SMC2912

garadacimab solution for injection in pre-filled pen (Andembry®)

CSL Behring UK Ltd

09 October 2026

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutics Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following a full submission

garadacimab (Andembry®) is accepted for use within NHSScotland.

Indication under review: for routine prevention of recurrent attacks of hereditary angioedema (HAE) in adult and adolescent patients aged 12 years and older.

A double-blind, phase III study demonstrated that garadacimab significantly reduced the number of HAE attacks per month compared with placebo. Indirect comparisons suggest that garadacimab may have at least similar efficacy to berotralstat, lanadelumab, and a plasma-derived intravenous C1 esterase inhibitor.

This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.

Co Vice Chair
Scottish Medicines Consortium

1. Clinical Context

1.1. Medicine background

Garadacimab is a monoclonal antibody that binds and inhibits Factor XIIa, a protein that triggers the production of bradykinin, which is associated with inflammation and swelling in hereditary angioedema (HAE) attacks.[1, 2] The recommended dose is an initial loading dose of 400 mg garadacimab, administered subcutaneously as two 200 mg injections on the first day of treatment, followed by a monthly dose of 200 mg garadacimab. Consideration should be given to discontinuing treatment in patients who have shown insufficient reduction in attacks after 3 months of treatment.[1]

1.2. Disease background

HAE is a rare, serious and potentially life-threatening genetic disease that is most commonly caused by mutations in the gene coding for C1-esterase inhibitor, resulting in deficiency or dysfunction of C1-inhibitor protein. It is characterised by recurrent, acute, often unpredictable attacks of painful swelling typically in the skin, pharynx, larynx, gastrointestinal tract, genitals, or extremities. Cutaneous and abdominal attacks are the most common sites, however the most serious risk for patients with HAE is laryngeal attacks which can be life-threatening. Laryngeal episodes account for less than 1% of all attacks, however all patients with HAE are at risk and more than 50% will experience a laryngeal attack in their lifetime.[3] HAE is associated with a sizeable reduction in quality of life, driven by fear of unpredictable attacks. School and work absenteeism is usually high, and there is a negative impact on patients' mental health.[4]

1.3. Treatment pathway and relevant comparators

Treatment of HAE includes acute treatment of attacks, short-term (for example, pre-procedural) and long-term prophylactic treatment. Long-term prophylaxis involves the regular use of medication aimed at achieving complete disease control by preventing attacks. All patients should be evaluated for long-term prophylaxis. Treatment choice is individualised and based on disease severity, quality of life, age, treatment burden and patient preferences.[4]

First-line long-term prophylactic treatment options include lanadelumab (SMC2206), which was accepted by SMC for restricted use within NHSScotland for patients who would otherwise be considered for long-term prophylaxis treatment with C1-esterase inhibitor, and berotralstat (SMC2405) which was accepted by SMC for restricted use in patients who experience ≥2 clinically significant attacks per month.

When first-line treatments are unavailable, not feasible, or not tolerated, an intravenous C1-esterase inhibitor, attenuated androgens (such as stanozolol and danazol), or tranexamic acid may be used.[4]

1.4. Category for decision-making process

Eligibility for a PACE meeting

Garadacimab meets SMC orphan equivalent criteria for this indication.

2. Summary of Clinical Evidence

2.1. Evidence for the licensed indication under review

Evidence to support the efficacy and safety of garadacimab for routine prevention of recurrent attacks of HAE comes from the VANGUARD study. Details are summarised in Table 2.1.

Table 2.1. Overview of relevant studies

Criteria	VANGUARD[3,5]
Study design	International, randomised, double-blind, phase III study

Eligible patients	• ≥12 years of age
	• Clinically confirmed diagnosis of HAE with C1-INH deficiency (type I/II HAE), defined as:
	  ○ Documented clinical history consistent with type I and II HAE (subcutaneous or mucosal, nonpruritic swelling episodes without accompanying urticaria), and
	  ○ C1-INH antigen and/or functional activity ≤50% of normal as documented in the patient's medical record, and
	  ○ C4 antigen concentration below the lower limit of the reference range (reference range: 0·16 to 0·38 mg/mL)
	• Experienced ≥3 HAE attacks during the 3 months before screening (inclusion criteria for the run-in period)
	• Experienced an average of ≥1 HAE attack per month during the run-in period (inclusion criteria for the treatment period)

Treatments	Garadacimab 400 mg loading dose then 200 mg once per month thereafter, administered via subcutaneous injection, or placebo. Patients were permitted to receive on-demand (acute) treatments for HAE and treatments for the prevention of HAE attacks before any surgical procedure.
Randomisation	Patients were randomised in a 3:2 ratio. Randomisation was stratified according to age (≤17 years versus >17 years), and for adults, the patient's baseline attack rate (1 to <3 attacks/month versus ≥3 attacks/month).
Primary outcome	Time-normalised number of investigator-confirmed HAE attacks (per month and annualised) during treatment from day 1 through day 182 (6 months).
Key secondary outcomes	• Percent reduction in monthly attack rate compared with placebo (day 1 to 182). • Number of attack-free patients through day 91. • Percentage of patients rating therapy as "good" or better (that is, "excellent") through the SGART at day 182.
Statistical analysis	Efficacy analyses were performed in the ITT population, which included all patients who underwent randomisation. A hierarchical statistical testing strategy was applied in the study to control for type I error across the primary outcome and three key secondary outcomes.

Abbreviations: C1-INH = C1-esterase inhibitor; HAE = hereditary angioedema; ITT = intention-to-treat; SGART = Subject's Global Assessment of Response to Therapy.

During the 6-month treatment period, the mean number of investigator-confirmed HAE attacks per month was significantly lower in the garadacimab group compared with placebo. Key secondary outcomes were also statistically significant. See Table 2.2 for details. In the company's submission, an alternative case was also presented in the subpopulation of patients who experience ≥2 attacks per month at baseline (which aligns with berotralstat SMC2405 advice).

Table 2.2. Key efficacy results for VANGUARD.[3, 5, 6]

	ITT population	
	Garadacimab (n=39)	**Placebo (n=25)**
Number of evaluable patients, n	39	24
Total number of HAE attacks (day 1 to day 182)	63	264
Primary outcome: time-normalised number of HAE attacks per month		
Mean number of HAE attacks per month	0.27	2.01
P-value	p<0.001	
Key secondary outcomes		
Percentage difference in the mean number of HAE attacks per month versus placebo during entire 6-month treatment period, p-value	-87% (95% CI: -96% to -58%) p<0.001	
Patients with no attacks during the first 3 months of the treatment period	72%	8.3%
P-value	p<0.001	
Percentage of patients rating therapy as good or better through the SGART at day 182	82%	33%
P-value	p<0.001	

Abbreviations: CI = confidence interval; HAE = hereditary angioedema; ITT = intention-to-treat; SGART = Subject's global assessment of response to therapy

2.2. Health-related quality of life outcomes

Health Related Quality of Life (HRQoL) was assessed using the following questionnaires: EQ-5D-5L, Angioedema quality of life (AE-QoL) questionnaire, Work Productivity and Activity Impairment: General Health (WPAI:GH) questionnaire and Investigator's Global Assessment of Response to Therapy. Overall, descriptive results suggest a greater improvement in quality of life in the garadacimab group compared with placebo, as evidenced by total mean AE-QoL scores measured at baseline, day 31, and day 182 (adults only).[3]

2.3. Supportive studies

CSL312_3002 is a single-arm, open-label extension study investigating the long-term safety and efficacy of garadacimab in patients with HAE. Patients could enrol in the study if they had completed the prior phase II or the phase III VANGUARD study or as a newly enrolled patient. Overall, 161 patients entered the CSL312_3002 study (92 rollover patients and 69 newly enrolled patients). At the interim analysis (data-cut February 2023), median exposure to garadacimab was 13.8 months. In the overall population (rollover patients and newly enrolled), 60% were attack-free; mean percentage difference in number of HAE attacks per month versus run-in period was -95%.[7] The submitting company also presented a post-hoc pooled analysis of the VANGUARD and CSL312_3002 studies which also supports maintenance of treatment effect in patients who were randomised to garadacimab in VANGUARD and rolled over.[8]

*Other data were also assessed but remain confidential.**

2.4. Indirect evidence to support clinical and cost-effectiveness comparisons

In the absence of direct evidence comparing garadacimab with berotralstat, lanadelumab, and plasma-derived IV C1-esterase inhibitors, the submitting company presented an indirect treatment comparison. This has been used to inform the economic base-case, specifically the time-normalised number of HAE attacks and the time-normalised number of HAE attacks requiring on-demand treatment outcomes.

Table 2.3: Summary of indirect treatment comparison

Criteria	Overview
Design	NMA
Population	Patients aged ≥12 years with HAE type 1 or 2
Comparators	Berotralstat, lanadelumab and a plasma-derived IV C1-INH (Cinryze®)
Studies included	• Garadacimab: Phase 3 VANGUARD study (garadacimab 200 mg SC once monthly versus placebo)[9]. In the economic base-case, the phase II CSL312_2001 study was also included. • Berotralstat: Phase 3 APeX-2 study (berotralstat 150 mg oral once daily versus placebo)[10] and Phase 3 APeX-J study (berotralstat 150 mg oral once daily versus placebo)[11] • Lanadelumab: Phase 3 HELP-03 study (lanadelumab 300 mg SC once every 2 weeks or lanadelumab 300 mg SC once every 4 weeks versus placebo)[12] • Cinryze®: Phase 3 CHANGE study (IV Cinryze® [1000 IU] twice weekly versus placebo)[13] • SC Berinert®: Phase 3 COMPACT study (SC Berinert® 0.12 mL/kg [60 IU/kg] twice weekly versus placebo)[a,14]
Outcomes	Time-normalised number of attacks, time-normalised number of HAE attacks that were moderate/severe, time-normalised number of HAE attacks that required on-demand treatment, attack-free days, safety and HRQoL
Results	In the fixed-effects model, garadacimab significantly improved time-normalised number of HAE attacks, time-normalised number of HAE attacks that were moderate/severe, and time-normalised number of HAE attacks that required on-demand treatment compared with lanadelumab 300 mg once every 4 weeks and berotralstat; no evidence of a difference was observed versus lanadelumab 300 mg once every 2 weeks. For the random effects model, central point estimates for hazard ratios/rate ratios were similar to the fixed-effects model, however 95% credible intervals were very wide. A separate analysis was conducted to compare garadacimab with Cinryze® that assessed only time-normalised number of HAE attacks; garadacimab had significantly fewer time-normalised number of HAE attacks versus Cinryze®.

[a]The submitting company noted that the COMPACT (SC Berinert®) study was included in the full NMA report as it was intended to be adapted for global use and SC Berinert® is a comparator of interest in other countries however, since SC Berinert® is not considered a relevant comparator in this submission, comparative results for garadacimab against SC Berinert® were not discussed.

*Other data were also assessed but remain confidential.**

3. Summary of Safety Evidence

Evidence from VANGUARD supports the relative safety of garadacimab compared with placebo for the routine prevention of recurrent attacks of HAE. However, placebo is not considered a relevant comparator in this submission. Data presented are from the 6-month treatment period.

In the garadacimab (n=39) and placebo (n=25) groups respectively, 64% and 60% had a treatment-emergent adverse event (TEAE) of which 10% and 12% had a TEAE related to study treatment; 2.6% in the garadacimab group had a serious, severe AE (laryngeal attack, considered unrelated to treatment by investigator); no patients in either group had a TEAE that led to study

discontinuation or death. The most common TEAEs that occurred in ≥5% of patients were upper-respiratory tract infection (10% versus 8.0%), nasopharyngitis (8% versus 4.0%), and headache (7.7% versus 16%). Injection-site reactions occurred in 5.1% and 12% in the respective groups.[5]

Overall, regulators considered the safety profile of garadacimab to be acceptable. No monitoring requirements are stated in the SPC.[1, 3]

4. Summary of Clinical Effectiveness Considerations

4.1. Key strengths

- Garadacimab is a first-in-class medicine with a novel mechanism of action.[5]
- The phase III VANGUARD study met its primary outcome. During the 6-month treatment period, the mean number of investigator-confirmed hereditary angioedema attacks per month was significantly lower in the garadacimab group compared with placebo. The primary outcome selected was clinically relevant and the results were considered to be clinically meaningful by regulators.[3]
- Key secondary outcomes were also significantly improved in the garadacimab group compared with placebo. A significantly higher number of patients were attack-free during the first 3 months of treatment with garadacimab than placebo, and significantly more patients receiving garadacimab than placebo rated their response to treatment as good or better.[3]
- Combined data from VANGUARD and the open-label extension study suggest that treatment effect is maintained beyond 6 months.[7, 8]

4.2. Key uncertainties

- There are no direct data comparing garadacimab with relevant comparators used in Scottish clinical practice. An NMA was conducted to address this however it was associated with some limitations. Results were presented for garadacimab versus berotralstat, lanadelumab and Cinryze®. There was heterogeneity across studies, including variations in definitions of HAE attacks, study size, study design, patient population, outcomes assessed, and placebo response. Evidence networks were generally sparse, with most treatment connections informed by single placebo-controlled studies rather than head-to-head studies, increasing uncertainty and the risk of biased treatment-effect estimates.
- The VANGUARD study was limited in terms of sample size (n=64), which may be expected given the rarity of the condition.[5] The sample size of the ≥2 HAE attacks per month subgroup was even smaller, and these subgroup analyses were not powered to detect statistical differences between the two treatment groups.
- The 6-month treatment period of VANGUARD is relatively short considering HAE is a chronic, life-long condition and garadacimab is a treatment used for long-term prophylaxis.[3, 5] Pooled evidence from the open-label extension study suggests treatment effect is maintained however these data are limited by the single-arm, non-randomised study design.
- There are very limited clinical data available on the use of garadacimab in patients with HAE who have normal C1-esterase inhibitor activity. Some subcategories of normal C1-esterase

inhibitor HAE may not respond to treatment with garadacimab. The SPC recommends genetic testing according to current HAE guidelines and to discontinue treatment if clinical response is not observed.[1, 3]

- Results for laryngeal attacks were provided post-hoc, and since incidence of laryngeal attacks was low in both treatment groups it remains uncertain whether garadacimab reduces the frequency or severity of laryngeal attacks.[3]

4.3. Clinical expert input

Clinical experts consulted by SMC considered that garadacimab fills an unmet need and is a therapeutic advancement in this therapeutic area due to its novel mechanism of action and the limited treatment options available for long-term prophylaxis. Clinical experts considered the place in therapy would be as an additional first-line treatment option for patients requiring long-term prophylaxis.

4.4. Service implications

There are no service implications anticipated with the introduction of garadacimab to NHSScotland. Garadacimab may have some advantages for patients in terms of storage requirements (can be stored at room temperature for up to two months), route of administration (compared with intravenous comparators) and frequency of administration (once monthly).

*Other data were also assessed but remain confidential.**

5. Summary of Patient and Carer Involvement

No patient group submission was received.

6. Summary of Comparative Health Economic Evidence

6.1. Economic case

Table 6.1 provides a summary of the economic case.

Table 6.1 Description of economic analysis

Criteria	Overview
Analysis type	Cost-utility analysis
Time horizon	Lifetime horizon
Population	The analysis included two patient populations: • Base case 1 - comprising adults and adolescents aged ≥12 years receiving routing prevent of recurrent attacks of HAE was considered in the economic case. The population represented the full licensed indication under review. • Base case 2 (subgroup analysis) – patients experiencing ≥2 HAE attacks per month at baseline.
Comparators	For base case 1, comparators reflected the use of intravenous C1-esterase inhibitors (Cinryze® and Berinert®) and lanadelumab. For the subgroup analysis, berotralstat was considered the relevant comparator. Patients receiving long-term prophylaxis may continue to experience breakthrough attacks requiring on-demand treatment; therefore, on-demand treatments were also included in the model. These were modelled as a basket of treatments, with the distribution based on market share data.

Model description	A Markov model with 28-day cycles comprising of three health states: alive attack free, alive attack, and death. Transitions between the alive health states are determined by the expected HAE attack rate associated with each treatment.
Clinical data	Clinical inputs for garadacimab were primarily informed by pooled data from VANGUARD and the CSL312_3002 open-label extension study.[5, 7] Baseline characteristics for both populations were informed by VANGUARD, except for weight and baseline HAE attack rates. Baseline attack rates were sourced from the UK CITRN registry.[15] Comparative efficacy was informed by rate ratios from the NMA (sensitivity analysis excluding phase II studies) for lanadelumab and berotralstat during months 0-3. As this analysis did not provide an estimate for Cinryze®, the estimate from the NMA including phase II studies was retained, with Berinert® assumed to have equivalent efficacy to Cinryze®. Subsequent berotralstat efficacy beyond 3 months was informed by the responders population of the CITRN registry.
Extrapolation	For garadacimab, cycle-specific percentage reductions in HAE attacks were derived from pooled data from VANGUARD/CSL312_3002 and applied to the baseline attack rates up to month 36. Beyond month 36, long-term efficacy was estimated based on the average reduction observed during months 12-36. For base case 1 comparators, NMA-derived rate ratios were applied to the garadacimab attack rates over the model time horizon. For base case 2 (subgroup), efficacy beyond month 3 was informed by the CITRN registry up to 24 months; beyond this the average reduction observed during months 12-24 was applied. No treatment waning was assumed for any treatments. For lanadelumab, 45% of patients were assumed to switch from Q2W to Q4W dosing linearly over the first year, with corresponding Q4W efficacy applied following switching. Attack severity distributions from VANGUARD were assumed to apply to all long-term prophylaxis treatments. Discontinuation for non-oral prophylaxis was informed by the garadacimab data from CSL312_3002 and applied across treatments. For berotralstat, the company assumed that some patients with an inadequate response at the 3-month assessment would discontinue treatment, with inadequate response defined as <50% reduction in attack frequency.
Quality of life	Baseline utility was recalculated in each model cycle according to patient age and the frequency of HAE attacks experience in the previous cycle, using a regression equation derived from Nordenfelt et al (2014).[16] When a HAE attack occurred, an additional attack related disutility was applied according to attack severity, also informed by Nordenfelt et al (2014).[16] Treatment administration disutilties were applied per administration and sourced from Matza et al (2013).[17] Adverse event distuilities were included and sourced from published literature.
Costs and resource use	Costs included in the analysis were treatment acquisition and administration, and healthcare resource use; including monitoring and management of HAE attacks.
PAS/contract price	A Patient Access Scheme (PAS) was submitted by the company and assessed by the Patient Access Scheme Assessment Group (PASAG) as acceptable for implementation in NHSScotland. Under the PAS, a discount was offered on the list price. PAS discounts or contract price agreements are in place for lanadelumab, berotralstat, Cinryze®, and Berinert®, and these were included in the results used for decision-making by using estimates of the comparator PAS/contract price. Additionally, there are contract price agreements in place for icatibant acetate which was used in the on-demand treatment basket.

6.2. Results

SMC considered results for decision-making that took into account all relevant PAS and contract price agreements. SMC is unable to present these results due to competition law issues.

6.3. Sensitivity analyses

A range of sensitivity and scenario analyses were considered and descriptions of these key scenarios are provided in table 6.2. Sensitivity analysis included deterministic, probabilistic and scenario analysis. One-way sensitivity analysis indicated that relative efficacy, attack rate and baseline number of attacks are key parameters of influence.

Table 6.2: Sensitivity and Scenario Analysis Results

	Parameter	**Base case**	**Scenario**
1	Age	Starting age	Ages 12-100
2	Tunnel state-approach	1 month in tunnel	6 months in tunnel
3a	Discontinuation	Discontinuation included for all non-oral treatments	No discontinuation
3b		Assumed a proportion of patients would discontinue treatment at 3 months	Assumed 50% of patients would discontinue treatment at 3 months
4	Management source selection	Clinical opinion	Alternate HAE attack management source
5	Baseline utility	Nordenfelt et al (2014)[16]	VANGUARD phase III utility
6	HAE attack disuility	Nordenfelt et al (2014)[16]	Alternate HAE disutility – Aygören-Pürsün et al. (2014)[19]
7	Administration disutility	Included administration disutility	Exclusion of administration disutility
8	Attack duration	Based on estimate from Lumry et al 2010[20]	HAE attack disutility duration informed by VANGUARD
9			Seven-day HAE attack disutility
10	Adults caregiver support	Severe and laryngeal attacks only (>18-year-olds)	Adults caregiver support for some attacks
11	Caregiver outcomes	Caregiver disutility included	No caregiver disutility
12a	Baseline characteristic	Based on all patients in the licensed indication	≥2 attacks per month characteristics
12b		≥2 attacks per month characteristics	Based on all patients in the ITT population

13	Extrapolation approach garadacimab	PAARRFC	AARRFC
14	Berotralstat efficacy	CITRN registry 3+ months	NMA used for berotralstat
15	Lanadelumab switching	45% of patients switch to 4 weekly dose and take on a change in efficacy	No change in efficacy when switching

Abbreviations: AARRFC = average attack rate carried forward; HAE = hereditary angioedema; ITT = intention to treat; PAARRFC = partial average attack rate carried forward

6.4. Key strengths

- The Markov model appeared appropriate and similar structures have been used in previous economic evaluation in this disease area.
- The analysis captured the main costs associated with HAE management. Resource use and unit costs were informed by relevant published evidence, clinical expert opinion and appropriate NHS costing sources.
- The distribution of HAE attack severity was assumed to be the same across all long-term prophylactic treatments. This was an appropriate and reasonable assumption.

6.5. Key uncertainties

- There were no direct data comparing garadacimab with relevant comparators. The garadacimab evidence versus placebo (pooled VANGUARD/CSL312_3002 data) was also limited by small sample size and relatively short follow up. Given these limitations with the clinical evidence used in the economic model, the results are uncertain.
- Comparative efficacy in base case 1, and during the initial 0–3-month period of base case 2, was therefore reliant on indirect treatment comparisons. The NMA was subject to some uncertainty and the NMA-derived rate ratios were key drivers in the economic one-way sensitivity analysis for base case 1.
- Long-term attack rates were extrapolated beyond follow-up with no treatment waning assumed. For garadacimab the average attack-rate reduction observed during months 12-36 was carried forward, and for berotralstat (base case 2) the later CITRN responder data were similarly used to inform long-term efficacy. Although the same general assumption of maintained efficacy was applied across treatments, it remains uncertain whether these later observed attack rates are representative of effectiveness over the lifetime horizon.
- The model assumed that 45% of patients switch from lanadelumab Q2W to Q4W over the first year and subsequently take on Q4W efficacy estimates from the NMA. The impact of maintaining Q2W efficacy after switching was explored which showed limited impact on the results.
- As baseline utility was adjusted according to attack frequency in the previous cycle, while separate attack-specific disutilities were applied for current attacks, there was risk of double counting the quality-of-life impact of HAE attacks.

- Scenario analysis (scenario 7) indicated that excluding administration disutility was a key driver in change in incremental QALYs for base case 1. Treatments requiring more frequent administration accrue larger cumulative administration disutilities over time. Garadacimab is only administered once monthly and therefore incurs a small administration burden compared to comparators. Given their substantial influence on the results, there is uncertainty regarding whether the magnitude of these disutilities remains representative of patient preferences in clinical practice.

7. Conclusion

After considering all the available evidence, the Committee accepted garadacimab for use in NHSScotland.

8. Guidelines and Protocols

The World Allergy Organisation (WAO) and the European Academy of Allergy and Clinical Immunology (EAACI) guideline for the management of hereditary angioedema was revised and updated in 2021.[21]

The WAO guidelines for the classification, diagnosis, and treatment of hereditary angioedema, with consideration of worldwide disparities were published in 2025.[4]

9. Additional Information

9.1. Product availability date

08 October 2025

Table 9.1 List price of medicine under review

Medicine	Dose regimen	Cost per month (£)
garadacimab	**400 mg loading dose then 200 mg once per month thereafter (administered subcutaneously)**	**First month: £41,250 Subsequent months: £20,625**

Costs taken from BNF online on 05 August 2026. Costs do not take any patient access schemes into consideration.

10. Company Estimate of Eligible Population and Estimated Budget Impact

SMC is unable to publish the with PAS budget impact due to commercial in confidence issues. A budget impact template is provided in confidence to NHS health boards to enable them to estimate the predicted budget with the PAS. This template does not incorporate any PAS/contract price discounts associated with comparator medicines.

*Other data were also assessed but remain confidential.**

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This assessment is based on data submitted by the applicant company up to and including 11 September 2026.

**Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal:*https://www.scottishmedicines.org.uk/about-us/policies-publications/

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC includes Scottish national contract prices in its decision-making. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document.

Patient Access Schemes (PAS): A PAS is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. The Patient Access Scheme Assessment Group (PASAG), established under the auspices of Public Services Delivery Scotland, reviews and advises NHS Scotland on the feasibility and acceptability on implementing proposed schemes. PASAG operates separately from SMC to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHS Scotland on the basis of a PAS that has been considered acceptable for implementation by PASAG, a set of guidance notes on the operation of the scheme will be circulated to health boards' Area Drugs and Therapeutics Committees prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after careful consideration and evaluation of the available evidence. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.