

standardised allergen extract of pollen from white birch (*Betula verrucosa*) sublingual lyophilisate (Itulazax®)

ALK-Abello Ltd

4 September 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

standardised allergen extract of pollen from white birch (*Betula verrucosa*) (Itulazax®) is accepted for restricted use within NHSScotland.

Indication under review: in adults and children (5 years or older) for the treatment of moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous. It is indicated in patients with a clinical history of symptoms despite use of symptom-relieving medication and a positive test of sensitisation to a member of the birch homologous group (skin prick test and/or specific IgE).

SMC restriction: for use in adults, 18 to 65 years.

Area Drug and Therapeutic Committees (ADTCs) may make formulary decisions on paediatric licence extensions for medicines that are accepted for use (or restricted use) in adults.

Evidence from a double-blind phase III study demonstrated that in combination with standard care one tree pollen season's treatment with Itulazax® significantly improved a combined measure of rhinoconjunctivitis symptom severity and medication use (total combined score) compared with placebo plus standard care.

Chair
Scottish Medicines Consortium

1. Clinical Context

1.1. Medicine background

Standardised allergen extract of pollen from white birch (*Betula verrucosa*) (hereafter referred to by its brand name, Itulazax®) is an allergy immunotherapy that repeatedly administers allergens to allergic individuals to modify their immunological response to the allergen. The mechanism of action is not fully understood but may involve an increase in white birch specific immunoglobulin G4 (IgG4) and a systemic antibody response that competes with immunoglobulin E (IgE) in the binding of white birch allergens. It is administered as one (12 standardised quality units of *Betula verrucosa* [SQ-Bet]) sublingual lyophilisate once daily. Treatment should be initiated at least 16 weeks before and continued during the tree (birch homologous group) pollen season. There are no clinical data available for an in-season treatment start. International treatment guidelines refer to a treatment period of 3 years for allergy immunotherapy to achieve disease modification. Long-term efficacy has not yet been established. If no improvement is observed during the first year, there is no indication for continuing treatment. The first dose should be taken under medical supervision, and the patient should be monitored for at least half an hour. See summary of product characteristics (SPC) for further information.¹

1.2. Disease background

Allergic rhinitis is IgE-mediated inflammation of the upper respiratory tract due to allergen exposure in an allergic individual that is characterised by nasal pruritus, sneezing, rhinorrhoea, and nasal congestion. It may be associated with palate, throat, ear, and eye itching plus eye redness, puffiness, and watery discharge. It may exacerbate asthma, disturb sleep and substantially impact quality of life, with secondary effects on concentration, mood and behaviour, leading to fatigue and difficulties with work and other daily activities. It can affect all ages, with about 80% developing symptoms before 20 years of age.^{2, 3}

1.3. Company proposed position

The submitting company provided evidence for the use of Itulazax® in adult patients, 18 to 65 years. ADTCs may make formulary decisions on paediatric licence extensions for medicines that are accepted for use (or restricted use) in adults.

1.4. Treatment pathway and relevant comparators

The British Society for Allergy and Clinical Immunology (BSACI) guideline recommends allergen avoidance, especially for seasonal allergies. For treatment of symptoms, it recommends intranasal corticosteroids for initial treatment for moderate-to-severe allergic rhinitis and, if an inadequate response is achieved, they may be combined with antihistamines. Depending on response and symptoms, further treatment options (which may not be licensed specifically for birch homologous group allergic rhinoconjunctivitis) include topical ipratropium bromide, leukotriene receptor antagonist, and short course of intranasal decongestant. They note that ocular manifestations of seasonal rhinoconjunctivitis can often be suppressed by oral antihistamines and by intranasal agents (corticosteroids and antihistamines) but they are often better treated using topical eye drops that contain mast cell stabilisers (sodium cromoglycate, nedocromil sodium and lodoxamide); antihistamines (azelastine, emedastine and epinastine) or olopatadine, which has

mast cell stabilising and antihistaminic properties. Tear supplement drops can provide a measure of symptomatic relief. Topical steroid eye drops are effective in suppressing inflammation but can have potentially sight-threatening adverse effects including ocular hypertension/glaucoma, cataract and the risk of infection. Allergen immunotherapy is noted as an option for patients with seasonal pollen induced rhinoconjunctivitis whose symptoms persist despite maximal drug therapy (combinations of intranasal corticosteroid and antihistamine taken regularly).³

The submitting company consider the relevant comparator to be standard of care that may include intranasal corticosteroid, oral antihistamine, and eye drops (olopatadine). Clinical experts consulted by SMC state that current standard of care may include intranasal corticosteroid with or without antihistamine, oral antihistamine, eye drops (including sodium cromoglycate or antihistamines), and potentially off-label use of oral leukotriene receptor antagonists, such as montelukast.

2. Summary of Clinical Evidence

2.1. Evidence for the licensed indication under review

Evidence is from the TT-04 study, detailed in Table 2.1.^{1, 4, 5}

Table 2.1. Overview of relevant study.^{4, 5}

Criteria	TT-04
Study design	Multi-national, double-blind, phase III study
Eligible patients	Patients, 12 to 65 years, with persistent moderate-to-severe allergic rhinitis and/or conjunctivitis induced by birch pollen, despite use of symptom-relieving medication during previous two tree pollen seasons, that affected quality of life during the preceding birch pollen season: sleep disturbance; impairment of daily activities, leisure, and/or sport; impairment of school or work; or troublesome symptoms. They had a positive skin prick test response (wheal diameter ≥ 3 mm) to birch; positive Bet v 1-specific IgE level (≥ 0.7 kU/L). Patients with uncontrolled asthma or severe exacerbations of asthma were excluded.
Treatments	Itulazax® 12 SQ-Bet or placebo sublingual once daily from September or October 2016, ≥ 16 weeks before start of 2017 tree pollen season, and continued to its end in May or June 2017. Corticosteroid nasally (mometasone 50 microgram) and antihistamine orally (desloratadine 5 mg) and eye drops (olopatadine 1 mg/mL) could be used as needed when the investigator confirmed that the tree pollen season had started.
Randomisation	Assigned equally with no stratification.
Primary outcome	Average daily allergic rhinoconjunctivitis TCS during the birch pollen season. ^A
Key secondary outcomes	Average DSS during birch pollen season. ^A Average TCS and average DSS during tree pollen season. ^B
Statistical analysis	Efficacy was assessed in the full analysis set, which comprised all patients with at least one diary record in the birch pollen season. It was assessed in the hierarchical order listed above for the primary then key secondary outcomes.

Abbreviations: DSS = daily symptom score, which ranges from 0 to 18 and is the sum of rhinoconjunctivitis symptom score (runny nose; blocked nose; sneezing; itchy nose; gritty, red or itchy eyes; and watery eyes each scored from 0 [no symptom] to 3 [severe]). TCS = total combined score, which ranges from 0 to 38 and is the sum of the DSS and the daily medication score (DMS; where oral antihistamine scored 0 to 6 [score of 6 per tablet] and nasal corticosteroid scored 0 to 8 [scored 2 per puff] and antihistamine eye drops scores 0 to 6 [1 per eye]; range 0 to 20).

A = the birch pollen season start date was the first of three consecutive days with birch pollen count ≥ 30 grains/m³ and stop date was the last day of three consecutive days below this level.

B = the tree pollen season start date was the first of three consecutive days with hazel, alder or birch pollen ≥ 10 grains/m³ and stop date was the last day of three consecutive days below this level.

Itulazax®, compared with placebo, significantly improved the primary outcome, average daily allergic rhinoconjunctivitis total combined score (TCS) during the birch pollen season, and the key secondary outcomes: daily symptom score (DSS) during the birch pollen season and TCS and DSS during the tree pollen season. There also appeared to be improvements in the proportion of days with severe and mild symptoms, as detailed in Table 2.2.^{1, 4, 5}

Table 2.2: Results of TT-04 study.^{1, 4, 5}

	Birch pollen season		Tree pollen season	
	Itulazax® N=282	Placebo N=292	Itulazax® N=282	Placebo N=292
Average daily allergic rhinoconjunctivitis total combined score (TCS)				
Adjusted mean	4.61	7.62	3.95	6.22
Difference (95% CI)	3.02 (1.99 to 4.05), p<0.001*		2.27 (1.44 to 3.11), p<0.001	
Average allergic rhinoconjunctivitis daily symptom score (DSS)				
Adjusted mean	2.28	3.60	2.03	3.02
Difference (95% CI)	1.32 (0.84 to 1.81), p<0.001		0.99 (0.60 to 1.38), p<0.001	
Average allergic rhinoconjunctivitis daily medication score (DMS)				
Adjusted mean	1.63	3.21	1.37	2.58
Difference (95% CI)	1.58 (0.94 to 2.22)		1.20 (0.69 to 1.72)	
Proportion of severe symptom days				
Percentage	12%	23%	9.3%	16%
Odds ratio (95% CI)	0.47 (0.43 to 0.52)		0.54	
Proportion of mild symptom days				
Percentage	59%	43%	66%	53%
Odds ratio (95% CI)	1.92 (1.79 to 2.06)		1.70	

Abbreviations: CI = confidence interval; * primary outcome.

2.2. Evidence to support the positioning proposed by the submitting company

In TT-04, the subgroup of adults (18 to 65 years), which comprises 90% (518/575) of the study population, provides evidence to support the positioning in this age group with moderate-to-severe allergic rhinitis and/or conjunctivitis induced by birch pollen, despite use of symptom-relieving medication. In this adult subgroup, within the Itulazax® and placebo groups, results for the primary outcome, mean adjusted average TCS, were consistent with results in the overall population.⁵

2.3. Health-related quality of life outcomes

Health-related quality of life was assessed by the rhinoconjunctivitis quality of life questionnaire with standardised activities (RQLQ(S)), which comprises 28 questions, each scored on a 7-point scale (0 to 6 = worst) and it measures 7 domains: activity limitation, sleep problems, nose symptoms, eye symptoms, non-nose/eye symptoms, practical problems and emotional function. The overall adjusted mean RQLQ(S) for Itulazax® appeared lower than placebo in the birch pollen season (0.99 and 1.45) and the tree pollen season (0.95 and 1.32) on a score that can range from 0 to 6.⁴

2.4. Supportive studies

In a retrospective observational study (REACT), 47,440 patients in Germany who received allergy immunotherapy for allergic rhinitis (due to house dust mite, grass or tree pollen) between 2008 to 2016, compared with untreated control patients in a propensity score-matched population, had greater reductions in allergic rhinitis prescriptions from the pre-index year of -0.46 versus -0.38 at year 3, -0.57 versus -0.45 at year 5, and -0.65 versus -0.52 at year 9.⁶

[Other data were also assessed but remain confidential.](#)*

3. Summary of Safety Evidence

Patients taking Itulazax[®] should primarily expect mild to moderate local allergic reactions to occur within the first few days of treatment and disappear within a few months (in many cases within a week or two). For the majority of events, the reaction should be expected to start within 10 minutes after intake of Itulazax[®] and abate within an hour. Local allergic reactions are manifested in the upper respiratory or gastrointestinal system. Oral pruritus was reported in 38% of the patients, throat irritation in 29% of the patients and tongue pruritus was reported in 13% of the patients. Cases of eosinophilic oesophagitis have been reported in association with Itulazax[®] treatment. Systemic allergic reactions, including anaphylactic reactions, are known risks in patients receiving allergy immunotherapy and are considered a class effect.¹

In TT-04, within the Itulazax[®] and placebo groups, adverse events were reported by 82% (262/320) and 56% (176/314), respectively, and were possibly treatment-related in 75% and 23%. Most were mild or moderate, with only 6.9% and 1.6% of patients having severe reactions. Serious reactions were reported by 1.2% and 1.9% in the respective groups and adverse events lead to treatment discontinuation in 7.8% and 2.5% of patients.⁴

In TT-04, in the Itulazax[®] group, common adverse events included oral pruritus, oral paraesthesia, tongue pruritus, mouth swelling, lip swelling, oral discomfort, swollen tongue, throat irritation, pharyngeal oedema, ear pruritus, oropharyngeal pain, and nasopharyngitis.⁵

Treatment with Itulazax[®] may worsen the symptoms of existing oral allergy syndrome, and there have been a few new events of oral allergy syndrome reported. Symptoms typically occur at treatment initiation and may resolve with continued treatment.¹

[Other data were also assessed but remain confidential.](#)*

4. Summary of Clinical Effectiveness Considerations

4.1. Key strengths

- In a double-blind, phase III study, during the birch pollen and tree pollen seasons, Itulazax[®] compared with placebo significantly improved symptoms and medication use associated with rhinoconjunctivitis. This was assessed via the primary outcome, the average daily allergic rhinoconjunctivitis TCS during the birch pollen season, and the key secondary outcomes: DSS during the birch pollen season and TCS and DSS during the tree pollen season.^{4, 5}
- The primary and key secondary outcomes were supported by reductions in the proportion of days with severe symptoms from 23% to 12% in the birch pollen season and 16% to 9% in the

tree pollen season, with corresponding increases in the days with mild symptoms from 43% to 59% and from 53% to 66% in the respective seasons.

- Itulazax® is the first allergen immunotherapy licensed for allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group.¹

4.2. Key uncertainties

- The clinical relevance of the improvements in allergic rhinoconjunctivitis symptoms and medication use and quality of life with Itulazax® is uncertain. It should be noted that in the Itulazax® and placebo groups the percentage of days in the tree pollen season that were classified as mild symptom days were 66% and 53% respectively. A larger treatment effect was observed in the shorter birch pollen season in which a smaller proportion of the placebo group had mild symptoms, 43%, versus 59% with Itulazax®.^{4, 5} Clinical experts consulted by SMC considered that the results from TT-04 may be clinically meaningful to patients.
- The SPC notes that international treatment guidelines refer to a treatment period of three years for allergy immunotherapy to achieve disease modification.¹ This is supported by a literature review.⁷ TT-04 is limited to one tree pollen season. Real-world data from REACT, which are limited by retrospective observational design, suggest small reductions compared with control patients in the number of prescriptions for allergic rhinitis medication several years after immunotherapy use. The SPC notes that long-term efficacy of Itulazax® has not yet been established. There are no data to characterise and quantify the long-term effects of Itulazax® on symptoms of allergic rhinoconjunctivitis, and it is not clear whether it has a disease modifying effect after three years of treatment.
- The SPC notes that asthma is a known risk factor for severe systemic allergic reactions. Itulazax® has not been studied in patients with severe and or uncontrolled asthma and is contraindicated in those with a severe exacerbation or uncontrolled asthma within the last three months prior to initiation.¹

4.3. Clinical expert input

Clinical experts consulted by SMC considered that Itulazax® fills an unmet need in this therapeutic area, namely it provides a treatment option for patients with symptoms inadequately controlled by current standard of care. They note that it is a therapeutic advance for this reason and that it would be added to current standard of care.

4.4. Service implications

Some clinical experts consulted by SMC considered that the introduction of this medicine may impact on service delivery due to the additional clinic visits for monitoring and follow-up requirements associated with Itulazax® therapy, which is expected to be given as a three-year course.

5. Summary of Patient and Carer Involvement

The following information reflects the views of the specified Patient Group.

- We received a patient group submission from Allergy UK, which is a registered charity.
- Allergy UK has received 6.17% pharmaceutical company funding in the past two years, including from the submitting company.
- Those living with birch pollen allergy, thought to affect approximately 25% of hay fever sufferers, experience allergic rhinitis symptoms during the peak pollen season. Symptoms include itching of the nose, sneezing, rhinorrhoea, and nasal congestion. Frequently there is associated palate, throat, ear, and eye itching as well as eye redness, puffiness, and watery discharge. Day to day this impacts patients' ability to work, meet their predicted academic grades, and participate in social activities, and therefore has a social and economic impact on families. For young people the impact on their education can have lifelong consequences.
- Some patients remain symptomatic despite good adherence to their treatments, meaning that the medicines currently available to them are not adequately managing their condition. Immunotherapy with Itulazax® offers a further treatment option.
- Itulazax® can help patients effectively manage their symptoms which is expected to improve their quality of life, reduce the financial impacts of the condition by reducing sick days and improve educational attendance and emotional and social well-being.

6. Summary of Comparative Health Economic Evidence

6.1. Economic case

The economic case is summarised in Table 6.1.

Table 6.1 Description of economic analysis

Criteria	Overview
Analysis type	Cost-utility analysis
Time horizon	Lifetime.
Population	Adult patients aged 18 to 65 years with moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group of trees.
Comparators	Established clinical management (ECM) compared to Itulazax® plus ECM. Background care consisted of oral antihistamines, nasal corticosteroid sprays, and antihistamine eye drops.
Model description	De novo cohort-level Markov model tracking individual cohorts across two discrete health states (alive and dead) using annual cycles.
Clinical data	Short-term effectiveness was derived from the pivotal Phase III field study (TT-04). Health outcomes in the single 'alive' state were calculated as a weighted average across the tree pollen season and remainder of the year, based on daily symptom and medication diary scores from TT-04. Long-term disease modification trajectories were informed by literature and expert consensus. Mortality was based on Office for National Statistics (ONS) life tables.
Extrapolation	Single-season study data were extended across a lifetime horizon. The treatment effect was assumed to improve by 2.5% per cycle until Year 10, remain stable, and wane linearly from Year 15 with an 80% loss of benefit by Year 20.
Quality of life	As generic EQ-5D data were not directly collected in the TT-04 study, health state utilities were mapped from daily symptom and medication diaries in the TT-04 study to generic EQ-5D-5L values using a statistical mapping regression function from Dick et al. (2019). ⁸ This

	yielded an annual QALY gain of 0.0068 for the Itulazax® arm. Adverse event disutilities were excluded.
Costs and resource use	Medicine costs included acquisition costs for Itulazax® and background ECM therapies. Primary and secondary healthcare resource quantities were derived from a five-expert Delphi panel conducted in January 2025. National unit costs were sourced from appropriate sources.
PAS	No patient access scheme (PAS) was submitted.

6.2. Results

The deterministic base case results are presented in Table 6.2.

Table 6.2. Base case deterministic results

	Total costs (£)	Total QALYs	Total LYs	Incr. costs (£)	Incr. QALYs	Incr. LYs	ICER (£/QALY)
Itulazax®	£9,622	18.86	22.00	-£2,082	0.10	0.00	Dominant
ECM	£11,705	18.76	22.00				

Abbreviations: ECM, established clinical management; ICER, incremental cost-effectiveness ratio; LY, life year; QALY, quality-adjusted life year.

Dominant: Itulazax® was dominant compared to ECM meaning it was estimated as resulting in lower costs and better health outcomes for patients.

6.3. Sensitivity analyses

Key scenario analyses are presented in Table 6.3. Itulazax® was cost-effective versus ECM in all scenarios ran.

Table 6.3. Deterministic scenario analysis results

	Parameter	Base case	Scenario	Incr. Costs (£)	Incr. QALYs	ICER (£/QALY)
	Base case			-£2,082	0.10	Itulazax® dominant
1.a.	Time horizon	Lifetime	10 years	-£132	0.06	Itulazax® dominant
1.b.			20 years	-£1,616	0.09	Itulazax® dominant
2.a.	Treatment waning in the Itulazax® arm	Waning starts in Year 15, and by Year 20, 80% of patients have lost treatment benefit	100% loss of treatment benefit after 15 years	-£1,089	0.08	Itulazax® dominant
3.b.			Full treatment benefit for 20 years (100% loss at year 20)	-£2,237	0.10	Itulazax® dominant
3.a.	Proportion to receive Itulazax® benefit following discontinuation	50%	0%	-£1,779	0.09	Itulazax® dominant
3.b.			100%	-£2,386	0.10	Itulazax® dominant
4.	Source of relative reduction in secondary care visits	Probabilistic Delphi panel	REACT study	-£37	0.10	Itulazax® dominant
5.a.	Proportion of each cycle for which treatment benefit is applied	137 days (the full dataset from Dick et al., 2019)	100 days per cycle (TPS only)	-£2,074	0.08	Itulazax® dominant
5.b.			42 days per cycle (BPS only)	-£2,064	0.05	Itulazax® dominant

6.a.	Proportion of patients retreated with Itulazax® after 10 years	5%	0%	-£2,008	0.10	Itulazax® dominant
6.b.			20%	-£2,306	0.11	Itulazax® dominant
6.c.			50%	-£2,753	0.13	Itulazax® dominant

Abbreviations: BPS, birch pollen season; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year; TPS, tree pollen season.

6.4. Key strengths

- The economic evaluation was directly informed by clinical evidence from study TT-04, ensuring that the baseline patient characteristics and short-term clinical efficacy outcomes directly reflected the target patient population. Concomitant background symptomatic rescue medication consumption was also modelled using patient-reported data collected in the study.
- The model excluded acute healthcare resource events, which was a conservative assumption.
- The company explored key structural and parameter uncertainties which showed the results were robust, with Itulazax® maintaining dominance across all evaluated scenarios.
- The analysis implemented a realistic approach to patient non-compliance and early discontinuation by factoring in prescription wastage.

6.5. Key uncertainties

- The primary drivers of the cost savings were estimated reductions in general practitioner (GP) consultations and secondary care outpatient visits derived from a small, five-expert Delphi panel rather than empirical study data. When this subjective resource data was replaced with real-world findings from the REACT study in a scenario analysis, the net cost savings almost entirely reduced, falling from -£2,082 to just -£37, indicating that the baseline approach was optimistic compared to what may be experienced in actual NHS Scotland practice.
- The health state utility values used to QALY gains, which emerged as the second most influential driver in the deterministic sensitivity analysis, were derived using a mapping function from an external study (Dick et al., 2019)⁸ developed using study data for a grass pollen sublingual tablet and validated using Itulazax® (tree pollen) study data. While validated on the study population for Itulazax®, deriving quality-of-life weights via a mapping algorithm based on a different allergen indication rather than direct study utility collection may introduce uncertainty into the health benefit calculations.
- The model relied on the optimistic structural assumption that 50% of patients who discontinued active therapy early during the three-year course would permanently retain full active treatment efficacy over the lifetime horizon. This assumption lacked strong empirical justification and served to artificially sustain long-term health benefits and cost offsets for non-compliant patients, biasing the scale of the long-term economic benefits in favour of Itulazax®.

- While the model incorporates an additional Year 1 adverse event discontinuation rate to reflect initial tolerability dropouts, the general discontinuation rate across all three years is derived from a single-year clinical study frame. Applying a single-year study rate across a three-year regimen may not fully reflect real-world compliance dynamics or long-term treatment fatigue over a three-year regimen. When combined with the unevidenced assumption that dropouts permanently retain 50% of active treatment efficacy, applying a single-year trial rate creates structural uncertainty around both cumulative drug acquisition costs and downstream health gains.
- The handling of treatment side effects introduced further optimism by completely omitting any specific utility decrements for localised adverse events from the base case. This was despite a high proportion of patients in the intervention arm experiencing local administration-site reactions in the clinical study. Failing to explicitly capture the short-term toll of starting active therapy may have exaggerated the total net health benefits in favour of the medicine.

7. Conclusion

After considering all the available evidence, the Committee accepted Itulazax® for restricted use in NHSScotland.

8. Guidelines and Protocols

In July 2017, the British Society for Allergy and Clinical Immunology (BSACI) updated the 'BSACI guideline for the diagnosis and management of allergic and non-allergic rhinitis (Revised Edition 2017; First edition 2007)'.³

9. Additional Information

9.1. Product availability date

9 August 2021

Table 9.1 List price of medicine under review

Medicine	Dose regimen	Cost per year (£)
standardised allergen extract of pollen from white birch (Itulazax®)	one (12 SQ-Bet) sublingual lyophilisate once daily	972

Costs from BNF online on 10 June 2026. Costs do not take any patient access schemes into consideration.

10. Company Estimate of Eligible Population and Estimated Budget Impact

The submitting company estimated there would be 2,573 patients eligible for treatment with Itulazax®. The estimated uptake rate was 5% in year 1 and 15% in year 3. This resulted in 129 patients estimated to receive treatment in year 1 rising to 386 patients in year 3.

The gross impact on the medicines budget was estimated to be £110k in year 1 rising to £360k in year 3. As other medicines were assumed to be displaced, the net medicines budget impact was estimated to be £37k in year 1 and £360k in year 3.

References

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This assessment is based on data submitted by the applicant company up to and including 14 August 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/](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.