

## National Institute for Health and Care Excellence

## Health Technology Evaluation

## Glycopyrronium bromide cream for treating severe primary axillary hyperhidrosis ID6487

## Response to stakeholder organisation comments on the draft remit and draft scope

**Please note:** Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

## Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	Hyperhidrosis UK	Whilst treatments for axillary hyperhidrosis are more plentiful than other body areas a further effective topical treatment modality would be welcome by patients. A single technology appraisal seems appropriate for this pharmaceutical intervention.	Thank you for your comment.
	British Association of Dermatologists	Appropriate evaluation for a novel therapy for a difficult-to-treat condition with limited efficacious treatments.	Thank you for your comment.
	Leith	We are pleased that NICE acknowledges the importance of reimbursing more treatment options for patients with hyperhidrosis. The need for improved clinical guidance and evidence-based treatments has been well described in the outputs from the recent James Lind Alliance Hyperhidrosis Priority Setting Partnership, <sup>1</sup> the selection of interventions for hyperhidrosis by Cochrane Skin ( <a href="https://skin.cochrane.org/prioritisation-results-2020">https://skin.cochrane.org/prioritisation-results-2020</a> ), and the subsequent Cochrane Review Protocol published in 2022. <sup>2</sup>	Thank you for your comment. The STA route is considered an appropriate route for GPB 1% cream as NICE are not aware of any other upcoming

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		<p>Compared with other disorders of similar prevalence, hyperhidrosis research is less well funded. Until recently, there were only nine clinical trials for hyperhidrosis recruiting worldwide, whereas psoriasis, with a similar prevalence, had 193.<sup>1</sup> As the appraisal remit states, however, the burden of the condition can be substantial, and is comparable to severe psoriasis.</p> <p>To date, no medicinal therapies for hyperhidrosis have been assessed by NICE, and we are pleased that the proposed appraisal plans to address this. However, the lack of previous appraisals contributes to anticipated challenges associated with assessing glycopyrronium bromide (GPB) 1% cream. These are outlined briefly below.</p> <p>The company agrees that Single Technology Appraisal (STA) is likely the most appropriate route for any assessment. Given the lack of previous NICE appraisals, a Multiple Technology Appraisal may also be appropriate in this patient population. Within the STA route, there are likely to be substantial challenges with conducting a cost-effectiveness analysis, such that a cost-comparison approach may be the most appropriate option to assess the economic value of GPB 1% cream.</p>	<p>treatments in this area. A cost comparison appraisal is only possible if the intervention is clinically similar enough to another intervention which has previously been recommended by NICE for the same population.</p>
Wording	Hyperhidrosis UK	N/A	N/A
	British Association of Dermatologists	Glycopyrronium bromide cream for treating primary axillary hyperhidrosis – it should not be limited to severe disease.	Thank you for your comment. GPB 1% cream will be appraised in line with its UK marketing authorisation.

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	Leith	Yes, the remit is appropriate. GPB 1% cream is for the treatment of severe primary axillary hyperhidrosis.	Thank you for your comment.
Timing issues	Hyperhidrosis UK	Generally acceptable treatment options for treating axillary hyperhidrosis are available. There is no clinical urgency. It is non-life-threatening.	Thank you for your comment.
	British Association of Dermatologists	N/A	N/A
	Leith	GPB 1% cream will receive a marketing authorisation in [REDACTED] according to the most recent timetable estimates based on communication with the MHRA.	Thank you for your comment.
Additional comments on the draft remit	Hyperhidrosis UK	N/A	N/A
	British Association of Dermatologists	N/A	N/A
	Leith	We expect that GPB 1% cream will be prescribed by healthcare professionals working in primary care for patients presenting with severe hyperhidrosis of the axillae that has not been adequately resolved by treatment with conservative therapy. Given that patients can self-administer the treatment and that determining the effectiveness of the product is straightforward, we expect the introduction of GPB 1% cream will place a very limited additional burden on healthcare resources. Based on sales performance in other countries that have launched GPB and early budget impact modelling, the estimated annual acquisition costs associated with GPB 1% cream at year five is expected to be [REDACTED]	Thank you for your comment.

## Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	Hyperhidrosis UK	<p>The background should make it clear that primary axillary hyperhidrosis rarely occurs in isolation and is usually associated with palmar and plantar hyperhidrosis with a slight preponderance for females (Glaser et al 2016 Dermatol Surg 42: 1347-53).</p> <p>Figures on the prevalence of hyperhidrosis vary considerably and I do not think we really know the true number. There may be regional differences but I think much of that is down to study methodology. I am not sure about the higher prevalence in Caucasians that seems to be cited in most NICE literature on hyperhidrosis.</p> <p>It should also be highlighted that sympathectomy is very much a last resort option because of the almost inevitability of compensatory sweating and it is not reversible. Additionally, since so few of these are now performed there will be fewer vascular surgeons trained and competent in the procedure.</p> <p>Antiperspirants contain either aluminium chloride or aluminium chloride hexahydrate (and sometimes zirconium salts also).</p> <p>It would be worth mention that other topical anticholinergics have been licensed by the FDA in the US and other far Eastern territories e.g. sofpironium bromide (Sofdra) and glycopyrronium tosylate (Qbrexza). We get asked about the availability of such products in the UK frequently.</p>	<p>Thank you for your comments. The scope has been updated to acknowledge that primary axillary hyperhidrosis rarely occurs in isolation. It is acknowledged that the true prevalence is unknown, this is reflected in the scope. The sentence stating a higher prevalence in Caucasians has been removed. The scope has been updated to state “aluminium-based antiperspirants” to cover both aluminium chloride or aluminium chloride hexahydrate formulations.</p> <p>NICE considers only treatments available in the NHS as comparators in</p>

Section	Consultee/ Commentator	Comments [sic]	Action
			<p>technology appraisals. Other treatments available internationally have therefore not been discussed in the background section.</p> <p>Comparators have now been updated in line with feedback at a scoping workshop and through follow-up emails with local commissioners. Please see “comparators” section below.</p>
	British Association of Dermatologists	N/A	N/A
	Leith	The background does not mention the work impairment and productivity loss that can be caused by severe axillary hyperhidrosis. Research from Japan has aimed to characterise this, <sup>3</sup> and it is an important aspect of the burden of severe axillary hyperhidrosis for patients.	<p>Thank you for your comments. The background section aims to give a brief overview of the condition only. Additional information can be raised by the</p>

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			company in the company's submission.
Population	Hyperhidrosis UK	Yes, the definition is defined. In clinical practice, what will be the criteria for the drug to be prescribed, HDSS 3 or 4?	Thank you for your comment. This will be detailed in the final guidance issued by NICE if GPB 1% cream is recommended.
	British Association of Dermatologists	We acknowledge the indication in the (German) SmPC for glycopyrronium bromide, however, it would be ideal if it was not limited to severe axillary hyperhidrosis only.	Thank you for your comment. GPB 1% cream will be appraised in line with its UK marketing authorisation.
	Leith	Yes, the population is defined appropriately based on the anticipated license for GPB 1% cream.	Thank you for your comment.
Subgroups	Hyperhidrosis UK	If or when safety data becomes available for the use of the drug in adolescents, this could have the greatest impact. Since the condition onsets or becomes most problematic in teenage years the psychosocial effects can be especially marked for such patients.	Thank you for your comment. It is acknowledged that GPB 1% cream may have the greatest impact in adolescents. However, GPB 1% cream will be appraised in line with its UK marketing authorisation.

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	British Association of Dermatologists	N/A	N/A
	Leith	The company is not aware of any subgroups in which GPB 1% cream is either more clinically or cost-effective.	Thank you for your comment.
Comparators	Hyperhidrosis UK	Yes but antiperspirants are no longer prescribed on the NHS in most areas, iontophoresis is only available for a trial treatment period (in some areas, not available in many areas) and botulinum toxin is no longer available on the NHS.	<p>Thank you for your comment. Comparators have now been updated following scope consultation comments, discussions at the scoping workshop and follow-up correspondence with local commissioners.</p> <p>Antiperspirants and iontophoresis have been removed as comparators. Because botulinum toxin is commissioned by some integrated commissioning boards in the NHS it has been included as a comparator</p>

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	British Association of Dermatologists	<p>The comparators are reasonable, but not all of them are standard treatments currently used in the NHS, apart from antiperspirants (containing aluminium salts) and oral antimuscarinics such as oral propantheline.</p> <p>Trials of treatment with iontophoresis are not available in some NHS departments of dermatology and patients would need to purchase or hire their own iontophoresis machines (and purchase axillary pads) for continued treatment.</p> <p>Botulinum toxin injections for axillary hyperhidrosis are also unavailable in many NHS departments of dermatology.</p> <p>Surgical options for sweat gland ablation and thoracic sympathectomy may not be available throughout NHS trusts and these options are not often chose by patients due to potential risks of the procedures and risks of rebound sweating in the same area and compensatory sweating at other sites.</p>	<p>Thank you for your comments.</p> <p>Comparators have now been updated following scope consultation comments, discussions at the scoping workshop and follow-up correspondence with local commissioners.</p> <p>Antiperspirants have been removed as a comparator because anticipated that these will be used before glycopyrronium bromide cream. Surgery and iontophoresis have been removed as comparators because not routinely commissioned at the anticipated position in the treatment pathway at which glycopyrronium bromide will be used. Because botulinum toxin is commissioned by some integrated commissioning boards</p>



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			in the NHS it has been included as a comparator Please see below for further details.
	Leith	<p>GPB 1% cream is expected to be used for patients after initial conservative therapy has failed. This will typically mean that a patient will have made lifestyle modifications and found that topical self-purchased and/or prescribed (20% concentration) aluminium-based antiperspirants have proved inadequate in addressing their excess sweating.</p> <p>At this point in the treatment pathway, patients then initiate specialist treatment options, typically oral and topical therapy, and potentially iontophoresis. Botulinum toxin type A is indicated for the management of severe hyperhidrosis of the axillae, which does not respond to topical treatment with antiperspirants or antihidrotics, and surgical treatment options are typically reserved for later lines of therapy. As a licensed antihidrotic, GPB 1% cream would occupy a new position as a topical treatment option after conservative therapy has failed but that should be considered for use prior to botulinum toxin type A, and prior to surgery. At this treatment line, the only oral medicine licensed for hyperhidrosis is propantheline bromide.</p> <p>We provide our response to each of the proposed comparators below. Text in italics below relates to a 2017 review of interventions for hyperhidrosis that explored clinical data availability for the proposed therapies.<sup>4</sup></p> <p><b>Aluminium Chloride</b></p>	<p>Thank you for your comments. Comparators have now been updated following scope consultation comments, discussions at the scoping workshop and follow-up correspondence with local commissioners. Details are provided below for each potential comparator in turn.</p> <p><b>Aluminium-based antiperspirants – not a comparator. Agreed</b></p>

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		<p>GPB 1% cream is anticipated to be positioned after failure on an aluminium-based antiperspirant. Therefore, this is not an appropriate comparator for this appraisal.</p> <p><b>Propantheline bromide</b></p> <p>Propantheline bromide is the only licensed systemic anticholinergic treatment for hyperhidrosis. There may be some degree of displacement of propantheline bromide by GPB 1% cream given that oral anticholinergic use is also considered after failure of initial conservative therapy. However, it is noted that systemic treatments are best used for generalised hyperhidrosis. Despite its license there is no randomised clinical trial data for propantheline bromide in hyperhidrosis 'There were no studies assessing the clinical effectiveness of propantheline bromide for hyperhidrosis'. This is anticipated to make indirect comparisons for the relative clinical efficacy of GPB 1% cream vs. propantheline bromide challenging to conduct.</p> <p><b>Botulinum toxin type A</b></p> <p>Botulinum toxin type A is indicated for management of severe hyperhidrosis of the axillae, which does not respond to topical treatment with antiperspirants or antihidrotics.<sup>5</sup> The topical antihidrotic GPB 1% cream will be used prior to botulinum toxin type A and is not anticipated to displace botulinum toxin type A in clinical care pathways. Therefore, this is not an appropriate comparator for this appraisal.</p>	<p>these would be used as a 1L treatment and GPB 1% cream would be used after these. Not considered a comparator.</p> <p><b>Oral anti-muscarinics such as propantheline bromide</b></p> <p>The scope has been updated to include other oral antimuscarinic treatments (off-label oxybutynin and off-label oral glycopyrronium bromide) as comparators, in addition to propantheline bromide because all 3 of these oral antimuscarinic treatments may be used in NHS clinical practice.</p> <p><b>Botulinum toxin type A.</b> – routinely commissioned in some parts of the UK but not others. Included as a comparator.</p>

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		<p>Notwithstanding this, the company would also highlight that access to botulinum toxin type A is restricted, subject to a significant degree of regional variation and requires access to trained professionals to administer the treatment, in comparison to GPB 1% cream which will be self-administered by the patient and potentially initiated and/or managed and maintained in primary care.</p> <p><b>Iontophoresis</b></p> <p>Iontophoresis is predominantly used for hyperhidrosis of the hands and feet, not for the axillae. Additionally, 'There were no studies assessing the clinical effectiveness of iontophoresis for hyperhidrosis of the axilla.' Therefore, this is not an appropriate comparator for this appraisal.</p> <p><b>Sympathectomy</b></p> <p>As sympathectomy use is only for patients who have not responded to other treatments it would be positioned further along the treatment pathway than GPB 1% cream. 'Sympathectomy is end-of-line treatment and NICE recommends Endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb only for patients 'suffering from severe and debilitating primary hyperhidrosis that has been refractory to other treatments'. Therefore, this is not an appropriate comparator for this appraisal.</p> <p>Finally, there are other off-label, systemic treatments included in the scope. These are typically intended for generalised hyperhidrosis and there are limited clinical trial data to support their use.</p>	<p><b>Iontophoresis</b></p> <p>Scoping workshop attendees and local commissioners confirmed that iontophoresis not routinely commissioned and is self-funded. Has been removed as a comparator in scope.</p> <p><b>Surgery</b></p> <p>Scoping workshop attendees confirmed rarely done as this can have poor outcomes, and if performed would be later in the treatment pathway. Removed as a comparator in the scope</p>

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			<p><b>Transcutaneous microwave ablation</b> – scoping workshop attendees were not familiar with this. Not included as a comparator in the scope</p> <p><b>Off label treatments including beta-blockers, antihypertensives and anxiolytics</b></p> <p>Scoping workshop attendees confirmed these are used for treating secondary hyperhidrosis only. Not included as comparators in the scope.</p>
Outcomes	Hyperhidrosis UK	<p>Yes, but how are these outcome measures being assessed, what methods/instruments are being used?</p> <p>As the drug product does not currently have a marketing authorisation, the price has not yet been set so economic modelling will be difficult to achieve.</p>	<p>Thank you for your comment.</p> <p>Outcomes listed in the scope are those which are anticipated to be useful to assess the</p>

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			clinical benefits of glycopyrronium bromide cream in the economic evaluation. The exact methods/instruments are not defined in the scope. The company will set the price for GBP 1% cream, which will then be used in the modelling.
	British Association of Dermatologists	<p>Health-related quality of life outcome measures such as the Hyperhidrosis Disease Severity Scale (HDSS), Hyperhidrosis Quality of Life Index (HidroQOL©) and/or Dermatology Life Quality Index (DLQI) are pragmatic outcome measures that can be completed by patients in an NHS setting.</p> <p>Measuring absolute changes in sweat production using gravimetric measurements would be difficult to implement in busy NHS hospital or GP settings.</p>	<p>Thank you for your comments. HDSS, HidroQOL and DLQI have not been added to the scope as outcomes but could be considered under the outcomes of disease severity (added) and health-related quality of life. Specific scales or instruments are not mentioned in the scope to avoid giving the impression that some measures are more acceptable than others and to discourage the exclusion of clinical</p>

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			trials that used measurement scales/instruments not specified. The outcomes listed are those intended for economic evaluation not for monitoring or defining eligibility which may be done in clinical practice.
	Leith	Yes, the outcomes listed are anticipated to capture the most important health benefit and harms.	Thank you for your comment.
Equality	Hyperhidrosis UK	Whilst the remit is for primary idiopathic hyperhidrosis there are individuals with other medical conditions or who take drugs that have sweating as a side effect that can develop secondary axillary hyperhidrosis and could benefit from this treatment.	Thank you for your comment. GPB 1% cream will be appraised in line with its UK marketing authorisation.
	British Association of Dermatologists	N/A	N/A
	Leith	Hyperhidrosis is often self-managed, and there is a significant out of pocket cost for patients. <sup>3</sup> For some treatments, this is likely to lead to inequality based on income and affordability.	Thank you for your comments. These have been noted and will be raised at the appraisal committee meeting.

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		<p>Furthermore, there are challenges for some current therapies regarding geographic availability. In a survey of dermatologists, 78% of respondents stated that iontophoresis was available and 58% of respondents stated that botulinum toxin type A was available.<sup>4</sup></p> <p>While these issues are not anticipated to directly impact on the current appraisal because neither iontophoresis nor botulinum toxin type A are considered appropriate comparators, they do support the appropriateness of appraising GPB 1% cream for national reimbursement, thereby providing comprehensive access to treatment across England and Wales.</p>	
Other considerations	Hyperhidrosis UK	<p>Given this is a new drug, post-market surveillance of adverse drug reactions should be high. The cited incidences of some ADRs in the SmPC (of the EU licensed product) seem low compared to those of the other licensed topical anticholinergics.</p> <p>As is commonly the case with botulinum toxin, I predict that the product will be used off label for other body areas such as the hands, feet, face, groin etc and for compensatory sweating post ETS surgery. Despite being off label, post market vigilance of such use is very important.</p>	Thank you for your comments. This is outside of the remit of NICE and should be considered by the regulator.
	British Association of Dermatologists	N/A	N/A
	Leith	N/A	N/A
Questions for consultation	Hyperhidrosis UK	N/A	N/A

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	British Association of Dermatologists	<p><b>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:</b></p> <ul style="list-style-type: none"> <li><b>antiperspirants (including aluminium chloride hexahydrate)</b></li> <li><b>surgical options (including subcutaneous curettage, tumescent liposuction, thoracic sympathectomy)</b></li> </ul> <p>Topical glycopyrronium bromide cream might be used in patients who fail to respond to or tolerate topical antiperspirants (including aluminium hexahydrate), ahead of iontophoresis and oral propantheline, oral oxybutynin and oral glycopyrronium bromide as:</p> <ol style="list-style-type: none"> <li>Short-term trials of iontophoresis may be available in some NHS departments of dermatology. However, patients who would like to use iontophoresis in the medium-to-long term would have to purchase or rent the machines, and would have to purchase axillary pads for the treatment of axillary hyperhidrosis. Many patients find it difficult to afford iontophoresis machines and axillary pads are not easy to use.</li> <li>Surgery is no longer offered routinely due to the risks associated with the procedures and risks of rebound sweating at the same site or compensatory hyperhidrosis at other sites with procedures such as endoscopic thoracic sympathectomy.</li> </ol> <p><b>Are the following treatments used to treat severe primary axillary hyperhidrosis in the NHS?</b></p> <ul style="list-style-type: none"> <li><b>Off label oral glycopyrronium bromide?</b></li> </ul> <p>Oral glycopyrronium bromide may not be on the formulary in some regions and in other regions, they are only available on prescription from hospital</p>	<p>Thank you for your responses.</p> <p>Comparators have now been updated following scoping consultation comments, discussions at the scoping workshop and follow-up correspondence with local commissioners. Please see comparator section for details. Off label glycopyrronium bromide and off label oxybutynin have been added as potential oral antimuscarinic drugs.</p>



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		<p>dermatologists. This may mean increased pressure in NHS departments of dermatology and inconvenience to patients who have travel to hospital for appointments and to obtain the medication.</p> <ul style="list-style-type: none"> <li>• <b>Off label oxybutynin?</b></li> </ul> <p>Off-label oxybutynin is sometimes prescribed by GPs for patients who fail to respond to or cannot tolerate topical antiperspirants.</p> <ul style="list-style-type: none"> <li>• <b>Transcutaneous microwave ablation?</b></li> </ul> <p>This is unavailable in most NHS departments of dermatology.</p> <ul style="list-style-type: none"> <li>• <b>Off label beta blockers, anxiolytics and antihypertensives? If so, which medicines are used?</b></li> </ul> <p>These treatments might be used in the management of primary hyperhidrosis but many dermatologists might not be comfortable or familiar with their use of hyperhidrosis.</p> <p><b>Would glycopyrronium bromide cream ever be used as an add on to current treatments?</b></p> <p><b>Are there treatments in the comparator list that are used together?</b></p> <p>There is potential for it to be added to treatment with oral propantheline (a licensed treatment for hyperhidrosis), e.g. if their hyperhidrosis is most severe at the axillae and higher doses of propantheline would result in adverse effects that are difficult to tolerate such as very dry mouth. It can also be difficult for some patients to take oral propantheline on an empty stomach (1h before meals and 2h after meals) to aid absorption, due to work commitments, etc.</p>	

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		<p><b>Please select from the following, will glycopyrronium bromide cream be:</b></p> <p><b>A. Prescribed in primary care with routine follow-up in primary care</b></p> <p><b>B. Prescribed in secondary care with routine follow-up in primary care</b></p> <p><b>C. Prescribed in secondary care with routine follow-up in secondary care</b></p> <p><b>D. Other (please give details):</b></p> <p>Prescribed in primary care with routine follow-up in primary care due to a lower risk of adverse effects (except perhaps for irritancy), compared with glycopyrronium bromide wipes according to the phase III trial by Abels et al. (2021). In both the phase III trial and in the long term open-label study by Szeimies (2022), most of the adverse effects (AEs) were localised skin issues, the participants do report anticholinergic AEs – but it should not stop prescribing in primary care as GPs can already prescribe oral propantheline, which has anticholinergic AEs, on the recommendation of specialists in many regions.</p> <p><b>For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.</b></p> <p>No – trial the treatment and stop if not working.</p> <p><b>Would glycopyrronium bromide cream be a candidate for managed access?</b></p>	

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		<p>Yes – if needed/dependant on provisional cost if it means that patients can have access to treatment while more cost effectiveness data is being gathered.</p> <p><b>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?</b></p> <ol style="list-style-type: none"> <li>1. Reduction of axillary hyperhidrosis would reduce discomfort/irritant dermatitis from damp clothes in the axillary area.</li> <li>2. It would make performing usual activities more tolerable – many patients with axillary hyperhidrosis bring changes of clothes to work and only wear dark coloured clothes so that damp patches are less visible.</li> <li>3. Reduction in axillary hyperhidrosis would reduce anxiety as patients would be less self-conscious of damp patches on their clothes especially in situations in which there is physical exertion or where there is heightened anxiety, e.g. work meeting/presentations, etc.</li> </ol> <p><b>Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.</b></p> <p><b>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</b></p>	

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		<p><b>for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.</b></p> <p>We are not aware of the marketing authorisation for glycopyrronium bromide in the UK; the German SmPC indicates a similar approach to the clinical trial methodology:</p> <p>The recommended dosage of Axhidrox® is two pump actuations per armpit (equivalent to 540 mg of cream or 4.4 mg glycopyrronium per armpit). After priming, the pump must be pressed down all the way twice to get the desired dose of 540 mg cream (4.4 mg glycopyrronium). During the first 4 weeks of treatment, Axhidrox® is applied to each armpit evenly, once a day, preferably in the evening. From the 5th week on, the frequency of application of Axhidrox® may be reduced to twice a week, depending on the reduction of axillary sweating. Continuous treatment of primary axillary hyperhidrosis with Axhidrox® is required to maintain the effect.</p>	
	Leith	<p><b>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:</b></p> <ul style="list-style-type: none"> <li>• <b>antiperspirants (including aluminium chloride hexahydrate)</b></li> <li>• <b>surgical options (including subcutaneous curettage, tumescent liposuction, thoracic sympathectomy)</b></li> </ul> <p>To supplement the information provided above, the company confirms that GPB 1% cream is not anticipated to be used in either population.</p>	<p>Thank you for your responses.</p> <p>Comparators have now been updated following, scoping consultation comments, discussions at the scoping workshop and follow-up correspondence with local commissioners. Please see above for details.</p>

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		<p><b>Would glycopyrronium bromide cream ever be used as an add-on to current treatments?</b></p> <p>In the clinical trials of GBP 1% cream, it was the only treatment used for hyperhidrosis.</p> <p><b>Please select from the following, will glycopyrronium bromide cream be:</b></p> <p><b>A. Prescribed in primary care with routine follow-up in primary care</b></p> <p><b>B. Prescribed in secondary care with routine follow-up in primary care</b></p> <p><b>C. Prescribed in secondary care with routine follow-up in secondary care</b></p> <p><b>D. Other (please give details):</b></p> <p>It is anticipated that prescriptions and follow up will take place in primary care (Option A).</p> <p><b>For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.</b></p> <p>The setting for prescribing and routine follow-up for GBP 1% cream is anticipated to be the same as for prescription medicine interventions currently used after aluminium-based antiperspirants and before botulinum toxin type A. The setting, prescribing and follow up for subsequent treatment (i.e.</p>	

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		<p>botulinum toxin type A and surgical options) will be different to GPB 1% cream.</p> <p><b>Would glycopyrronium bromide cream be a candidate for managed access?</b></p> <p>No. The company anticipates that there may be uncertainty regarding magnitude of clinical benefit. However, this is related to lack of data available for the anticipated comparator, which managed access would not address.</p> <p><b>Do you consider that the use of glycopyrronium bromide 1% cream can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?</b></p> <p>Hyperhidrosis has a substantial patient burden, both clinical and economic, some of which is unlikely to be captured in the QALY calculation. For example, hyperhidrosis has a negative impact on productivity and number of days at work.<sup>6</sup> Improving outcomes for patients with hyperhidrosis is anticipated to provide productivity benefits that are unlikely to be captured in the QALY calculation.</p> <p><b>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</b></p>	

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		<p><b>you think that the proposed remit and scope may need changing in order to meet these aims.</b></p> <p>The company does not anticipate any changes to the remit to address NICE's commitment.</p>	
Additional comments on the draft scope	Hyperhidrosis UK	N/A	N/A
	British Association of Dermatologists	N/A	N/A
	Leith	N/A	N/A

**The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope**

N/A

## References

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