NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Glycopyrronium bromide cream for treating severe primary axillary hyperhidrosis ID6487

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of glycopyrronium bromide cream within its marketing authorisation for treating severe primary axillary hyperhidrosis.

Background

Hyperhidrosis is a condition in which sweating is in excess of that necessary to maintain normal body temperature. Primary (idiopathic) hyperhidrosis has no recognised cause and mainly affects focal areas of the body, such as the armpits, feet, hands or head and face. Primary axillary hyperhidrosis affects the armpits. Severe primary axillary hyperhidrosis can be defined as a score of 3 or 4 on the Hyperhidrosis Disease Severity Scale. Primary hyperhidrosis usually starts before the age of 18 years, although it can happen at any age. It is usually life-long, although in a few people symptoms can spontaneously improve over time. Excessive sweating can have a profound effect on quality of life, interfering with daily activities and causing anxiety and embarrassment.

The true prevalence of hyperhidrosis is unknown, as it is often under-reported by patients and under-diagnosed by healthcare professionals. Hyperhidrosis is estimated to occur in 1% to 1.6% of people in the United Kingdom.[1] Around 90% of these are primary hyperhidrosis and more than half affect the axilla (armpits).[2] Primary hyperhidrosis affects males and females equally but there is a higher prevalence of axillary hyperhidrosis in white people.[2]

There are no NICE guidelines for treating primary axillary hyperhidrosis. First-line management of primary axillary hyperhidrosis includes lifestyle measures such as avoiding known triggers and tight clothing, and using antiperspirants (including aluminium chloride hexahydrate). For more severe cases, treatments include iontophoresis, botulinum-toxin A injection, and oral medications such as antimuscarinics, beta-blockers, antihypertensives and anxiolytics. If these do not work, surgical options include local sweat-gland excision by subcutaneous curettage or tumescent liposuction, or thoracic sympathectomy (cutting or clamping the nerves controlling sweating). NICE guidance on transcutaneous microwave ablation for severe primary axillary hyperhidrosis (IPG601) only recommends its use with special arrangements for clinical governance, consent and audit or research.

The technology

Glycopyrronium bromide cream (Axhidrox, Leith Healthcare) does not currently have a marketing authorisation in the UK for severe primary axillary hyperhidrosis. It has been studied in clinical trials alone compared with placebo in adults with severe primary axillary hyperhidrosis.

Intervention(s)	Glycopyrronium bromide cream
Population(s)	Adults with severe primary axillary hyperhidrosis

Comparators	• antiperspirants (including aluminium chloride hexahydrate)
	• iontophoresis
	• botulinum-toxin A injection
	• oral antimuscarinics such as propantheline bromide
	• off label treatments including:
	  ○ beta-blockers
	  ○ antihypertensives
	  ○ anxiolytics
	• surgical options for sweat gland ablation or thoracic sympathectomy

Outcomes	The outcome measures to be considered include: • absolute change in sweat production • response rates • 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.
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 technology appraisals:**

	None **Related highly specialised technology appraisals:** None **Related technology appraisals in development:** None **Related highly specialised technology appraisals in development:** None **Related NICE guidelines:** None **Related NICE guidelines in development:** None **Related interventional procedures:** Transcutaneous microwave ablation for severe primary axillary hyperhidrosis (2017) NICE interventional procedures guidance 601 Endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb (2014) NICE interventional procedures guidance 487

Questions for consultation

Where do you consider glycopyrronium bromide cream will fit into the existing care pathway for severe primary axillary hyperhidrosis? Would it be used in people who would otherwise have:

- antiperspirants (including aluminium chloride hexahydrate)
- surgical options (including subcutaneous curettage, tumescent liposuction, thoracic sympathectomy)

Are the following treatments used to treat severe primary axillary hyperhidrosis in the NHS?

- Off label oral glycopyrronium bromide
- Off label oxybutynin?
- Transcutaneous microwave ablation?
- Off label beta blockers, anxiolytics and antihypertensives? If so, which medicines are used?

Would glycopyrronium bromide cream ever be used as an add on to current treatments?

Are there treatments in the comparator list that are used together?

Please select from the following, will glycopyrronium bromide cream 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 glycopyrronium bromide cream be a candidate for managed access?

Do you consider that the use of glycopyrronium bromide cream 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.

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

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 glycopyrronium bromide cream 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. Ricchetti-Masterson, K, et al. Epidemiology of hyperhidrosis in 2 population-based health care databases. Journal of the American Academy of Dermatology 78.2 (2018): 358-362.

2. McConaghy, J.R. and Fosselman, D. (2018) Hyperhidrosis: Management Options. *American Family Physician* 97(11), 729-734.