Dronedarone for the treatment of atrial fibrillation and atrial flutter
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Record Status
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Citation

Authors' conclusions
The effectiveness of dronedarone as an adjunctive treatment to standard care is highly uncertain, the key issue being the generalisability of the ATHENA study which reflects a moderate- to high-risk elderly AF population relative to the general AF population. In terms of the broader comparison of dronedarone with AADs, the ERG considers that the clinical evidence is highly uncertain for the key drivers of the cost-effectiveness of dronedarone: all-cause mortality and stroke. The uncertainty arises because the potential clinical and statistical heterogeneity of the included RCTs has not been adequately considered, and the exchangeability of the ATHENA study with the other studies is questionable. Also, the additional restrictions imposed on the inclusion of RCTs in the MTC are likely to increase the overall decision uncertainty compared to a fuller use of this evidence. Furthermore, the question of how the reduction in all-cause mortality or stroke is mediated, given that dronedarone is the least effective AAD in terms of AF recurrence, remains to be elucidated.

Key issues specifically relevant to the economic evaluation include: establishing the most appropriate source of data to inform the baseline event rates applied in the model; the potential cost-effectiveness of dronedarone in a range of alternative and feasible treatment sequences; the potential HRQoL benefits of dronedarone and the maintenance of benefits over the longer term; and the absence of a final confirmed acquisition price at the time of the submission of the ERG report. Finally, the lower initiation and monitoring costs assumed for dronedarone are uncertain, although these do not appear to have a significant impact on the final ICER results.

Implications for research Further and longer term trials or the implementation of registries would be helpful to further establish the efficacy and safety of dronedarone relative to other AAD treatments that are regularly used in this indication within UK clinical practice. This is of particular importance in regard to outcomes of all-cause mortality and stroke, as these appear to be the key drivers of the cost-effectiveness results. Given the lack of existing HRQoL data, future RCTs of dronedarone and other AADs should also consider using a relevant HRQoL measure. Additional evidence related to the effectiveness of AADs for patients with AFL would also be valuable.

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