

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Aliskiren for hypertension

Draft scope (Pre-referral)

Draft remit/ appraisal objective

To appraise the clinical and cost effectiveness of aliskiren for hypertension.

Background

Hypertension means persistently raised blood pressure. Blood pressure rises and falls as the heart pumps and is measured with two readings. The highest reading is called the systolic pressure and the lowest reading is called the diastolic pressure. A person is said to have persistently raised blood pressure if either their systolic blood pressure is above 140 mmHg or their diastolic blood pressure is higher than 90 mmHg, and if this is the case when their blood pressure is measured at a number of different visits.

Over 90 per cent of people with hypertension have no immediately identifiable cause for their condition. They are described as having essential hypertension. In those patients with an identifiable cause, such as endocrine or kidney disorders, the hypertension is described as secondary.

Most people with hypertension do not have symptoms, but some with very severe hypertension experience headaches, impaired vision, fits or blackouts. People with hypertension are also at increased risk of developing coronary heart disease (CHD), stroke, kidney disease and damaged eyesight.

In England and Wales in 2003, on average 34% percent of men over 16 years and 30% of women over 16 years had hypertension ($\geq 140/90$ mmHg) or were taking medicine affecting blood pressure (an estimated total of 13.8 million people). The proportion of people with hypertension increases with age. It is estimated that in about 56% percent of men and 59% of women receiving anti-hypertensive medication, hypertension remains uncontrolled.

The current NICE guideline (CG034) specifies that drug therapy is appropriate for patients with:

- a persistent blood pressure of 160/100 mmHg or more or
- a raised cardiovascular risk (10-year risk of cardiovascular disease (CVD) of 20% or more or existing CVD or target organ damage) with a persistent blood pressure of more than 140/90mmHg.

Lifestyle advice is currently recommended for people with a blood pressure between 140/90 mmHG and less than 160/100 mmHg without raised CVD risk or target organ damage.

There are several classes of drugs which are used to lower blood pressure, including thiazide diuretics, angiotensin converting enzyme (ACE) inhibitors, angiotensin II receptor antagonists, alpha blockers, calcium-channel blockers and beta-blockers.

The technology

Aliskiren (Rasilez, Novartis) belongs to a new class of drugs called direct renin inhibitors. It works by blocking the conversion of angiotensinogen to angiotensin I. Angiotensin I normally becomes converted to angiotensin II, which is a powerful vasoconstrictor, and inhibition of its synthesis in hypertensive patients results in a fall in peripheral vascular resistance and a lowering of blood pressure.

Aliskiren does not currently hold a UK marketing authorisation. It has been investigated in randomised clinical trials as monotherapy in comparison with other anti-hypertensive drugs, and also as an add-on in combination with them. It has been evaluated against other vasodilators (ACE inhibitors and calcium-channel blockers) and also against diuretics which work in a different way.

Intervention(s)	Aliskiren as monotherapy or in combination with other anti-hypertensive drugs
Population(s)	<p>Adults who have:</p> <ul style="list-style-type: none"> • a persistent blood pressure of 160/100 mmHg or more or • a raised cardiovascular risk (10-year risk of cardiovascular disease (CVD) of 20% or more or existing CVD or target organ damage) with a persistent blood pressure of more than 140/90mmHg.
Current standard comparators	<ul style="list-style-type: none"> • Standard treatments for hypertension (including angiotensin II receptor antagonists, ACE inhibitors, thiazide diuretics, calcium channel blockers, alpha blockers, beta-blockers given alone or in combination).

Outcomes	<p>Outcomes to be considered include:</p> <ul style="list-style-type: none"> • Decrease in mean diastolic blood pressure • Decrease in mean systolic blood pressure • Cardiovascular events • Overall survival • Health-related quality of life • Adverse effects of treatment
Economic analysis	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The time horizon for the economic evaluation should reflect the chronic nature of the condition</p> <p>The economic evaluation should be undertaken in accordance with NICE guidance on the management of hypertension</p> <p>Costs will be considered from a NHS and Personal Social Services Perspective.</p>
Other considerations	<p>If evidence allows, the appraisal will seek to identify subgroups of individuals for whom the technology is particularly clinically and cost-effective.</p> <p>Guidance will be issued in accordance with the marketing authorisation.</p>
Related NICE recommendations	<p>Related Technology Appraisals: none</p> <p>Related Clinical Guidelines:</p> <p>Hypertension: management of hypertension in adults in primary care (CG 34) June 2006.</p> <p>Management of type 2 diabetes - management of blood pressure and blood lipids October 2002. Currently being reviewed- due February 2008</p>

Questions for consultation

What is the likely place of aliskiren in the pathway of care for hypertension?

Should the comparators for the appraisal be limited to certain classes of anti-hypertensives or specific anti-hypertensive drugs?