NHS
Telford and Wrekin
Clinical Commissioning Group

Amiodarone
for the treatment of severe rhythm disorders
Effective Shared Care Agreement

Section 1: Shared Care arrangements and responsibilities

Section 1.1 Agreement to transfer of prescribing of amiodarone to GP

Patient details

Name: _____

Address: _____

Date of Birth: _____

NHS number: _____

Contact details
Specialist:
Address:

Email:

Contact number:

GP

Address:

Email:

Contact number:

Patient

Name:

Contact number:

Agreement to shared care, to be signed by GP and Specialist before prescribing is transferred to GP

Specialist Signature: _____

Date: _____

GP Signature: _____

Date: _____

Patient Signature: _____

Date: _____

Section 1.2: Shared Care responsibilities

This shared care agreement outlines suggested ways in which the prescribing responsibilities can be shared between the specialist and GP. GPs are invited to participate. If the GP feels that undertaking the roles outlined in the shared care agreement is outside their area of expertise or has clinical concerns about the safe management of the drug in primary care, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient's health remains with the specialist. If a specialist asks the GP to prescribe, the GP should reply to this request as soon as practicable. Sharing of care assumes communication between specialist, GP and patient.

If a specialist asks the GP to prescribe, the GP should reply to this request within 2 weeks

The prescriber of the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Responsibilities of the specialist initiating treatment

- Discuss with the patient options for treatment and the suitability of amiodarone
- Discuss the potential benefits and side effects of treatment with the patient
- Undertake baseline tests: **Thyroid function test, U&Es, LFTs**
- Perform a **chest x-ray** before initiating treatment
- Perform an **ECG** before initiating treatment, after one week, at months 6 and 12, and then annually.
- Ensure the patient has an annual **ophthalmological examination** during treatment.
- Initiate amiodarone treatment and continue prescribing until maintenance dosage reached.
- Ask the GP whether he or she is willing to participate in shared care, and agree with the GP as to who will discuss the shared care arrangement with the patient. Specialist attaches copy of Shared Care Agreement (SCA) from the trust intranet to printed letter.
- Ensure agreed signed shared care form has been received back from GP to indicate that the GP is in agreement with prescribing and monitoring.
- Ensure this has been discussed with patient, and that patient has signed SCA form
- Regular follow-up of patient (at least annually)
- Communicate promptly with the GP when treatment is changed
- Advise GP on dosage adjustment and when and how to stop treatment
- Have a mechanism in place to receive rapid referral of a patient from the GP in the event of deteriorating clinical condition and ensure that clear backup arrangements exist for GPs to obtain advice and support
- Report adverse events to the MHRA (via Yellow Card)

Responsibilities of the General Practitioner

- Prescribe amiodarone.
- Arrange and record on-going monitoring as agreed with specialist: **TFTs, U&Es, LFTs every 6 months.**
- Ensure the patient has an annual **ophthalmological examination** during treatment.
- Check for possible drug interactions when newly prescribing medication and avoid prescribing interacting drugs.
- Refer patient to specialist if his or her condition deteriorates.
- Continued prescribing is appropriate for patients attending regular review
- Report adverse events to the MHRA (via Yellow Card)

Responsibilities of the patient

- To take the prescribed medication regularly unless advised by GP or specialist

- To attend scheduled appointments with specialist and GP and for monitoring as detailed above
- Report any adverse effects to the specialist or GP.
- Share any concerns in relation to treatment.
- Report to the specialist or GP if they do not have a clear understanding of the treatment

Section 2: General Information on amiodarone

Licensed Indication

Oral amiodarone is indicated only for the treatment of severe rhythm disorders not responding to other therapies or when other treatments cannot be used.

Tachyarrhythmias associated with Wolff-Parkinson-White Syndrome.

Atrial flutter and fibrillation when other drugs cannot be used.

All types of tachyarrhythmias of paroxysmal nature including: supraventricular, nodal and ventricular tachycardias, ventricular fibrillation: when other drugs cannot be used.

Dosage and administration

Initial Stabilisation

Treatment should be started with 200mg, three times a day and may be continued for 1 week. The dosage should then be reduced to 200mg, twice daily for a further week.

Maintenance

After the initial period the dosage should be reduced to 200mg daily, or less if appropriate. Rarely, the patient may require a higher maintenance dose. The scored 100mg tablet should be used to titrate the minimum dosage required to maintain control of the arrhythmia. The maintenance dose should be regularly reviewed, especially where this exceeds 200mg daily.

Contraindications

Sinus bradycardia and sino-atrial heart block. In patients with severe conduction disturbances (high grade AV block, bifascicular or trifascicular block) or sinus node disease, amiodarone should be used only in conjunction with a pacemaker.

Evidence or history of thyroid dysfunction. Thyroid function tests should be performed in all patients prior to therapy.

Known hypersensitivity to iodine or to amiodarone, or to any of the excipients. (One 100mg tablet contains approximately 37.5mg iodine).

The combination of amiodarone with drugs which may induce torsades de pointes is contra-indicated.

Pregnancy - except in exceptional circumstances.

Lactation.

Side effects

Below are listed the most common side effects of amiodarone, please consult the Summary of Product Characteristics for a full list of possible side effects:

- Bradycardia, generally moderate and dose-related.
- Hypothyroidism
- Hyperthyroidism, sometimes fatal
- Corneal microdeposits usually limited to the area under the pupil, which are usually only discernible by slit-lamp examinations. They may be associated with coloured halos in dazzling light or blurred vision. Corneal micro-deposits consist of complex lipid deposits and are reversible following discontinuation of treatment. The deposits are considered essentially benign and do not require discontinuation of amiodarone.
- Benign gastrointestinal disorders (nausea, vomiting, dysgeusia) usually occurring with loading dosage and resolving with dose reduction.
- Isolated increase in serum transaminases, which is usually moderate (1.5 to 3 times normal range), occurring at the beginning of therapy. It may return to normal with dose reduction or even spontaneously.
- Acute liver disorders with high serum transaminases and/or jaundice, including hepatic failure, which are sometimes fatal
- Extrapyramidal tremor, for which regression usually occurs after reduction of dose or withdrawal
- Nightmares
- Sleep disorders.
- Pulmonary toxicity [hypersensitivity pneumonitis, alveolar/interstitial pneumonitis or fibrosis, pleuritis, bronchiolitis obliterans organising pneumonia (BOOP)], sometimes fatal.
- Photosensitivity.
- Slate grey or bluish pigmentations of light-exposed skin, particularly the face, in case of prolonged treatment with high daily dosages; such pigmentations slowly disappear following treatment discontinuation.

Monitoring

Monitoring	TFTs	Urea and Electrolytes	Ophthalmologic Examination	ECG	LFTs	Chest X-ray	Lung Function Test
Baseline	Consultant	Consultant		Consultant	Consultant	Consultant	Consultant
Week 1				Consultant			
Month 6	GP	GP		Consultant	GP		
Month 12	GP	GP	Ophthalmologist	Consultant	GP		
Thereafter	6-monthly	6-monthly	Annually	Annually	6-monthly		Annually

All tests at baseline and week 1 to be undertaken by specialist.

TFTs, U&Es and LFTs at 6 & 12 months to be undertaken by GP.

ECGs at 6 and 12 months to be undertaken by specialist.

Annual lung function test to be undertaken by specialist.

Both GP and specialist will need to ensure patient undergoes annual ophthalmologic examination.

Drug Interactions[1]

Amiodarone raises the plasma concentrations of **oral anticoagulants (warfarin)** and **phenytoin** by inhibition of CYP 2C9. The dose of warfarin should be reduced accordingly. More frequent monitoring of prothrombin time both during and after amiodarone treatment is recommended. Phenytoin dosage should be reduced if signs of overdosage appear, and plasma levels may be measured.

Administration of amiodarone to a patient already receiving **digoxin** will bring about an increase in the plasma digoxin concentration and thus precipitate symptoms and signs associated with high digoxin levels. Clinical, ECG and biological monitoring is recommended and digoxin dosage should be halved. A synergistic effect on heart rate and atrioventricular conduction is also possible.

Combined therapy with the following drugs which prolong the QT interval is contra-indicated due to the increased risk of torsades de pointes; for example:

• Anti-arrhythmic drugs e.g**. quinidine, procainamide, disopyramide, sotalol**

• Intravenous **erythromycin, co-trimoxazole or pentamidine** injection

• Some anti-psychotics e.g. **chlorpromazine, thioridazine, fluphenazine, pimozide, haloperidol, amisulpiride and sertindole**

• **Lithium** and tricyclic anti-depressants e.g., **amitriptyline**

• Anti-malarials e.g. **quinine, mefloquine, chloroquine, halofantrine**.

There have been rare reports of QTc interval prolongation, with or without torsades de pointes, in patients taking amiodarone with **fluoroquinolones**. Concomitant use of amiodarone with **fluoroquinolones** should be avoided (concomitant use with **moxifloxacin** is contra-indicated).

Combined therapy with the following drugs is not recommended:

• **Beta blockers** and certain calcium channel inhibitors (**diltiazem, verapamil**); potentiation of negative chronotropic properties and conduction slowing effects may occur.

• **Stimulant laxatives**, which may cause hypokalaemia thus increasing the risk of torsades de pointes; other types of laxatives should be used.

Caution should be exercised over combined therapy with the following drugs which may also cause hypokalaemia and/or hypomagnesaemia, e.g. **diuretics, systemic corticosteroids, tetracosactide, intravenous amphotericin.**

In cases of hypokalaemia, corrective action should be taken and QT interval monitored. In case of torsades de pointes antiarrhythmic agents should not be given; pacing may be instituted and IV magnesium may be used.

- **Grapefruit juice** inhibits cytochrome P450 3A4 and may increase the plasma concentration of amiodarone. Grapefruit juice should be avoided during treatment with oral amiodarone.

• **Ciclosporin**: plasma levels of ciclosporin may increase as much as 2-fold when used in combination. A reduction in the dose of ciclosporin may be necessary to maintain the plasma concentration within the therapeutic range.

• **Statins**: the risk of muscular toxicity is increased by concomitant administration of amiodarone with statins metabolised by CYP 3A4 such as simvastatin, atorvastatin and lovastatin. It is recommended to use a statin not metabolised by CYP 3A4 when given with amiodarone.

• Other drugs metabolised by cytochrome P450 3A4: examples of such drugs are **lidocaine, tacrolimus, sildenafil, fentanyl, midazolam, triazolam, dihydroergotamine and ergotamine.**

Given that **flecainide** is mainly metabolised by CYP 2D6, by inhibiting this isoenzyme, amiodarone may increase flecainide plasma levels; it is advised to reduce the flecainide dose by 50% and to monitor the patient closely for adverse effects. Monitoring of flecainide plasma levels is strongly recommended in such circumstances.

A full list of interactions can be found in the Summary of Product Characteristics

[1] BNF 66 September 2013-March 2014