

Single Technology Appraisal

Glycopyrronium bromide cream for treating severe primary axillary hyperhidrosis [ID6487]

Committee Papers

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

SINGLE TECHNOLOGY APPRAISAL

Glycopyrronium bromide cream for treating severe primary axillary hyperhidrosis [ID6487]

Contents:

The following documents are made available to stakeholders:

1. [**Comments on Draft Guidance 2 from Leith Healthcare**](#)
2. [**Comments on Draft Guidance 2 from experts:**](#)
 - a. [Mr Shanka Benaragama, Consultant Vascular and Endovascular Surgeon – Clinical Expert](#)
3. [**External Assessment Group critique of company response to the DG2:**](#)
 - a. [EAG Critique](#)
 - b. [EAG Addendum](#)

Any information supplied to NICE which has been marked as confidential, has been redacted. All personal information has also been redacted.

**Glycopyrronium bromide cream for treating severe primary axillary hyperhidrosis
[ID6487]**

Draft guidance comments form

Consultation on the draft guidance document – deadline for comments end of day on 27 March 2026. Please submit via NICE Docs.

	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly. The Appraisal Committee is interested in receiving comments on the following: • has all of the relevant evidence been taken into account? • are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? • are the provisional recommendations sound and a suitable basis for guidance to the NHS? 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 preliminary recommendations may need changing in order to meet these aims. In particular, please tell us if the preliminary recommendations: • could have a different impact on people protected by the equality legislation than on the wider population, for example 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 provide any relevant information or data you have regarding such impacts and how they could be avoided or reduced.
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	Leith Healthcare

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Disclosure Please disclose any funding received from the company bringing the treatment to NICE for evaluation or from any of the comparator treatment companies in the last 12 months. [Relevant companies are listed in the appraisal stakeholder list.] Please state: - the name of the company - the amount - the purpose of funding including whether it related to a product mentioned in the stakeholder list - whether it is ongoing or has ceased.	N/A
Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	N/A
Name of commentator person completing form:	
Comment number	Comments Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
1	We are pleased that GPB 1% cream has progressed to this stage of the appraisal process and will be available for some patients with primary axillary hyperhidrosis (PAHH), though note that the current recommendation positions GPB 1% cream after oral antimuscarinics. We are concerned that this recommendation does not fully take into account the evidence presented in the company submission and heard during the committee meetings, and – importantly – restricts clinicians and

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	patients from choosing the most appropriate treatment for patients based on their needs, and willingness to tolerate the adverse events associated with oral anticholinergics. In particular the company is concerned that requiring patients to try a therapy which patient groups and clinicians have confirmed is associated with systemic anticholinergic effects that lead to lack of compliance with treatment, does not constitute patient-centred care, particularly as it is based on an indirect treatment comparison associated with substantial uncertainty, driven by lack of robust comparator data with which to compare with GPB 1% cream's randomised controlled trial data. Furthermore, oral anticholinergics have not been appraised through the NICE process for PAHH, meaning their relative clinical and cost-effectiveness have not been formally evaluated for use in the NHS. GPB 1% cream is the first non-invasive topical anticholinergic treatment specifically indicated for severe PAHH, and we believe requiring preferential consideration of oral antimuscarinics before GPB 1% cream, fails to take into full account several areas of the evidence available to NICE, and specific aspects of the management of PAHH: Difference in the levels of evidence for GPB 1% cream and propantheline bromide for the treatment of PAHH Propantheline bromide has not been appraised by NICE and lacks robust prospective or retrospective trial data for PAHH. The comparative evidence supporting its use is weak and consequently the data preferred by the committee is for a different drug, methantheline bromide, which is not used in routine clinical practice. The main basis for assuming propantheline bromide provides better efficacy than GPB 1% cream are ITCs showing a numerical, but not statistically significant, difference versus GPB 1% cream. These analyses have numerous limitations and should not be interpreted as reflective of real-world outcomes. Importantly, the confidence intervals for these ITCs cross the boundary of 1.0, leading to substantial uncertainty around the relative efficacy of propantheline bromide vs GPB 1% cream. Minor changes in odds ratios for these ITCs shift the net monetary benefits to favour GPB 1% cream. Safety, tolerability, and patient preference considerations Oral antimuscarinics like propantheline bromide require dosing multiple times a day and have systemic side effects, whereas GPB 1% cream is topical cream with dosing from as low as twice a week after the initiation period, with a more favourable tolerability profile. Due to the adverse effects associated with long-term use of oral antimuscarinic medications, patients are often advised to use them only when necessary (e.g. when going to public events), rather than on a daily basis¹. There are also practical challenges with long term use of oral antimuscarinics, such as needing to take tablets on an empty stomach. Patients should be able to choose the treatment that best balances efficacy, safety and practicality for them. Importantly, the data used in the ITCs do not reflect these real-world treatment patterns for oral anticholinergic use i.e. the ITCs are based on limited trial data for a short period where compliance was higher than would be expected in routine longer term clinical practice. Heterogeneous disease population PAHH varies widely between patients in severity and impact. A rigid sequence does not reflect the clinical heterogeneity seen in practice. Allowing choice between therapies supports individualised care, especially considering differences in tolerability, application, and patient preference. For some patients, GPB 1% cream may be more suitable than oral therapy.
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	Based on the available evidence and real-world practice, we believe that it would be more appropriate to recommend that GPB 1% cream can be used as an option without preferential consideration of oral antimuscarinics. We believe the recommendation should be amended to <i>Glycopyrronium bromide (GPB) cream can be used as an option for treating severe primary axillary hyperhidrosis in adults, if lifestyle advice and topical aluminium-based antiperspirants</i> <i>• have not controlled underarm sweating, or</i> <i>• are contraindicated or not tolerated</i> <i>The choice of treatment with GPB 1% cream or oral antimuscarinics should be made after an informed discussion between the clinician and the person about the benefits and risks of each option.</i> This wording would better reflect the evidence base for GPB 1% cream, the heterogeneity of patient needs, and the importance of individualised treatment decisions. We set out further evidence in support of our position below.
2	Limited evidence for oral antimuscarinics – international guidelines recommend topical anticholinergics first As previously noted in the 2017 systematic review¹, there was no prospective or retrospective data available for propantheline bromide in the treatment of hyperhidrosis identified. The company's systematic literature review of 2025 did not identify any new data since the 2017 systematic review. The most recently updated international hyperhidrosis guideline is the Japanese 2023 Guideline for Primary Focal Hyperhidrosis². Updates were needed because topical anticholinergic medications became reimbursable (Sofpironium bromide gel (2020) & glycopyrronium tosylate wipes (2022)). Like the UK, propantheline bromide is the only licensed oral antimuscarinic for the treatment of hyperhidrosis in Japan. The Japanese guidelines provide a recommendation rating and evidence level*. For axillary hyperhidrosis, the ratings are. • Topical anticholinergics and botulinum toxin a. Grade B (Recommended. Supported by lower quality Level II, good Level III, or very good Level IV evidence.) • Oral anticholinergics. Grade C1. May be considered, but evidence is insufficient. Evidence is weak (low quality III–IV, multiple V, or expert consensus). The Japanese guidelines recommend a stepwise approach; aluminium chloride antiperspirants > topical anticholinergics > botulinum toxin a > oral anticholinergics > device based treatments > Sympathectomy This aligns with the treatment approach for PAHH outlined by the International Hyperhidrosis Society³ (updated 2024). In this treatment guide, after antiperspirants have proved inadequate, treatment with topical anticholinergics or botulinum toxin a is recommended before consideration of oral anticholinergics.

Glycopyrronium bromide cream for treating severe primary axillary hyperhidrosis [ID6487]

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	Primary Axillary Hyperhidrosis Treatment Guide Throughout care journey, consider combination therapy to maximize efficacy and minimize risk of side effects. Adjust to patient experiences, preferences and disease presentation. BEGIN *For all at-home topical treatments, educate patients regarding application regimen, and other techniques to maximize efficacy and minimize side effects.
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	Expert 2 said that his secondary care clinic had experience with topical GPB application (used by his clinic as an unlicensed medicine). He said that they had observed significant efficacy, durability and tolerability for topical GPB compared to oral propantheline bromide. Expert 1 said he did not have any personal experience with topical GPB. He went on to say that the mechanisms of action for GPB 1% cream and oral anticholinergics are the same, most of the data for oral treatment is from generalised HH and therefore data needs to be extrapolated to PAHH. He said that clinicians are used to oral preparations as there is not a lot of access to topical treatments but noted that, when looking at the clinical data so far, it did appear that GPB 1% cream can be effective with reductions in HDSS and sweat production. Expert 1 then concluded that he believed it was reasonable for GPB 1% cream to be a second line therapy although his personal preference would be to use it as an adjuvant until more data is collected. Just as the ITCs have wide confidence intervals that cross the boundary of 1.0, meaning that the overall direction of relative efficacy cannot be concluded, the feedback from the experts also indicates that the direction of relative efficacy cannot be concluded. This further supports the company's position that patients should have a choice of treatment with topical or oral therapy after failure of antiperspirants.
4	Additional evidence of the real-world efficacy of GPB 1% cream shows high levels of effectiveness when compared to similar evidence for oxybutynin in PAHH We reiterate the importance of the real-world data we provided that was not available at the time of our initial submission. This data was critiqued in draft guidance 2. 'The company also cited real-world evidence⁴ by Gioacchini et al. (2025) which it suggested showed higher HDSS response rates with GPB 1% cream than with oral antimuscarinics in PAHH. The committee noted that Gioacchini et al. was a small retrospective observational study done in 2 Italian centres, including 68 people with primary hyperhidrosis affecting different areas. It also noted that the HDSS change-from baseline efficacy data was reported only for GPB 1% cream and did not include oral antimuscarinics. So, the committee thought that this study did not provide a valid basis for comparing GPB 1% cream with oral antimuscarinics' We agree with the committee that these data are not comparative. However, they provide information on real-world outcomes for GPB 1% cream, which is of importance given the limitations in the data used for oral antimuscarinics throughout the appraisal, and knowledge about real-world outcomes for oral antimuscarinics (described below). The data presented by the company confirms the real-world efficacy of GPB 1% cream and – crucially – is in a patient population of interest given 69% of the patients had had previous treatment with antiperspirants. The HDSS responder rate for the 31 patients with PAHH of 76% at week 4, 70% at week 12 with dosing frequency reduced, needs to be considered as part of the totality of evidence to assess the likely effectiveness of GPB 1% cream. By contrast, retrospective data for the oral anticholinergic oxybutynin⁵ for HDSS responder rates in patients with PAHH from Wolosker et al. (2020) showed HDSS responder rates of 59%, considerably lower than the rates for GPB 1% cream. While we appreciate that these are naïve comparisons and not adjusted for differences in patient population, we do not believe that they

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	support a recommendation based on oral anticholinergic providing better efficacy than GPB 1% cream. This further supports the company's position that patients should have a choice of treatment with topical or oral therapy after failure of antiperspirants.

Insert extra rows as needed

Checklist for submitting comments

- Use this comment form and submit it as a Word document (not a PDF).
- Complete the disclosure about funding from the company and links with, or funding from, the tobacco industry.
- Combine all comments from your organisation into one response. We cannot accept more than one set of comments from each organisation.
- Do not paste other tables into this table – type directly into the table.
- In line with the [NICE Health Technology Evaluation Manual](#) (sections 5.4.4 to 5.4.21), if a comment contains confidential information, it is the responsibility of the responder to provide two versions, one complete and one with the confidential information removed (to be published on NICE's website), together with a checklist of the confidential information. Please underline all confidential information, and separately highlight information that is submitted as 'confidential [CON]' in turquoise, and all information submitted as 'depersonalised data [DPD]' in pink. If confidential information is submitted, please submit a second version of your comments form with that information replaced with asterixis and highlighted in black.
- Do not include medical information about yourself or another person from which you or the person could be identified.
- Do not use abbreviations.
- Do not include attachments such as research articles, letters or leaflets. For copyright reasons, we will have to return comments forms that have attachments without reading them. You can resubmit your comments form without attachments, it must send it by the deadline.
- If you have received agreement from NICE to submit additional evidence with your comments on the draft guidance document, please submit these separately.

Note: We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

Comments received during our consultations 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 comments we received, and are not endorsed by NICE, its officers or advisory committees.

**Glycopyrronium bromide cream for treating severe primary axillary hyperhidrosis
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References

1. Wade R, Rice S, Llewellyn A, Moloney E, Jones-Diette J, Stoniute J, et al. Interventions for hyperhidrosis in secondary care: a systematic review and value-of-information analysis. *Health Technology Assessment (Winchester, England)* 2017; **21**: 1-280.
2. Primary Focal Hyperhidrosis Guideline Development Committee, Japanese Dermatological Association. (2023). Guidelines for the Management of Primary Focal Hyperhidrosis: 2023 Revision [原発性局所多汗症診療ガイドライン 2023 年改訂版]. *Journal of the Japanese Dermatological Association*, 133(2), 157–188.
3. Primary Axillary Hyperhidrosis Treatment Guide. Revised February 2025 © International Hyperhidrosis Society.
<https://www.sweathelp.org/treatments-hcp/clinical-guidelines/primary-focal-hyperhidrosis/primary-focal-axillary.html>
4. Gioacchini H, Marani A, Diotallevi F, Rossi A, Lambiase S, Maffei V, et al. Efficacy and Safety of Glycopyrronium Bromide 1% Cream in Axillary and Extra-Axillary Primary Hyperhidrosis: A Real-Life Two-Center Experience on 68 Subjects. *Dermatologic Therapy*. 2025;2025(1):7069427.
5. Wolosker N, Kauffman P, de Campos JRM, Faustino CB, da Silva MFA, Teivelis MP, et al. Long-term results of the treatment of primary hyperhidrosis with oxybutynin: follow-up of 1,658 cases. *Int J Dermatol*. 2020 Jun;59(6):709–15

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Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	Royal Free Hospital NHS Trust London

**Glycopyrronium bromide cream for treating severe primary axillary hyperhidrosis
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Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	None
Name of commentator person completing form:	Mr Shanka Benaragama
Comment number	Comments Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
Example 1	We are concerned that this recommendation may imply that
1	I am concerned that the draft recommendation requires oral antimuscarinics to be considered before GPB 1% cream for the treatment of hyperhidrosis of the axillae. In our experience using topical GPB cream we have found it to be effective and well tolerated for focal hyperhidrosis. If

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**Glycopyrronium bromide cream for treating severe primary axillary hyperhidrosis
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	antiperspirants have failed to provide sufficient control of axillary hyperhidrosis, we would expect topical GPB cream to be a next step for healthcare professionals in primary care to take, prior to referring patients to secondary care hyperhidrosis specialists. (will follow the treatment ladder for the hyperhidrosis) Given the difficulties many patients with long term oral antimuscarinic use, and the limited usefulness of oral antimuscarinics for focal hyperhidrosis compared to generalised hyperhidrosis, we do not agree with the recommendation that GPB 1% cream should only be considered after oral antimuscarinics.
2	
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Insert extra rows as needed

Checklist for submitting comments

- Use this comment form and submit it as a Word document (not a PDF).
- Complete the disclosure about funding from the company and links with, or funding from, the tobacco industry.
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EAG response to company draft guidance 2 comments

April 2026

Source of funding

This report was commissioned by the NIHR Evidence Synthesis Programme as project number 175751.

1 Summary

This document provides the External Assessment Group's (EAG's) critique of the company's response to the draft guidance 2 (DG2) document produced by the National Institute for Health and Care Excellence (NICE) for the appraisal of glycopyrronium bromide (GPB) 1% cream for treating severe primary axillary hyperhidrosis (PAHH).

Overall, the EAG considers that no new evidence has been put forward by the company to enable a robust comparison of GPB 1% cream versus oral anticholinergics; the EAG's detailed response to the company's comments on DG2 is provided in Section 2. However, the EAG maintains its view, detailed in the EAG response to company draft guidance 1 comments, that the indirect treatment comparison (ITC) for antimuscarinics versus GPB 1% cream using antimuscarinics data from Schollhammer *et al.* comprises the most robust estimate for the comparison of GPB 1% cream versus oral antimuscarinics based on all the data presented by the company to date.

2 EAG critique of company comments

The company provided four comments on the draft guidance for glycopyrronium bromide (GPB) 1% cream, and the EAG has provided detailed responses to each comment in the subsections below.

2.1 Company comment 1: Wording for the NICE recommendation

The wording of the relevant draft recommendation by NICE is: GPB cream can be used as an option for treating severe PAHH in adults, if lifestyle advice, topical aluminium-based antiperspirants and oral antimuscarinics have not controlled underarm sweating, or are contraindicated or not tolerated.¹ The EAG notes that the company is arguing for GPB 1% cream to be recommended for use prior to oral antimuscarinics, and the EAG does not consider the company to have provided any new clinical or cost-effectiveness evidence for GPB 1% cream in the company response document.

2.2 Company comment 2: Limited evidence for oral antimuscarinics

In the company response, the Japanese 2023 Guideline for Primary Focal Hyperhidrosis² is detailed but the EAG notes the guideline is in Japanese and the EAG was unable to obtain a formal translation to fully review the guideline in the time available. The EAG notes that this guideline is not a UK guideline and that the treatment approach recommended, therefore, does not necessarily reflect treatments available in the NHS in England. The EAG notes that the company highlights how the Japanese guideline and the International Hyperhidrosis Society³ provide similar recommendations for the treatment of PAHH after antiperspirants have proved inadequate, with both guidelines recommending treatment with topical anticholinergics or botulinum toxin A prior to oral anticholinergics. The EAG considers it important to highlight that the availability of botulinum toxin A was reported by clinical experts in appraisal committee meeting two (ACM2) to be limited in the UK, and there may be restrictions on the number of treatment cycles.¹ In addition, oral anticholinergics were presented as a treatment alternative to botulinum toxin A in secondary care in the proposed treatment pathway in Figure 2 of the company submission. The EAG notes that the company's proposed positioning of GPB 1% cream remains unchanged from the company submission in terms of being positioned after lifestyle advice and topical aluminium-based antiperspirants. However, the EAG reiterates that no new evidence has been provided by the company to demonstrate that GPB 1% cream is cost-effective compared to oral anticholinergics.

2.3 Company comment 3: Expert input provided to NICE during ACM2 about the relative efficacy of topical GPB and oral anticholinergics

The company cited information provided by the clinical experts at ACM2 in the company response, concluding that it provides support for the company's position that patients should have a choice of treatment with topical or oral therapy after failure of antiperspirants. The EAG received additional feedback from two of its clinical experts, and [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The EAG notes that the clinical evidence available for the treatments remains unchanged, with no new clinical data provided by the company.

2.4 Company comment 4: Additional evidence of the real-world efficacy of GPB 1% cream

The company reiterated the real-world evidence (RWE) by Gioacchini *et al.* 2025⁴ that they provided in the company response to draft guidance following appraisal committee meeting one (ACM1) as providing further support for the efficacy of GPB 1% cream. Gioacchini *et al.* 2025 reported real-world evidence from two Italian tertiary centre dermatology clinics. Results were reported for 68 patients (43% male, 57% female; mean age 40 ± 16 years) who were prescribed GPB 1% cream for primary hyperhidrosis. The sites affected by hyperhidrosis were axillary, palmar, plantar, craniofacial or multiple localisations (axilla and palmoplantar, and axilla and craniofacial) and a total of 31 patients (45%) had only localised PAHH. Patients were ≥ 18 years of age, had primary hyperhidrosis for a minimum of six months and a Hyperhidrosis Disease Severity Scale (HDSS) of 3 or 4. Baseline prior treatments were reported for the overall study population rather than only the PAHH subgroup, but most patients (69%) had received antiperspirant as prior treatment with a small percentage who had received other treatments (between 3% to 12% received either iontophoresis, botulinum toxin, oral anticholinergic or "other"). Overall, 10% of patients in the study had received no prior treatment.

The EAG notes that the percentage of patients in the Gioacchini *et al.* 2025 study who achieved a response defined as a ≥ 2 -point reduction in HDSS score at four weeks was 76% for PAHH patients. In addition, despite a reduction in GPB 1% cream dosing frequency after 4 weeks in the study that does not directly align with the MHRA marketing authorisation⁵, the percentage of patients who achieved

a response was still 70% for PAHH patients at 12 weeks. However, the EAG notes that this study does not provide suitable data to enable a reliable comparison between GPB 1% cream and oral antimuscarinics due to the single-arm nature of the study.

In the company response a further study (Wolosker *et al.* 2020)⁶ was discussed with regard to HDSS response data for the oral anticholinergic oxybutynin. The EAG notes that this study was referred to in the company response to draft guidance following ACM1 in relation to the discontinuation rates for antimuscarinics in clinical practice. The EAG notes that it is a non-randomised study and considers it to be unclear how the study was identified; therefore, the EAG recommends caution in drawing any conclusions from this study. The study by Wolosker *et al.* 2020 was a retrospective analysis of patients with primary hyperhidrosis treated with oral oxybutynin as first-line treatment in Brazil and included 569 patients with PAHH. It provides no comparative data for oral antimuscarinics and GPB 1% cream, is not a UK based study and the data are limited to first-line treatment. The EAG therefore does not consider it appropriate to use the Wolosker *et al.* 2020 study to draw conclusions on the comparative efficacy of oral oxybutynin versus GPB 1% cream.

In conclusion, the EAG is concerned with the potentially selective identification of RWE for GPB cream and oral antimuscarinics. In addition, the EAG does not consider the data presented from the RWE studies in the company response to be suitable for drawing reliable conclusions on the efficacy of GPB 1% cream versus oral antimuscarinics. The EAG maintains its view detailed in the EAG response to company draft guidance 1 comments⁷, that the indirect treatment comparison (ITC) for antimuscarinics versus GPB 1% cream using antimuscarinics data from Schollhammer *et al.*⁸ comprises the most robust estimate for the comparison of GPB 1% cream versus oral antimuscarinics from all the data presented by the company so far. In addition, as previously highlighted, the EAG does not consider a lack of statistical significance in the results from the company's ITCs to be sufficient evidence to conclude clinical equivalence.

3 References

1. National Institute for Health and Care Excellence (NICE). Draft guidance 2 consultation – Glycopyrronium bromide cream for treating severe primary axillary hyperhidrosis, 2026. Available from: <https://www.nice.org.uk/guidance/GID-TA11628/documents/draft-guidance-2>. Date accessed: April 2026.
2. Primary Focal Hyperhidrosis Guideline Development Committee. Japanese Dermatological Association Guidelines for the Management of Primary Focal Hyperhidrosis: 2023 Revision [In Japanese]. *Journal of the Japanese Dermatological Association* 2023; **133**: 157–88.
3. International Hyperhidrosis Society. Primary Axillary Hyperhidrosis Treatment Guide, 2025. Available from: <https://www.sweathelp.org/pdf/axillary-2024%20Axillary%20guideline.pdf>. Date accessed: April 2026.
4. Gioacchini H, Marani A, Diotallevi F, Rossi A, Lambiase S, Maffei V, et al. Efficacy and Safety of Glycopyrronium Bromide 1% Cream in Axillary and Extra-Axillary Primary Hyperhidrosis: A Real-Life Two-Center Experience on 68 Subjects. *Dermatologic Therapy* 2025; **2025**: 7069427.
5. Medicines and Healthcare products Regulatory Agency. SUMMARY OF PRODUCT CHARACTERISTICS - Axhidrox pump-pack 2.2 mg/pump actuation cream 2025. Available from: <https://mhraproducts4853.blob.core.windows.net/docs/d04c96f47621161bdee5a331f818386695775db5>. Date accessed: April 2026.
6. Wolosker N, Kauffman P, de Campos JRM, Faustino CB, da Silva MFA, Teivelis MP, et al. Long-term results of the treatment of primary hyperhidrosis with oxybutynin: follow-up of 1,658 cases. *Int J Dermatol* 2020; **59**: 709-15.
7. BMJ-Technology Assessment Group. Glycopyrronium bromide cream for treating severe primary axillary hyperhidrosis [ID6487]: EAG response to company draft guidance comments, 2025. Available from: <https://www.nice.org.uk/guidance/gid-ta11628/documents/committee-papers-2>. Date accessed: April 2026.
8. Schollhammer M, Brenaut E, Menard-Andivot N, Pillette-Delarue M, Zagnoli A, Chassain-Le Lay M, et al. Oxybutynin as a treatment for generalized hyperhidrosis: a randomized, placebo-controlled trial. *British journal of dermatology* 2015; **173**: 1163-8.



Glycopyrronium bromide cream for treating severe primary axillary hyperhidrosis [ID6487]

ACM 4 scenario

April 2026

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1 Summary

This document provides the results of a scenario requested by the National Institute for Health and Care Excellence (NICE) for committee consideration for appraisal committee meeting 4 (ACM 4) for the topic of glycopyrronium bromide (GPB) 1% cream treating severe primary axillary hyperhidrosis. The scenario implements an assumption previously provided by the company, assuming equal effectiveness of GPB 1% cream and oral antimuscarinics and this is applied to the committee preferred base case post appraisal committee meeting 2 (ACM 2).

As a reminder, the results of the committee preferred base case for the primary and secondary care models are presented in Table 1 (primary care model) and Table 3 to Table 5 (secondary care model). Results of the NICE requested scenario are presented in Table 2 (primary care model) and Table 6 (secondary care model).

The EAG notes that under the assumption of equal effectiveness, GPB 1% cream results in a [REDACTED] in both the primary and secondary care models compared to oral antimuscarinics, leading to results that might have an impact on committee decision making. In the model, treatment discontinuation is greater for oral antimuscarinics than with GPB 1% cream. Therefore, combined with a reduction in effectiveness for oral antimuscarinics to be equal to GPB 1% cream, there is a reduction in the improvement in HDSS scores for patients on oral antimuscarinics as well as remaining in the better HDSS health states, compared with the committee base case, resulting in the [REDACTED] for GPB 1% cream.

However, the EAG maintains its view, detailed in the EAG response to company draft guidance 1 comments, that the indirect treatment comparison (ITC) for antimuscarinics versus GPB 1% cream using antimuscarinics data from Schollhammer *et al.* comprises the most robust estimate for the comparison of GPB 1% cream versus oral antimuscarinics based on all the data presented by the company to date.

1.1 Primary care model

Table 1. Primary care model – committee base case post ACM2, GPB 1% cream versus propantheline bromide

Interventions	Total Costs (£)	Total LY	Total QALYs	Incremental costs (£)	Incremental LYs	Incremental QALYs	ICER (£/QALY)
Deterministic results							
Propantheline bromide				-	-	-	-
GPB 1% cream							
Probabilistic results							
Propantheline bromide				-	-	-	-
GPB 1% cream							
Abbreviations: GPB, glycopyrronium bromide; ICER, incremental cost-effectiveness ratio; LY, life year; QALY, quality-adjusted life-year; SW, south-west.							

1.1.1 Scenarios around the primary care model base case

Table 2. NICE requested scenario analysis

Scenario	Incremental costs	Incremental QALYs	ICER (£/QALY)
Committee base case			
Equal effectiveness of propantheline bromide and GPB 1% cream			
Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year; SW, south-west.			

1.2 Secondary care model

Table 3. Secondary care model – committee preferred assumption, GPB 1% cream versus modified-release oxybutynin

Interventions	Total Costs (£)	Total LY	Total QALYs	Incremental costs (£)	Incremental LYs	Incremental QALYs	ICER (£/QALY)
Deterministic results							
Modified-release oxybutynin				-	-	-	-

Interventions	Total Costs (£)	Total LY	Total QALYs	Incremental costs (£)	Incremental LYs	Incremental QALYs	ICER (£/QALY)
Deterministic results							
GPB 1% cream							
Probabilistic results							
Modified-release oxybutynin				-	-	-	-
GPB 1% cream							
Abbreviations: GPB, glycopyrronium bromide; ICER, incremental cost-effectiveness ratio; LY, life year; QALY, quality-adjusted life-year; SW, south-west.							

Table 4. Secondary care model – committee preferred assumptions, GPB 1% cream versus botulinum toxin A

Interventions	Total Costs (£)	Total LY	Total QALYs	Incremental costs (£)	Incremental LYs	Incremental QALYs	ICER (£/QALY)
Deterministic results							
Botulinum toxin A				-	-	-	-
GPB 1% cream							
Probabilistic results							
Botulinum toxin A				-	-	-	-
GPB 1% cream							
Abbreviations: GPB, glycopyrronium bromide; ICER, incremental cost-effectiveness ratio; LY, life year; QALY, quality-adjusted life-year; SW, south-west.							

Table 5. Fully incremental analysis (based on PSA results) – Secondary care model, committee preferred assumptions

Interventions	Total Costs (£)	Total LY	Total QALYs	Incremental costs (£)	Incremental LYs	Incremental QALYs	ICER (£/QALY)
Modified-release oxybutynin				-	-	-	-
GPB 1% cream							
Botulinum toxin A							
Abbreviations: GPB, glycopyrronium bromide; ICER, incremental cost-effectiveness ratio; LY, life year; QALY, quality-adjusted life-year; SW, south-west.							

1.2.1 Scenarios around the secondary care model

Table 6. NICE requested scenario analysis

Scenario	Oral antimuscarinics			Botulinum toxin A		
	Incremental costs	Incremental QALYs	ICER (£/QALY)	Incremental costs	Incremental QALYs	ICER (£/QALY)
Committee base case						
Equal effectiveness of modified release oxybutynin and GPB 1% cream						

Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year; SW, south-west.