
- 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 400mg daily (usually 5mg/kg/day, based on actual body weight).

The risk of significant toxicity increases with doses above 5mg/kg/day (based on actual body weight) as per RCOpthal guidelines.

Doses should not exceed 6.5mg/kg/day (based on actual body weight).

The initial period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

200mg to 400mg daily (usually 5mg/kg/day, based on actual body weight).

The risk of significant toxicity increases with doses above 5mg/kg/day (calculated from actual body weight) as per RCOpthal guidelines.

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

Please note that for rheumatology conditions, a patient may be initiated on more than one DMARD. All DMARDs are long-term treatments. The clinical benefit may take up to 3 months. The duration of treatment will be determined by the specialist based on clinical response and tolerability.

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 (see SPC) .

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	Hydroxychloroquine sulfate 200 mg tablets (Plaquenil® or Quinoric®)
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, azithromycin, 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)
- Take history of eye disease/symptoms and advise patient to attend a yearly optician review.
- Electrocardiogram (ECG), only 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** and will include a reminder to see local optician.
- 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**, the specialist will refer the patient to ophthalmology (or other commissioned service as appropriate) for annual monitoring for retinopathy. **Patients who are at higher risk of retinal toxicity (on concomitant tamoxifen, impaired renal function, high hydroxychloroquine dose) 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

• Discuss with and remind patients that they need to attend annual optician reviews and that they will require referral to ophthalmology for retinal toxicity monitoring when they have been on hydroxychloroquine for five years. Patients who are at higher risk of retinal toxicity will need to be referred earlier. If patients have not been referred to ophthalmology at 5 years, the specialist team must be contacted to organise the referral 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.
	• Annually after 5 years of treatment, **or**
	• After 1 year if additional risk factors are present. **Risk factors include:**
	  ○ hydroxychloroquine dose (>5mg/kg/day)
	  ○ concomitant tamoxifen use
	  ○ impaired renal function (eGFR <60mL/min/1.73m^2)

• Patients aged from 50 years who are severely immunosuppressed and have not received the shingles vaccine before will be eligible for the shingles vaccine (varicella zoster). This will be provided as two doses of the non-live vaccine. If patient is taking additional DMARDs, check advice for all drugs. Refer to Green Book Chapter 6 (Contraindications and special considerations) and Green Book Chapter 28a (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: Chapter 28a (Shingles). • Influenza vaccination: annual. It is advisable to add the patient to the influenza vaccine list. • Other vaccinations as per national schedule, e.g., COVID-19.
(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 a full list of side effects and information on incidence of ADRs, refer to the BNF or see relevant summaries of product characteristics.

IF YOU ARE IN ANY DOUBT ABOUT ANY POTENTIAL ADVERSE REACTION, PLEASE CONTACT THE RHEUMATOLOGY SPECIALIST TEAM.

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. Other benchmark values may be set by secondary care in specific clinical circumstances. This will be communicated by the specialist.	
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/ ophthalmologist / optician.
Vision disturbances including blurred vision, changes in visual acuity or abnormal colour vision	Withhold and refer to optician/ ophthalmologist who will 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 should be reported **immediately** to an optician/GP for referral to ophthalmology.
- 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 (OTC) 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:

- VersusArthritis 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: Hydroxychloroquine in pregnancy (Bumps)

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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Name: **Named Rheumatology Consultant as per clinic letter**

Role and specialty: **Consultant Rheumatologist**

Daytime telephone number: **NUH**: 0115 919 4477 Secretaries Extension: 78947

SFH: 01623 676002 then dial option 2.

Email address: **NUH**: Nuhnt.ntcrheumatologysecretaries@nhs.net

SFH: sfh-tr.rheumqueries@nhs.net*F*

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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- Royal College of Ophthalmologists. 2020. Hydroxychloroquine and Chloroquine Retinopathy: Recommendations on Monitoring. Accessed via https://www.rcophth.ac.uk/standards-publications-research/clinical-guidelines/.
- Immunisation against infectious diseases (The Green Book). Accessed via https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book.
- NICE Clinical Knowledge Summary. DMARDS: Hydroxychloroquine. Last revised April 2020. Accessed via https://cks.nice.org.uk/topics/dmards/management/hydroxychloroquine/.
- Stockley's Drug Interactions. Accessed via www.medicinescomplete.com.
- NEWT Guidelines. Hydroxychloroquine. Last updated November 2012. Accessed via https://access.newtguidelines.com/H/Hydroxychloroquine.html.
- RMOC Advice on the monitoring requirements for HCQ

16. Other relevant national guidance

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- 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.

- The request for shared care should be accompanied by individual patient information, outlining all relevant aspects of the patient's care and which includes direction to the shared care protocols on the APC website.
- The specialist will request shared care with the GP in writing.
- If the GP doesn't agree to shared care, they should inform the specialist of their decision in writing within 14 days, outlining the reason for the decline. The agreement can be assumed if the GP does not provide a written decline.
- In cases where shared care arrangements are not in place or where problems have arisen within the agreement, and patient care may be affected, the responsibility for the patient's management, including prescribing, reverts back to the specialist.
- Should the patient's condition change, the GP should contact the relevant specialist using the details provided with the shared care request letter.