Extended Shared Care Agreement (Amiodarone)

For patients to be eligible for a shared care prescribing arrangement, the following points must be met beforehand:

- Prescribing responsibility is only transferred when there is mutual agreement between the specialist and patient's GP that the patient's condition is stable.
- Patient will be given adequate supply from the provider to allow enough time for the shared care process to be completed.
- All amiodarone scripts are to be re appraised annually aiming for cessation unless specified by specialist

1. Areas of responsibility		
Specialist/Consultant	**GP**	**Patient**
1. Confirm patient has no contraindications to treatment (and review any cautions). 2. Discuss the benefits, limitations, monitoring requirements and side effects of treatment with the patient, and obtain informed consent. 3. Provide the patient with an amiodarone patient information leaflet and inform patient of warning symptoms to report, ensuring patient understands the dosing regimen. 4. Ensure patient is Initiated on an appropriate loading and stabilised on a maintenance dose prior to shared care. 5. Prescribe first month's supply or a sufficient prescription until the maintenance dose prior to shared care. 6. Ask the GP whether he or she is willing to participate in shared care, and discuss the shared care arrangement with the patient and provide the patient with a monitoring and dosage record. 7. Perform and provide results of baseline tests and recommend frequency of monitoring as outlined in the monitoring section (3f) – Make results available to patient's GP. 8. Address any concerns with the GP regarding the patient's treatment. 9. Periodically review the patient's condition (initially annually), to assess treatment response and disease progression - Communicate promptly with the GP when treatment is changed. 10. Report adverse events through	1. Reply to the request for shared care as soon as practicable. 2. Confirm indication of amiodarone with patient's specialist/consultant, if not already clear in the patient's notes. 3. Prescribe amiodarone at the dose recommended and adjust the dose as advised by the specialist. Ensure continuous prescribing remains clinically appropriate at this dose. 4. Ensure compatibility with other concomitant medication (making sure interacting drugs are not taken following initiation with amiodarone). 5. Ensure that the patient understands the dosing regimen, and which warning symptoms to report. 6. Perform monitoring tests as outline in the monitoring section below (3f). 7. Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises. 8. Identify adverse events if the patient presents any signs. 9. Report adverse events to the specialist/consultant and via the MHRA yellow card scheme. 10. Refer to specialist/consultant if patient's condition worsens. 11. Notify specialist/consultant if treatment with amiodarone is discontinued.	1. Report to the specialist or GP if he or she does not have a clear understanding of the treatment. 2. Share any concerns in relation to treatment with amiodarone. 3. Inform specialist or GP of any other medication being taken, including over-the-counter products. 4. Report any adverse effects, warning symptoms or if their condition worsens to the specialist or GP whilst taking amiodarone. 5. Patients should not stop taking amiodarone as prescribed, unless told to do so.

the MHRA yellow card scheme and GP. 11. Ensure that clear arrangements exist for GPs to obtain advice and support. 12. Notify GP of the indication for treatment if treatment with amiodarone is discontinued.		

2. Communication and Support

Contact details	Telephone No	Bleep	Email address
Consultant cardiologist	6504/7543	Mobile via switch	E referral
Hospital Pharmacy Dept.:…			
Other:……..			

3. Clinical Information

(a) Indication	Oral amiodarone is indicated only for the treatment of severe rhythm disorders when other therapies are ineffective or contraindicated: 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. (Treatment should be initiated and normally monitored only under hospital/specialist supervision).
(b) Therapeutic Summary	Amiodarone is an antiarrhythmic. It acts on both supraventricular and ventricular arrhythmias.
(c) Dose & route of administration	**Initiated in hospital or under specialist supervision.** **Loading Dose (by mouth):** 200mg three times a day for ONE week, then reduced to 200mg twice daily for a further week, followed by a maintenance dose. **The loading dose will be prescribed by the secondary care specialist, and GPs only asked to prescribe amiodarone at the maintenance dose.** **Maintenance Dose:** is usually 200mg daily or the minimum dose required to control the arrhythmia.
(d) Duration of treatment	As per specialist advice.
(e) Adverse effects	Refer to the SPC and BNF for a full list of adverse effects and more information. **Common or very common:** constipation; corneal deposits; hypothyroidism; movement disorders; photosensitivity reaction; sleep disorders; taste altered; vomiting. **Uncommon:** cardiac conduction disorders; dry mouth; myopathy (usually reversible on discontinuation); peripheral neuropathy (usually reversible on discontinuation). **Rare or very rare:** alopecia; aplastic anaemia; epididymo-orchitis; erectile dysfunction; haemolytic anaemia; pulmonary haemorrhage; thrombocytopenia; vertigo. **Frequency not known:** altered smell sensation; appetite decreased; parkinsonism; vasculitis.

	Additional Information: **Corneal microdeposits** Patients taking amiodarone may develop corneal microdeposits (reversible on withdrawal of treatment). However, if vision is impaired or if optic neuritis or optic neuropathy occur, amiodarone must be stopped to prevent blindness and expert advice sought. **Thyroid function** Amiodarone contains iodine and can cause disorders of thyroid function; both hypothyroidism and hyperthyroidism can occur. Hypothyroidism can be treated with replacement therapy without withdrawing amiodarone if it is essential; careful supervision is required. **Hepatotoxicity** Amiodarone is also associated with hepatotoxicity and treatment should be discontinued if severe liver function abnormalities or clinical signs of liver disease develop. **Pulmonary toxicity** Pneumonitis should always be suspected if new or progressive shortness of breath or cough develops in a patient taking amiodarone.
(f) Monitoring requirements	**<u>Specialist/ Consultant Monitoring</u>** <u>Baseline Monitoring –</u> - **ECG**, **Heart rate**, **Blood pressure**, - **U&Es (Potassium and Magnesium)** - **Thyroid function tests – TSH, T4, T3** - **LFTs** - **INR (if applicable)** - **Digoxin level (if applicable)** - **Chest X-ray:** - **Eye exam** - **Check for drug interactions** <u>After Loading –</u> - **ECG, Heart rate, Blood pressure** - **Thyroid function tests – TSH, T4, T3 –** every 6 months - **LFTs –** every 6 months - **INR (if applicable)** - **Digoxin level (if applicable)** - **Chest X-ray –** Repeat if clinically indicated - **Eye exam** – Repeat if clinically indicated - **Check for drug interactions** when new medicines are prescribed for patient. <u>Further Information –</u> - **Heart rate:** Bradycardia is usually dose-related. - **Blood pressure:** May cause hypotension (usually in loading dose period). - **TSH, T4, T3:** May cause hypothyroidism or hyperthyroidism. - **INR (if applicable) –** Warfarin clearance is reduced and can lead to sudden/pronounced increase in INR – Therefore more frequency monitoring of INR both during and after amiodarone treatment. - **Digoxin level (if applicable) –** Digoxin plasma level increases, therefore precipitates symptoms and signs associated with high digoxin levels – Assess serum digoxin levels if

dose increases or toxicity suspected.

- **Chest X-ray:** Pulmonary toxicity including hypersensitivity pneumonia, or fibrosis may occur.

GP Monitoring

Parameter	Frequency	Action
Heart rate and ECG	Annually	Follow SPC.
U&Es (Potassium and Magnesium)	Annually	Correct electrolyte imbalance and re-check U&Es.
TFTs (TSH, T4, T3)	Every 6 months.	Follow SPC.
LFTs	Every 6 months	Follow SPC.
INR (if applicable)	More frequency monitoring of INR both during and after amiodarone treatment by the patient's usual warfarin monitoring service.	May require dose adjustment of warfarin according to INR.
Digoxin level (if applicable)	Assess serum digoxin levels if dose increased or toxicity is suspected.	May require adjustment/discontinuation of digoxin if toxic. Contact initiating specialist for advice if required.
Check for drug interactions	Repeat if new medicines are prescribed for patient.	See info in specific drug interaction section for further details.
Check for adverse effects	Most serious toxicity is seen with long-term use and may therefore present first to the GP.	See adverse effects section for advice.

(g) Clinically relevant drug interactions (as per SPC)

Amiodarone has interactions with many commonly used drugs. The SPC or BNF should be consulted before initiating any new drug therapy.

Amiodarone has a long average plasma half-life of 50 days (range 20-100 days). **There is potential for drug interactions to occur several weeks or months after stopping treatment and the onset of drug interactions may be slo**w after initiating amiodarone.

COMMON DRUG INTERACTIONS (Note: For a full list and details of interactions, please refer to BNF and SPC)	
Digoxin	Amiodarone may increase plasma levels of digoxin. If concurrent use is indicated, prescribe half the recommended dose of digoxin, and monitor the person closely in view of potential toxicity.
Warfarin	Amiodarone raises plasma concentration of warfarin. The dose of warfarin should be reduced accordingly. More frequent monitoring of prothrombin time both during and after amiodarone treatment is recommended.
Dabigatran	Caution should be exercised when amiodarone is co administered with dabigatran due to the risk of bleeding. It may be necessary to adjust the dosage of dabigatran as per its label.

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<tr><td>Beta-blockers and heart rate lowering calcium channel blockers (diltiazem, verapamil)</td><td>Combined therapy with amiodarone is not recommended – potential of negative chronotropic properties and conduction slowing effects may occur.</td></tr>
<tr><td>Drugs that induce Torsade de Pointes or prolong QT interval.</td><td>Only specialists should co-prescribe amiodarone and drugs that prolong the QT interval.
Please refer to SPC and BNF for list of drugs.</td></tr>
<tr><td>Stimulant laxatives</td><td>May induce hypokalaemia.</td></tr>
<tr><td>Phenytoin</td><td>Amiodarone raises plasma concentration of phenytoin. Phenytoin dose should be reduced if signs of overdosage (resulting in neurological signs), and plasma levels may be measured.</td></tr>
<tr><td>Statins</td><td>Risk of muscular toxicity (e.g. rhabdomyolysis)</td></tr>
<tr><td>Grapefruit Juice</td><td>Inhibits cytochrome P450 3A4 and may increase the plasma concentration of amiodarone. Grapefruit juice should be avoided during treatment with oral amiodarone.</td></tr>
<tr><td>Hepatitis C drugs</td><td>Concomitant use of amiodarone with some drugs used to treat hepatitis C (sofosbuvir in combination with another hepatitis C drug such as daclatasvir, simeprevir or ledipasvir) may increase risk of bradycardia or heart block.</td></tr>
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Please refer to SPC and BNF for full list and details of interactions.
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<tr><td>(h) Contra-indications</td><td>
- Sinus bradycardia and sino-atrial heart block: In patients with severe conduction disturbances (high grade AV block, bi-fascicular or tri-fascicular block) or sinus node disease, amiodarone should only be used in conjunction with a pacemaker.
- Known hypersensitivity to iodine or amiodarone or to any excipients listed in the tablets
- Evidence of history of thyroid dysfunction (thyroid function tests should be performed prior to therapy in all patients)
- Pregnancy (unless exceptional circumstances)
- Breastfeeding
- Combination with drugs that increase the risk of Torsades de Pointes (see drug interactions)
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<tr><td colspan="2">This information does not replace the SPC, this should be read in conjunction with this document available from: https://www.medicines.org.uk/emc</td></tr>
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