National Institute for Health and Care Excellence

Health Technology Evaluation

Betula verrucosa (Itulazax 12 SQ-Bet) for treating moderate to severe allergic rhinitis, conjunctivitis, or both, caused by tree pollen [ID6462]
Response to stakeholder organisation comments on the draft remit and draft scope

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

Comment 1: the draft remit and proposed process

Section	Stakeholder	Comments [sic]	Action
Appropriateness of an evaluation and proposed evaluation route	ALK-Abelló Ltd	The company agrees that NICE should consider this topic for appraisal. The single technology appraisal route is the most appropriate route for ITULAZAX®.	Thank you for your comment. No action required.
	Association of Respiratory Nurses	I can see this is proposed as a single technology but appears to be like the SQ-MDM SLIT technology and think having a comparison or combination of the two maybe useful.	Thank you for your comment. The 2 treatments have different indications and would not be considered comparators. No change to the scope required.

Section	Stakeholder	Comments [sic]	Action
	Royal College of Pathologists	Topic is appropriate for evaluation. There is NICE approved treatment for tree pollen immunotherapy, and provision of this is very variable throughout the UK. Allergic rhinitis can be severe, and there is a proportion of patients where symptom-relieving medication is inadequate. This group of patients are debilitated by their disease, and provision of immunotherapy would be beneficial for them. Single technology appraisal would be appropriate.	Thank you for your comment. No action required.
	Royal College of Physicians	Topic is appropriate for evaluation. There is NICE approved treatment for tree pollen immunotherapy, and provision of this is very variable throughout the UK. Allergic rhinitis can be severe, and there is a proportion of patients where symptom-relieving medication is inadequate. This group of patients are debilitated by their disease, and provision of immunotherapy would be beneficial for them.Single technology appraisal would be appropriate.	Thank you for your comment. No action required.
Wording	ALK-Abelló Ltd	The wording of the remit is accurate, and the company suggests no further changes.	Thank you for your comment. No action required.
	Association of Respiratory Nurses	There is a good explanation of how IGE medicated birch pollen allergy can affect a person the scientific background and symptom burden. There are clear instructions that it would be for use in people with moderate to severe allergic rhinitis or conjunctivitis. However, I cannot see how much the treatment would cost per person and cost compared to regular treatments already used such as nasal steroidal sprays and antihistamines. It's suggested between 2022-23 there was 2,132 admissions and 2,140 2finished consults episodes" for allergic rhinitis due to pollen. It is not clear what is meant by this – what is a finished consult episode? This needs to be explained and also there needs to be hard evidence of admissions due to allergic rhinitis as I would find it difficult to know that the admission is a consequence of allergic rhinitis, but I can understand patients having	Thank you for your comment. The statistics regarding hospital admissions are taken from NHS England. The reference is listed in the scope. The wording has been updated to explain the term 'finished consultant episodes'.

Section	Stakeholder	Comments [sic]	Action
		acknowledged symptoms of rhinitis during a admission which may be a co-existing treatable trait during the admission but not necessarily the reason for admission.	
	Royal College of Pathologists	Yes, the wording is appropriate.	Thank you for your comment. No action required.
	Royal College of Physicians	Yes, the wording is appropriate.	Thank you for your comment. No action required.
Timing Issues	ALK-Abelló Ltd	Despite appropriate administration and compliance with existing treatments, a subset of moderate-to-severe allergic rhinitis (AR) and/or conjunctivitis patients have uncontrolled disease (36% moderate and 45% severe AR), and as such their treatment satisfaction is low. (1) Currently, there are no oral allergen immunotherapies (AITs) licensed for tree pollen allergy in the UK, with current disease modifying treatments limited to subcutaneous immunotherapy and unlicensed treatments, leaving treatment with general antihistamines and avoidance practices as the main treatment strategies for birch pollen-induced AR. ITULAZAX® is an AIT in the form of a sublingual immunotherapy (SLIT) lyophilisate tablet, providing an alternative treatment option for patients with moderate-to-severe AR and/or conjunctivitis induced by pollen from the birch homologous group, whose symptoms are inadequately controlled despite compliant use of existing treatments. (2, 3) With a lack of treatment options available for this population, AIT offers a novel and innovative treatment option, being the only treatment available that is able to target the underlying	Thank you for your comment. NICE aims, where possible, to provide timely guidance in line with marketing authorisation. No action required.

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		mechanisms of the disease, and change its course, inducing immune tolerance, and preventing disease progression. (4, 5) It is therefore of high importance that NICE consider this intervention for approval. References: 1.Data on file. Modified Delphi advisory panel. 2023. 2. Akdis CA, Barlan IB, Bahceciler N, Akdis M. Immunological mechanisms of sublingual immunotherapy. Allergy 2006;61:11-4. 3. Bousquet J, Khaltaev N, Cruz AA, Denburg J, Fokkens WJ, Togias A, et al. Allergic Rhinitis and its Impact on Asthma (ARIA) 2008 update (in collaboration with the World Health Organization, GA(2)LEN and AllerGen). Allergy. 2008;63 Suppl 86:8-160. 4. Jutel M, Agache I, Bonini S, others. International consensus on allergy immunotherapy. J Allergy Clin Immunol. 2015;136(3):556–68. 5. Bonertz A, Roberts GC, Hoefnagel M, others. Challenges in the implementation of EAACI guidelines on allergen immunotherapy: a global perspective on the regulation of allergen products. Allergy. 2018;73(1):64–76.	
	Association of Respiratory Nurses	It doesn't appear urgent as there are already treatments available for allergic rhinitis and is a add on therapy. It does state that there is currently not any NICE guidance on allergy avoidance.	Thank you for your comment. No action required.
	Royal College of Pathologists	There are no NICE approved therapies for this group of patients, and current provision is very variable throughout the UK.	Thank you for your comment. No action required.
	Royal College of Physicians	There are no NICE approved therapies for this group of patients, and current provision is very variable throughout the UK.	Thank you for your comment. No action required.

Section	Stakeholder	Comments [sic]	Action
Additional comments on the draft remit	ALK-Abelló Ltd	No further comments	Thank you for your comment.

Comment 2: the draft scope

Section	Consultee/ Commentator	Comments [sic]	Action
Background information	ALK-Abelló Ltd	The background is defined appropriately.	Thank you for your comment. No action required.
	Association of Respiratory Nurses	I feel more information is needed, the background of the treatable matter is explained well but the statistics do not seem accurate with regards to hospital admissions.	Thank you for your comment. The statistics regarding hospital admissions are taken from NHS England. The reference is listed in the scope.

Section	Consultee/ Commentator	Comments [sic]	Action
	Royal College of Pathologists	Allergen avoidance is not easy at all for tree pollens. The background information may wish to also include the number of primary care consultations, and potential effects on educational attainment and work productivity due to uncontrolled hayfever symptoms. There is published data available for this. There is also a NICE CKS (last revised January 2024) on allergic rhinitis, where it is mentioned that immunotherapy may be appropriate for some people.	Thank you for your comment. The background section is not intended to be exhaustive. No action needed.
	Royal College of Physicians	Allergen avoidance is not easy at all for tree pollens. The background information may wish to also include the number of primary care consultations, and potential effects on educational attainment and work productivity due to uncontrolled hayfever symptoms. There is published data available for this. There is also a NICE CKS (last revised January 2024) on allergic rhinitis, where it is mentioned that immunotherapy may be appropriate for some people.	Thank you for your comment. The background section is not intended to be exhaustive. No action needed.
Population	ALK-Abelló Ltd	The population is defined appropriately.	Thank you for your comment. No action required.
	Association of Respiratory Nurses	Yes	Thank you for your comment. No action required.

Section	Consultee/ Commentator	Comments [sic]	Action
	Royal College of Pathologists	Yes	Thank you for your comment. No action required.
	Royal College of Physicians	Yes	Thank you for your comment. No action required.
Subgroups	ALK-Abelló Ltd	There are no subgroups that should be considered separately.	Thank you for your comment. No action required.
	Association of Respiratory Nurses	This is just aimed at one subgroup of allergy to birch pollen and feel it could be grouped together with other new technology proposals for allergic rhinitis.	Thank you for your comment. NICE Technology Appraisals can only evaluate technologies within their marketing authorisation. For this evaluation, only people with moderate to severe allergic rhinitis, conjunctivitis or both caused by tree pollen can be included in the scope. No change to the scope required.

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	Royal College of Pathologists	There are no other obvious subgroups.	Thank you for your comment. No action required.
	Royal College of Physicians	There are no other obvious subgroups.	Thank you for your comment. No action required.
Comparators	ALK-Abelló Ltd	The comparators are defined appropriately.	Thank you for your comment. The scope has been updated to include Pollinex Trees as an example of established clinical management. The committee will decide the most appropriate comparators based on evidence presented to it.
	Association of Respiratory Nurses	no comparators listed – just pre-established treatment.	Thank you for your comment. The scope has been updated to include Pollinex Trees as an example of established clinical

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			management. The committee will decide the most appropriate comparators based on evidence presented to it.
	Royal College of Pathologists	Pollinex tree pollen is a licensed treatment for subcutaneous immunotherapy against tree pollen. There are also various other unlicensed subcutaneous and sublingual immunotherapy products used in the UK. Provision and availability of these is very variable as there is no standardised policy nationally.	Thank you for your comments. The scope has been updated to include Pollinex Trees as an example of established clinical management. The committee will decide the most appropriate comparators based on evidence presented to it.
	Royal College of Physicians	Pollinex tree pollen is a licensed treatment for subcutaneous immunotherapy against tree pollen. There are also various other unlicensed subcutaneous and sublingual immunotherapy products used in the UK. Provision and availability of these is very variable as there is no standardised policy nationally.	Thank you for your comments. The scope has been updated to include Pollinex Trees as an example of established clinical management. The committee will decide the most appropriate comparators based on

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			evidence presented to it.
Outcomes	ALK-Abelló Ltd	The outcomes are defined appropriately.	Thank you for your comment. No action required.
	Association of Respiratory Nurses	I think the outcome measures seem appropriate, although I would consider the total nasal symptoms score questionnaire to be used as a measurement and cost benefits.	Thank you for your comment. The outcomes listed are inclusive with 'total nasal symptoms score' potentially being captured under the listed outcomes. No action required.
	Royal College of Pathologists	Yes	Thank you for your comment. No action required.
	Royal College of Physicians	Yes	Thank you for your comment. No action required.

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Equality	ALK-Abelló Ltd	The company have identified no issues in the draft remit or scope pertaining to equality.	Thank you for your comment
	Association of Respiratory Nurses	No comment	Thank you for your comment
	Royal College of Pathologists	No specific equality issues noted.	Thank you for your comment
	Royal College of Physicians	No specific equality issues noted.	Thank you for your comment
Other considerations	ALK-Abelló Ltd	The company believes no other issues need to be considered at this point in time.	Thank you for your comment. No action required.
	Association of Respiratory Nurses	Please could it be noted how much this would cost per treatment, how often it is given, benefits to the patients needs to be clearer and what benefit is compared to standard treatment which is available.	Thank you for your comment. The scope does not typically include detailed costing information as this may be subject to change. However, the committee will assess both the clinical benefits and cost-effectiveness

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			of the treatment before making any recommendations. This evaluation will also include a comparison with standard treatments (usual care) to ensure the benefits are clearly understood.
Questions for consultation	ALK-Abelló Ltd	**Is a test for birch pollen sensitisation (for example, skin prick test and/or specific IgE) routinely undertaken for all people with birch pollen induced allergic rhinoconjunctivitis?** Birch pollen sensitisation testing is routinely undertaken for people with birch pollen-induced allergic rhinoconjunctivitis. The test for birch pollen sensitisation is carried out in both primary and secondary care. Approximately half of patients are diagnosed with AR in primary care, using clinical history supported by a nasal exam, and a response to first line treatments. (6) If a patient's symptoms persist despite initial pharmacotherapy, further testing may be carried out. This most commonly takes the form of skin prick testing, although some centres offer radioallergosorbent (RAST) or fractional exhaled nitric oxide (FeNO) testing. (1)	Thank you for your comments. The range of tests which may be required prior to treatment with Itulazax 12 SQ-BET SLIT which would not otherwise have occurred and should be included in the economic modelling has been updated. No further action required.

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		Currently, a more advanced diagnosis, including the specific allergen sensitisation and type of rhinitis, is made in secondary care, using clinical history, FeNO testing, skin prick tests, and/or blood test (IgE). (1) • **When is the test undertaken in clinical practice?** Testing is carried out for patients whose symptoms cannot be self-managed, symptoms are chronic, or where diagnosis is uncertain. These tests can be undertaken in primary care. Further testing in secondary care could also include patients with a more severe disease, or where symptoms persist despite optimal management in primary care. **In routine practice, how would you define moderate to severe allergic rhinitis and/or conjunctivitis?** AR can be classified according to the Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines as mild, moderate, or severe, and is defined on the basis of the presence or absence of impairment in any of the four health-related quality of life items: sleep, daily activities/sport, work/school, and troublesome symptoms. Patients with mild AR have no affected items, patients with moderate AR have 1 to 3 affected items, and patients with severe AR have all four affected items (6-8). **What is established clinical management for moderate to severe allergic rhinitis or conjunctivitis caused by pollen from the birch homologous group?** AR patients are typically treated in UK clinical practice with a range of symptomatic therapies, in line with NICE guidelines in primary care and British Society for Allergy and Clinical Immunology (BSACI) and ARIA guidelines in secondary care. (1, 6, 8, 9) The overall treatment pathway for AR in the UK is based on the BSACI rhinitis treatment algorithm. (1, 9) If a person has a diagnosis of AR, advice on allergen avoidance is usually recommended; in the context of pollen allergy this includes patients wearing sunglasses and nasal filters (6, 9).	

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		For patients with mild-to-moderate, intermittent, or mild persistent symptoms, oral or intranasal antihistamines are the first line of therapy. (6, 9) For patients with moderate-to-severe persistent symptoms, or those for whom initial treatment is ineffective, intranasal corticosteroids are recommended. (6, 9) If symptoms continue to persist despite these treatments, combination therapies can be explored, including combinations of oral antihistamines and intranasal corticosteroids, or combined preparations of intranasal corticosteroids and intranasal antihistamines. (6, 9) If these treatments are ineffective, despite compliance and proper technique, clinicians can then consider add-on therapies, such as allergen immunotherapy, depending on the persistent/refractory symptoms. (6, 9) **Do you consider Itulazax treatment to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?** Unlike current therapies, ITULAZAX® is an aetiological treatment which aims to modify the patient's immune response to birch tree homologous group pollen allergens. ITULAZAX® works by addressing the cause of birch pollen homologous group-induced allergic rhinitis and/or conjunctivitis. (10) Whilst the exact mechanism of the clinical effect is not fully understood, the modification of the immune response has been demonstrated in the upper airways through the increase in birch pollen-specific IgG4, and its induction of a systemic antibody response that can compete with immunoglobin E (IgE) in the binding of birch pollen allergens. (10) The underlying protection provided by ITULAZAX® leads to improvement in disease control and improved quality of life, demonstrated through symptom relief and a reduced need for other symptomatic medications such as nasal	

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		steroids. International treatment guidelines refer to a treatment period of 3 years for allergy immunotherapy to achieve disease modification. (3, 10-12) **Where do you consider Itulazax will fit into the existing care pathway for moderate to severe allergic rhinitis or conjunctivitis caused by birch pollen?** ITULAZAX® is indicated for adult patients for the treatment of moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group. Eligible patients are required to have a positive test of sensitisation to a member of the birch homologous group (skin prick test and/or specific IgE). AR patients are typically treated in UK clinical practice with a range of symptomatic therapies, in line with NICE guidelines in primary care and BSACI and ARIA guidelines in secondary care. (6, 8, 9) The overall treatment pathway for AR in the UK is based on the BSACI rhinitis treatment algorithm. (9) Notably, the BSACI guidelines recommend allergy immunotherapy (AIT) for the treatment of AR in patients with a seasonal allergy to pollen whose symptoms persist despite maximal drug therapy, combinations of intranasal corticosteroid and antihistamine taken regularly. (9) The current ARIA guidelines recommend the consideration of AIT for patients with AR and AA comorbidity caused predominantly by allergen exposure, with poor symptom reduction despite adequate pharmacotherapy during the allergy season and/or change in natural allergy history. (8) In line with these guidelines ITULAZAX® is expected to be used as an add-on therapy for patients with a clinical history of symptoms despite the use of symptom-relieving medication. (10) • **Will Itulazax be used in addition to established clinical management as an add-on therapy?**	

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		Yes, ITULAZAX® is expected to be used as an add-on therapy to established clinical management. **Please select from the following, will Itulazax be:** **A. Prescribed in primary care with routine follow-up in primary care** **B. Prescribed in secondary care with routine follow-up in primary care** **C. Prescribed in secondary care with routine follow-up in secondary care** **D. Other (please give details):** It is believed that ITULAZAX® will be initially prescribed and initiated by physicians with experience in the treatment of allergic diseases (likely this will take place in secondary care). As ITULAZAX® is a once-daily tablet, patients can self-administer at home with follow-up taking place in primary or secondary care. **For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.** For moderate-to-severe allergic rhinitis and/or conjunctivitis it is not expected that the setting for prescribing and routine follow-ups will change. **Would Itulazax be a candidate for managed access?** It is not expected that ITULAZAX® would be recommended under a managed access scheme. **Do you consider that the use of Itulazax can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?** We don't believe there are any additional benefits that are uncaptured in the QALY calculation at this time.	

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		Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits. TT-04 is the pivotal phase III randomised control trial to be considered for the efficacy of ITULAZAX® in subjects with moderate-to-severe allergic rhinitis and/or conjunctivitis induced by pollen from the birch homologous group. (13) **References**: 1. Data on file. Modified Delphi advisory panel. 2023. 2. Akdis CA, Barlan IB, Bahceciler N, Akdis M. Immunological mechanisms of sublingual immunotherapy. Allergy 2006;61:11-4. 3. Bousquet J, Khaltaev N, Cruz AA, Denburg J, Fokkens WJ, Togias A, et al. Allergic Rhinitis and its Impact on Asthma (ARIA) 2008 update (in collaboration with the World Health Organization, GA(2)LEN and AllerGen). Allergy. 2008;63 Suppl 86:8-160. 4. Jutel M, Agache I, Bonini S, others. International consensus on allergy immunotherapy. J Allergy Clin Immunol. 2015;136(3):556–68. 5. Bonertz A, Roberts GC, Hoefnagel M, others. Challenges in the implementation of EAACI guidelines on allergen immunotherapy: a global perspective on the regulation of allergen products. Allergy. 2018;73(1):64–76. 6. National Institute for Health and Care Excellence. Clinical Knowledge Summaries: Allergic Rhinitis. 2023.	

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		7. Valero A, Ferrer M, Sastre J, Navarro AM, Monclus L, Marti-Guadano E, et al. A new criterion by which to discriminate between patients with moderate allergic rhinitis and patients with severe allergic rhinitis based on the Allergic Rhinitis and its Impact on Asthma severity items. J Allergy Clin Immunol. 2007;120(2):359-65. 8. Bousquet J, Hellings PW, Agache I, Amat F, Annesi-Maesano I, Ansotegui IJ, et al. Allergic Rhinitis and its Impact on Asthma (ARIA) Phase 4 (2018): Change management in allergic rhinitis and asthma multimorbidity using mobile technology. J Allergy Clin Immunol. 2019;143(3):864-79. 9. Scadding GK, Kariyawasam HH, Scadding G, Mirakian R, Buckley RJ, Dixon T, et al. BSACI guideline for the diagnosis and management of allergic and non-allergic rhinitis (Revised Edition 2017; First edition 2007). Clin Exp Allergy. 2017;47(7):856-89. 10. ALK-Abelló A/S Ltd. ITULAZAX® 12 SQ-Bet oral lyophilisate. Summary of product characteristics: Electronic Medicines Compendium,; 2023 [11. Muraro A, Roberts G, Halken S, Agache I, Angier E, Fernandez-Rivas M, et al. EAACI guidelines on allergen immunotherapy: Executive statement. Allergy. 2018;73(4):739-43.	

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		12. Roberts G, Pfaar O, Akdis CA, Ansotegui IJ, Durham SR, Gerth van Wijk R, et al. EAACI Guidelines on Allergen Immunotherapy: Allergic rhinoconjunctivitis. Allergy. 2018;73(4):765-98. 13. Biedermann T, Kuna P, Panzner P, others. The SQ tree SLIT-tablet is highly effective and well tolerated: results from a randomized, double-blind, placebo-controlled Phase III trial. J Allergy Clin Immunol. 2019;143(3):1058–66. 14. Medicines and Healthcare products Regulatory Agency. ITULAZAX 12 SQ-Bet oral lyophilisate Public Assessment Report (PL 10085/0059). 2021.	
	Association of Respiratory Nurses	Would patient adherence to regular treatment need to be checked first before considering this treatment to see if they are taking them correctly and regularly as this can often be the case for worsening of symptoms of rhinitis.	Thank you for your comment. Patient adherence to current treatments is typically reviewed as part of a standard clinical consultation. Ensuring that patients are using their medications correctly and consistently is important before considering any changes to the treatment regimen, as poor adherence can often contribute to the

Section	Consultee/ Commentator	Comments [sic]	Action
			worsening of rhinitis symptoms. However, this cannot be covered within this technology appraisal and should be considered as part of any implementation strategy. No action needed.
	Royal College of Pathologists	Testing for birch pollen sensitisation would likely be undertaken for almost all patients seen in an allergy service. Within primary care, if the birch pollen allergy symptoms are milder or can be controlled with symptom-relieving medication, the test may not necessarily be done as it would not necessarily change management. There is variability in practice regarding this in primary care. A practical working definition of moderate/severe allergic rhinitis is when sleep, daily activities and/or work/school are affected or impaired. Established clinical management of moderate/severe allergic rhinitis is symptom-relieving medication (intranasal steroids/combination sprays, antihistamines, anti-allergy eye drops) used regularly and correctly. If this is insufficient, allergen immunotherapy would be the next step. However, provision of allergen immunotherapy is very variable and there is a postcode lottery, in the absence of a national policy on this. Itulazax would be a step-change up from symptom-relieving medication. There are other immunotherapy products (both licensed and unlicensed) but variable availability/provision of these. Itulazax is also available and already being used in some allergy centres in the UK.	Thank you for your comments. No action needed.

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		Itulazax would be additional therapy if a patient continues to have moderate/severe symptoms despite symptom-relieving medication. Itulazax should be prescribed in secondary care with routine follow-up in secondary care. It may also be initiated in secondary care, with shared care prescribing by primary care, but continued follow-up in secondary care.	
	Royal College of Physicians	Testing for birch pollen sensitisation would likely be undertaken for almost all patients seen in an allergy service. Within primary care, if the birch pollen allergy symptoms are milder or can be controlled with symptom-relieving medication, the test may not necessarily be done as it would not necessarily change management. There is variability in practice regarding this in primary care. A practical working definition of moderate/severe allergic rhinitis is when sleep, daily activities and/or work/school are affected or impaired. Established clinical management of moderate/severe allergic rhinitis is symptom-relieving medication (intranasal steroids/combination sprays, antihistamines, anti-allergy eye drops) used regularly and correctly. If this is insufficient, allergen immunotherapy would be the next step. However, provision of allergen immunotherapy is very variable and there is a postcode lottery, in the absence of a national policy on this. Itulazax would be a step-change up from symptom-relieving medication. There are other immunotherapy products (both licensed and unlicensed) but variable availability/provision of these. Itulazax is also available and already being used in some allergy centres in the UK. Itulazax would be additional therapy if a patient continues to have moderate/severe symptoms despite symptom-relieving medication.	Thank you for your comments. No action needed.

Section	Consultee/ Commentator	Comments [sic]	Action
		Itulazax should be prescribed in secondary care with routine follow-up in secondary care. It may also be initiated in secondary care, with shared care prescribing by primary care, but continued follow-up in secondary care.	
Additional comments on the draft scope	ALK-Abelló Ltd	No additional comments	Thank you for your comment

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

None