

## **Appendix B**

### **NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

#### **Proposed Health Technology Appraisal**

#### **SGT320 for treating persistent allergic rhinitis caused by house dust mites**

#### **Draft scope (pre-referral)**

##### **Draft remit/appraisal objective**

To appraise the clinical and cost effectiveness of SGT320 within its marketing authorisation for treating persistent allergic rhinitis caused by house dust mites.

##### **Background**

Allergic rhinitis is inflammation of the inside of the nose caused by an allergen, such as pollen, dust, mould, or flakes of skin from certain animals. It can be seasonal or perennial, and is classified as intermittent or persistent depending on the frequency of symptoms<sup>i</sup>. Most people are sensitive to more than one allergen, but house dust mites are the most common indoor allergen that cause rhinitis<sup>ii</sup>.

Allergic rhinitis typically causes cold-like symptoms, such as sneezing, itchiness and a blocked or runny nose. For many people symptoms can be managed with over the counter medicines. However, for some people symptoms can be severe and persistent, affecting physical and psychological wellbeing, causing sleep problems and interfering with everyday life. Allergic rhinitis is associated with other inflammatory conditions, including allergic conjunctivitis, rhinosinusitis and asthma, and can sometimes lead to complications such as nasal polyps, sinusitis or middle ear infections<sup>iii</sup>.

Allergic rhinitis has the highest prevalence of all allergic respiratory disease, affecting up to 20% of the UK population<sup>iv</sup>. It affects people of all ages, with around 80% of people diagnosed before the age of 20<sup>v</sup>. The prevalence of house dust mite activated allergic rhinitis is estimated at about 5 million people in England<sup>vi</sup>. Of these, about 1 million (20%) have allergic rhinitis caused by house dust mites that is not adequately controlled by currently available pharmacotherapies<sup>vii</sup>.

There is no NICE guidance for treating persistent allergic rhinitis caused by house dust mites. Current practice includes avoiding the allergen where appropriate, followed by pharmacological therapies aimed at symptom control. These include oral and nasal antihistamines and nasal corticosteroids. Decongestants and saline nasal douching (regularly rinsing nasal passages with a salt water solution to keep the nose free of irritants) can be used alongside standard medicines to help treat unresponsive symptoms. Oral corticosteroids may be used for a short time if symptoms are severe.

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Immunotherapy is usually only considered if the disease is severe, has not responded to standard therapy and the exact causative allergen has been confirmed by a skin prick test or blood test.

### The technology

SGT320 (Actair, Stallergenes) is an allergen immunotherapy designed to develop allergy desensitisation. It is administered sublingually.

SGT320 does not currently have a marketing authorisation in the UK for treating persistent allergic rhinitis caused by house dust mites. It has been studied in randomised placebo-controlled clinical trials in adults and adolescents (aged 12 – 65 years) with house dust mite associated allergic rhinitis and sensitisation to *D. pteronyssinus* or *D. farinae* confirmed by skin prick test.

<b>Intervention(s)</b>	SGT320
<b>Population(s)</b>	Adults and adolescents with persistent allergic rhinitis caused by house dust mites
<b>Comparators</b>	<p>Standard treatments</p> <ul style="list-style-type: none"><li>• Oral antihistamines (such as acrivastine, bilastine, cetirizine, desloratadine, fexofenadine, ketotifen, levocetirizine, loratadine, mizolastine)</li><li>• Nasal corticosteroids (such as beclometasone, betamethasone, budesonide, fluticasone, mometasone)</li><li>• Nasal antihistamines (such as azelastine)</li></ul> <p>Adjuvant treatments</p> <ul style="list-style-type: none"><li>• Saline nasal douching</li><li>• Nasal decongestants (such as oxymetazoline, xylometazoline, ipratropium)</li><li>• Oral decongestants (such as ephedrine, phenylephrine, pseudoephedrine)</li><li>• Oral corticosteroids (such as prednisolone)</li></ul>
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"><li>• mortality</li><li>• severity of patient-reported rhinitis symptoms</li><li>• immunological markers</li><li>• complications of allergic rhinitis (such as nasal</li></ul>

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	<p>polyps, sinusitis or middle ear infections)</p> <ul style="list-style-type: none"> <li>• adverse effects of treatment</li> <li>• health-related quality of life</li> </ul>
<b>Economic analysis</b>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The use of SGT320 is conditional on the presence of house dust mite allergy confirmed by allergy testing (skin prick test or blood test). The economic modelling should include the costs associated with allergy testing in people with persistent allergic rhinitis who would not otherwise have been tested. A sensitivity analysis should be provided without the cost of the diagnostic test. See section 5.9 of the <a href="#">Guide to the Methods of Technology Appraisals</a>.</p>
<b>Other considerations</b>	<p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
<b>Related National Policy</b>	<p>Manual for prescribed specialised services. Chapter 59 Highly specialist allergy services (adults and children)  <a href="https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/pss-manual-may16.pdf">https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/06/pss-manual-may16.pdf</a></p> <p>Department of Health, NHS Outcomes Framework 2016-2017 (published 2016): Domains 2 and 3.  <a href="https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017">https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</a></p> <p>NHS England (2013/14) B09/S/b NHS Standard Contract for Specialised Allergy Services (all ages)  <a href="https://www.england.nhs.uk/wp-content/uploads/2013/06/b09-spec-allergy.pdf">https://www.england.nhs.uk/wp-content/uploads/2013/06/b09-spec-allergy.pdf</a></p>

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### Questions for consultation

Have all relevant comparators for SGT320 been included in the scope?

- Which treatments are considered to be established clinical practice in the NHS for persistent allergic rhinitis caused by house dust mites?
- Are leukotriene receptor antagonists used to treat persistent allergic rhinitis caused by house dust mites?
- Does treatment of persistent allergic rhinitis caused by house dust mites differ according to severity of symptoms (for example, mild, moderate, severe)?

Where is SGT320 likely to be used in the treatment pathway for persistent allergic rhinitis caused by house dust mites?

- Would SGT320 be used after standard treatments have been tried?
- Would adjuvant treatments be used alongside SGT320?

Is skin prick testing routinely undertaken for all people with persistent allergic rhinitis?

- Would all people having SGT320 need a skin prick test to confirm sensitisation?

Are the outcomes listed appropriate?

Are there any subgroups of people in whom SGT320 is expected to be more clinically effective and cost effective or other groups that should be examined separately?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which SGT320 will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

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Do you consider SGT320 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)?

Do you consider that the use of SGT320 can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at <http://www.nice.org.uk/article/pmg19/chapter/1-Introduction>).

## References

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- <sup>i</sup> World Allergy Organisation [Rhinitis](#). Accessed August 2017.
  - <sup>ii</sup> British Society for Allergy and Clinical Immunology [Guidelines for the management of allergic and non-allergic rhinitis](#). Accessed August 2017
  - <sup>iii</sup> NHS Choices [Allergic rhinitis](#). Accessed August 2017.
  - <sup>iv</sup> Walker SM, Durham SR, Till SJ et al. (2011) [Immunotherapy for allergic rhinitis](#). Clinical & Experimental Allergy 41(9): 1177-1200.
  - <sup>v</sup> Greiner AN, Hellings PW, Rotiroti G et al. (2011) [Allergic rhinitis](#). Lancet 378(9809): 2112-2122.
  - <sup>vi</sup> Demoly P, Emminger W, Rhem D et al. (2015) [Effective treatment of house dust mite-induced allergic rhinitis with 2 doses of the SQ HDM SLIT-tablet: results form a randomized double-blind, placebo-controlled phase III trial](#). Journal of Allergy & Clinical Immunology doi: 10.1016.
  - <sup>vii</sup> NIHR Horizon Scanning Centre. (2013) [House dust mite allergen immunotherapy tablet \(Mitizax\) for house dust mite allergy-induced rhinitis and conjunctivitis – third line](#). Accessed August 2017.