

AMIODARONE Drug Specific Monitoring Document

TARGET AUDIENCE	Board-wide
PATIENT GROUP	All patients aged 12 years and older taking oral Amiodarone

References

- British National Formulary (2024). *BNF / NICE*. [online] NICE. Available at: <https://bnf.nice.org.uk/>.
- Specialist Pharmacy Service (2021). *Medicines Monitoring*. [online] SPS - Specialist Pharmacy Service. Available at: <https://www.sps.nhs.uk/home/tools/drug-monitoring/>.
- Electronic Medicines Compendium (2019). *Home - electronic medicines compendium (emc)*. [online] Medicines.org.uk. Available at: <https://www.medicines.org.uk/emc>

Governance information for drug specific document

Lead Author(s):	Medicines Policy and Guidance Team
Endorsing Body:	Area Drug and Therapeutics Committee
Version Number:	V1.1
Approval date	18.06.2025
Review Date:	18.06.2026
Responsible Person (if different from lead author)	Kirsty Macfarlane/Mark Russell

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Medication Name	AMIODARONE
Actions by specialist clinician before initiation	<ul style="list-style-type: none"> • LFTs • U&Es • TFTs • Chest x-ray • ECG <p><i>For all drugs, specialist clinicians should consider whether vaccination/exclusion of other contraindications (including active infection), is required and arrange as appropriate.</i></p>
DIS actions on starting treatment and following dose titration during initiation period	<i>This box is intentionally blank.</i>
Ongoing monitoring in Primary Care once stable	<ul style="list-style-type: none"> • 6 monthly <ul style="list-style-type: none"> ○ TFTs ○ LFTs ○ U&Es • After stopping amiodarone, continue TFT testing for a further 1 year; at 6 and 12 months. • Annually <ul style="list-style-type: none"> ○ Consider chest x-ray if new, unexplained respiratory symptoms present ○ Consider Ophthalmology referral if blurred or decreased vision. ○ Patients should be encouraged to attend optometrist annually due to the potential for micro-deposits
Action if monitoring is outside reference range	<p>Hypothyroidism</p> <ul style="list-style-type: none"> • In clinically euthyroid patients, amiodarone may cause isolated biochemical changes (increase free-T4, slight decrease/normal free-T3). There is no reason to discontinue unless there is clinical or further biological (TSH) evidence of thyroid disease. • The following advice is available: <ul style="list-style-type: none"> ○ Free T4 is low; TSH is greater than 4.5 mU/L Consider treating with levothyroxine if amiodarone is considered essential. ○ Free T4 is normal; TSH is greater than 10 mU/L; duration is over 6 months Consider treating with levothyroxine or repeat again in 3 months. ○ Free T4 is elevated; TSH is greater than 4.5 mU/L; duration is less than 3 months Observe and repeat in 3 months. <p>Hyperthyroidism</p> <ul style="list-style-type: none"> • High circulating free T4 is associated with high or high/normal free T3 and undetectable TSH <ul style="list-style-type: none"> ○ A diagnosis of amiodarone-associated hyperthyroidism is possible ○ Withdraw amiodarone and seek specialist (endocrinology) referral ○ Clinical recovery usually occurs within a few months but precedes normalisation of TFTs ○ Severe cases, sometimes resulting in fatalities, have been reported • TSH is less than 0.1 mU/L, and T3 and T4 normal or minimally increased <ul style="list-style-type: none"> ○ Repeat test in 2-4 weeks • TSH is less than 0.1 mU/L and T4 elevated, T3 elevated or 50% greater than baseline <ul style="list-style-type: none"> ○ Discuss urgently with a specialist (endocrinologist) who may advise amiodarone withdrawal ○ Arrange for TSH-receptor antibodies and TPO antibodies <p>LFTs</p> <ul style="list-style-type: none"> • Amiodarone dose should be reduced or the treatment discontinued if the transaminases increase exceeds three times the normal range.
Actions to take if restarting medication after treatment break	<p>Actions needed may vary - consult specialist team for further guidance</p> <p>Patients should be referred by the specialist clinician to the drug initiation hub if re-titration or enhanced monitoring is required</p>

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CONSULTATION AND DISTRIBUTION RECORD	
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Distribution	Acute specialist consultants and pharmacists, Senior primary care pharmacists, all individuals involved with the Drug Initiation Service, LMC and GP sub-committee

CHANGE RECORD			
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