**North of Tyne, Gateshead and North Cumbria Area Prescribing Committee**

# Amiodarone
# Shared Care Guidance

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| Introduction | **Indication:** Supraventricular and Ventricular Arrhythmias when other drugs cannot be used<br><br>**Usual loading dose**: 200mg THREE times daily for 1 week, then reduced to 200mg TWICE daily for 1 week, and then<br><br>**Usual maintenance dose:** 200mg daily (or the minimum dose to control arrhythmia). |
| Specialist Responsibilities | **Initial assessment and prescribing:**<br>• Post-surgical: Initiate and supply medication for first 8 weeks (post-surgical) as a minimum or until the dose is stabilised.<br>  ○ **NOTE:** patients will be reviewed at 6-8 weeks post cardiothoracic surgery where it will usually be stopped, should treatment need to be continued then prescribing will be transferred to the GP at this point.<br><br>• Medical:<br>  ○ AF<br>  ▪ Initiate and supply medication for first 3 months (or until review)<br>  ○ Other arrhythmias:<br>  ▪ Initiate and supply medication until review.<br><br>• If amiodarone prescribed for postoperative AF following cardiothoracic surgery, ensure patient has a cardiothoracic review at 6 weeks<br><br>**Initial safety monitoring:**<br>• Prior to treatment<br>  ○ TFTs<br>  ○ LFTs<br>  ○ Chest x-ray<br>**Ongoing Responsibilities:**<br>  ○ Assess and monitor patients' response to treatment and the need to continue therapy on at least a 6 monthly basis including assessment by ECG. Review patient for thyroid, liver, pulmonary and ophthalmological toxicity.<br><br>• Provide the GP with relevant information for each patient including treatment plan<br>• Report any suspected ADRs to CSM via Yellow Card system.<br>• Provide GP with any further advice if required |
| GP Responsibilities | **Maintenance prescribing:**<br>• Prescribe maintenance dose as directed by cardiologist<br>**Physical Monitoring:**<br>• **Monitor**<br>  ○ TFTs and LFTs on a 6 monthly basis<br>**Further Responsibilities:**<br>• Have a low threshold for suspecting amiodarone induced pulmonary toxicity. New or progressive SOB or cough not explained by other causes, |

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| | following clinical assessment – suspect pneumonitis and refer back to cardiologist<br>• If a patient reports new visual changes: Patients taking amiodarone may develop corneal micro deposits which are reversible (see below). However if vision is impaired optic neuritis or optic neuropathy must be suspected – refer for an urgent ophthalmological assessment and contact the patient's cardiologist once the results are known.<br>• Liver and thyroid function tests: should be repeated until 12 months after stopping the amiodarone as very occasionally thyroid dysfunction has been documented up to a year after stopping it. |
| Adverse Effects, Precautions, Contraindications | **Amiodarone is contraindicated in**<br>• Patients with sinus bradycardia, and sino-atrial heart block. (Note it should be used only in conjunction with a pacemaker in patients with severe conduction disturbance or sinus node disease).<br>• Patients with evidence or history of thyroid dysfunction or known hypersensitivity to iodine or amiodarone.<br>• Pregnancy (unless exceptional circumstances).<br>• Breastfeeding<br><br>**Adverse effects: Remember many adverse effects are dose-related and reversible with reduction in dose; however, because of its long half-life this can take some time and adverse effects may develop after treatment is stopped.**<br><br>• Gastro-Intestinal – nausea, vomiting and taste disturbance.<br>• Cardiovascular – bradycardia (reduce dose or if severe withdraw treatment, conduction disturbances withdraw treatment). Note amiodarone has a long half-life so may require pacemaker, beta adrenostimulants or glucagon – see SPC for further information<br>• Endocrine disorders - hypothyroidism (20% patients) and hyperthyroidism (5% of patients) occur commonly and thyroid function should be carefully monitored. If the patient becomes hypothyroid amiodarone may be withdrawn if clinically acceptable in which case the hypothyroidism usually resolves within 12 months. However some patients may need treatment for their hypothyroidism with levothyroxine – see under monitoring for more information. If patients become thyrotoxic refer for specialist endocrine advice immediately.<br>• Eye disorders- corneal micro deposits occur almost always in patients on continuous therapy. They may be associated with dazzling light or blurred vision. Drivers should be advised that this may cause them to be dazzled by headlights at night. Corneal micro-deposits consist of complex lipid deposits and are reversible following discontinuation of treatment and do not require discontinuation of amiodarone. Optic neuropathy and/or optic neuritis require amiodarone withdrawal.<br>• Hepato-biliary disorders- increases in serum transaminases are very common early in therapy and these may resolve spontaneously, or with reduction of dosage. Acute liver disorders, with high transaminases/jaundice have been reported. Very rarely chronic liver reactions have been seen, including hepatitis and cirrhosis. See monitoring requirements.<br>• Pulmonary toxicity is a common side effect and patients should be advised to report new respiratory problems.<br>• Skin photosensitivity is very common and patients should be cautioned to |

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| | avoid exposure of skin to direct sunlight or sun lamps. A wide spectrum sunscreen such as RoC Total Sunblock should be used to protect against both long ultraviolet and visible light. Amiodarone may also cause slate-grey pigmentation of the skin. This is slowly reversible on discontinuation of treatment.<br>**Stopping treatment with amiodarone**<br>• Amiodarone can be stopped abruptly<br>• Amiodarone lingers long after the drug is stopped. Plasma concentration falls by 50% in the first two weeks but it may then take a further 6 months before it is eliminated completely<br>• Liver and thyroid function tests: should be repeated until 12 months after stopping the amiodarone as very occasionally thyroid dysfunction has been documented up to a year after stopping it. |
| Common Drug Interactions | **Amiodarone has a long half-life and there is potential for interactions to occur for several weeks after treatment with amiodarone has been stopped.**<br>**This is a list of commonly occurring drug interactions (not exhaustive)**<br>• Anticoagulants- enhances anticoagulant effect of warfarin, phenindione and dabigatran. Smaller doses are required.<br>  ○ Warfarin: the INR will decrease upon stopping amiodarone. In most cases it is sufficient to repeat the INR one week after stopping in the expectation that a dose increase will be necessary<br>• Digoxin- increases plasma concentration of digoxin and half doses are usually required.<br>• Flecainide-plasma concentration of flecainide is increased<br>• Diltiazem, verapamil and beta blockers- increased risk of bradycardia and myocardial depression<br>• Any medication that prolongs QTc interval may increase the risk of torsades de pointes if used in combination with amiodarone. These include Class 1a and Class III antiarrhythmic drugs e.g. quinidine, procainamide, disopyramide and sotalol; IV erythromycin, co-trimoxazole or pentamidine injection; antipsychotics; quinolone antipsychotics; quinolone antibiotics; lithium and tricyclic antidepressants; anti-malarials. Concomitant use of these medicines is contra-indicated with amiodarone. If further advice is required, this should be discussed with the cardiologist.<br>• Statins - the risk of muscular toxicity is increased with statins metabolised by CYP 3A4 such as simvastatin, atorvastatin and lovastatin. Manufacturer of simvastatin recommends using a maximum of 20mg and atorvastatin a lower maximum dose.<br>• Grapefruit juice inhibits cytochrome P450 3A4 and may increase the plasma concentration of amiodarone. |
| Communication/Contact Details | Northumbria Heathcare NHS FT<br>• Cardiologists via switch 03448118111<br>Newcastle Upon Tyne Hospitals NHS FT<br>• Cardiologists via switchboard. 01228 523444<br>QE Gateshead<br>• 0191 4820000<br>North Cumbria Health and Social Care System<br>• Cumberland Infirmary: 01228 523444 West Cumberland Hospital: 01946 693181 |

Adapted from the Amiodarone Shared Care Guideline (York Teaching Hospital)

**This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the SPC or the BNF**

**Private and Confidential**

# Amiodarone - Shared Care Request/Confirmation

- Specialist Prescriber to complete first section of form and send to patient's GP.
- GP to complete second section of form and return to specialist prescriber within 28 days
- A copy of the full shared care guideline can be viewed at www.northoftyneapc.nhs.uk

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| **Specialist Prescriber** | | | | |
| **Department** | | | | |
| **Hospital** | | | | |
| **Telephone** | | | | |
| **Patient details (use hospital label if preferred)** | | | | |
| **Name** | | | | |
| **Address** | | | | |
| **Postcode** | | | | |
| **NHS or Hosp reg no** | | **Male / Female** | **DoB** | |

| **Treatment Requested for Prescribing in Accordance with an Approved Shared Care Arrangement** | | | | | |
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| **Drug Information – Amiodarone** | | | | | |
| **Formulation** | | **Dose** | | **Frequency** | |
| **Indication – Supraventricular and Ventricular Arrhythmias** | | | | | |
| **Other information (if appropriate)** | | | | | |
| **Signed (Specialist Prescriber)** | | **Name (Print)** | | **Date** | |

| **To be completed by GP** | **Please tick one box** |
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| **I ACCEPT the proposed shared care arrangement for this patient** | ❑ |
| **I ACCEPT the proposed shared care arrangement with the caveats below** | ❑ |
| **I DO NOT ACCEPT the proposed shared care arrangement for this patient** | ❑ |
| **My caveats/reason(s) for not accepting include:** | |
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| **Signed** | | **Name (print)** | | **Date** | |

**N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the specialist prescriber and the patient's GP**

Approved: 10/2020 Review: 10/2023