NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

SGT320 for treating allergic rhinitis or rhinoconjunctivitis caused by house dust mites ID1278

Draft scope

Draft remit/appraisal objective

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

Background

House dust mites (HDM) are microscopic organisms found in the dust that builds up in the house. House dust mite allergy is an IgE-mediated hypersensitive reaction to proteins in the droppings of dust mites. These proteins can act as allergens (cause an allergic reaction) in the upper or lower respiratory tract causing the symptoms of rhinitis and asthma[1].

Allergic rhinitis is an inflammation of the inside of nose caused by an allergen. Depending on the nature of the allergen, allergic rhinitis has traditionally been categorised as either seasonal allergic rhinitis (e.g., induced by pollen) or perennial allergic rhinitis (e.g., induced by animals or dust mites). The disease can further be categorised as either ‘mild’, ‘moderate’ or ’severe’, depending on the severity of symptoms and impact on quality of life (QoL). In the United Kingdom, the most common allergic trigger for perennial allergic rhinitis is the house dust mite[2].

The prevalence of house dust mite activated allergic rhinitis is estimated at around 5 million people in England[1], of these around 1 million (20%) people have house dust mite activated allergic rhinitis which is not currently adequately controlled[3]. Diagnosis involves carefully taken history in combination with sensitization to HDM allergens. Four out of 5 people with an allergy to HDM are also allergic to other allergens in the air such as pollens or flakes of skin from certain animals)[1]. Allergic rhinitis commonly occurs with allergic conjunctivitis (inflammation of the thin layer of skin on the inside of the eye causingred, itchy eyes) and is known as rhinoconjunctivitis. Allergic rhinitis can also occur with rhinosinusitis and asthma, and can sometimes lead to complications such as nasal polyps, sinusitis or middle ear infections[4].

There is no NICE guidance or national guidelines for treating allergic rhinitis caused by house dust mites. Initial treatment may involve allergy avoidance[4]. This can be followed by pharmacotherapy aimed at symptom control (mainly antihistamines and topical nasal corticosteroids). For people with more severe allergic rhinitis, which does not respond to usual therapy, specific

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desensitisation to the house dust mite allergens with immunotherapy may be considered[4].

The technology

SGT320 (Actair, Stallergenes) is a tablet containing standardised house dust mite allergen extracts from *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae.* itis an allergen immunotherapy designed to develop allergy desensitisation. It is administered sublingually.

SGT320 has a marketing authorisation in the UK for adolescents (12-17 years) and adults for treatment of moderate to severe house dust mite-induced allergic rhinitis or rhinoconjunctivitis, diagnosed by clinical history and a positive test of house dust mite sensitisation (skin prick test and/or specific IgE).

Intervention(s)	SGT320
Population(s)	Adolescents (12-17 years) and adults with moderate to severe house dust mite-induced allergic rhinitis or rhinoconjunctivitis
Comparators	• Established clinical management without SGT320
Outcomes	The outcome measures to be considered include: • severity of rhinitis symptoms • immunological response to treatment • complications of allergic rhinitis (such as nasal polyps, sinusitis or middle ear infections) • rhinitis medication use • adverse effects of treatment • health-related quality of life • overall survival
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. 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. Costs will be considered from an NHS and Personal Social Services perspective.

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	The use of SGT320 is conditional on the presence of house dust mite allergy confirmed by allergy testing (skin prick test and/or specific IgE). 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 Guide to the Methods of Technology Appraisals'.
Other considerations	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. If the evidence allows subgroups will be considered by disease severity.
Related NICE recommendations and NICE Pathways	Related Interventional Procedures: Intranasal phototherapy for allergic rhinitis (2018) NICE interventional procedures guidance 616 Related Diagnostics Guidance: ImmunoCAP ISAC 112 and Microtest for multiplex allergen testing (2016) NICE diagnostics guidance 24 Related Clinical Knowledge Summaries: Allergic rhinitis (2018) NICE Clinical Knowledge Summary
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019). Chapter 59 Highly specialist allergy services (adults and children) Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domain 2. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

Questions for consultation

Is a test for house dust mite sensitisation (for example, skin prick test and/or specific IgE) routinely undertaken for all people with house dust mite induced allergic rhinitis?

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- When is the test undertaken in clinical practice?
- Which test is most commonly used?

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

Which treatments are considered to be established clinical practice in the NHS for allergic rhinitis or rhinoconjunctivitis caused by house dust mites? In particular:

- Would SGT320 be used as an alternative to first- line treatments for allergic rhinitis such as antihistimines and intranasal corticosteroids, or would it be used only if first line treatments had not adequately controlled the allergic rhinitis.
- What immunotherapies, if any, are currently used? Is SGT320 already used in the NHS?
- Does treatment of allergic rhinitis caused by house dust mites differ according to severity of symptoms (for example, mild, moderate, severe)?
- Would SGT320 be added on to standard therapy for allergic rhinitis?

Are the outcomes listed appropriate?

Are the subgroups suggested in 'other considerations appropriate? Are there any other 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.

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

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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

1. 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

2. Bauchau, V, Durham, SR Prevalence and rate of diagnosis of allergic rhinitis in Europe. European Respiratory Journal (2004) 24[5] 758-64

3. NIHR Horizon Scanning Centre. (2013) House dust mite allergen immunotherapy tablet (Mitizax) for house dust mite allergy-induced rhinitis and conjunctivitis – third line. Accessed November 2021.

4. NHS Choices Allergic rhinitis. Accessed November 2021.

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