Sussex Community Dermatology Service NHS

EFFECTIVE SHARED CARE AGREEMENT (ESCA)

DRUG NAME: **HYDROXYCHLOROQUINE**
INDICATION/S COVERED: **active rheumatoid arthritis, juvenile idiopathic arthritis, discoid and systemic lupus erythematosus**

Coastal West Sussex Traffic Light system classification: Amber

N.B. The eligibility criteria included here apply to new patients commencing treatment under this agreement & not to existing patients whose treatment was initiated under the previous version. However, monitoring and discontinuation criteria apply to all patients.

NOTES to the primary care prescriber

Amber drugs: Prescribing to be initiated by a consultant / specialist but with the potential to transfer to primary care. The expectation is that this agreement should provide sufficient information to enable primary care prescribers to be confident to take clinical and legal responsibility for prescribing these drugs**.**

The questions below will help you confirm this:

- Is the patient's condition predictable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this effective shared care agreement?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this ESCA), then it is appropriate for you to accept prescribing responsibility. Sign and return a copy of the final page to the requesting consultant / specialist. Until the requesting consultant / specialist has received a signed copy of the final page indicating that shared care has been agreed all care (including prescribing) remains with the consultant / specialist.

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should write to the consultant / specialist within 14 days, outlining your reasons for NOT prescribing. If you do not have the confidence to prescribe, we suggest you discuss this with your local Trust/specialist service, which will be willing to provide training and support. If you still lack the confidence to accept clinical responsibility, you still have the right to decline. Your Medicines Management pharmacist will assist you in making decisions about shared care.

Prescribing unlicensed medicines or medicines outside the recommendations of their marketing authorisation alters (and probably increases) the prescriber's professional responsibility and potential liability. The prescriber should be able to justify and feel competent in using such medicines.

The patient's best interests are always paramount

The primary care prescriber has the right to refuse to agree to shared care, in such an event the total clinical responsibility will remain with the consultant

Information

This information sheet does not replace the Summary of Product Characteristics (SPC), which should be read in conjunction with this guidance. Prescribers should also refer to the appropriate paragraph in the current edition of the BNF.

1. **Link to the relevant SPC website**:

http://www.medicines.org.uk/EMC/medicine/6977/SPC/Plaquenil+Tablets/

2. **Background to use for the indication/s, including licence status**

Hydroxychloroquine (Plaquenil®) decreases the immune response in rheumatic disease.

Licensed indications: treatment of active rheumatoid arthritis, juvenile idiopathic arthritis, discoid and systemic lupus erythematosus.

3. **Dose & administration**

- **Route:** Oral. Tablets swallowed whole with a glass of milk or with a meal.
- **Dose:** Recommended starting dose is 400mg per day in divided doses. Maintenance dose 200mg per day. Occasionally alternate day dosing is used e.g. 200mg and 400mg on alternate days. Maximum dose 400mg per day, not to exceed 6.5mg/kg/day. Therapeutic effects may take up to six months.

4. **Cautions**

- Pregnancy & breastfeeding (see below)
- Reduce dose if severe renal impairment
- Patients with liver impairment (BSR/BHPR guideline)

5. **Contraindications**

- Pregnancy & breastfeeding – The SPC advises against use but clinical experience/research suggests safe in rheumatology doses in practice but caution weighing benefit versus potential risk in each case.
- Pre-existing maculopathy of the eye
- Known hypersensitivity to 4-aminoquinoline compounds (e.g. chloroquine)

6. **Side effects**

- **Ocular effects:** retinopathy (uncommon if recommended daily dose not exceeded), corneal changes, blurring of vision.
- **Haematopoietic:** Bone marrow suppression is most frequently manifested by leucopenia, thrombocytopenia (which are usually reversible) and anaemia, or any combination may occur (rare). May precipitate or exacerbate porphyria.
- **Gastrointestinal:** GI disturbances such as nausea, diarrhoea, anorexia, abdominal pain and vomiting.
- **Hepatic:** Raised liver transaminases (rare).
- **Central Nervous System:** Less frequently, dizziness, vertigo, tinnitus, hearing loss, ototoxicity, headache, mental changes, convulsions.
- **Neuromuscular effects:** skeletal muscle myopathy or neuromyopathy.
- **Dermatological:** Skin reactions (rashes, pruritis). Rarely hair depigmentation, alopecia and discoloration of skin, nails, and mucous membranes, exfolitative dermatitis, Stevens–Johnson syndrome, photosensitivity.
- **Cardio-vascular effects:** ECG changes and cardiomyopathy (rare).

7. **Interactions**

- May increase plasma concentration of **digoxin** and **ciclosporin**
- **Antacids** reduce absorption (4 hour interval recommended)
- **Cimetidine** inhibits metabolism
- Effects of **hypoglycaemic** medication maybe enhanced (may need to reduce dose of insulin or antidiabetic drugs accordingly)
- Avoid use with **amiodarone, mefloquine, quinine, moxifloxacin and droperidol** (black dot in BNF)
- Occasionally **reduce seizure threshold**

- Reduce antibody response to primary immunisation with **rabies vaccine**

8. Criteria for use

As given under licensed indications. Should only be initiated by clinicians experienced in the treatment of chronic inflammatory rheumatic and skin disease.

9. Any further information (e.g. supporting therapies)

N/A

10. References

1. Summary of Product Characteristics: Plaquenil tablets (Sanofi-aventis), last updated: 01/12/2011. Available to access at: http://www.medicines.org.uk/EMC/medicine/6977/SPC/Plaquenil+Tablets/
2. Chakravarty K *et al*. BSR/BHPR guideline for disease-modifying anti-rheumatic drug (DMARD) therapy in consultation with the British Association of Dermatology. *Rheumatology* 2008; 47: 924-5. Available to access at: http://rheumatology.oxfordjournals.org/content/suppl/2008/05/31/kel216a.DC1/kel216b.pdf

RESPONSIBILITIES and ROLES

	Consultant / Specialist responsibilities
1	Confirmation of diagnosis and identification of suitable patients.
2	Request agreement of shared care with primary care prescriber.
3	Initiation of appropriate therapy.
4	Discussion of risks and benefits with patients, outline possible side effects and inform patient to contact their primary care prescriber or Hospital Rheumatology Clinic immediately is any side effects occur.
5	To ensure and take responsibility for baseline and ongoing monitoring, act on the results appropriately and communicate these results to the GP. ***Before Treatment*:** Exclude pregnancy Blood tests - Liver Function Tests (LFTS), U&Es (including AST/ALT), Full Blood Count (FBC) (including differential white blood cell count and platelet count). Ask about visual impairment (not corrected by glasses) Record far and near vision with appropriate glasses if worn Refer to optician if corrected vision recorded is less than 6/9 (far vision) and N5 (near vision) in either eye (prior to treatment) ***During treatment*:** Check for visual disturbance at clinic visits. Annual optician eye test and/or enquiry about visual symptoms and repeat testing as above Periodic examination of skeletal muscle function and tendon reflexes if on long term treatment. Discuss with ophthalmologist if treatment > 5yrs. The Rheumatology Team will provide patients with blood forms to present to their GP/Phlebotomist for all monitoring blood tests (we will ensure the consultants name is on the form).
6	Issuing initial prescription(s) until the patient is stabilised (minimum of one month) and until ESCA is in place.
7	Ensure that all newly treated patients (and/or their carers) receive appropriate education and advice regarding their drug therapy and shared care arrangements. This should include written information where appropriate including the manufacturer's patient information leaflet in each pack of tablets, a Rheumatology Shared Care Patient Booklet and specific drug information leaflet from the Arthritis Research UK.
8	Providing primary care prescriber with clinic letter stating planned introduction and reviews.
9	Provide outpatient reviews, monitor effectiveness/side effects.
10	Give a copy of the information sheet to the patient / carer and explain their roles.
11	Notify the primary care prescriber of the patient's failure to attend for clinical review or drug monitoring.
12	To refer if necessary to an ophthalmologist if specific concerns regarding treatment with hydroxychloroquine, prior to initiating therapy.

	Primary care prescriber responsibilities
1	Initial referral to secondary care.
2	To inform the consultant within one week of receipt of the consultant's letter if unwilling to enter into shared-care arrangements.
3	To provide repeat prescriptions once ESCA is agreed and in place and the patient is stabilised (not before initial one month stabilisation period). A demonstrable system should be in place to ensure that prescribing is reviewed by the primary care prescriber if there is no record of the fact that monitoring has taken place within the agreed time scales.
4	To record any changes in therapy in the prescribing record on receipt of such communication from secondary care.
5	To monitor patients overall health and well-being and to report any adverse drug reactions or interactions to secondary care.
6	Liaise with the Rheumatology Team if any cause for concern or drug discontinued.
7	To provide a copy of this ESCA to the patient to ensure that they are familiar with all roles and responsibilities.
8	To review the appropriateness of prescribing for patients who have not been seen by a specialist for over 6 months.

Patient's / Carer's role

1	Ask the Rheumatology Team or primary care prescriber for information, if he or she does not have a clear understanding of the treatment.
2	Share any concerns in relation to treatment with hydroxychloroquine.
3	Tell the rheumatology consultant/specialist or primary care prescriber of any other medication being taken, including over-the-counter products.
4	Read the patient information leaflet included with the medication and report any side effects or concerns to the rheumatology consultant/specialist or primary care prescriber.
5	Arrange blood tests as per rheumatology consultant/specialist request.
6	To be aware of side effects and report to their rheumatology consultant/specialist or primary care prescriber any relevant symptoms.

BACK-UP ADVICE AND SUPPORT

	Name / position	Telephone	Email
Medicine Management Lead:	Dr Andrew Morris Consultant Dermatologist	For further information & advice, please contact Grace Hancock (Assistant Service Manager): 01903 703281	grace.hancock@nhs.net
Hospital Pharmacy:	Worthing Hospital St Richards Hospital	01903 205 111, ext 5698 01243 788 122, ext 3347	pharmacy@wsht.nhs.uk
Out of hours (e.g. medical team on call):	On call physicians On call	Bleep 118 or 119 01903 205 111	

Version History			
Document Name:		Effective Shared Care Agreement (ESCA) for hydroxychloroquine for active rheumatoid arthritis, juvenile idiopathic arthritis, discoid and systemic lupus erythematosus	
Document Type:		Effective Shared Care Agreement	
Relevant to:		All primary care prescribers working within Coastal West Sussex and all relevant clinicians at Sussex Community Dermatology Service.	
Version No.	Date	Author of original development or review	Details of document development
1	June 2008	Julie Sadler (Prescribing Support Pharmacist)	Original development
2	16/10/12	Julie Sadler (Medicines Management Pharmacist)	Full review and re-draft
3	15/01/13	Julie Sadler (Medicines Management Pharmacist)	Removal of blood monitoring
4	08/10/13	Jo Piper Senior Pharmaceutical Commissioning Technician	Alteration of 'Effective from' date from 22/10/14 to 22/10/12.
5	01/08/14	Chris Emerson	Modified for use within Sussex Community Dermatology Service

Approval for organisational use	
ESCA authorised for use in Coastal West Sussex by	**Medicine Management Lead:** Dr Andrew Morris

EFFECTIVE SHARED CARE AGREEMENT (ESCA)

DRUG NAME: **HYDROXYCHLOROQUINE**
INDICATION: **active rheumatoid arthritis, juvenile idiopathic arthritis, discoid and systemic lupus erythematosus**

Agreement for transfer of prescribing to PRIMARY CARE PRESCRIBER

Patient details:

Name:

Address:

DoB:

NHS No:

Hospital No:

Drug name and dose:

The following tests and investigations have been carried out:
Details of tests:

Date treatment initiated:

At the last patient review the drug appeared to be effectively controlling symptoms / providing benefit:
Yes/No

The patients has now been stabilised on a dose of:

I will arrange to review this patient regularly. Date of next clinic appointment:

Title of specialist:
Name:

Department:
Hospital Address:

Contact Number:

Primary care prescriber:

Address:

Contact Number:

Main Carer:

Contact Number:

Key worker if appropriate:

Contact Number:

Agreement to shared care, to be signed by primary care prescriber and Medicine Management Lead:

Medicine Management Lead signature:

Date:

Primary care prescriber signature:

Date:

If shared care is agreed and the primary care prescriber has signed above please return a copy of this page to the requesting consultant or alternatively fax to: 01903 340849