Powys Shared Care Protocol

AMIODARONE

for severe cardiac rhythm disorders

	✶PLEASE CHECK THE POWYS FORMULARY WEB PAGE FOR THE LATEST VERSION OF THIS PROTOCOL✶
General guidance	This protocol has been agreed by the Powys Primary Care Drugs and Therapeutics Committee and sets out details for the shared care arrangements of patients initiated on **amiodarone**. It should be read in conjunction with the general guidance for shared care. It is the responsibility of all healthcare professionals to ensure adequate patient education and the provision of suitable patient information. This document should be read in conjunction with the: 1. Shared Care Agreement Form (attached below). 2. Summary of Product Characteristics (SPC or Data Sheet) for amiodarone (Cordarone X®) – available at: www.medicines.org.uk/emc/
1. Licensed indications	Amiodarone is licensed for the treatment of severe cardiac rhythm disorders where other treatments either cannot be used or have failed.
2. Therapeutic use & Background	**The *All Wales Medicines Strategy Group* recommends that shared care arrangements are suitable for patients newly initiated on amiodarone. This protocol has been endorsed by the *Wales Council of the British Geriatric Society*. The consultation process has included Local Medical Committees and Welsh Drugs & Therapeutics Committees.** **This shared care agreement is endorsed in the following circumstances:** • Patients receiving amiodarone for life-threatening arrhythmias will normally be reviewed (annually) by cardiologists. • For remaining indications where lifelong treatment is appropriate, stable patients with no requirement for regular hospital surveillance and/or those where hospital review is practically difficult, consultants may in individual cases, after agreement with the relevant general practitioner, decide to discharge a patient to primary care monitoring. • Urgent access to advice and/or review from the initiating department will be available whether the patient is under follow-up or not. This protocol does not cover the use of oral amiodarone in short term treatment prior to cardioversion. Amiodarone is commonly used to maintain sinus rhythm in patients with atrial fibrillation or who have converted from, or relapsed into atrial fibrillation following cardioversion. It is also used before heart surgery to help prevent atrial fibrillation. Amiodarone has been used for prevention of ventricular arrhythmias.
3. Contra-indications	Hypersensitivity to iodine or amiodarone or any excipients, evidence or history of hyperthyroidism, uncorrected hypothyroidism, sinus bradycardia and sino-atrial heart block, combined use with drugs that may induce torsades de pointes (see section 5. Drug Interactions below), pregnancy (except in exceptional circumstances) & breast feeding. In patients with severe conduction disturbances or sinus node disease, amiodarone should be used only in conjunction with a pacemaker.
4. Typical dosage regimen (adults)	**A loading regimen is necessary and will be prescribed by secondary care** **Loading**: 200mg three times daily for one week, then 200mg twice daily for one week, then a further reduction to 200mg daily.

	Maintenance dose is usually 200mg daily; however 100mg daily may be sufficient in elderly patients. The minimum dose to control arrhythmia is used. In rare cases a maintenance dose of above 200mg daily may be required. **All dose adjustments will be done by secondary care unless directions have been specified in the medical letter to the GP.**
5. Drug interactions For a comprehensive list consult the *BNF* (Appendix 1) or Summary of Product Characteristics	Amiodarone is metabolised by the cytochrome P450 system and therefore has the potential to cause many drug interactions. The Summary of Product Characteristics or *BNF* (Appendix 1) should be consulted before initiating any new drug therapy. Amiodarone has an average plasma half life of 50 days (range 20 to 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.** **Statins**: Increased risk of myopathy. **Simvastatin- restrict dose to 20mg daily**. Other statins: counsel patients to report any muscle pain or weakness immediately. **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. **Beta blockers**: increased risk of bradycardia, AV block and myocardial depression. Sotalol-avoid concomitant use. **Calcium channel blockers** (diltiazem and verapamil): increased risk of bradycardia, AV block and myocardial depression. **Ciclosporin** Amiodarone increases levels of ciclosporin. Reduced dose of ciclosporin is recommended. **Digoxin** dose should be halved when amiodarone is started. **Diuretics**: increased risk of cardiotoxicity if hypokalaemia occurs. **Drugs that prolong the QT interval**: Concurrent therapy is contra-indicated due to the increased risk of torsades de pointes, • **Antiarrhythmics**: e.g. quinidine, procainamide, disopyramide, sotalol. • **Antipsychotics**: e.g. phenothiazines, haloperidol, amisulpiride. • **Antihistamines**: e.g. mizolastine and terfenadine. • **Antimalarials**: e.g. chloroquine, hydroxychloroquine, mefloquine, quinine • **Lithium and tricyclic antidepressants**. **Others**: co-trimoxazole, IV erythromycin, moxifloxacin, pentamidine, some antivirals.
6. Adverse drug reactions For a comprehensive list (including rare and very rare adverse effects), or if significance of possible adverse event uncertain, consult Summary of Product Characteristics or *BNF*	**Most serious toxicity is seen with long-term use and may therefore present first to GPs.** Adverse reaction frequency are classified using the following convention: Very common (≥ 10%), common (≥ 1% and < 10%); uncommon (≥ 0.1% and < 1%).

Clinical condition	***Management***
Lung Onset of **DYSPNOEA** or non-productive **COUGH** may be related to pulmonary toxicity- pneumonitis, diffuse alveolitis and pulmonary fibrosis (common). Sometimes fatal.	Diagnosis based on clinical and radiological findings and exclusion of other causes. Damage is usually reversible if amiodarone is withdrawn early. Consider CXR. **Seek specialist advice.**
Heart Dose dependent sinus **BRADYCARDIA** (common). Worsening of arrhythmia (uncommon). May present as **BLACKOUTS.**	**Seek specialist advice.**
Thyroid disorders (common): Hyperthyroidism: **WEIGHT LOSS,** asthenia, restlessness, increase in heart rate, onset of arrhythmia, angina, congestive heart failure. Sometimes fatal. Hypothyroidism (common).	Perform thyroid function tests. Action: See section 8 Monitoring.

Adverse drug reactions cont'd.

Clinical condition	*Management*
Eyes: Corneal microdeposits – coloured halos in dazzling light or blurred vision (very common).	Corneal microdeposits are reversible and amiodarone can be continued.
Optic neuropathy/neuritis that may progress to blindness (very rare): **BLURRED OR REDUCED VISION.**	Prompt opthalmological examination including fundoscopy. Appearance of optic neuropathy and/or optic neuritis requires amiodarone withdrawal due to the potential progression to blindness.
Liver: Increase in serum transaminases (Very common) usually 1.5 to 3 times normal range.	It may return to normal with dose reduction or even spontaneously.
Acute liver disorders (common) with high serum transaminases and/or jaundice, including hepatic failure. Sometimes fatal.	**Seek specialist advice.**
Nervous system extrapyramidal tremor, nightmares, sleep disorders (common).	Tremor: regression usually occurs after reduction of dose or withdrawal.
Peripheral sensorimotor neuropathy and/or myopathy (uncommon).	Both these conditions may be severe, although recovery usually occurs within several months after amiodarone withdrawal, but may sometimes be incomplete.
Gastrointestinal: taste disturbance, nausea, vomiting (Very common).	Usually occurring with loading dosage and resolve with dose reduction.
Skin: Blue-grey skin discolouration (common).	Reversible.
Photosensitivity (very common): May persist for months after treatment is stopped.	Patients should be cautioned to avoid exposure of skin to direct sunlight or sun lamps. A wide spectrum sunscreen should be used.

IF YOU SUSPECT AN ADVERSE REACTION HAS OCCURRED, PLEASE CONTACT THE SPECIALIST DEPARTMENT.
All serious adverse reactions should be reported to the CHM via the "Yellow Card" scheme.
The patient should be advised to report any of the following signs or symptoms without delay:

- Increasing breathlessness, dyspnoea or non-productive cough
- Altered vision
- Loss of appetite/weight loss
- Sleep disturbance /nightmares

Tremor / Loss of coordination

7. Baseline investigations

To be undertaken by secondary care
Chest X-ray (ensure CXR within the last 12 months),
TFT (T_3, T_4 & TSH), LFTs, urea & electrolytes and creatinine, ECG.
Consideration could be given to lung function tests and examination of skin, eyes, and neurological systems.

8. Monitoring

It is essential to have a recall system to identify patients who do not attend, especially following abnormal results

Monitoring	*Frequency*	*Results*	*Action*	*By*
Clinical adverse effects	**Every 6 months***	Assess for adverse effects detailed in **section 6** Assess patient remains in sinus rhythm and heart rate is satisfactory.		**Both, if patient had life-threatening arrhythmia.**
Clinical effectiveness	**Every 6 months ***	***Patient is assessed twice per year: Clinical GP assessment *alternates approximately 6 monthly with* Clinical/ECG specialist centre assessment unless otherwise agreed (see discharge summary).		

Monitoring cont'd

Monitoring	*Frequency*	*Results*	*Action*	*By*
LFT	**Every 6 months**	>1.5 fold rise in AST or ALT, or signs of jaundice.	**Discuss with specialist** who may advise amiodarone withdrawal.	**Primary Care**
TFT: T_3,T_4&TSH (Adapted from Amiodarone and the thyroid, Basaria S, Cooper D, *Am J Med* 2005 Jul;118(7):706-714.)	T_3, T_4 & TSH If normal repeat **every 6 months**	Normal.	It is not unusual for patients on amiodarone to have slight elevations of TSH and T_4.	
	TSH > 4.5	TSH > 4.5, fT_4 elevated and duration less than 3 months.	Observe Repeat in 3 months.	
	Sub clinical hypothyroidism	TSH > 10, fT_4 normal persisting for over 6 months.	Consider treating with levothyroxine or repeat in 3 months.	
	Hypothyroid	TSH > 4.5, fT_4 low.	May be treated with levothyroxine if amiodarone is considered essential.	
	Thyrotoxicosis	TSH < 0.1mU/l T_3 & T_4 normal or minimally increased	Repeat in 2 to 4 weeks.	
		TSH < 0.1mU/l & T_4 elevated, T_3 elevated or 50% greater than baseline.	**Discuss urgently with specialist** who may advise amiodarone withdrawal. Arrange TSH-receptor antibodies and TPO antibodies.	
Electrolyte	**Every 6 months** in patients taking diuretics	Avoid hypokalaemia.	Correct the cause of hypokalaemia.	Primary Care
Eyes	**Annual**	Opthalmological examination recommended in data sheet.	Patient should be encouraged to attend optician annually.	Both
	If blurred or decreased vision	Arrange urgent opthalmological assessment.	**Discuss urgently with specialist.**	Both

9. Pharmaceutical aspects

No special considerations

10. Secondary care contact information

If stopping medication or needing advice please contact:
Dr
……..
Contact number

……
Hospital:

11. Criteria for shared care

Prescribing responsibility will only be transferred when:

- Treatment is for a specified indication and duration.
- Treatment has been initiated and established by the specialist centre.

	➢ The patient's initial reaction to and progress on the drug is satisfactory. ➢ The GP has agreed in writing in each individual case that shared care is appropriate. ➢ The patient's general physical, mental and social circumstances are such that he/she would benefit from shared care arrangements.
12. Responsibilities of initiating consultant	➢ Initiate treatment. ➢ Undertake baseline monitoring. ➢ Dose adjustments. ➢ Monitor patient's initial reaction to and progress on the drug. ➢ Ensure that the patient is taking a maintenance dose and has an adequate supply of medication until GP supply can be arranged. ➢ For patients initiated following life-threatening arrhythmia, continue to monitor and supervise the patient annually according to this protocol, while the patient remains on amiodarone. ➢ For remaining indications where lifelong treatment is appropriate, stable patients with no requirement for regular hospital surveillance and/or those where hospital review is practically difficult, consultants may in individual cases, after agreement with the relevant general practitioner, decide to discharge a patient to primary care monitoring. ➢ Provide GP with: o Diagnosis, relevant clinical information and baseline results, treatment to date and treatment plan, duration of treatment before consultant review. o Provide GP with details of outpatient consultations, ideally within 14 days of seeing the patient *or* inform GP if the patient does not attend appointment. o Advice on when to stop amiodarone. ➢ Provide patient with relevant drug information to enable: o Informed consent to therapy. o Understanding of potential side effects and appropriate action. o Understanding of the role of monitoring.
13. Responsibilities of primary care	➢ To monitor and prescribe in collaboration with the specialist according to this protocol. ➢ To ensure that the monitoring and dosage record is kept up to date. ➢ Symptoms or results are appropriately actioned, recorded and communicated to specialist centre when necessary. ➢ Provision of shared care is in accordance with Local Enhanced Scheme, where available.
14. Responsibilities of patients	➢ To attend hospital and GP clinic appointments, bring monitoring booklet (if issued). ➢ Failure to attend will result in medication being stopped on specialist advice. ➢ To report adverse effects to their specialist or GP. ➢ To attend optician annually and inform optician that they are taking amiodarone.
15. Responsibilities of all prescribers	**Any suspected serious adverse reaction to an established drug should be reported to MHRA via the "yellow card scheme."** **http://yellowcard.mhra.gov.uk/**
16. Supporting documentation	Patient information leaflet for Cordarone X®: **http://emc.medicines.org.uk/emc/assets/c/html/DisplayDoc.asp?DocumentID=10928** Alternative format patient leaflet: **http://xpil.medicines.org.uk/ViewPil.aspx?docid=10928**
17. GP letter	**Attached below**

Powys Amiodarone Shared Care Agreement Form

To be added at end of outpatient letter when a patient is initiated /discharged on amiodarone

Place addressograph here

Baseline assessment		***Notes***
Indication: (*please tick box*)	❑Paroxysmal AF. ❑Persistent AF. ❑Other SVT. ❑Post CABG. ❑Pre/Post Cardioversion. ❑VT or previous VF.	
Start date: *(please specify)*	……	
Maintenance dose: *(please specify if less than 200mg daily)* Note: Initiation doses will be prescribed by hospital	200mg daily	
Duration of therapy: *(please specify if not long term)*	……months***** ❑Long term	*******Short term therapy (3 months or less) does not require specific monitoring*
CXR: (*please tick box*) - within the last 12 months Date if not undertaken during this admission/outpatient visit:	❑Normal ❑Abnormal ……	
T_3, T_4 & TSH: (*please tick box*)	❑Normal ❑Abnormal	
LFTs, urea & electrolytes and creatinine: (*please tick box*)	❑Normal ❑Abnormal	
ECG	❑Normal ❑Abnormal	
Next appointment in: (*please specify*)	……months	

This drug has been accepted for Shared Care by *AWMSG* and the *Powys Medicines Management Group.*

❑ The patient has **further follow-up planned** as above but we would be grateful if you could ensure appropriate monitoring as per protocol.

❑ This patient was not started on amiodarone for a life-threatening arrhythmia.
Routine follow-up is not planned
Life-long treatment is likely to be appropriate, there are no other ongoing medical problems that require input in secondary/tertiary care and/or hospital follow-up is practically difficult for the patient. Please continue to monitor them closely in primary care according to this protocol.

Printed name: …… **Phone numbers *and/or* e-mail:** ……	**Signature:** …… **Date:** ……

GP RESPONSE (Please tick as appropriate)

A. I am willing to undertake:

Shared Care ❑ for this patient

B. I wish to discuss this request with you ❑

C. I am unable to undertake Shared Care for this patient ❑ *please tick reason(s) below*

Practice does not participate in Shared Care ❑ Training issues ❑

Unwilling to take responsibility for prescribing this drug ❑ Time issues ❑

Patient currently not stabilised on drug ❑

Other - please state _____

_____

GP Signature_____ Date _____

Practice Address/Stamp

Please return whole completed form or a photocopy to the consultant requesting shared care prescribing ***within two weeks.***

About your Tablets

Your tablets contain amiodarone hydrochloride. Your doctor will decide which strength of tablet is suitable for you. You may start the medication on a high dose which is then adjusted to suit your condition.

What your tablets are for

Amiodarone is used to control an irregular or fast heartbeat.

How they work

Your tablets correct the electrical impulses of the heart when their 'timing' goes out of control.

It is very important that health professionals know that you are taking amiodarone. Please take an up-to-date list of your medicines whenever you attend hospital, the dentist, the optician or other clinics either routinely or in an emergency.

Medicines which interfere or cause problems with your tablets

Amiodarone can affect the way certain medicines work and can also be affected by some medicines that you can buy and foods.

These can include herbal and Chinese remedies, so make sure that your doctor knows that you take them.

Other advice:-

- Try to use the same Community Pharmacy on a regular basis.
- Do NOT buy medicines over the Internet.
- You should not take amiodarone if you are allergic to iodine.
- Do not drink grapefruit juice or eat grapefruit whilst taking amiodarone.

Side-effects and interactions can last for up to six months and possibly longer after stopping amiodarone.

More information about medicines which interact can be found in the Patient Information Leaflet.

Side-effects

Amiodarone can cause a number of unwanted side-effects. These are described in the Patient Information Leaflet with your tablets.

Tell your doctor if you have or develop any of the following:

- Breathlessness or a new or unexplained cough that does not resolve as expected.
- A deterioration in your eyesight.
- A rash or skin changes.
- Sunburn on exposure to sun. To prevent this cover your skin, use sunblock and wear a hat. This may occur after you have been taking the tablets for a while.
- A tremor, headaches, difficulty sleeping, unsteadiness.
- Numbness, pins & needles.
- Symptoms of an underactive thyroid (tiredness, weight gain, constipation, feeling cold, dry skin, depression).
- Symptoms of an overactive thyroid (increased appetite, weight loss, excessive sweating, nervousness).

When taking amiodarone you should have a blood test at least every 6 months to check your thyroid gland and liver function. You should also have an annual eye test and a chest X-Ray before starting treatment.

Whenever you have a blood test, eye test or chest X-ray please ask your doctor or optician to fill in the monitoring record below. **If you haven't had these tests please ask your GP/clinic to arrange them for you.**

Date	Thyroid Test	Liver Test	Eye Test	Chest X-Ray
Example 26.06.09	✓	✓		

GIG CYMRU NHS WALES
Bwrdd Iechyd Addysgu Powys
Powys Teaching Health Board

For further advice about this medication please ask your Pharmacist, GP or cardiology clinic.

This leaflet is available in large print on request.

With thanks to Betsi Cadwaladr Local Health Board who originally produced this leaflet.

Powys Teaching Health Board Medicines Management Team
Mansion House, Bronllys, Brecon, Powys LD3 0LS
Tel: 01874 712 641

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INFORMATION ABOUT AMIODARONE for patients/carers

Patient Name:

DOB:

GP: