THE SHEFFIELD AREA PRESCRIBING GROUP

Prescribing Guideline

For

Hydroxychloroquine in Adults

Prescribing guideline developed by:

Sharron Kebell, Specialised Commissioning Pharmacist, NHS Sheffield
Mr Christopher Brand Consultant Ophthalmologist, STHFT
Dr Sarah Cockayne, Consultant Dermatologist, STHFT
Dr James Maxwell, Consultant Rheumatologist, STHFT

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Hydroxychloroquine Prescribing Guideline

Statement of Purpose

This prescribing guideline has been written to enable the continuation of care by primary care clinicians of patients initiated on hydroxychloroquine by dermatologists or rheumatologists. Primary care will only be requested to take over prescribing of hydroxychloroquine within its licensed indication unless specifically detailed otherwise below.

Responsibilities of consultant clinician

- To discuss benefits and side effects of treatment with the patient/carer and obtain informed consent.
- To initiate hydroxychloroquine in appropriate patients
- Rheumatologist or dermatologist to organise baseline retinal monitoring at STH ophthalmology department
- To prescribe the first 3 month's supply or until patient stable
- To contact patient's GP to request prescribing and send a link to or copy of the prescribing guideline.
- To advise the GP regarding continuation of treatment, including the length of treatment and dose prescribed
- To discuss any concerns with the GP regarding the patient's therapy
- The patient to remain under the consultant's care whilst ever the patient is being prescribed hydroxychloroquine
- After patient has been on hydroxychloroquine for 5 years, dermatologist/rheumatologist to re-refer patient for retinal monitoring unless considered at high risk (see below). Ophthalmology will recall patients annually thereafter, whilst patient continues on hydroxychloroquine.
- If high risk (ie concomitant tamoxifen, renal impairment with eGFR <60ml/min/1.73m^2 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 screen
- Dermatologist or rheumatologist to take necessary action arising from retinal monitoring
- Ophthalmologist to write to patient, rheumatologist/dermatologist and GP if patient defaults annual appointment

Responsibilities of the primary care clinician

- To refer appropriate patients to secondary care for assessment
- To agree to prescribe for patients in line with the prescribing guideline
- To report any adverse reaction to the MHRA and the referring consultant
- To continue to prescribe for the patient as advised by the consultant
- To inform the consultant if the patient discontinues treatment for any reason
- To seek the advice of the consultant if any concerns with the patient's therapy
- To contact ophthalmology department for advice if patient develops risk factors for retinopathy, i.e. concomitant tamoxifen, renal impairment (eGFR<60 ml/min/1.73 m^2)
- To conduct an annual medication review with patient or more frequent if required. Following baseline retinal monitoring appointment discuss retinal monitoring as part of this review to ensure patient is being monitored in accordance with this guideline

- In the event that the GP is not able to prescribe, or where the guideline is agreed but the consultant is still prescribing certain items e.g. hospital only product; the GP will provide the consultant with full details of existing therapy promptly by fax on request.
- For medication supplied from another provider GPs are advised to follow recommendations for Recording Specialist Issued Drugs on Clinical Practice Systems

Responsibilities of Patients or Carers

- To attend rheumatology/ dermatology, GP and ophthalmology assessment clinic appointments. Failure to attend will potentially result in the medication being stopped.
- Present rapidly to the GP or specialist should their clinical condition significantly worsen.
- Report any suspected adverse effects to their specialist or GP whilst taking hydroxychloroquine
- To read the medicines information given to them
- To take hydroxychloroquine as prescribed
- Inform the specialist, GP or community pharmacist dispensing their prescriptions of any other medication being taken – including over-the-counter medication.

Indication

- Rheumatoid arthritis / Inflammatory Arthritis
- Discoid and systemic lupus erythematosus
- Photosensitive dermatological conditions

Hydroxychloroquine is used routinely in the early arthritis pathway for new onset rheumatoid arthritis alongside methotrexate and is also used in connective tissue diseases.

It is considered a disease-modifying drug (DMARD) because it can decrease the pain and swelling of arthritis and it may prevent joint damage and reduce the risk of long-term disability. It is believed that hydroxychloroquine interferes with communication of cells in the immune system.

Selection of patients

All adult patients should be initiated and stabilised on hydroxychloroquine by a secondary care specialist. Patients initiated on therapy are suitable for referral to a primary care service once stabilised on treatment – this will usually take 3 months. However the GP practice and the hospital may agree to transfer patients sooner where they judge this clinically appropriate or specified through patient choice.

Dosage

The minimum effective dose should be employed. This dose should not exceed 5mg/kg/day (actual body weight) and will usually be either 200mg, 300mg or 400mg per day.

Contra-indications

- Known hypersensitivity to 4-aminoquinoline compounds e.g. chloroquine
- Pre-existing maculopathy of the eye

Side –effects

The details below are not a complete list and the BNF and the SPC remain authoritative

Adverse effect	Action
Rash	Stop drug and contact specialist nurse for advice / management.
Nausea, vomiting, diarrhoea	Discuss with specialist nurse
Development of blurred vision or changes in visual acuity	Refer in the first instance to see usual high street optometrist

Monitoring

New patients initiated on hydroxychloroquine should receive a baseline* formal ophthalmic assessment from STH ophthalmology department, within one year of commencing hydroxychloroquine. This will be organised by the rheumatologist/ dermatologist.

Baseline examination should include a colour fundus photograph and a spectral domain optical coherence tomography (SD-OCT) scan.

*N.B. Baseline retinal monitoring is a local requirement and is not in line with RCOphth guideline.

After 5 years of therapy, patients should have annual retinal monitoring. This includes SD-OCT and widefield fundus autofluorescence imaging (FAF) of the macula.

Patients with abnormalities will be considered for further testing including multifocal electroretinography.

For patients currently under the care of a dermatologist / rheumatologist, who have already been on hydroxychloroquine for:

- ≥4 years duration, patients will be referred by dermatologist/ rheumatologist for a baseline retinal screen and will subsequently be recalled annually by ophthalmology
- < 4 years duration, patients will be referred by dermatologist/rheumatologist for a baseline retinal screen; they will be re-referred to ophthalmology after they have been on hydroxychloroquine for 5 years. Subsequently they will be recalled annually by ophthalmology

Rheumatologist / dermatologist will inform the patient that retinal monitoring is necessary and will refer patients for baseline or annual monitoring after 5 years of therapy or if high risk, after 1 year of therapy. The Ophthalmology department will ensure that patients are recalled for annual retinal monitoring if high risk or after 5 years.– see also under consultant responsibilities section.

The patient, GP and rheumatologist / dermatologist will receive a retinal monitoring results letter from ophthalmology stating: Normal, Possible or Definite hydroxychloroquine retinopathy. The GP should add the Snomed code 1104901000000103 for hydroxychloroquine retinopathy monitoring to the patients clinical record on either SystmOne or Emis Web.

The rheumatologist / dermatologist will then make a decision as to whether to stop or continue hydroxychloroquine, based on the result.

Patients should be advised to continue to have their usual eye test on a regular basis at their local high street optometrist
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.

On stopping hydroxychloroquine, retinal monitoring should be discontinued.

Interactions

The details below are not a complete list and the current BNF and the SPC remain authoritative.

- Hydroxychloroquine can increase plasma digoxin levels.
- Antacids may reduce absorption of hydroxychloroquine so it is advised that a 4 hour interval be observed between hydroxychloroquine and antacid.
- Hydroxychloroquine may enhance the effects of hypoglycaemic treatments so a decrease in doses of insulin or antidiabetic drugs may be required.

Additional information

Hydroxychloroquine can be continued during pregnancy and it is compatible with breastfeeding, as evidenced in the BSR guidelines on pregnancy and lactation. It is however recommended that advice be sought from rheumatologists / dermatologists in pregnancy and breastfeeding as this is outwith the SPC.
Men may continue taking hydroxychloroquine while trying to conceive.

Re-Referral guidelines

See under monitoring section above.
Pregnancy and / or preconception advice / management
Deterioration of disease
Discuss with ophthalmology if develops risk factors for retinopathy

Support, education and information

A patient information leaflet is issued to patients by the specialist and also by the ophthalmology department.

If any problems occur or you have any concerns please contact relevant specialist:

Rheumatology help line (Mon-Fri 0900-1600) (0114) 2713086 (option 3)

Dermatology help line (24 hour answering machine)	(0114) 2712018
Ophthalmology	(0114) 226 1469
On call specialist via STH NHS Foundation Trust switchboard:	(0114) 2711900

Patient information leaflets

These are provided to patient by secondary care, but can also be downloaded from -

https://www.versusarthritis.org/about-arthritis/treatments/drugs/hydroxychloroquine/

A wide range of leaflets can also be downloaded from the British Association of Dermatologists website. There are specific leaflets, here: http://www.bad.org.uk/for-the-public/patient-information-leaflets

References

R College Ophthalmology Guideline 2020
https://www.rcophth.ac.uk/wp-content/uploads/2020/12/Hydroxychloroquine-and-Chloroquine-Retinopathy-Monitoring-Guideline.pdf

BSR guidelines 2017
https://academic.oup.com/rheumatology/article/56/6/865/3053478#supplementary-data

Pregnancy and lactation: BSR guidelines
https://academic.oup.com/rheumatology/article/55/9/1693/1744535#90343088

Full list of side-effects is given in the hydroxychloroquine summary of product characteristics (SPC), available from www.emc.medicines.org.uk

Current BNF https://bnf.nice.org.uk/

Amendment September 2021

Added reference under dosage to 300 mg per day being an option since 300mg hydroxychloroquine tablets now available.

Amendment January 2020:

Updated reference to RCOphth Guideline 2020; clarification that local procedure is to continue to undertake baseline monitor within the first year; change in the renal impairment eGFR to <60ml/min/1.73m^2; modify monitoring to reflect current local practice; changed Read code to Snomed; and review date extended to Jan 2023.