National shared care protocol adapted for local use: Amiodarone for patients within adult services

As well as these protocols, please ensure that <u>summaries of product</u> <u>characteristics</u> (SPCs), <u>British National Formulary</u> (BNF) or the <u>Medicines and</u> <u>Healthcare products Regulatory Agency</u> (MHRA) or <u>NICE</u> websites are reviewed for up-to-date information on any medicine.

Specialist responsibilities

- Assess the patient and provide a diagnosis; ensure that this diagnosis is within the scope of this shared care protocol (<u>section 2</u>) and communicated to primary care.
- Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling (see <u>section 11</u>) to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Assess for contraindications and cautions (see <u>section 4</u>) and interactions (see <u>section 7</u>).
- Conduct required baseline investigations and initial monitoring (see section 8).
- Initiate and optimise treatment as outlined in <u>section 5</u>. Transfer to primary care is normally after the patient has been treated for at least 4 weeks. Once the patient is known to be tolerating the medicine, transfer to shared care would normally take place.
- If shared care is considered appropriate, and once treatment is optimised, write to the
 patient's GP practice and request shared care; detailing the diagnosis, current and ongoing
 dose, baseline and most recent test results, details of other treatments being received, and
 when the next monitoring is required. Include the specialist service contact information
 (section 13). This can be in the form of a clinic letter or using the shared care request letter
 on the Nottinghamshire Joint Formulary.
- Prescribe sufficient medication (quantity to provide at least 4 weeks of supply) to enable transfer to primary care, including where there are unforeseen delays to transfer of care. Further prescriptions will be issued if, for unforeseen reasons, arrangements for shared care are not in place. Patients should not be put in a position where they are unsure where to obtain supplies of their medication. The specialist team will be responsible for monitoring and prescribing the medicine during this initial period.
- Conduct the required reviews and monitoring in <u>section 8</u> and communicate the results in writing to primary care within 14 days, where possible. After each review, provide primary care with a written summary within 14 days, advising whether treatment should be continued, confirming the ongoing dose and whether the ongoing monitoring outlined in <u>section 9</u> remains appropriate.
- Provide the patient with details of their treatment, including any dosage changes made, follow-up appointments, monitoring requirements, and specialist team contact details. Highlight the importance of monitoring to the patient and explain the potential withdrawal of treatment if monitoring appointments are not attended.
- Reassume prescribing responsibilities if a patient becomes or wishes to become pregnant.

- Provide advice to primary care on the management of adverse effects if required and provide training for primary care prescribers if necessary to support the shared care agreement.
- Review patients annually.
- NOTE: amiodarone may be used for post-operative Atrial Fibrillation. These patients are usually able to stop the amiodarone, which will be determined during their follow up review. Secondary care will supply sufficient amiodarone until the review date. Shared care will then be set up if amiodarone needs to continue.

Primary care responsibilities

- If shared care is not accepted, inform the specialist of the decision in writing within 14 days with reasons as to why shared care cannot be entered into. If shared care is accepted, ensure knowledge and understanding of the therapeutic issues relating to the patient's clinical condition. Undergo any additional training necessary to carry out the prescribing and monitoring requirements.
- Agree that, in their opinion, the patient should receive shared care for the diagnosed condition unless good reasons exist for the management to remain within the secondary care.
- If accepted, prescribe ongoing treatment as detailed in the specialist's request and as per <u>section 5</u>, taking into account any potential drug interactions in <u>section 7</u>.
- Adjust the dose of amiodarone prescribed as advised by the specialist and communicate any changes made to the patient.
- Conduct the required monitoring as outlined in <u>section 9</u>. Communicate any abnormal results to the specialist.
- Ensure the patient is given the appropriate follow-up and monitoring appointments. If a patient fails to attend, contact the patient in a timely manner to arrange alternative appointments. It is the GP's responsibility to decide whether to continue treatment in a patient who does not attend follow-up and monitoring appointments. If the patient regularly fails to attend the monitoring appointment, the GP may withhold the prescription and inform the consultant responsible for the patient's care.
- Manage adverse effects as detailed in <u>section 10</u> and discuss with the specialist team when required. Refer the patient back to the specialist team if further investigation is required.
- Stop amiodarone and make an urgent referral to the specialist if hyperthyroidism, thyrotoxicosis, new or worsening arrhythmia or heart block, ophthalmological effects, hepatotoxicity, pulmonary toxicity, or bullous skin reactions are suspected.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.

Patient and/or carer responsibilities

- Take amiodarone as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist and keep contact details up to date with both prescribers. If unable to attend, inform the relevant practitioner as soon as possible and arrange an alternative appointment. Be aware that medicines may be stopped if they do not attend.

- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms, as detailed in <u>section 11</u>.
- Report the use of any over-the-counter medications to their primary care prescriber and be aware they should discuss the use of amiodarone with their pharmacist before purchasing any OTC medicines.
- Avoid grapefruit juice while taking amiodarone and for several months after discontinuation.
- Moderate their alcohol intake to no more than 14 units per week to reduce the risk of hepatotoxicity.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.
- Store the medication securely away from children.
- Read the information supplied by the GP, specialist, and pharmacist, and contact the relevant practitioner if they do not understand any of the information given.

Community pharmacist responsibilities

- Professionally check prescriptions to ensure they are safe for the patient and contact the GP if necessary to clarify their intentions.
- Fulfil the legal prescriptions unless they are considered unsafe.
- Counsel the patient on the proper use of their medication and potential side effects.
- Advise patients suspected of experiencing an adverse reaction with their medicines to contact their GP.

1. Background

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Amiodarone is used in the treatment of arrhythmias, as detailed in <u>section 2</u>. It has an important place in the treatment of severe cardiac rhythm disorders where other treatments either cannot be used or have failed. Amiodarone has potentially serious adverse effects, and its use requires regular monitoring.

Due to the significant safety concerns, NHS England (NHSE) and NHS Clinical Commissioners' (NHSCC) <u>guidance</u> 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 <u>Atrial fibrillation: NG196</u>. 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.

Where there is an existing cohort of patients taking amiodarone who are not currently under shared care, it is recommended that these patients be reviewed to ensure that prescribing remains safe and appropriate, and a shared care arrangement is introduced.

This document applies to adults aged 18 and over.

2. Indications

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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.

3. Locally agreed off-label use

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National scoping did not identify any additional appropriate off-label indications.

4. Contraindications and cautions

This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see BNF & SPC for comprehensive information.

Contraindications:

- Sinus bradycardia and sino-atrial heart block/severe conduction disturbances (high-grade AV block, bifascicular or trifascicular block) or sinus node disease (unless pacemaker fitted)
- History of thyroid dysfunction. Use of amiodarone may be considered in patients who are euthyroid after a case-by-case assessment of the risks and benefits and with appropriate monitoring.
- Known hypersensitivity to iodine or amiodarone, or any of the excipients (including patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption)
- Concurrent use of medicines that may prolong the QT interval or increase the risk of Torsades de Pointes
- Pregnancy except in exceptional circumstances (see section 12)
- Breastfeeding

Cautions:

 Amiodarone can cause serious adverse reactions affecting the eyes, heart, lung, liver, thyroid gland, skin, and peripheral nervous system; it is subject to a number of cautions. Because these reactions may be delayed, patients on long-term treatment should be carefully supervised. As undesirable effects are usually dose-related, the minimum effective maintenance dose should be given.

5. Initiation and ongoing dose regimen

- Transfer to primary care is normally after the patient has completed the loading regimen and been treated for at least 4 weeks. Once the patient is known to be tolerating the medicine, transfer to shared care would normally take place.
- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- All dose or formulation adjustments will be the responsibility of the initiating specialist unless directions have been discussed and agreed with the primary care clinician.
- Termination of treatment will be the responsibility of the specialist.

Initial stabilisation:

200mg three times per day for one week, then reduce to 200mg twice per day for one week.

Amiodarone is initiated with a loading dose in order to achieve adequate tissue levels rapidly. Rarely, the specialist team may use an alternative loading regimen.

The loading period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

200mg per day, or less if appropriate. The minimum dose required to control the arrhythmia should be used.

Rarely, a higher maintenance dose may be required. The maintenance dose should be reviewed regularly, particularly if it exceeds 200mg per day. Treatment is potentially lifelong.

The initial maintenance dose must be prescribed by the initiating specialist.

Both the titration and maintenance doses are prescribed by secondary care in the initial amiodarone prescription.

Conditions requiring dose adjustment:

Although there is no evidence that dose requirements for elderly patients are lower, they may be more susceptible to bradycardia and conduction defects if too high a dose is prescribed. The minimum effective dose should be used. Particular attention should be paid to monitoring thyroid function.

6. Pharmaceutical aspects

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Route of administration:	Oral
Formulation:	Tablets; 100mg and 200mg
Administration details:	For oral administration. Maintenance dose can be given once daily, however doses >200 mg daily (including loading period) may be given as split doses to minimise nausea. If necessary, tablets may be crushed and dispersed in water but have a bitter taste (unlicensed). Different brands may disperse in water at notably different rates. The solution for injection is irritant and should not be given orally.

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Other important information:	The half-life of amiodarone is very long, with an average of 50 days (range 20- 100 days). Side effects slowly disappear as tissue levels fall. Following drug withdrawal, residual tissue-bound amiodarone may protect the patient for up to a month. However, the likelihood of recurrence of arrhythmia during this period should be considered.
	Grapefruit juice should be avoided during treatment with oral amiodarone and for several months after discontinuation (see <u>section 7</u>).

7. Significant medicine interactions

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The following list is not exhaustive. Please see <u>BNF</u> or <u>SPC</u> for comprehensive information and recommended management.

Amiodarone is associated with a large number of interactions, some of which are significant enough to contraindicate concurrent use, require a dose adjustment and/or additional monitoring (see <u>section 4</u>).

Amiodarone is an enzyme inhibitor and can increase exposure to a number of medicines, including:

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

Amiodarone interacts with other medicines that:

- induce Torsade de Points or prolong QT (e.g. other anti-arrhythmics, antipsychotics, antidepressants, lithium, clarithromycin, erythromycin, anti-malarial)
- 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 <u>MHRA advice</u>

Due to the long half-life of amiodarone, there is potential for drug interactions to occur for several weeks/months after treatment has been discontinued. See <u>SPC</u> for information on managing interactions.

8. Baseline investigations, initial monitoring, and ongoing monitoring to be undertaken by specialist <u>Ba</u>

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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 the immediate future will prescribing and monitoring be transferred to primary care.

Baseline investigations:

- Thyroid function tests (free T4, free T3 and TSH)
- Liver function tests (LFTs, particularly transaminases)
- Urea and electrolytes (U&Es, including magnesium and potassium)
- Electrocardiogram (ECG)
- Chest X-ray
- For patients taking warfarin: Monitor international normalised ratio (INR) at baseline and at least weekly during the loading regimen - continue for two months or until stabilised. Amiodarone is expected to increase the anticoagulant effect of warfarin and a dose reduction is usually required (dose reduction should be individualised but a reduction of 25-50% has been suggested). Weekly INR monitoring should be undertaken for several weeks after stopping amiodarone.
- For patients taking digoxin: clinical monitoring is recommended, and the digoxin dose should be halved. Digoxin levels should be monitored appropriately.

Initial monitoring:

None specifically recommended by the manufacturer.

If thyroid function tests are borderline, consider repeating the test every 6 weeks until stable.

See info above for patients taking warfarin – monitor INR weekly for two months.

Ongoing monitoring:

- ECG (at least annually see below regarding primary care availability).
- Chest CT scan and pulmonary function tests if respiratory symptoms or toxicity suspected (patient is to be referred back to the initiating Specialist for any investigations).
- After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined in <u>section 9</u> remains appropriate.

9. Ongoing monitoring requirements to be undertaken by primary care

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See <u>section 10</u> for further guidance on the management of adverse effects/responding to monitoring results. For <u>local supporting document for Primary Care Reviews see here</u>.

Monitoring and advice	Frequency
 Thyroid function tests (TSH, free T4, free T3). Only request TSH, the lab will automatically test T3 and T4 if TSH abnormal. LFTs (particularly transaminases) 	Perform all tests every 6 months during treatment LFTs and U&Es should continue to be monitored for up to 6 months after discontinuation.

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 U&Es (including magnesium and potassium) 	Thyroid function should continue to be monitored for up to 12 months after discontinuation, with frequency determined clinically.
• ECG (may be conducted in primary care where this service is available)	At least annually.
Respiratory symptoms	Monitor regularly for signs and symptoms that may indicate lung toxicity i.e. breathlessness, new/worsening cough, shortness of breath or deterioration in general health (fatigue, weight loss, fever). If suspected and all other possible causes have been ruled out, refer back to the initiating consultant/cardiology for investigations (chest CT, lung function tests).
Optician	Encourage the patient to attend an optician at least annually and any time that new or worsening visual symptoms occur. A common side effect is a "blue halo" effect when looking into bright lights at night-time.

(If relevant) If monitoring results are forwarded to the specialist team, please include clear clinical information on the reason for sending to inform action to be taken by secondary care.

10. Adverse effects and other management

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

For information on the 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:				

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 Heart rate 50 - 60bpm without symptoms 	Continue amiodarone. Repeat monitoring. No action is required unless symptoms develop, or the heart rate decreases further.
 Heart rate ≤ 50bpm, or ≤ 60bpm with symptoms 	Discuss with the 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 the local reference range	Continue amiodarone. Repeat the test after 6 weeks.
<u>Hyper</u> thyroidism / thyrotoxicity: high T4, normal/high T3, low TSH	Stop amiodarone. Urgent referral to initiating specialist and endocrinologist.
<u>Hypo</u> thyroidism: 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 <u>hypo</u> thyroidism normal T4, raised TSH; clinical features not overtly manifest	Contact the 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; blurred or decreased vision	Stop amiodarone. Urgent referral to initiating specialist and ophthalmology.
Corneal micro-deposits: blueish halos when looking at bright lights, with no blurred or decreased vision	Continue amiodarone and monitor; 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 a specialist if persistent.
Hepatotoxicity: abnormal LFTs +/- symptoms of hepatic injury (e.g. hepatomegaly, weakness, ascites, jaundice)	If serum transaminases are 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 a 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 a specialist.
Pulmonary toxicity: including pneumonitis or fibrosis	Stop amiodarone. Urgent referral to initiating specialist, to investigate (i.e. pulmonary function tests and CT scan). Admission may be required.

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new/worsening cough, shortness of breath or deterioration in general health (e.g. fatigue, weight loss, fever)	
Bullous skin reactions: Life threatening or even fatal cutaneous reactions Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN)	Stop amiodarone. Urgent referral to dermatology, inform initiating specialist.
Photosensitivity	Continue amiodarone. Reinforce appropriate self-care, e.g. sun avoidance and purchasing 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 a specialist. Reinforce self-care measures (as for photosensitivity above). Pigmentation slowly disappears following treatment discontinuation.

11. Advice to patients and carers

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The specialist will counsel the patient with regard to 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 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** (excluding blueish halos when looking at bright lights, with no blurred or decreased vision)
- 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 are 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. (note that the maximum recommended dose of simvastatin is 20mg daily when used with amiodarone).
- Avoid grapefruit and grapefruit juice while taking amiodarone and for several months after discontinuation.
- Although there has 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.

Patient information:

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British Heart Foundation – anti-arrhythmics:

https://www.bhf.org.uk/informationsupport/heart-matters-magazine/medical/drug-cabinet/antiarrhythmics

AF Association: Amiodarone Advice – Patient Information

AFA Amiodarone Advice - (P).indd (heartrhythmalliance.org)

Information for healthcare professionals: https://www.sps.nhs.uk/medicines/amiodarone/

12. Pregnancy, paternal exposure and breastfeeding

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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.

Pregnancy:

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

Breastfeeding:

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

13. Specialist contact information

Specialists and primary care prescribers are encouraged to communicate directly where questions arise around the shared care for a particular patient. If issues remain after these discussions, the Chief/Senior Pharmacist at the ICB or hospital Trust should be contacted for advice.

In consultation with cardiology consultants and specialist pharmacists: Joe Morris, Lead Pharmacist – medicine, Sherwood Forest Hospitals Trust, Pharmacy Department

Beth Savage, Specialist Clinical Pharmacist – cardiology, Nottingham University Hospital NHS Trust, Ext. 79374

Out of hours: a consultant, specialist registrar or pharmacist may be contacted via the appropriate hospital switchboard.

NOTTINGHAM UNIVERSITY HOSPITALS switchboard 0115 924 9924 SHERWOOD FOREST HOSPITAL switchboard 01623 622515

14. Additional information

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Where patient care is transferred from one specialist service or GP practice to another, a new shared care agreement must be completed. Ensure that the specialist is informed in writing of any changes to the patient's GP or their contact details.

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15. References

- eBNF accessed via BNF (British National Formulary) | NICE
- Amiodarone hydrochloride 200mg tablets Ennogen Pharma Ltd). Date of revision of the text 20/02/2023. Accessed via <u>Home electronic medicines compendium (emc)</u>.
- NHS England and NHS Clinical Commissioners. Aug 2019. <u>NHS England » Items which</u> should not be routinely prescribed in primary care: Guidance for CCGs
- NICE. NG196: Atrial fibrillation: diagnosis and management. Last updated June 2021. Accessed via <u>https://www.nice.org.uk/guidance/ng196</u>.
- Specialist Pharmacy Service. Lactation Safety Information: Amiodarone. Last reviewed 05/07/2021. Accessed via <u>https://www.sps.nhs.uk/medicines/amiodarone/</u>.
- Specialist Pharmacy Service Medicines Monitoring. Published July 2021. Accessed via <u>Amiodarone monitoring – SPS</u>.
- LiverTox. Amiodarone. Last updated 01/03/2016. Accessed via https://www.ncbi.nlm.nih.gov/books/NBK548109/.
- NEWT Guidelines: amiodarone. Accessed via <u>NEWT Guidelines</u>
- Stockley's Drug Interactions accessed via Medicines Complete. Last updated March 2015. Accessed via: <u>MedicinesComplete — CONTENT > Stockley's Drug Interactions ></u> <u>Interaction: Coumarins and related drugs + Amiodarone</u>

16. Other relevant national guidance

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- NHSE guidance Responsibility for prescribing between primary & secondary/tertiary care. Available from <u>https://www.england.nhs.uk/publication/responsibility-for-prescribing-between-primary-and-secondary-tertiary-care/</u>
- General Medical Council. Good practice in prescribing and managing medicines and devices. Shared care. Available from https://www.gmc-uk.org/ethical-guidance/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care
- NICE NG197: Shared decision making. Last updated June 2021. <u>https://www.nice.org.uk/guidance/ng197/</u>

17. Local arrangements for referral

Define the referral procedure from hospital to primary care prescriber & route of return should the patient's condition change.

- Prescribing and monitoring responsibility will only be transferred when it is agreed by the specialist and the patient's primary care prescriber that the patient is stabilised on their medication regimen without adverse effect and with benefits demonstrated.
- The specialist will request shared care with the GP in writing.
- If the GP doesn't agree to shared care, they should inform the specialist of their decision in writing within 14 days, outlining the reason for the decline. The agreement can be assumed if the GP does not provide a written decline.

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- In cases where shared care arrangements are not in place or where problems have arisen within the agreement, and patient care may be affected, the responsibility for the patient's management, including prescribing, reverts back to the specialist.
- Should the patient's condition change, the GP should contact the relevant specialist using the details provided with the shared care request letter.

18. Supporting Document for Primary Care Reviews

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amiodarone-supporting-document-for-primary-care-reviews-v20.pdf

Available via Nottingham and Nottinghamshire Medicine Optimisation website