THE SHEFFIELD AREA PRESCRIBING GROUP

Shared Care Guideline

For

Amiodarone

5th edition

Shared care guideline reviewed by:

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Amiodarone Shared Care Guideline (SCG)

Statement of Purpose

This shared care guideline has been written to enable the safe and appropriate continuation of care for patients initiated on amiodarone in hospital. The SCG acknowledges that amiodarone is a useful medication but has potentially serious side effects. Practices are encouraged to audit all patients receiving amiodarone against this SCG to ensure they are being adequately monitored.

Responsibilities of the secondary care clinician

i. To initiate amiodarone in appropriate patients (see indications)
ii. To discuss benefits and side effects of treatment with the patient/carer and obtain informed consent.
iii. To issue the amiodarone passport (patient hand held book)
iv. To ensure patients are commenced on an appropriate loading and then maintenance dose prior to shared care
v. To prescribe the first month's supply or a sufficient prescription until the maintenance dose is reached by the patient
vi. To contact patient's GP to request prescribing under shared care using the amiodarone Transfer of Care (ToC) form and send a link to or copy of the SCG
vii. To make the baseline test results available to the GP continuing care
viii. To advise the GP regarding the duration of treatment
ix. To address any concerns with the GP regarding the patient's treatment

Responsibilities of the primary care clinician

i. To refer appropriate patients to secondary care for assessment
ii. If appropriate, to agree to prescribe in accordance with the SCG by returning the amiodarone ToC form to the referring consultant
iii. In the event that the GP is not able to prescribe, or where the SCG is agreed but the consultant is still prescribing certain items e.g. hospital only product, the GP will provide the consultant with full details of existing therapy promptly by fax on request
iv. To report any adverse reaction to the MHRA and the referring consultant
v. To continue to prescribe for the patient as advised by the consultant
vi. To undertake monitoring as per SCG
vii. To inform the consultant if the patient discontinues treatment for any reason
viii. To seek the advice of the consultant if any concerns with the patient's treatment
ix. **To conduct a six monthly face to face medication review or more frequent if required;** enquiring specifically about adverse effects and considering possible interacting drugs.
x. For medication supplied from another provider GPs are advised to follow recommendations for Recording Specialist Issued Drugs on Clinical Practice Systems

Responsibilities of Patients or Carers

i. To attend hospital and GP clinic appointments and to bring amiodarone passport (patient hand held book).Failure to attend will potentially result in the medication being stopped.
ii. Present rapidly to the GP or specialist should their clinical condition significantly worsen.
iii. Report any suspected adverse effects to their specialist or GP whilst taking amiodarone.
iv. To read the drug information given to them
v. To take amiodarone as prescribed
vi. Inform the specialist, GP or community pharmacist dispensing their prescriptions of any other medication being taken – including over-the-counter medication.

Indication/Patient selection

Treatment should be initiated by specialists only. Monitoring should take place by the specialist or as part of the SCG.

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

- As an adjunctive short-term treatment prior to DC cardioversion of atrial flutter/fibrillation (unlicensed indication)
- 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

Other indications fall outside this shared care guideline and the patient should be referred back to the original prescriber.

Dosage

A specialist should initiate loading with amiodarone and an oral or intravenous route may be used, according to the clinical situation and indication.

The loading dose by mouth is: 200mg 3 times daily for 1 week reduced to 200mg twice daily for a further week. The loading dose should be prescribed by secondary care and GPs only asked to prescribe amiodarone at the maintenance dose.

Maintenance dose usually 200mg daily or the minimum required to control the arrhythmia. Maintenance doses above 200mg daily should be managed by secondary care and are not part of the SCG.

Contra-indications, drug interactions and side effects

The lists below are not exhaustive, for full details on contraindications; drug interactions and side effects see SPC and the British National Formulary.

Drug interactions

Drug	Action recommended
Digoxin	Reduce digoxin dose by half; ECG and monitoring of levels is recommended.
Warfarin	For patients taking warfarin prior to starting amiodarone the warfarin dose should be reduced by approximately one-third when amiodarone is started. INRs should then be checked weekly for 4-6 weeks and until INR stable. If amiodarone is stopped the interacting effect may persist for up 6 weeks or more, so INR should be checked weekly until stable. Note that amiodarone-induced hyperthyroidism will increase warfarin dose requirements. For patients monitored at STH, inform the anticoagulation clinic.
Simvastatin	Reduce simvastatin dose to 20mg.
Phenytoin	Reduce dose of phenytoin and measure levels if toxicity noticed.
Contraindicated with class Ia and other class III anti-arrhythmia drugs	

Side-effects

Amiodarone can cause serious adverse reactions affecting the eyes, heart, lung, liver, thyroid gland, skin and peripheral nervous system. Patients on long term treatment should be carefully supervised because these reactions may be delayed. The minimum effective maintenance dose should be given because undesirable effects are usually dose related.

See table on page 5 for further details

The details below are not a complete list and the SPC and the BNF remain authoritative

Table of amiodarone adverse effects

Adverse effect	Frequency %	Investigation & Diagnosis	Treatment
Pulmonary toxicity (suggested by new or worsening cough and/or shortness of breath)	2 to 17	CXR and ECG to exclude alternative diagnoses	If pulmonary toxicity is suspected: refer urgently to initiating cardiologist or respiratory physician. Specialist to request PFTs including DLCO* and HRCT** chest scan (see also advice under monitoring on page 6)
Hyperthyroidism	2	Free T4, TSH	See algorithm Appendix 1
Hypothyroidism	6	Free T4, TSH	See algorithm Appendix 1
Liver toxicity	1	LFT	See algorithm Appendix 2
Optic neuropathy	0.13	Ophthalmologic examination	If optic neuropathy/neuritis is suspected, refer urgently to ophthalmology and discuss the possibility of stopping amiodarone & alternative antiarrhythmic therapy with patient's cardiologist
Pro-arrhythmia	<1	ECG	Stop amiodarone
Extrapyramidal Tremor Peripheral Neuropathy Myopathy	<10 <1	History and clinical examination	Reduce dosage or withdraw if possible Usually reversible on withdrawal of the drug recovery can take several months, but may sometimes be incomplete
Bradycardia	2-4	Examination, ECG	If severe, discuss with cardiologist whether to stop amiodarone or insert pacemaker
Nausea, anorexia	30	History + examination	Reduce dosage
Corneal micro-deposits	>90	Slit-lamp examination	None
Photosensitivity	4-9	History, examination	Use sunblock
Blue discolouration of skin	<9	Examination	Reduce dosage if possible

*DCLO is Diffusing Capacity of Lung for carbon monoxide.
**HCRT is High Resolution Computed Tomography
Where dose reductions have been recommended please consult cardiology specialist for advice.

Monitoring

Monitoring should take place during the loading of amiodarone, and then every 6 months whilst treatment continues. See table below. Please ensure that "Patient on Amiodarone" is marked on every lab test form.

Monitoring at baseline and during loading is the responsibility of secondary care.

Further monitoring is the responsibility of primary care.

	Baseline	Loading	At 6 months and every 6 months thereafter unless otherwise stated
History & examination (H&E)	✓		Continue annually
H&E relating to adverse effects[1]	✓	✓	✓
Heart rate and ECG	✓	✓	Continue annually
TFTs	✓		✓
U & Es	✓		✓
LFTs (ALT)	✓	✓	✓
Digoxin level (if on digoxin)	✓	✓	Assess serum digoxin levels if dose increased or toxicity is suspected
INR (if on warfarin)	✓	✓	Monitor INR levels. Adjust warfarin dose accordingly
CXR	✓	If suspected pulmonary toxicity	
PFTs inc DLCO	✓	If suspected pulmonary toxicity	
Eye examination	Assess if new or worsening visual symptoms occur		

NB. An increase of up to 40% above the baseline T4 is a normal effect of amiodarone. This occurs approximately 2 months after initiation of therapy and does not require discontinuation.

The development of thyrotoxicosis is much less easy to predict than hypothyroidism - it is suggested if the TSH is low, can occur quite rapidly (i.e. between tests) and such patients should be referred to an endocrinologist.

[1]Ask about breathlessness and non-productive cough, relating to possible pulmonary toxicity, at each review visit.

Note: Healthcare providers should have a low threshold for suspecting amiodarone induced pulmonary toxicity.

Re referral guidelines

If any problems occur or you have any concerns please contact the specialist who initiated the drug, also see monitoring.

Secondary care clinician details:

Arrhythmia nurse specialists: phone 0114 2269064 fax 0114 2269543.

Cardiology consultant (electrophysiologists) secretaries: 0114 2715389 or 0114 2715379.

Secondary care assumes responsibility for the monitoring and re-prescription of amiodarone until maintenance dosage has been successfully achieved.

Clinicians are reminded that the prescriber is responsible for ensuring the appropriate monitoring of the patient on the medication prescribed, in the case of shared care this will usually be the primary care clinician.

Support and information

Copies of this shared care guideline are available from:
http://www.intranet.sheffieldccg.nhs.uk/Medicines%20Management/medicines-prescribing/shared-care-protocols.htm

References

Full prescribing information is given in the amiodarone summary of product characteristics (SPC), available from www.emc.medicines.org.uk .

NICE CG36: Atrial fibrillation is available at http://guidance.nice.org.uk/CG36

Amiodarone Monitoring Protocol Derbyshire Joint Area Prescribing Committee Updated Dec 2016

http://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical_Guidelines/Formulary_by_BNF_chapter_prescribing_guidelines/BNF_chapter_2/Amiodarone_monitoring.pdf

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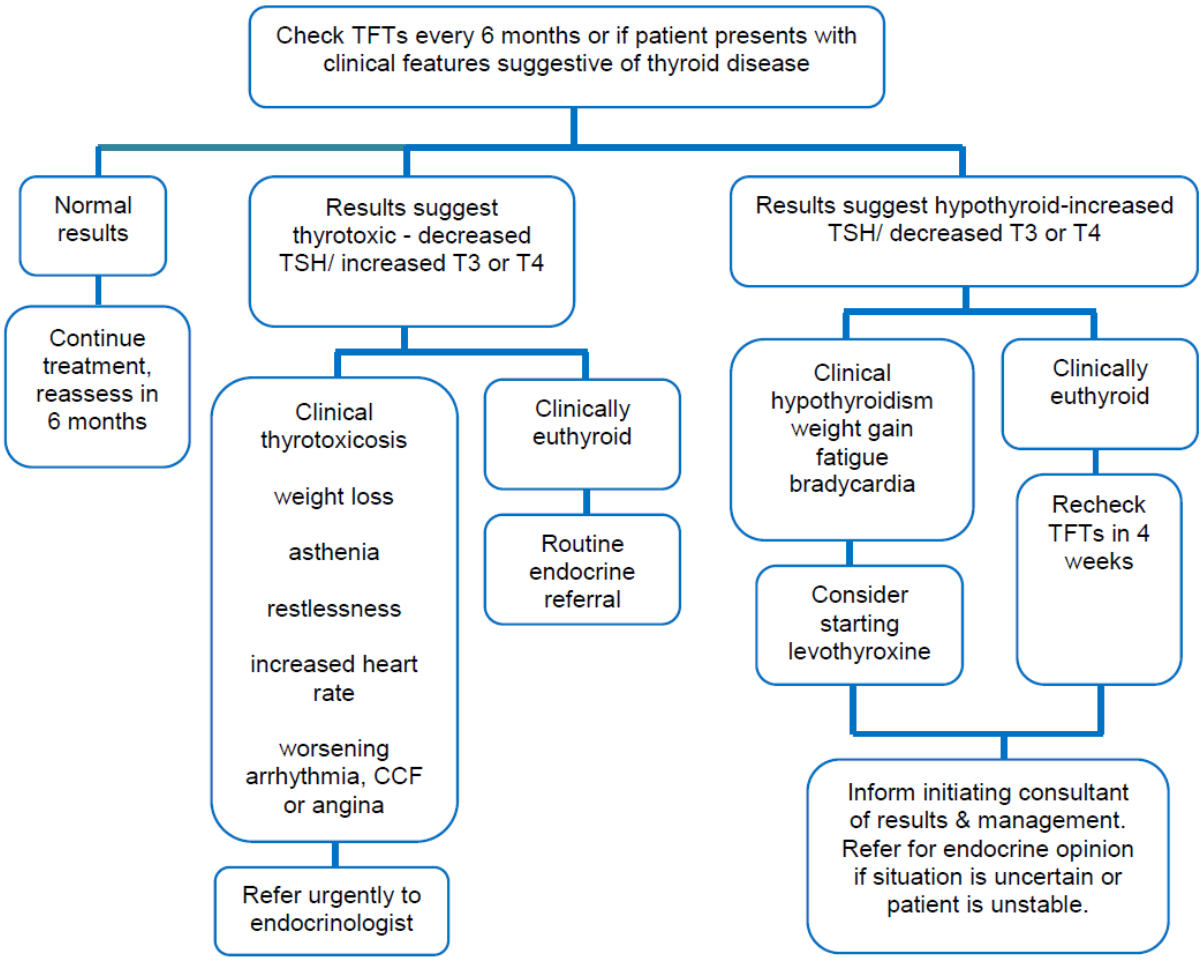
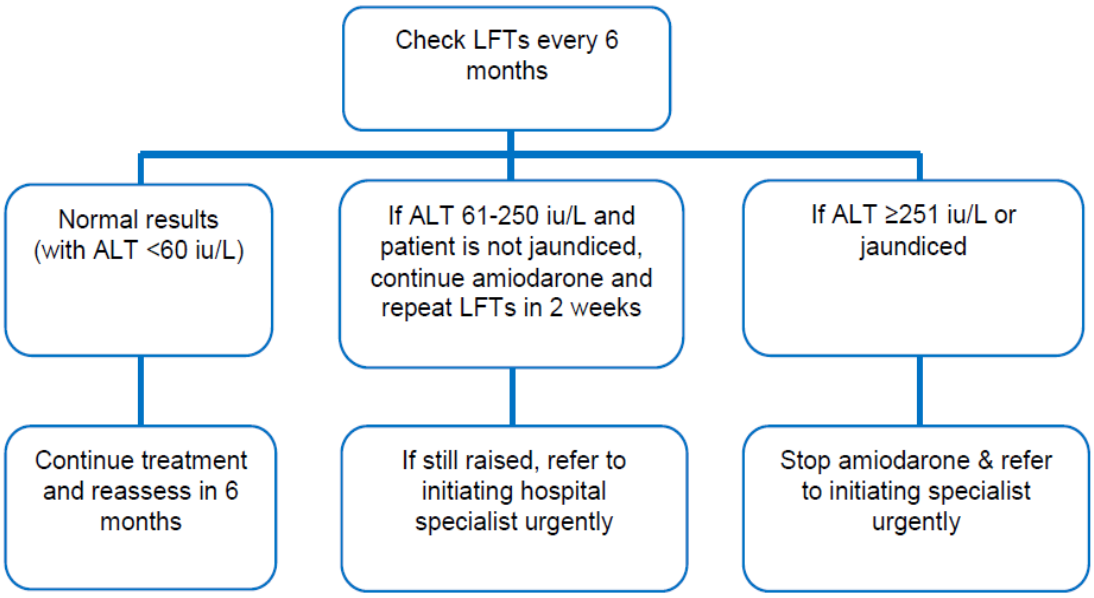
Appendix 1

Thyroid function: TFTs every 6 months



Appendix 2

Liver Function Tests



Patients taking amiodarone may have co-morbidities that affect LFTs; these should be considered when interpreting LFTs.