NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Glycopyrronium bromide cream for treating severe primary axillary hyperhidrosis ID6487

Final scope

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 but rarely occurs in isolation and is usually associated with hyperhidrosis in other areas. 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

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 aluminium-based antiperspirants. If these do not work, then oral antimuscarinics such as propantheline bromide, off-label oxybutynin or off-label oral glycopyrronium bromide may be used. Botulinum-toxin A (botox) injection is another option that is commissioned in some parts of the UK.^{3,4,5,6}

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	Glycopyrronium bromide 1% cream
Population	Adults with severe primary axillary hyperhidrosis
Comparators	 oral antimuscarinics such as propantheline bromide, off-label oxybutynin or off-label oral glycopyrronium bromide botulinum-toxin A (botox) injection
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Outcomes	The outcome measures to be considered include:
	disease severity
	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.
	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 interventional procedures: <u>Transcutaneous microwave ablation for severe primary</u> <u>axillary hyperhidrosis</u> (2017) NICE interventional procedures guidance 601
	Endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb (2014) NICE interventional procedures guidance 487

References

- 1. Ricchetti-Masterson, K, et al. Epidemiology of hyperhidrosis in 2 populationbased 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.
- 3. NHS Pan Mersey, Area Prescribing Committee. <u>BOTULINUM TOXIN TYPE A</u> <u>injection for severe axillary hyperhidrosis</u>. Accessed 21 February 2025.
- 4. NHS Bedfordshire, Luton and Milton Keynes Integrated Care Board. <u>Hyperhidrosis.</u> Accessed 21 February 2025.
- 5. NHS Devon. <u>Botulinum Toxin A for the management of focal hyperhidrosis.</u> Accessed 21 February 2025.
- NHS Nottinghamshire Area Prescribing Committee, Joint Formulary. <u>Chapter</u> <u>13: Skin 13.2 Antiperspirants Botulinum toxin type A.</u> Accessed 21 February 2025.