Royal Cornwall Hospitals
NHS Trust

Amiodarone (Adults)
Shared Care Clinical Guideline

V2.0

June 2024

1. Aim/Purpose of this Guideline

1.1 This guideline applies to medical, nursing and pharmacy staff regarding the safe and appropriate prescribing and administration of amiodarone.

1.2 Amiodarone is an antiarrhythmic drug that increases the duration of ventricular and atrial muscle action by inhibiting Na^+-K^+-activated myocardial adenosine triphosphatase, resulting in decreased heart rate and vascular resistance.

1.3 Amiodarone hydrochloride is used in the treatment of arrhythmias, particularly when other drugs are ineffective or contraindicated. It can be used for paroxysmal supraventricular, nodal, and ventricular tachycardias, atrial fibrillation and flutter, and ventricular fibrillation. It can also be used for tachyarrhythmias associated with Wolff-Parkinson-White syndrome.

1.4 Due to the significant safety concerns, NHS England (NHSE) and NHS Clinical Commissioners' (NHSCC) guidance advises that prescribers should not initiate amiodarone in primary care for any new patients. In exceptional circumstances, if there is a clinical need for amiodarone to be prescribed, this must be initiated by a specialist and only continued under a shared care arrangement in line with NICE clinical guidance Atrial fibrillation: NG196. NICE defines the place in therapy of amiodarone in NG196 and has made a "Do not do" recommendation: "Do not offer amiodarone for long-term rate control". Amiodarone may also be suitable in patients prior and post cardioversion or in specific patients who have heart failure or left ventricular impairment.

1.5 These guidelines provide additional limited information necessary to aid in the treatment these patients. As with all shared care guidelines they highlight relevant prescribing issues but should be used in conjunction with relevant NICE guidance, the BNF, ABPI summary of product characteristics and do not replace them.

1.6 This version supersedes any previous versions of this document.

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Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

2. The Guidance

2.1 Atrial fibrillation is the most common sustained cardiac arrhythmia, and estimates suggest its prevalence is increasing. If left untreated atrial fibrillation is a significant risk factor for stroke and other morbidities. Men are more commonly affected than women and the prevalence increase with age. The aim of treatment is to prevent complications, particularly stroke, and alleviate symptoms. Drug treatments include anticoagulants to reduce the risk of stroke and antiarrhythmics to restore or maintain the normal heart rhythm or to slow the heart rate in people who remain in atrial fibrillation.

2.2 Non-pharmacological management includes electrical cardioversion, which may be used to 'shock' the heart back to its normal rhythm, and catheter or surgical ablation to create lesions to stop the abnormal electrical impulses that cause atrial fibrillation.

2.3 According to NICE CG196 amiodarone is no longer recommended for long term rate control however there are instances where it is prescribing remains appropriate:

- **Acutely presenting atrial fibrillation** - If pharmacological cardioversion has been agreed, intravenous amiodarone hydrochloride, or alternatively flecainide acetate, can be used. Flecainide must not be used if structural heart disease is present.

- **Elective cardioversion** - Consider amiodarone hydrochloride to be started 4 weeks before and continuing for up to 12 months after electrical cardioversion to increase success of the procedure, and to maintain sinus rhythm; particularly in patients with left ventricular impairment or heart failure.

- **Paroxysmal Atrial Fibrillation** - In symptomatic paroxysmal atrial fibrillation, ventricular rhythm is controlled with a standard beta-blocker. Alternatively, if symptoms persist or a standard beta-blocker is not appropriate, an oral anti-arrhythmic drug such as dronedarone (see NICE guidance), sotalol hydrochloride, flecainide acetate, propafenone hydrochloride, or amiodarone hydrochloride can be given. Only consider Amiodarone (long term i.e. greater than one year) if rate control or other pharmacological or ablative strategies for rhythm control are not suitable and in patients who are less likely to be exposed to long term side effects.

- **Atrial Flutter** - Atrial flutter generally responds less well to drug treatment than atrial fibrillation. Direct current cardioversion is usually the treatment of choice when rapid conversion to sinus rhythm is necessary (e.g. when atrial flutter is associated with haemodynamic compromise); catheter ablation is preferred for the treatment of recurrent atrial flutter. There is a limited role for anti-arrhythmic drugs as their use is not always successful. Amiodarone hydrochloride can be used when other drug treatments are contra-indicated or ineffective.

- **Ventricular Tachycardia** - All patients presenting with ventricular tachycardia should be referred to a specialist. Patients with unstable, sustained, ventricular tachycardia who continue to deteriorate with signs of hypotension or reduced cardiac output, should receive direct current cardioversion to restore sinus rhythm. If this fails, intravenous amiodarone hydrochloride should be administered, and direct current cardioversion repeated. Patients with sustained ventricular tachycardia who are haemodynamically stable can be treated with intravenous anti-arrhythmic drugs. Amiodarone hydrochloride is the preferred drug.

  Following restoration of sinus rhythm, patients who remain at high risk of cardiac arrest will require maintenance therapy. Most patients will be treated with an implantable cardioverter defibrillator. Beta-blockers or sotalol hydrochloride (in place of a standard beta-blocker), or amiodarone hydrochloride (in combination with a standard beta-blocker), can be used in addition to the device in some patients; alternatively, they can be used alone when use of an implantable cardioverter defibrillator is not appropriate.

- **Ventricular ectopy** – Some patients with a high frequency of ventricular ectopic beats develop or are at risk of developing left ventricular systolic dysfunction. Amiodarone may be used in the short term to see whether suppression improves LV function as a prelude to catheter ablation or, more rarely, considered as long-term therapy.

  Patients with cardiac resynchronisation devices may have sub-optimal pacing percentages as a consequence of ventricular ectopy and amiodarone may be recommended to improve this percentage.

2.4 Preparations and Dosage

- 100mg tablets and 200mg tablets. Injections at 30mg/mL and 50mg/mL.
- This SCG pertains to oral prescribing of amiodarone.
- Initially, 200mg THREE times daily for ONE week, then reduced to 200mg TWICE daily for ONE week, and then reduced to 200mg daily (or the minimum dose to control arrhythmia – the scored 100mg tablet can be used to achieve minimum effective dose if necessary). Rarely does a patient need more than 200mg daily.

2.5 Contraindications and Precautions

2.5.1 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.

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

2.5.3 Known hypersensitivity to iodine or to amiodarone (one 100mg tablet contains approximately 37.5mg iodine), or to any of the excipients listed in latest SPC.

2.5.4 The combination of amiodarone with drugs which may induce Torsades de Pointes is contra- indicated (see latest SPC).

2.5.5 Pregnancy - except in exceptional circumstances (see latest SPC)

2.5.6 Lactation (see latest SPC).

2.6 Monitoring

2.6.1. Tests prior to starting treatment

Treatment should be initiated, and the loading dose prescribed by a hospital or consultant cardiologist.

If the following tests are recent and available, the consultant will review and prescribe accordingly. If they are not available, then the consultant should request tests via ICE and review prior to initiating therapy:

TFTs (FT4, FT3 and TSH).

A UK guideline on TFTs also recommends measuring thyroid peroxidase antibodies (TPOAb) to assess risk for thyroid dysfunction.

LFTs (particularly transaminases).

U&Es including magnesium and potassium, and creatinine.

ECG before initiating treatment.

Chest X-ray within the last 12 months.

2.6.2. Monitoring until patient is stabilised

In warfarinised patients, more frequent monitoring of INR both during and after amiodarone treatment is recommended; initially weekly for first 7 weeks. Amiodarone potentiates warfarin and the dose should be reduced by 25% on initiation.

If on concurrent digoxin, assess serum digoxin level if either dose is increased or toxicity is suspected.

2.6.3. Ongoing monitoring

2.6.3.1 TFTs every 6 months and for some months after discontinuation (UK guideline on TFTs suggests up to 12 months after cessation).

Serum TSH should also be measured when thyroid dysfunction is suspected.

2.6.3.2 LFTs every 6 months. Isolated increase in serum transaminases, which is usually moderate (1.5 to 3 times normal range), commonly occurs at the beginning of therapy, it may return to normal with dose reduction or even spontaneously.

2.6.3.3 U&Es including magnesium, potassium, and creatinine, every 6 months.

2.6.3.4 Urgent computerised tomography (CT) scans if suspected pulmonary toxicity.

2.6.3.5 ECG every 12 months.

2.6.3.6 Unless blurred or decreased vision occurs, ophthalmological examination is recommended annually, although these are usually only necessary for patients with visual symptoms.

2.6.4. Action required if abnormal results:

2.6.4.1 If TFTs are borderline repeat test in 6 weeks.

2.6.4.2 Amiodarone may cause isolated biochemical changes (increased free-T4, slight decrease/normal free-T3) in clinically euthyroid patients, but there is no reason in such cases to discontinue amiodarone if there is no clinical or further biological (TSH) evidence of thyroid disease.

2.6.4.3 Amiodarone-associated hyperthyroidism should be diagnosed only if high circulating free T4 is associated with high or high/normal free T3 and undetectable TSH; such a diagnosis should prompt withdrawal of amiodarone and specialist referral. Clinical recovery usually occurs within a few months of drug withdrawal, although severe cases, sometimes resulting in fatalities, have been reported. Clinical recovery precedes normalisation of TFTs.

2.6.4.4 Diagnosis of hypothyroidism following development of symptoms is supported by increase in TSH and an exaggerated TSH response to TRH; also, T3 and T4 levels may be low. Euthyroidism is usually obtained within 3 months following discontinuation of treatment. In life-threatening situations, amiodarone therapy can be continued, in combination with levothyroxine.

2.6.4.5 Treatment should be discontinued if severe liver function abnormalities or clinical signs of liver disease develop.

2.6.4.6 If blurred or decreased vision occurs, complete ophthalmologic examination including fundoscopy should be promptly performed.

2.6.4.7 Appearance of optic neuropathy and/or optic neuritis requires amiodarone withdrawal due to the potential progression to blindness and expert opinion sought.

2.6.4.8 If pulmonary toxicity is suspected, computerised tomography (CT) scans should be undertaken and lung function tested, including where possible, measurement of transfer factor. Specialist referral advised.

2.6.4.9 Pneumonitis should always be suspected if new or progressive shortness of breath or cough develops in a patient taking amiodarone.

2.6.5. Additional notes

2.6.5.1 Most patients on amiodarone develop corneal microdeposits (reversible on withdrawal of treatment) which rarely interfere with vision, but drivers may be dazzled by headlights at night.

2.6.5.2 Fresh neurological symptoms should always raise the issue of peripheral neuropathy.

2.6.5.3 Patients should be advised to shield skin from light during treatment and for several months after discontinuing amiodarone and to use a wide-spectrum sunscreen to protect against both long UV and visible light.

2.6.5.4 Due to the long half-life of amiodarone, clinical problems may occur up to a year after stopping the drug (hyperthyroidism may occur up to several months after discontinuation).

2.6.5.5 Measurement of free T3 is required for interpreting results when free T4 or TSH values are outside reference limits, and it is important that information about drugs taken is available to laboratory so that correct thyroid tests can be selected, and erroneous interpretation avoided.

2.6.5.6 TPOAb are present in serum of patients with wide range of immunologically mediated thyroid disorders and may also be found in a small proportion of apparently healthy individuals; their appearance usually precedes development of thyroid disorders.

2.7 **Side Effects**

- See appendix 7 for an adverse event and recommended primary care actions with amiodarone, as recommended by NHS England.

- Most serious toxicity is seen with long-term use and may therefore present first to GPs.

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- 1% and < 10%) include: bradycardia (seek specialist advice); blue-grey skin discolouration (reversible); thyroid disorders; pulmonary toxicity; extrapyramidal tremor (regression usually occurs after dose reduction or withdrawal), nightmares and sleep disturbances.

- 0.1% and < 1%) include: worsening of arrhythmias and peripheral sensorimotor neuropathy and/or myopathy (usually reversible on withdrawal of the drug). Full details of adverse effects can be found in the SPC.

- If you suspect an adverse reaction has occurred, please contact the specialist department.

2.7.1. **The patient should be advised to report any of the following signs or symptoms without delay:**

- Increased breathlessness.
- Dyspnoea or non-productive cough.
- Altered vision.
- Loss of appetite/weight loss.
- Sleep disturbance/nightmares.
- Tremor/loss of co-ordination.

2.7.2. Amiodarone can cause photosensitivity which may persist for months after treatment is stopped, so patients should be cautioned to avoid exposure of skin to direct sunlight or sun lamps. A wide spectrum sunscreen should be used.

2.8 Significant Drug Interactions

2.8.1. Amiodarone is metabolised by the cytochrome P450 system and therefore has the potential to cause many drug interactions. The SPC or BNF should be consulted before initiating any new drug therapy.

2.8.2. Amiodarone has an 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 slow after initiating amiodarone.

2.8.3. The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

P-glycoprotein (PgP) substrates (e.g., digoxin, dabigatran).
CYP2C9 substrates (e.g., warfarin, phenytoin).
CYP3A4 substrates (e.g., ciclosporin, statins, fentanyl, sildenafil, colchicine).
CYP2D6 substrates (e.g., flecainide).

2.8.4. **Amiodarone, being highly protein bound, raises the plasma concentrations of other highly protein bound drugs:**

Anticoagulants: Amiodarone can increase anticoagulant effect. Consider warfarin dose reduction. Patients should be monitored closely, and the dose of anticoagulant altered accordingly, remembering that amiodarone levels take several weeks to stabilise.

Antiepileptics: Amiodarone can increase plasma concentration of phenytoin; phenytoin dose should be reduced. Note that small changes in phenytoin dose can result in large changes in phenytoin levels. Monitor patient closely and counsel on signs of toxicity.

Digoxin: Amiodarone can increase plasma digoxin level and can precipitate symptoms and signs associated with high digoxin levels. Clinical, ECG and biological monitoring is recommended, digoxin dose should be halved when amiodarone is started.

2.8.5. **Amiodarone interacts with other medicines that:**

Induce Torsade de Points or prolong QT (e.g. other anti-arrhythmics, antipsychotics, antidepressants, clarithromycin, erythromycin).

Lower heart rate (e.g. beta-blockers, calcium channel blockers).

Induce hypokalaemia (e.g. diuretics, stimulant laxatives).

Induce hypomagnesaemia (e.g. diuretics, systemic corticosteroids).

Other interactions include:

CYP3A4 and CYP2C8 inhibitors: may increase exposure to amiodarone (e.g. cimetidine, letermovir, ritonavir, darunavir, grapefruit juice).

Sofosbuvir with daclatasvir; sofosbuvir and ledipasvir; simeprevir with sofosbuvir: risk of severe bradycardia and heart block (mechanism unknown) see MHRA advice.

2.9 Discontinuation

2.9.1. Amiodarone can be stopped abruptly, however due to the extended half-life it can linger long after the drug is stopped. Plasma concentration falls by 50% in the first two weeks, but it may then take a further six months before it is eliminated completely.

2.9.2. Ventricular rate control and AF: if resting heart rate is < 75 bpm review in two weeks to consider increasing dose of other rate slowing drugs (NB the plasma level of digoxin will decrease upon withdrawal of amiodarone). If resting heart rate is > 75 bpm add in or increase beta blocker (e.g., start atenolol 25 mg or increase dose by same amount up to 100 mg), digoxin or a rate-limiting calcium channel blocker. A further review of heart rate at three months after stopping amiodarone is sensible.

2.9.3. Due to the long half-life of amiodarone, clinical problems (e.g., hyperthyroidism, photosensitivity) may occur/ persist for up to a year after stopping the drug. TFT should be monitored for up to twelve months after discontinuation.

2.9.4. 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.

2.10 Areas of Responsibility for the Sharing of Care

These are suggested ways in which the responsibilities for the management of adult patients with who are prescribed amiodarone can be shared between the specialist and the general practitioners. The expectation is that these guidelines should provide sufficient information to enable GPs to be confident to take clinical and legal responsibility for prescribing these drugs. If a specialist asks the GP to prescribe this drug the GP should reply to this request as soon as practical. Sharing of care assumes communication between the specialist, GP, and patient. The intention to share care should be explained to the patient and be accepted by them.

In the NHSE guidelines on responsibility for prescribing (January 2018) between hospitals and GPs, it is advised that legal responsibility for prescribing lies with the doctor who signs the prescription.

2.10.1. Specialist:

- It is the responsibility of the initiating specialist to ensure that a clear care plan, including indication, dose and duration of amiodarone therapy and hospital follow up, is sent to the patient's GP before expecting the GP to assume ongoing prescribing responsibility.
- It is the responsibility of the specialist to provide advice on the need for contraception to male and female patients on initiation and at each review, but the ongoing responsibility for providing this advice rests with both the primary care prescriber and the specialist.
- Reassume prescribing responsibilities if a patient becomes or wishes to become pregnant.
- If the initiating specialist is not a cardiologist, and there is not an end date for prescribing amiodarone, then the patient should be referred to a cardiologist for a long-term care plan.
- Where baseline TFTs, LFTs, U&Es, ECG, serum potassium, magnesium and Chest X-ray are available, review these prior to initiating the loading dose of amiodarone.
- Initiate and optimise treatment. Prescribe the maintenance treatment for at least 4 weeks and until optimized.
- Arrange shared care with the patient's GP for ongoing prescribing using the suggested wording template (Appendix 3). Provide patient/carer with relevant (preferably written) information on use, side-effects, and need for monitoring of medication.

- Monitor disease response to treatment and need to continue therapy.
- Consultant to continue to review patient when indicated, sending a written summary to the GP whenever the patient is reviewed.
- Ensure ECG and pulmonary function tests (PFTs) are performed at agreed intervals specified in patient's long-term care plan.
- Provide any other advice or information for the GP including dose adjustments, and advice on when to stop amiodarone.

2.10.2. General Practitioner:

- To respond to the shared care request from the consultant in writing without undue delay.
- Continue prescribing of amiodarone according to dose advised by specialist.
- Arrange and record ongoing monitoring as agreed with consultant cardiologist.
- Order and review initiating tests as stipulated in section 2.4 if not already reviewed by initiating cardiologist.
- **LFTs**: every six months: isolated increase in serum transaminases, which is usually moderate (1.5 to 3 times normal range), commonly occurs at the beginning of therapy, it may return to normal with dose reduction or even spontaneously.
- **U&Es:** every six months.
- **TFTs:** every six months (and for several months following discontinuation). Amiodarone may induce hypothyroidism or hyperthyroidism, particularly in patients with a personal history of thyroid disorders. If TFTs are borderline, repeat test in six weeks.
- **ECG:** should be performed regularly as agreed in patient's long-term care plan with specialist. ECG performed at baseline by specialist, and then annually thereafter in primary care. If patient develops severe bradycardia (heart rate <50) and or heart block on ECG contact the cardiologist and consider stopping amiodarone.
- **PFTs** performed if there is suspected toxicity.
- **Eye examination:** unless blurred or decreased vision occurs, ophthalmological examination is recommended annually. If blurred or decreased vision occurs, complete ophthalmologic examination including fundoscopy should be promptly performed. Appearance of optic neuropathy and/or optic neuritis requires amiodarone withdrawal due to the potential progression to blindness.

- **Onset of dyspnoea or non-productive cough** may be related to pulmonary toxicity, contact the specialist who reviews the patient in secondary care for advice.

- **Bullous skin reactions**: life threatening or even fatal cutaneous reactions Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis. Stop amiodarone. Urgent referral to dermatology, inform initiating specialist.

- Ensure that monitoring and dosage record is kept up to date.

- Report the adverse drug reactions to specialist and usual bodies (e.g., MHRA).

- Ensure no drug interactions with other medicines.

- Symptoms or results are actioned appropriately, recorded, and communicated to secondary care when necessary. See appendix 7 for list.

- Refer the management back to the specialist if the patient becomes or plans to become pregnant.

2.10.3. Patient / parent / guardian / carer:

- Ensure that they have a clear understanding of their treatment and relevant potential side effects.

- Report any adverse effects to their GP and/or specialist.

- The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:

  Breathlessness, non-productive cough, or deterioration in general health (e.g., fatigue, weight loss, fever)

  New or worsening visual disturbances.

  Progressive skin rash +/- blisters or mucosal lesions.

  Signs and symptoms of bradycardia or heart block, e.g., dizziness, fatigue, fainting, shortness of breath, chest pain or palpitations, confusion or trouble concentrating.

- The patient should be advised:

  To use appropriate self-care against the possibility of phototoxic reactions: e.g., sun avoidance, protective clothing, avoiding tanning (including tanning beds) and to purchase and use a broad spectrum sunscreen (at least SPF30). These measures to be continued for the duration of therapy and for several months after discontinuation.

If taking a statin and amiodarone, to report any signs of unexplained muscle pain, tenderness, weakness or dark coloured urine.

Avoid grapefruit and grapefruit juice while taking amiodarone and for several months after discontinuation.

Although there have been no case reports on enhanced hepatoxicity with alcohol, patients should be advised to moderate their alcohol intake to no more than 14 units per week while taking amiodarone.

Ensure they attend for monitoring requirements as per shared care guideline.

Awareness that treatment may be stopped under certain conditions.

The British Heart Foundation has a website section on anti-arrhythmics: https://www.bhf.org.uk/informationsupport/heart-matters-magazine/medical/drug-cabinet/anti-arrhythmics

3. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Compliance with prescribing and administration in accordance with this guideline (or other safe practice)
Lead	Head of Prescribing Support Unit
Tool	Audit and review tool using patient documentation.
Frequency	As required according to clinical incident reports
Reporting arrangements	Via Cornwall Area Prescribing Committee / Medication Practice Committee
Acting on recommendations and Lead(s)	Relevant Clinical Staff
Change in practice and lessons to be shared	Lessons and changes in practice will be communicated through various channels to relevant staff

4. Equality and Diversity

4.1 This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the Equality Diversity And Inclusion Policy or the Equality and Diversity website.

4.2 Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Amiodarone (Adults) Shared Care Guideline V2.0
This document replaces (exact title of previous version):	Amiodarone (Adults) Shared Care Guideline V1.2
Date Issued/Approved:	May 2024
Date Valid From:	June 2024
Date Valid To:	June 2027
Directorate / Department responsible (author/owner):	Andrew Allen, Cardiology and Anticoagulation Pharmacist.
Contact details:	01872 252598
Brief summary of contents:	Some clinical issues and details of prescribing responsibilities for GP and specialists.
Suggested Keywords:	Amiodarone
Target Audience:	**RCHT:** Yes **CFT:** No **ICB:** Yes
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Cornwall Area Prescribing Committee. Cardiology Governance Group Meeting.
General Manager confirming approval processes:	Richard Andrzejuk
Name of Governance Lead confirming approval by specialty and care group management meetings:	Kevin Wright
Links to key external standards:	None
Related Documents:	Codarone X 200mg Tablets (Amiodarone) SPC. Available from https://www.medicines.org.uk/emc/product/2823/smpc (Accessed 04/09/19)

Information Category	Detailed Information
	BNF Arrhythmia Treatment Summary. Available from https://bnf.nice.org.uk/treatment-summary/arrhythmias.html (Accessed 04/09/19) NICE 2021. CG196 Atrial Fibrillation: management. Available from: https://www.nice.org.uk/guidance/ng196 NHS England National shared care protocol: Amiodarone for patients within adult services. July 2022 Specialist Pharmacy Service 2018. Suggestions for Therapeutic Drug Monitoring in Primary Care. Available from: https://www.sps.nhs.uk/articles/suggestions-for-therapeutic-drug-monitoring-in-adults-in-primary-care/ (Accessed 04/09/19)
Training Need Identified?	No
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Pharmacy

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
March 2021	V1.0	Initial Version	Andrew Allen, Cardiology Pharmacist
Sept 2021	V1.1	Replacement of Shared Care Agreement Letter with suggested wording template instead (Appendix 3)	M Wilcock, Head of Prescribing Support Unit
May 2022	V1.2	Change from chest Xray to CT scan if pulmonary toxicity suspected at 2.6.3.5 and 2.6.4.8 and appendix 4	M Wilcock, Head of Prescribing Support Unit
May 2024	V2.0	Various additional text copied from NHS England shared care protocol and some references added and deleted.	M Wilcock, Head of Prescribing Support Unit

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are

to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance, please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity & Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Amiodarone (Adults) Shared Care Clinical Guideline V2.0
Directorate and service area:	Pharmacy
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Andrew Allen, Cardiology and Anticoagulation Pharmacist.
Contact details:	01872 252598

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	To provide information on prescribing of amiodarone to enable General Practitioners to take over prescribing responsibility from secondary care.
2. Policy Objectives	To promote a consistent level of shared care between primary and secondary care (in relation to RCHT catchment area).
3. Policy Intended Outcomes	Confident and competent prescribers, enabling medicines to be access in a primary care setting.
4. How will you measure each outcome?	Six monthly review.
5. Who is intended to benefit from the policy?	General practitioners, hospital specialists and community pharmacists – from understanding local guidance around use of these medicines. Patients/carers, from being able to access medicines from their GP.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: Yes • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Cornwall Area Prescribing Committee. Cardiology Governance Group Meeting.
6c. What was the outcome of the consultation?	Agreed.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:** No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment:
Andrew Allen, Cardiology Pharmacist.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Suggested wording for Specialist communication re commencement of shared care

This patient is suitable for treatment with (insert drug name) for the treatment of (insert indication) which has been accepted for Shared Care. I am therefore requesting your agreement to share the care of this patient, as they are now stable on the treatment. Where baseline investigations are set out in the shared care protocol, I have carried these out.

Treatment was started on (insert date started) (insert dose).

If you are in agreement, please undertake monitoring and treatment from (insert date). (please note: date must be at least 1 month from stabilisation of treatment.)

Baseline tests: (insert information)

Next review with this department: (insert date)

You will be sent a written summary within (XX) days. The medical staff of the department are available at all times to give you advice. The patient will not be discharged from out-patient follow-up while taking (insert drug name).

Please could you reply to this request for shared care and initiation of the suggested medication to either accept or decline within 14 days.

Appendix 4. Summary Table of Amiodarone Monitoring

Description	Baseline	Loading	At 6 months and every 6 months thereafter unless otherwise stated
History and examination (H and E)			Continue annually
H and 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		CT scan if suspected pulmonary toxicity	
PFTs including 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.

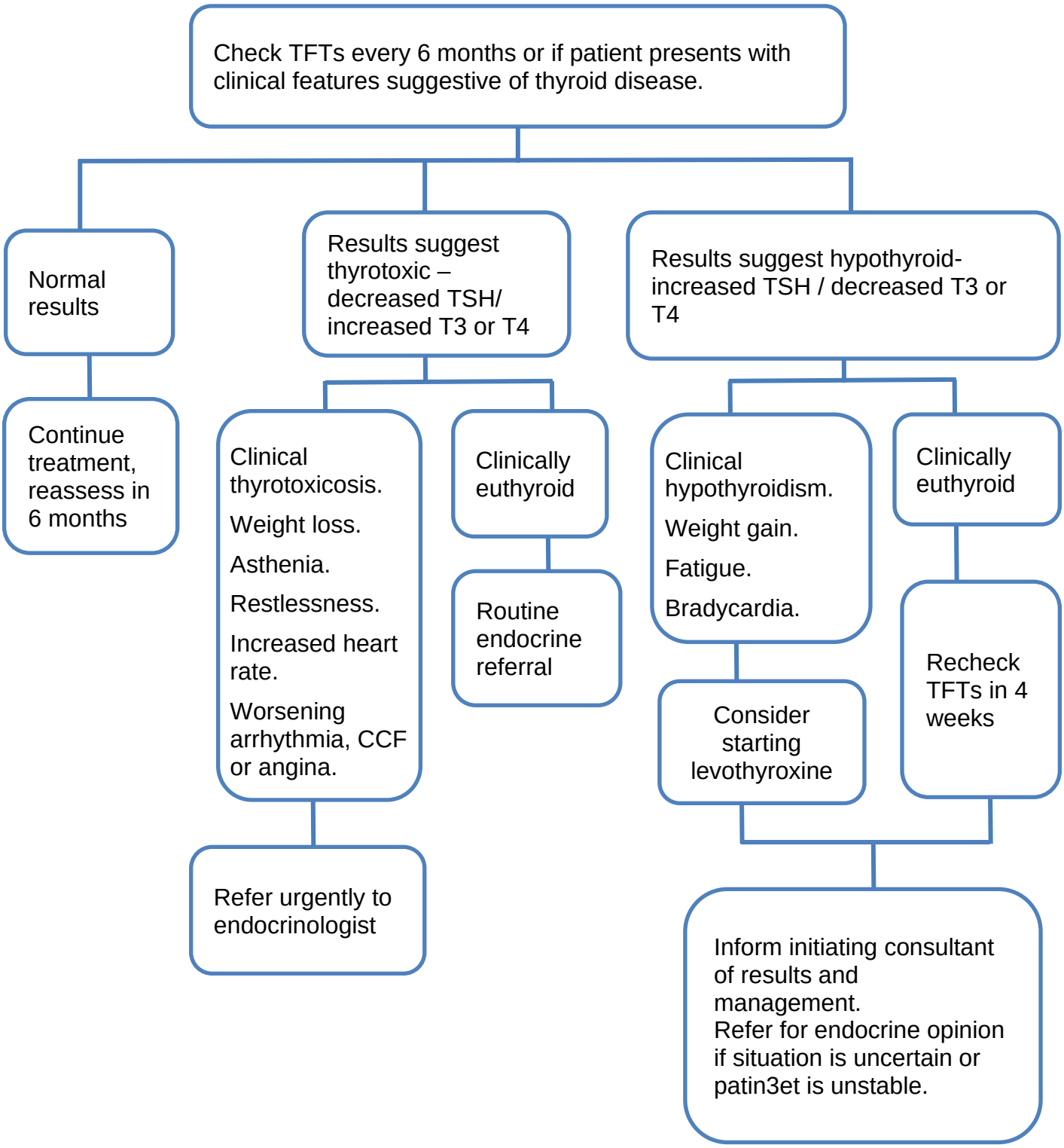
The development of thyrotoxicosis is much less easy to predict than hypothyroidism – it is suggested if the TSH is low, can occur quite rapidly (i.e. between tests) and such patients should be referred to an endocrinologist.

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.

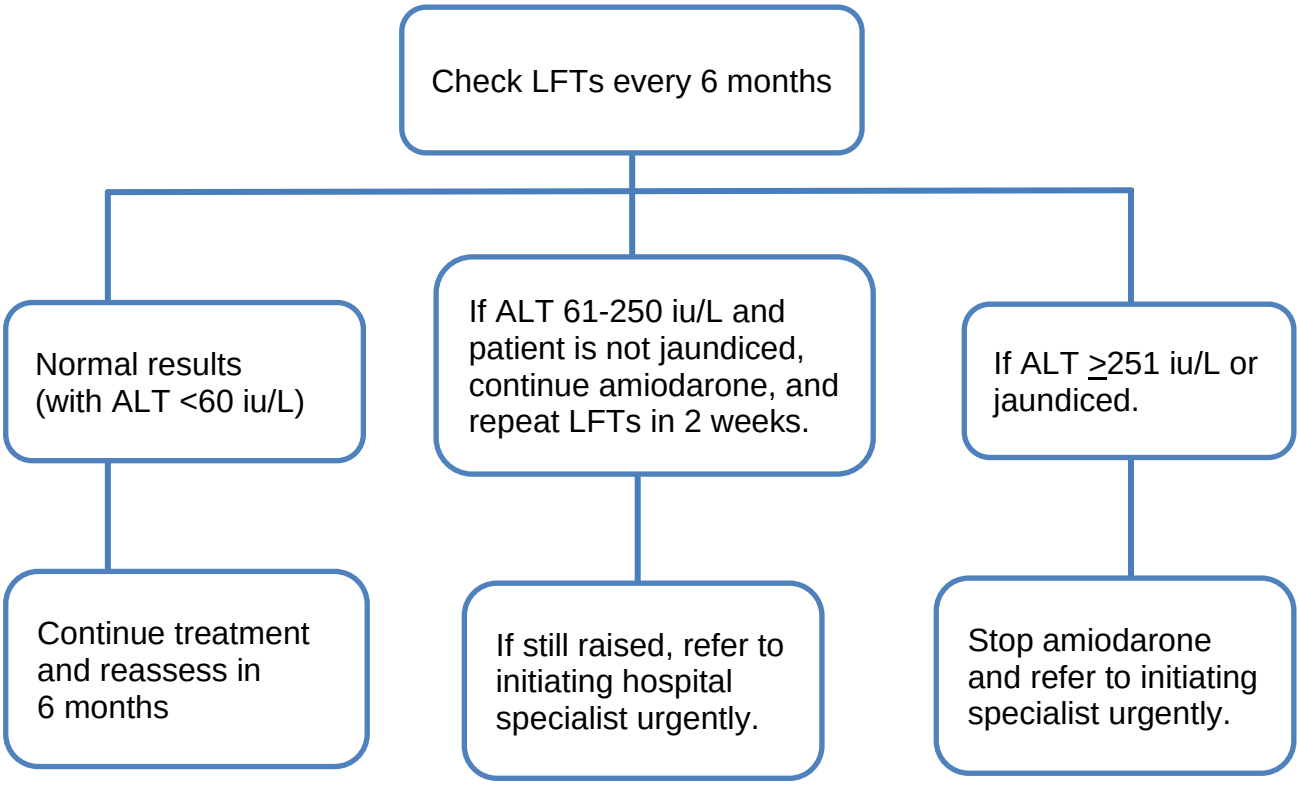
Appendix 5. Thyroid Function Flowchart

Thyroid Function: TFTs every 6 months.



Appendix 6. Liver Function Flowchart

Liver Function Tests



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

Appendix 7. Adverse events and Actions for Primary Care

Adverse effects and other management

Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard

For information on incidence of ADRs see relevant summaries of product characteristics

Result	**Action for primary care**
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance.	
The most serious toxicity with amiodarone is seen with long-term use and patients may therefore present first to primary care. Due to the long half-life of amiodarone, there is potential for adverse effects to occur for several weeks/months after treatment has been discontinued.	
Electrolyte deficiency: hypokalaemia / hypomagnesaemia	Continue amiodarone. Correct deficiency as per local guidelines. Review other medicines that may be contributing to a deficiency
Cardiovascular effects: Bradycardia: • Heart rate 50 - 60bpm without symptoms	Continue amiodarone. Repeat monitoring. No action required unless symptoms develop, or heart rate decreases further.
• with symptoms	Discuss with specialist team; dose reduction may be required
Worsening of arrhythmia, new arrhythmia, or heart block	**Stop amiodarone.** Urgent referral to initiating specialist.
Thyroid dysfunction: Borderline results according to local reference range	Continue amiodarone. Repeat test after 6 weeks.
Hyperthyroidism / thyrotoxicity: high T4, normal/high T3, low TSH	**Stop amiodarone.** Urgent referral to initiating specialist and endocrinologist.
Hypothyroidism: low/normal T4, low/normal T3, high TSH	Continue amiodarone. Inform initiating specialist. Consider starting levothyroxine based on initiating specialist's advice. Monitor levothyroxine according to local pathways.
Subclinical **hypo**thyroidism normal T4, raised TSH; clinical features not overtly manifest	Contact specialist team for advice, which may include input from endocrinology services. Anticipate the need for additional monitoring, investigations and potentially thyroid hormone replacement based on specialist recommendations.
Ophthalmological effects: Optic neuropathy/neuritis;	**Stop amiodarone.** Urgent referral to initiating specialist and ophthalmology.

blurred or decreased vision	
Corneal micro-deposits: blueish halos when looking at bright lights, with no blurred or decreased vision	Continue amiodarone; reversible on discontinuation. The deposits are considered essentially benign and do not require discontinuation of amiodarone.
GI disturbance: nausea, anorexia, vomiting, taste disturbance	Continue amiodarone. May require dose reduction; discuss with specialist if persistent.
Hepatotoxicity: abnormal LFTs +/- symptoms of hepatic injury (e.g. hepatomegaly, weakness, ascites, jaundice)	If serum transaminases elevated >3xULN but no symptoms of hepatic injury continue amiodarone and – repeat LFTs in 2 weeks. If still elevated may require dose reduction; discuss with specialist. If serum transaminases >5xULN or any symptoms of hepatic injury- **stop amiodarone**. Urgent referral to initiating specialist and hepatologist.
Neurological symptoms: Extrapyramidal tremor, ataxia, peripheral neuropathy, myopathy	Continue amiodarone. May require dose reduction; discuss with specialist.
Pulmonary toxicity: including pneumonitis or fibrosis. New/worsening cough, shortness of breath or deterioration in general health (e.g. fatigue, weight loss, fever).	**Stop amiodarone.** Urgent referral to initiating specialist and respiratory specialist. Admission may be required.
Bullous skin reactions: life threatening or even fatal cutaneous reactions Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis	**Stop amiodarone.** Urgent referral to dermatology, inform initiating specialist.
Photosensitivity	Continue amiodarone. Reinforce appropriate self-care e.g. sun avoidance and purchasing of a broad spectrum sunscreen (at least SPF30).
Skin discolouration (blue/grey): occurs in unprotected, light exposed skin	Continue amiodarone. May require dose reduction; discuss with specialist. Reinforce self-care measures (as for photosensitivity above). Pigmentation slowly disappears following treatment discontinuation.

Source: NHSE National Shared Care Protocol: Amiodarone for patients with adult services