NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Baxdrostat for treating uncontrolled or resistant hypertension ID6623

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of baxdrostat within its marketing authorisation for treating uncontrolled or resistant hypertension.

Background

Hypertension is a condition where blood leaves the heart at too high a pressure. Hypertension is defined as uncontrolled or treatment resistant when appropriate lifestyle measures and treatment with drugs fails to reduce systolic and diastolic BP values to <140 mmHg and/or <90 mmHg, respectively. If blood pressure is too high, it puts extra strain on the blood vessels, heart, brain, kidneys and eyes. Risk factors for uncontrolled or resistant hypertension include obesity, personal or family history of hypertension or cardiovascular disease, chronic kidney disease, autoimmune conditions, and stress.

Hypertension is the most common chronic disease and the leading risk factor for disability and premature deaths in the world[1,2]. A report by the Department of Health and Social Care (2024/25) shows 9,711,491 of the population in England have hypertension[3]. A meta-analyis suggests that around 15% of hypertension cases in Europe are resistant[4]. There is some evidence to suggest that blood pressure is less likely to be controlled by medication for people in African or African Caribbean groups[5].

Current clinical management for hypertension includes lifestyle modification and pharmacological management. NICE guideline 136 recommends lifestyle modifications including sodium restriction, regular exercise, reducing alcohol consumption and cessation of smoking. If these are unsuccessful at reducing blood pressure, NICE guideline 136 recommends escalating treatment with medication until blood pressure can be controlled, including an ACE inhibitor or angiotensin receptor blocker, a calcium-channel blocker, and a thiazide-like diuretic. If hypertension is not controlled in people taking the optimal tolerated doses of those drugs, they are considered to have resistant hypertension. Treatment for resistant hypertension includes the addition of either a fourth antihypertensive drug, or further diuretic therapy with low-dose spironolactone, or an alpha-blocker or beta-blocker.

The technology

Baxdrostat (brand name unknown, Astra Zeneca) does not currently have a marketing authorisation for treating uncontrolled hypertension. It has been studied as an add-on medication in clinical trials alone compared with placebo in people with uncontrolled or treatment resistant hypertension.

Intervention(s)	Baxdrostat
Population(s)	People with uncontrolled or treatment resistant hypertension
Subgroups	• People with uncontrolled hypertension (hypertension despite a stable regimen of 2 antihypertensive agents, one of which is a diuretic) • People with treatment resistant hypertension (hypertension despite a stable regimen of 3 or more antihypertensive agents, one of which is a diuretic)
Comparators	Established clinical management without baxdrostat. In people whose hypertension is uncontrolled, (hypertension despite a stable regimen of 2 antihypertensive agents, one of which is a diuretic), this may include: • a calcium-channel blocker In people with treatment resistant hypertension (hypertension despite a stable regimen of 3 or more antihypertensive agents, one of which is a diuretic), this may include: • a fourth antihypertensive drug not previously used • further diuretic therapy with the addition of low-dose spironolactone • an alpha-blocker or beta-blocker
Outcomes	The outcome measures to be considered include: • change in systolic blood pressure • change in diastolic blood pressure • mortality • adverse effects of treatment • health-related quality of life.

Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability of any managed access arrangement for the intervention will be taken into account The availability and cost of biosimilar and generic products should be taken into account
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related NICE guidelines:** Hypertension in adults: diagnosis and management (2019) NICE guideline 136. Last reviewed November 2023 **Related interventional procedures:** Percutaneous transluminal renal sympathetic denervation for resistant hypertension (2023) Interventional procedures guidance 754. Review date not stated. Implanting a baroreceptor stimulation device for resistant hypertension (2015) Interventional procedures guidance 533. Review date not stated. **Related quality standards:** Hypertension in adults (2013) Quality standard 28. Last reviewed September 2015

Questions for consultation

Will baxdrostat replace any existing treatments for uncontrolled or resistant hypertension?

Where do you consider baxdrostat will fit into the existing care pathway for hypertension?

Please select from the following, will baxdrostat be:

A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):

For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would baxdrostat be a candidate for managed access?

Do you consider that the use of baxdrostat can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which baxdrostat will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. GBD (2016) Global, regional, and national comparative risk assessment of 79 behavioural, environmental and occupational, and metabolic risks or clusters of risks, 1990– 2015: a systematic analysis for the Global Burden of Disease Study 2015. Lancet 388: pg1659–724.

2. WHO (2013) A global brief on hypertension: silent killer, global public health crisis. World Health Day. World Health Organization Press. Accessed December 2025

3. Department of Health and Social Care (2025) Public health profiles - Hypertension: QOF prevalence. Accessed December 2025

4. Noubiap JJ, Nansseu JR, Nyaga UF, et al. (2019) Global prevalence of resistant hypertension: a meta-analysis of data from 3.2 million patients. Heart 105: pg98-105

5. Eastwood SV, Hughes AD, Tomlinson L, et al. (2022) Ethnic differences in hypertension management, medication use and blood pressure control in UK primary care, 2006–2019: a retrospective cohort study. Lancet Regional Health 25: 100557