



# **National Institute for Health and Clinical Excellence**

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## **PRESS RELEASE**

### **New draft NICE guidance recommends limited use of dronedaronone for atrial fibrillation**

The National Institute for Health and Clinical Excellence (NICE) is currently appraising the use of dronedaronone (Multaq) for the treatment of atrial fibrillation (AF) – a disturbance of the heart’s rhythm. After considering comments received at public consultation on the previous draft guidance, the independent Appraisal Committee has revised its original recommendation that the drug should not be used to treat atrial fibrillation. Further draft guidance published today (30 March) recommends the limited use of the drug as a second-line treatment in people with additional cardiovascular risk factors whose AF has not been controlled by first-line therapy (usually including beta-blockers).

Although the committee did not change their conclusion that dronedaronone is not as effective as other anti-arrhythmic drugs in preventing the recurrence of AF, it accepted evidence that the drug did not lead to an increase in the risk of mortality, unlike the anti-arrhythmics with which it was compared. The Appraisal Committee also noted comments from patients and clinical experts received during consultation on the previous draft that all current anti-arrhythmic drugs, but particularly amiodaronone, had side effects which had a significant impact on quality of life with long term use. Overall, the Committee concluded that dronedaronone was likely to result in fewer adverse effects than amiodaronone.

**Andrew Dillon, Chief Executive of NICE said:** “Atrial fibrillation can be a distressing condition and people with it have an increased risk of suffering a stroke or heart attack. Unfortunately, anti-arrhythmic treatment options for people with atrial fibrillation are limited and those treatments that are available are associated with

side-effects which can have a significant impact on quality of life. Whilst dronedarone has not been shown to be as effective as existing treatment options in controlling atrial fibrillation, and is more expensive, short term evidence suggests that it is associated with fewer side-effects. Therefore we are pleased that, following public consultation on the first draft of this guidance, we have been able to identify circumstances in which dronedarone could be offered as a cost effective treatment option.”

This draft guidance has been issued for consultation and interested parties have an opportunity to comment on the draft recommendations made by the independent appraisal committee. **This draft guidance has been issued for consultation: NICE has not yet issued final guidance to the NHS.**

NICE’s preliminary recommendations are available for public consultation from 30 March until 22 April 2010. Comments received during this consultation will be considered by the committee.

Until NICE issues final guidance, NHS bodies should make decisions locally on the funding of specific treatments. Once NICE issues its guidance on a technology it replaces local recommendations across the country.

**Ends**

## **Notes to Editors**

### **About the guidance**

1. Atrial fibrillation is one of the most common heart rhythm disturbance conditions. It can cause symptoms such as palpitations and tiredness.
2. The cost per day based on the recommended dosage of dronedarone would be £2.25. The cost of an existing comparator drug, amiodarone, is approximately £0.05 per day.
3. Information on the NICE appraisal of dronedarone for atrial fibrillation is available at <http://guidance.nice.org.uk/TA/Wave19/57>

### **About NICE**

4. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
5. NICE produces guidance in three areas of health:
  - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
  - **health technologies** – guidance on the use of new and existing medicines, treatments and procedures within the NHS

- **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.