Northern Lincolnshire
Area Prescribing Committee

Prescribing Framework for Hydroxychloroquine in Rheumatic and Immunological Disease

Patients Name: …… **NHS Number:** ……

Patients Address: …… (Use addressograph sticker)

GP's Name: ……..

Communication

We agree to treat this patient within this Prescribing Framework.

Consultant's / Specialist's
Signature:……..Date:……..

GP's Signature:…… Date:…….

If the General Practitioner is unable to accept prescribing responsibility for the above patient the consultant should be informed within two weeks of receipt of this framework and consultant's / nurse specialist's letter. In such cases the General Practitioner are requested to update the consultant, by letter, of any relevant changes in the patient's medication / medical condition.

Contact Details:

NLaG Contact:
Via the Pharmacy Office: 01724 290095

VirginCare Contact: 01482 638571

Rheumatology Specialist Nurses: 03033 304849

APPROVAL PROCESS

Approved by:	**Northern Lincolnshire APC, April 2021**
Review Date:	**May 2024**

1. Background	DMARDs are fundamental to arresting the disease process in Rheumatoid Arthritis and other inflammatory arthritides. While early initiation of therapy is essential to arrest the disease process, sustained use is vital if disease suppression is to be maintained. Prolonged therapy requires long-term monitoring for toxicity and safety profile. Hydroxychloroquine is a DMARD which may be used for treatment of rheumatoid arthritis (NICE Guideline 100, www.nice.org.uk/guidance/ng100) and other rheumatic diseases. These guidelines aim to provide a framework for the prescribing of hydroxychloroquine by GPs and to set out the associated responsibilities of GPs and hospital specialists who enter into the shared care arrangements. The guidelines should be read in conjunction with the general guidance on prescribing matters given in EL (91) 127 "Responsibility for prescribing between hospitals and GPs".
2. Indications	Rheumatoid Arthritis, Connective Tissue Diseases, (e.g. systemic and discoid lupus), uncontrolled urticaria and some photosensitive dermatological conditions.
3. Locally agreed off-label use	None
4. Initiation and ongoing dose regime Note - •Transfer of monitoring and prescribing to Primary care is normally after the patient is on regular dose and with satisfactory investigation results for at least 4 weeks •The duration of treatment 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.	Specialist should ask about visual impairment (which is not corrected by glasses). Record near visual acuity of each eye (with correcting glasses if worn) using a standard reading chart. If visual impairment is suspected patient should be advised to consult an optometrist. If any apparent impairment is correctable with refraction, treatment may then commence. • Starting dose may be 200 - 400 mg daily. • Dosage may be reduced to 200 mg daily depending on clinical response. • Maximum dose should not exceed 6.5 mg/kg lean body weight per day.
5. Baseline investigations, initial monitoring and dose titration to be undertaken by specialist	**Baseline:** • FBC • U&Es • LFT Ophthalmological screening recommended if pre-existing ocular pathology and especially any retinal condition Impaired renal function and over the age of 70 Not generally recommended where pre-existing maculopathy of the eye. Royal College of Ophthalmologists, October 2009, Hydroxychloroquine and Ocular Toxicity: Recommendations on Screening. http://www.rcophth.ac.uk/page.asp?section=451&sectionTitle=Clinical+Guidelines

<table>
<tr><td rowspan="2">6. Ongoing monitoring requirements to be undertaken by primary care.</td><td>Monitoring</td><td>Frequency</td></tr>
<tr><td>• Renal function - in over 70's or if pre-existing renal impairment or when known hypertension/diabetes
• Formal annual ophthalmological screening</td><td>Annually

After 5 years of continuous treatment or more than 500 grams of Hydroxychloroquine in total has been taken – whichever is first.</td></tr>
<tr><td></td><td colspan="2">Consultant Rheumatologist/Nurse Practitioner will inform patient about expected response to treatment and side effects of medication.

Written information to be given and discussed with patient.

Patients will be advised to attend annual eye test with optometrist and report any changes in their vision to their doctor.</td></tr>
<tr><td>7. Responsibilities of clinicians involved</td><td colspan="2"><table>
<tr><th>Stage of treatment</th><th>Specialist</th><th>GP</th></tr>
<tr><td>Initiation</td><td>• Assess the patient following referral by GP
• Recommend appropriate treatment to GP
• Carry out full baseline full blood count and biochemistry profile
• Check visual acuity and advise patient on further monitoring. (Include details of visual acuity in clinic letter to GP).</td><td>Prescribe on FP10
Monitor for adverse effects</td></tr>
<tr><td>Maintenance</td><td>• Assess clinical response to treatment
• Provide adequate advice and support for the GP
• Discuss with ophthalmologist after 5-years treatment</td><td>Refer back to consultant where necessary</td></tr>
</table></td></tr>
<tr><td rowspan="4">8. Pharmaceutical aspects</td><td>Route of administration :</td><td>Oral</td></tr>
<tr><td>Formulation :</td><td>200mg Tablet</td></tr>
<tr><td>Administration details :</td><td>Take with or just after food, or a meal</td></tr>
<tr><td>Other important information:</td><td></td></tr>
<tr><td>9. Contraindications
Please note this does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it.</td><td colspan="2">• Pre-existing maculopathy.
• Known hypersensitivity to 4 - aminoquinoline compound.
• Breast feeding.
Use with extreme caution in patients with a history of epilepsy – may induce status epilepticus, severe renal impairment and moderate to severe hepatic impairment.</td></tr>
<tr><td>10. Significant interactions
For a comprehensive list consult the BNF or Summary of Product Characteristics (SPC)</td><td colspan="2">• Amiodarone - increased risk of ventricular arrhythmias (avoid concomitant use)
• Antacids - may reduce absorption (Avoid with 4 hours of dosage)
• Antimalarials – increased risk of ventricular arrhythmias with chloroquine, mefloquine, quinine and Riamet (avoid concomitant use)
• Ciclosporin – increase plasma concentration of ciclosporin
• Cimetidine - increase plasma concentration of hydroxychloroquine
• Digoxin - may increase plasma concentration of digoxin
• Moxifloxacin - increased risk of ventricular arrhythmias (avoid concomitant use)
Details of contraindications, cautions, drug interactions and adverse effects listed above are not exhaustive. For further information always</td></tr>
</table>

	check with BNF www.bnf.org.uk or SPC (www.medicines.org.uk).	
11. Adverse Effects and management	Result	Action
	Gastro-intestinal: Abdominal pain, Diarrhoea, Nausea	Discuss with specialist
	Decreased appetite	Discuss with specialist
	Headache	Discuss with specialist
	Skin reactions (rashes and pruritis)	Discuss with specialist
	Vision disorders	Stop medication and discuss with specialist
	Ocular toxicity - rare but requires monitoring – refer to specialist	Stop medication and discuss with specialist
12. Advice to patients and carers 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.	Consultant Rheumatologist/Nurse Practitioner will inform patient about expected response to treatment and side effects of medication. Written information to be given and discussed with patient. Patients will be advised to attend annual eye test with optometrist and report any changes in their vision to their doctor.	
13. Preconception care, Pregnancy and breast feeding 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 GP and the specialist.	**Pregnancy** – discuss with specialist if patient is pregnant or planning pregnancy **Breast feeding** — present in milk in small amounts. Specialist sources indicate risk of accumulation in infant due to long half-life; monitor infant for symptoms of uveitis e.g. eye redness or sensitivity to light.	
14. Specialist contact information	Rheumatology Specialist Nurses: 03033 304849 Dermatology Contact Details: (VirginCare) via 01482 638571	
15. Additional information	Patients with quinine sensitivity. Use in caution in patients with: Psoriasis - increased risk of flare. Patients taking medicines which may cause adverse ocular/skin reactions. Severe hypoglycaemia has been reported, even in the absence of anti-diabetic medication. Hepatic or renal disease, and in those taking drugs known to affect those organs - dosage adjusted accordingly (seek advice from Pharmacy). Important drug interactions: amiodarone, moxifloxacin, ciclosporin, digoxin. Antacids (advise a 4 hour interval). Use with caution in patients with a history of epilepsy – may lower seizure threshold. Advice will be given to the GP on duration of treatment and dose changes for each individual patient.	
16. References	• BNF Monograph: https://bnf.nice.org.uk/drug/hydroxychloroquine-sulfate.html#indicationsAndDoses • Summary of Product Characteristics: https://www.medicines.org.uk/emc/product/11516/smpc#gref	

17. To be read in conjunction with the following documents	https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf