Rationale for Initiation, Continuation and Discontinuation (RICaD)

Amiodarone

Treatment of ventricular and supraventricular arrhythmias including arrhythmias associated with Wolff-Parkinson-White syndrome when other treatments are not effective, cannot be used or are contra-indicated.

This document supports the use and transfer of an agent which is classified as **AMBER**.
It is intended for completion by specialists in order to give Primary Care prescribers a clear indication of the reason for recommending an **AMBER** medication together with suggested criteria for its subsequent continuation or discontinuation. This RICaD should be provided as a supplement to the specialist's clinical letter.

Patient details		**GP details**		**Specialist details**	
Name		**GP Name**	**Dr**	**Specialist Name**	
NHS Number		**GP address**		**I confirm that this patient is eligible to receive amiodarone under the restrictions listed below**	
DOB				**Signature**	
Patient address				**Date**	
				Contact details	

Rationale for Choice

Relevant Diagnosis:	Treatment of ventricular and supraventricular arrhythmias when other treatments are not effective, cannot be used or are contra-indicated.
Agreed Indication(s) for inclusion in the BSSE APC Formulary:	• Severe rhythm disorders not responding to other therapies. • Atrial flutter and fibrillation when other drugs cannot be used. • All types of tachyarrhythmias of paroxysmal nature including supraventricular, nodal and ventricular tachycardias and ventricular fibrillation when other drugs cannot be used.
Pre-treatment test results	Perform baseline ECG, blood pressure, heart rate, potassium levels, liver function tests, thyroid function tests (including free thyroid hormone levels) and chest x-ray.

Guidance on initiation

Initiation dose:	Specialist in hospital will initiate prescription starting with 200mg THREE times daily for 1 week, then reduced to 200mg TWICE daily for 1 week, and then reduced to 200mg daily (or the minimum dose to control arrhythmia). The initiation doses will be prescribed and supplied by the hospital.
Additional info:	It would be rare for patient to require more than 200mg daily to control arrhythmias. Often patients can be managed on a lower dose. Occasionally patients require a higher dose for control of ventricular arrhythmias (i.e. 400mg THREE times daily for 1 week). These patients will be initiated in hospital and usually require long term follow up with an electrophysiologist Tablets should be swallowed with water, with or without food. A liquid formulation is not available.
Monitoring:	Baseline lines tests at the time of initiation should be conducted by the initiating prescriber. This should include: • Urea and electrolytes • Liver function • Thyroid function (including TSH) • Chest x-ray if specialist deems it appropriate

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Suggested Criteria for Continuation or Discontinuation

Assessment of Efficacy	
Frequency	Monitoring of efficacy and adverse effects should be carried out regularly at least 6 monthly as outlined below.
Location	GP practice
Method (what tests are required)	All pre-treatment tests need to be carried out and can be conducted by the initiating prescriber. Thyroid function tests should be performed before treatment and then every 4 months. Clinical assessment of thyroid function alone is unreliable. Thyroxine (T4) may be raised in the absence of hyperthyroidism; therefore tri-iodothyronine (T3), T4, and thyroid-stimulating hormone (thyrotrophin, TSH) should all be measured. A raised T3 and T4 with a very low or undetectable TSH concentration suggest the development of thyrotoxicosis. If thyroid function tests are normal then tests should be repeated every 4 months by the GP. Liver function tests required before treatment and then every 4 months. Chest X-Ray if patient develops symptoms of respiratory disease (i.e. progressive shortness of breath and/or ongoing cough). If patient develops symptoms of shortness of breath then GP to inform the hospital specialist. Ophthalmological examination if patient reports vision changes, to be arranged by either the specialist or GP. The specialist should perform an ECG prior to starting treatment and this should be repeated if clinically indicated by the specialist.
Continuation Criteria	Stable thyroid and liver function with improvement in symptoms.
Discontinuation Criteria	Severe liver function abnormalities or clinical signs of liver disease. Evidence of significant hyperthyroidism after discussion with a cardiologist. Patients with hypothyroidism can often continue amiodarone with thyroid replacement. Successful treatment of arrhythmia by an alternative means such as ablation. Evidence of optic neuritis or optic neuropathy occur, amiodarone must be stopped to prevent blindness and expert advice sought. Pulmonary toxicity confirmed to discuss with hospital cardiologist specialist.
Follow up action	Monitoring requirements as outlined above.
Shared Care Read Code	In the patients notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement/ RICaD

GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing
SystmOne	XaB58	Shared care

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Appendix: Important information from the Summary of Product Characteristics (SPC)

Agreed Indication(s) for inclusion in the BSSE APC Formulary:	• Severe rhythm disorders not responding to other therapies. • Atrial flutter and fibrillation when other drugs cannot be used. • All types of tachyarrhythmias of paroxysmal nature including supraventricular, nodal and ventricular tachycardias and ventricular fibrillation when other drugs cannot be used. • Tachyarrhythmias associated with Wolff-Parkinson-White Syndrome.
Special precautions	Please refer to SPC
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. This is a list of commonly occurring drug interactions. • Anticoagulants - enhances anticoagulant effect of warfarin, phenindione and dabigatran. Doses may need to be reviewed. • Digoxin - increases plasma concentration of digoxin and half doses are usually required. • Flecainide-plasma concentration of flecainide is increased • Diltiazem, verapamil and beta blockers - increased risk of bradycardia and myocardial depression • Any medication that prolongs QTc interval- this 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 antibiotics; lithium and tricyclic antidepressants; antimalarials. Concomitant use of these medicines is contra-indicated with amiodarone. If further advice is required, this should be discussed with the cardiologist. • 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. • Grapefruit juice inhibits cytochrome P450 3A4 and may increase the plasma concentration of amiodarone. Please refer to SPC for full details on all drug interactions.
Additional info:	Amiodarone is contraindicated in • 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). • Patients with evidence of hyperthyroidism or known hypersensitivity to iodine or amiodarone. • Combination with drugs that increase the risk of torsades de pointes. • Pregnancy (unless exceptional circumstances). • Breast feeding.

Please note the information included in this document is correct at the time of writing. The manufacturer's Summary of Product Characteristics (SPC) and the most current edition of the British National Formulary should be consulted for up to date and more detailed prescribing information.

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