Frimley Health NHS Foundation Trust
North East Hampshire and Farnham CCG
East Berkshire CCG
Surrey Heath CCG
Buckinghamshire CCG

SHARED CARE Guideline for new initiation
Amber Traffic Light Classification

Name of medicine	Amiodarone Hydrochloride
Indication (including whether for adults and/or children)	Treatment of arrhythmias, particularly atrial fibrillation and ventricular tachycardia, in Adults
Author: Andrea Lavous, Lead Cardiac Arrythmia Nurse **Organisation:** Frimley Health NHS Foundation Trust	
Date noted at ICS Medicines Board	22 March 2023 (post approval at Drugs and Therapeutics Committee and Medicines Optimisation Board)

The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface.

This **AMBER** shared care sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer's Summary of Product Characteristics. Prescribing must be carried out with reference to those publications whenever appropriate.

The SCG must be used in conjunction with the agreed core roles and responsibilities stated in annex A.

An agreement notification form is included in annex B for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

Roles and Responsibilities

Listed below are specific medicine/indication related responsibilities that are additional to those core roles and responsibilities that apply to all SCGs listed in annex A.

Consultant / Specialist: Amiodarone will only be initiated by Cardiology and Arrhythmia Specialist Nurses

1. Assess the patient. Establish the diagnosis and assess the patient's ability to adhere to treatment.
2. Assess for contraindications and cautions and interactions.
3. Conduct baseline investigations and initial monitoring.
4. Initiate treatment, monitor, and titrate to a maintenance dose.
5. Contact the GP requesting shared care for the patient, including this shared care protocol.

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Valid from: January 2023	Review date:	Approved by:
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6. The Arrhythmia Team will be available for verbal (or written) advice to the GP if the patient's condition changes or deteriorates. Following this advice GP's may refer patients back to the Cardiology Consultant if this is required.
7. The Arrhythmia team will ensure the patient & carer(s) are given information regarding the treatment and a contact for the Arrhythmia team if they have any concern.

Primary Care Prescriber

1. Monitor patient's overall health and wellbeing.

2. Prescribe the drug once the patient has been stabilised and care transferred.

3. Report any adverse events to the hospital specialist, where appropriate.

4. Monitor blood results and action any abnormal results as necessary.

Patient Relatives & Carers

As listed in agreed core roles and responsibilities for the shared care of medicines - annex A

Key information on the medicine

Please refer to the current edition of the British National Formulary (BNF), available at https://bnf.nice.org.uk/ and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background to disease and use of medicine for the given indication

Amiodarone 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.

Amiodarone has an important place in the treatment of severe cardiac rhythm disorders where other treatments either cannot be used or have failed. It has potential toxic adverse effects, and its use requires regular monitoring.

NICE places greater emphasis on rate control than rhythm control for atrial fibrillation and has clarified the place of amiodarone within the pathway by issuing 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.

Existing patients on amiodarone should continue current arrangements with GP prescribing and monitoring. If there any concerns about these cohort of patients, they should be referred into Cardiology.

This document applies to adults aged 18 and over.

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Under a shared care arrangement, treatment must be recommended by a Consultant Cardiologist or Arrhythmia team. Initiation, dose titration, monitoring and prescribing for the first three months must be by the Consultant Cardiologist or Arrhythmia team. After the dose is stabilised, the patient can be transferred to the GP.

Indication

Licensed indications:

- Tachyarrhythmias associated with Wolff-Parkinson-White Syndrome.
- Atrial flutter fibrillation / atrial 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.

Monitoring

Monitoring requirements including frequency and appropriate dose adjustments	Responsible clinician
Monitoring at baseline and during initiation is the responsibility of the specialist; only once the patient is optimised on the chosen medication with no anticipated further changes expected in immediate future will prescribing and monitoring be transferred to the GP.	*Consultant Cardiologist or Arrhythmia team*
Initiation: **Baseline investigations:** • Thyroid function tests (TSH). If abnormal consider full thyroid screen including Free T3 and T4 • Liver function tests (particularly transaminases) • Urea and electrolytes (including potassium) • 12 lead ECG • For patients taking warfarin monitor international normalised ration (INR) at baseline and during dose stabilisation period • For patients taking digoxin clinical monitoring is recommended and the digoxin dose should be halved. Digoxin levels should be monitored appropriately. • Chest X-ray within last 12 months	*Consultant Cardiologist or Arrhythmia team*
Maintenance: **Ongoing monitoring:** • ECG (at least annually). If in persistent AF stop amiodarone and refer to Cardiology if appropriate • Chest X-ray and pulmonary function tests if respiratory symptoms or toxicity suspected • Thyroid function tests (TSH) every 6 months during treatment. Thyroid function should be monitored for up to 12 months after discontinuation. • Liver function tests (particularly transaminases) every 6 months during treatment, and for 6 months after discontinuation. • Urea and electrolytes (including potassium) every 6 months during treatment, and for 6 months after discontinuation. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose.	*GP*

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Abnormal results – Actions to be taken

The GP may contact the initial prescribing clinician for advice at any time if there are concerns.

The most commonly reported adverse reactions during treatment with amiodarone are thyroid and liver dysfunction and bradycardia. The most serious toxicity with amiodarone is seen with long-term use and patients may therefore present first to GPs. 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. For other side effects see SPC.

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

Side-effect/ test	Action
Electrolyte deficiency: hypokalaemia/ hypomagnesaemia	• Continue amiodarone. Correct deficiency as per local guidelines. Review other medicines that may be contributing to a deficiency.
Cardiovascular: Bradycardia: • Heart rate ≤ 60bpm	• Continue amiodarone. Repeat monitoring.
• Heart rate ≤ 50bpm or ≤ 60bpm 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	• 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.
Ophthalmological effects: Optic neuropathy/neuritis; blurred or decreased vision	• **Stop amiodarone.** Urgent referral to initiating specialist and ophthalmology.

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Corneal micro-deposits: blueish halos when looking at bright lights	• Continue amiodarone; reversible on discontinuation.
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 (SJS), Toxic Epidermal Necrolysis (TEN)	• **Stop amiodarone.** Urgent referral to secondary care, inform initiating specialist.
Photosensitivity	• Continue amiodarone. Reinforce appropriate self-care, e.g., sun avoidance and purchasing of a wide 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.

Cautions, contraindications: Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk .

Adverse effects and action to be taken (if appropriate) - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

Drug interactions - Refer to current Summary of Product Characteristics (SPC): www.medicines.org.uk

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Advice to patients and carers

The specialist will counsel the patient about the benefits and risks of treatment and will provide the patient with any relevant information and advice, including patient information leaflets on individual medicines

The patient should be advised to report any of the following signs or symptoms to their GP 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**

Attend regularly for monitoring and any review appointments. Be aware that medicines may be stopped if you do not attend.

Report the use of any over the counter medications and be aware you must discuss the use of amiodarone with your pharmacist before purchasing any over the counter medicines.

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

Pregnancy, paternal exposure and breast feeding

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 GP and the specialist.

Pregnancy

Due to the risk of neonatal goitre, amiodarone should only be prescribed in pregnancy if there is no alternative. Under these circumstances prescribing will be the responsibility of the initiating specialist.

Breastfeeding

Amiodarone is excreted into the breast milk in significant quantities; breast feeding is considered contraindicated due to the potential risk of iodine-associated adverse effects in the infant.

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Support and Advice Contact Details for Primary Care Prescribers:

Name	Speciality	Telephone No.	Email address
Dr Mark Norman	Cardiology Frimley Park	Via switchboard	
Dr Peter Clarkson	Cardiology Frimley Park	Via switchboard	
Dr Andrew Cox	Cardiology Wexham Park	Via switchboard	
Dr Paresh Mehta	Cardiology Wexham Park	Via switchboard	
Farkhanda Majidy	Cardiology Pharmacist	Via switchboard	Farkhanda.majidy@nhs.net
Preya Fakira	Cardiology Pharmacist (Wexham Park hospital)	Via switchboard	Preya.fakira@nhs.net
Andrea Lavous	Lead Arrhythmia Nurse Frimley Park	0300 613 2641	Andrea.lavous@nhs.net
Louise Foster	Lead Arrhythmia Nurse Wexham Park	0791 763 6865	Louise.foster2@nhs.net
Medicines Information	Pharmacy	0300 613 4744	fhft.medicines.information@nhs.net

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Annex A: Agreed core roles and responsibilities for the shared care of medicines

Patients

- To be informed by initiating specialist, that the drug is a shared care drug and what this means.

Relatives and Carers

- To support the patient.

Consultant/ Specialist

Good Prescribing Guidelines

- Be aware that if you recommend that a colleague, for example a junior doctor or Primary Care Prescriber, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required (Ref GMC).
- Be aware that if you delegate assessment of a patients' suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required.
- Be aware that you are asking the Primary Care Prescriber to take full medico-legal responsibility for the prescription they sign(Ref GMC). For this reason the shared care guidelines (SCGs) are agreed at the Frimley Health NHS Foundation Trust Area Prescribing Committee with input from specialists and Primary Care Prescribers, and, for individual patients, the patient's Primary Care Prescriber must agree to take over responsibility before transfer of care, before the patient is discharged from specialist care.
- Be aware of the formulary status and the traffic light classification of the medicine you are prescribing within the Frimley Health Formulary.
- Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with a member of the Pharmacy team who will facilitate an update via the Frimley Health NHS Foundation Trust Area Prescribing Committee.
- Counsel patient on possible benefits, risks and side effects of the drug.

Before initiating treatment

- Evaluate the suitability of the patient for treatment, including consideration of the patient's current medication and any significant interactions.

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- Discuss and provide the patient with information about the reason for choosing the medicine, the likelihood of both harm and benefits, consequences of treatment, and check that their treatment choice is consistent with their values and preferences
- Advise patient of unlicensed status of treatment (including off-label use) if appropriate and what this may mean for their treatment.
- Explain shared care status of drug and what this means to the patient.
- Undertake baseline monitoring and assessment.

Initiating and continuing treatment in secondary care

- Prescribe initial treatment and provide any associated training and counselling required.
- Inform the Primary Care Prescriber when initiating treatment so that the Primary Care Prescriber is aware what is being prescribed and can add to Primary Care Prescriber clinical record
- Continue to prescribe and supply treatment with appropriate monitoring until the patient's condition is stable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects.
- At any stage of treatment, advising Primary Care Prescriber of concerns regarding monitoring or potential adverse effects of treatment

Transfer of care to Primary Care prescriber

- Liaise with the primary care prescriber to agree to share the patient's care and provide relevant accurate, timely information and advice.
- Only advise the patient that shared care will take place, and prescribing will be transferred once the primary care prescriber has agreed to share responsibility of the patient care.
- If the primary care prescriber feels unable to accept clinical responsibility for prescribing, then the consultant must continue to prescribe the treatment to ensure consistency and continuity of care.
- Ensure that the patient (and carer/relatives) are aware of their roles and responsibilities under the SCG
- Provide sufficient information and training for the patient to participate in the SCG

Primary Care Prescriber

- Be aware of the formulary and traffic light status of the medicine you have been asked to prescribe.
- Be aware that Amber medicines have been assessed by the Frimley Heath Area Prescribing Committee as requiring careful transition between care settings but SCGs will be available to support safe transfer of care.
- It would be usual for Primary Care Prescribers to take on prescribing under a formal SCG. If you are uncertain about your competence to take responsibility for the patient's continuing care, you should seek further information or advice from the clinician with whom the patient's care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient and make appropriate arrangements for their continuing care.
- Be aware that if you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence (Ref GMC).
- Be aware that if you prescribe, you will be responsible for any prescription you sign (Ref GMC).

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- Keep yourself informed about all the medicines that are prescribed for the patient
- Be able to recognise serious and/ or frequently occurring adverse side effects, and what action should be taken if they occur.
- Make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
- Keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition.
- Respond to requests to share care of patients in a timely manner, in writing (including use of form in annex B)
- Liaise with the consultant to agree to share the patient's care in line with the SCG in a timely manner.
- Continue prescribing medicine at the dose recommended and undertake monitoring requirements
- Undertake all relevant monitoring as outlined in the monitoring requirements section below, and take appropriate action as set out in this shared care guideline
- Monitor for adverse effects throughout treatment and check for drug interactions on initiating new treatments
- Inform the Consultant or specialist of any issues that may arise
- Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the share care guideline (e.g., ensuring the patient record is correct in the event of a patient moving practice).

All

- Where it has been identified that a SCG requires update e.g. new information needed, liaise with the SCG author and/or your organisation's Frimley Health NHS Foundation Trust Area Prescribing Committee representative who will facilitate an update at the Committee.

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Appendix 1

SHARED CARE PRESCRIBING GUIDELINE

Shared care agreement notification form for medicines and indications approved as amber on the Frimley Health NHS Foundation Trust Formulary

Agreement for transfer of prescribing to GP

Patient details

Name……..

Address……..

……..

……..

DOB…….

Hospital No…….

NHS No……

Name of medicine	Amiodarone Hydrochloride
Discharge Dose	
Indication	Treatment of arrhythmias, particularly atrial fibrillation and ventricular tachycardia

Hospital/ Patient information		**Practice information**	
Specialist Making Request		GP Name:	
Consultant		Practice:	
Speciality		I agree to undertake shared care:	
Drug name		I do not agree to undertake shared care:	
Dose		If NOT please give reasons:	
Next Prescription Due		Signed:	
Next Thyroid test		Date:	
Next LFTs			
Next ECG			
Duration of treatment			
Please refer to the Frimley Health NHS Foundation Trust Formulary for relevant shared care documents.			

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