

Appraisal Consultation Document – Dabigatran Etxilate for the prevention of stroke and systemic embolism in atrial fibrillation

Response from Anticoagulation Europe

- Are there any equality related issues that need special consideration and are not covered in the appraisal consultation document?

Under the NICE Guidelines CG 36, it is recommended that AF patients be offered aspirin or warfarin (VKA) dependent on the level of risk.

Patients who commence warfarin treatment will need to be regularly monitored to ensure they stay in therapeutic range to avoid clots and bleeding episodes and make adjustments to diet for this purpose. Further adjustments to lifestyle will need to be considered – such as travel and factoring in regular venous or pin prick blood tests which may involve visiting a hospital, anticoagulation clinic setting or their GP Anticoagulant clinic.

Whilst AF is a condition that predominately is seen in a senior population, younger people do present with AF and therefore, the impact of having to undergo regular monitoring which involves managing work arrangements can lead to anxiety and concerns from the employer and employee. With the age of retirement increasing, individuals diagnosed with AF could be working longer and therefore their continued therapy management could impact on their working life.

Constant venous sampling can traumatise the veins and cause pain. Pinprick sampling whilst less invasive, can cause discomfort and bruising to the digits.

Many AF patients cannot tolerate warfarin for a number of clinical reasons and those with AF who receive no medication are at a fivefold increased risk of stroke.

Stroke accounts for around 53,000 deaths each year in the UK and an estimated 150,000 have a stroke in the UK each year.

Stroke can cause a range of disabilities with the NHS having to manage costly treatment and on going support to the patient.

The key conclusions as summarised in the ACD have acknowledged the issues surrounding warfarin usage and, under 'Equalities, considerations and social value judgements' section 4.2 'the Committee 'recognised the potential benefits of Dabigatran for people with AF'

By not considering Dabigatran as an alternative treatment to patients and in particular, those who cannot tolerate warfarin and therefore are left unprotected from the heightened risk of stroke could be deemed to be 'unfair' to those patients.

Patients need to reduce the anxiety of the fear of having a stroke when diagnosed with AF and knowing that there is a therapy to give that protection will bring re-assurance and confidence to patients.

In terms of equality, Dabigatran will offer an alternative oral anticoagulant for those patients for which warfarin is currently unviable. It will enable patients to manage their chronic condition with a treatment that has increased efficacy in reducing stroke. Defining equality as 'a state of being equal' puts this into perspective – depriving patients of an alternative therapy that can give protection is 'discriminating' against those who are unfortunate in that they can't stabilise on warfarin or it's deemed unsuitable by the clinicians.

Reducing risk of stroke in 'all' AF sufferers should be paramount in current healthcare provision in the UK.

Anticoagulation Europe

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