

Low priority prescribing: Amiodarone and Dronedarone factsheet for Medicines Optimisation Section 2023-24

Aim
To support practice review of amiodarone and dronedarone in line with NHS England Guidance, Items which should not be prescribed in Primary Care.

Background
Amiodarone and dronedarone are categorised by [NHS England](#) as products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns. In the year up to February 2023, 131 patients have been prescribed either Amiodarone or Dronedarone in 37 Lambeth Practices.

Key message
Where pharmacological treatment of atrial fibrillation is indicated, rate control is effective for most patients and can be achieved often by using less toxic drugs with less risk of harm. For the smaller proportion of patients who require rhythm control, dronedarone and amiodarone should only be used in the specific circumstances for which they are indicated, due to the safety risks associated with these drugs. Other safer treatment options should be tried first, wherever possible. Consequently, dronedarone and amiodarone are not recommended for routine prescribing in primary care.

Recommended actions

Amiodarone

- Practices to review the indication for amiodarone to ensure treatment is initiated in line with [NICE guidance](#). If the indication not documented, contact cardiology for further advice and guidance on rationale for therapy and duration of therapy.
- Ensure patients are regularly monitored in line with [SPS monitoring guidance](#) and manufacturer’s Summary of Product Characteristics. Amiodarone has been associated with serious and potentially life-threatening side effects, particularly of the lung, liver, and thyroid gland. Lung problems may have slow onset but then progress rapidly. For further information on side effects see also [MHRA](#) guidance.

Dronedarone

- Review all patients prescribed dronedarone. Dronedarone is categorised as RED and restricted to specialist or hospital prescribing only. Review whether prescribing remains appropriate in primary care and if clarity is required, contact cardiology for further advice. Discuss with patient and ensure indication and duration of therapy is documented in patient’s notes.

Item	Why is it a low priority medicine?	Circumstances in which use might be appropriate
Amiodarone	Amiodarone is no longer recommended for long-term rate control in atrial fibrillation (AF). There is a risk of potentially serious long-term side-effects, and alternative treatments are available.	Amiodarone may still be considered for: <ul style="list-style-type: none"> • Rhythm control in people with left ventricular impairment or heart failure • Pre (four weeks) and post (up to 12 months) electrical cardioversion • Pharmacological cardioversion in new onset AF with evidence of structural heart disease • Pharmacological cardioversion in new onset AF with no evidence of structural or ischaemic heart disease • People undergoing cardiothoracic surgery to reduce risk of post-operative AF For patients where other treatments cannot be used and fulfil the above criteria in line with NICE guidance In line with South East London Joint Formulary categorised as AMBER 1 meaning treatment can be

		initiated in primary care after a recommendation from an appropriate specialist.
Suggested alternative(s)		
A rate-control treatment (beta-blocker other than sotalol or rate limiting calcium-channel blocker) is recommended for most people with AF. Digoxin or dronedarone may be considered in specific circumstances. Flecainide may also be considered in people with no evidence of structural or ischaemic heart disease.		
Item	Why is it a low priority medicine?	Circumstances in which use might be appropriate
Dronedarone	<p>NICE puts greater emphasis on rate rather than rhythm control. Dronedarone is only recommended as an option for the maintenance of sinus rhythm after successful cardioversion in people with paroxysmal or persistent AF:</p> <ul style="list-style-type: none"> As a second-line treatment option (because AF is not controlled by first line therapy, usually including beta-blockers) and after alternative options have been considered. <p>and</p> <ul style="list-style-type: none"> For those who have at least one of the following cardiovascular risk factors: <ul style="list-style-type: none"> ➤ Hypertension requiring drugs of at least two different classes ➤ Diabetes mellitus ➤ Previous transient ischaemic attack, stroke or systemic embolism ➤ Left atrial diameter of 50 mm or greater or ➤ Age 70 years or older and ➤ Who do not have left ventricular systolic dysfunction and ➤ Who do not have a history of, or current, heart failure. 	<p>In line with South East London Joint Formulary categorised as RED and restricted to specialist or hospital prescribing only. Refer to SEL position statement</p>
Suggested alternative(s)		
A rate-control treatment (beta blocker except sotalol or a rate limiting calcium channel blocker) is recommended for most people with AF. Digoxin may be considered in specific circumstances.		

*The above table has been adapted from [NHS PrescQIPP Items which should not routinely be prescribed in primary care July 2019](#)

References:

- NHS England Items which should not routinely be prescribed in primary care: Guidance for CCGs. June 2019 <https://www.england.nhs.uk/wp-content/uploads/2019/08/items-which-should-not-routinely-be-prescribed-in-primary-care-v2.1.pdf>
- Specialist Pharmacy Service, Amiodarone monitoring. July 2021. <https://www.sps.nhs.uk/monitorings/amiodarone-monitoring/>
- Summary Product Characteristics Amiodarone Hydrochloride 200mg Tablets. February 2023. <https://www.medicines.org.uk/emc/product/13964/smpc#gref>
- NHS PrescQIPP Items which should not routinely be prescribed in primary care: Phase 3, July 2019. <https://www.prescqipp.info/umbraco/surface/authorisedmediasurface/index?url=%2fmedia%2f4136%2f243-nhs-lpp-phase-3-20.pdf>
- NHS PrescQIPP Dronedarone and amiodarone prescribing. April 2020. <https://www.prescqipp.info/umbraco/surface/authorisedmediasurface/index?url=%2fmedia%2f4824%2f248-nhse-lpp-dronedarone-and-amiodarone-20.pdf>
- NICE guideline [NG196] Atrial fibrillation: diagnosis and management. June 2021. <https://www.nice.org.uk/guidance/ng196>
- MHRA Drug Safety Update, Amiodarone (Cordarone X): reminder of risks of treatment and need for patient monitoring and supervision. March 2022. <https://www.gov.uk/drug-safety-update/amiodarone-cordarone-x-reminder-of-risks-of-treatment-and-need-for-patient-monitoring-and-supervision?UNLID=8003426512023117155835#amiodarone-and-risk-of-toxicity>