DRAFT FOR CONSULTATION

Clinical Commissioning Policy Proposition:

Temperature-controlled laminar airflow device for persistent allergic asthma (children)

Reference: NHS England E03X07/01

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Clinical Commissioning Policy Proposition: Temperature-controlled laminar airflow device for persistent allergic asthma (children)

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Plain Language Summary

This policy aims to confirm NHS England's commissioning approach to temperature-controlled laminar airflow devices for children with severe and persistent allergic asthma and specifically those affected by exposure to airborne allergens.

Temperature-controlled laminar airflow devices are primarily intended for home use by patients with poorly controlled persistent allergic asthma despite receiving high intensity treatment. Such patients are likely to be under the care of a hospital-based respiratory physician.

These devices are principally designed to operate by the bedside while the patient sleeps. It draws air from the room through a filter, which is then cooled to below ambient temperature before being slowly expelled. As the cooled air is more dense than the surrounding air, it descends to the patient's breathing zone. The device therefore provides filtered air around the patient's face throughout the night, breaking the natural body convection without creating draught or dehydration.

NHS England has reviewed the clinical evidence and concluded that there is insufficient evidence to support the routine commissioning of temperature-controlled laminar airflow devices.

1. Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to not routinely commission temperature-controlled laminar airflow devices for the treatment of persistent allergic asthma in children.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final decision as to whether temperature-controlled laminar airflow devices for persistent allergic asthma will not be routinely commissioned is planned to be made by NHS England by May 2016 following a recommendation from the Clinical Priorities Advisory Group.

2. The proposed intervention and clinical indication

The UK direct healthcare costs for asthma are over £1 billion per year, of which a high percentage is focused on those with the top quartile of severity-related drug requirements. Such patients require specialist tertiary investigation and care. Detailed assessment is required to establish which patients have truly therapy resistant disease compared with those that have potentially avoidable contributors to high morbidity, such as: poor concordance with therapy, significant co-morbidities (obesity, rhinitis etc), avoidable adjuvants such as cigarette smoke, wrong prescription or wrong diagnosis. Having excluded the former, those with severe persistent allergic asthma are considered for treatment with omalizumab.

This policy has considered the clinical evidence available to support the routine commissioning of temperature-controlled laminar airflow devices for children suffering from persistent allergic asthma as a treatment prior to the consideration of omalizumab.

3. Definitions

Temperature-controlled laminar airflow devices are a method of stringent aero-allergen avoidance by controlling the air quality around a patient's breathing zone throughout the night.

Persistent allergic asthma in children is defined as those who meet the Global Initiative for Asthma (GINA) 2002 step 4 criteria, requiring referral for specialist advice.

4. Aim and objectives

This policy aims to define the current commissioning proposition for Temperature-controlled Laminar Airflow based on the current evidence base.

The objective is to ensure the commissioning of interventions to improve outcomes for children with Persistent Allergic Asthma is evidence based.

5. Epidemiology and needs assessment

The quality and outcomes framework (2008) estimated that 5.9% of the UK population have asthma, with estimates ranging from 3 to 5.4 million. Asthma UK estimated that between 2008 and 2009 there were 79,794 emergency hospital admissions in England, of which 30,740 were of children aged up to 14 years. According to Asthma UK, 75% of all hospital admissions for asthma are avoidable through good asthma management and routine care.

6. Evidence base

This document describes the evidence that has been considered by NHS England in formulating a proposal to not routinely commission temperature-controlled laminar airflow devices for the treatment of persistent allergic asthma in children.

The evidence review looked to consider the following research questions:
Are temperature-controlled laminar airflow (TCLA) devices clinically effective in reducing airway inflammation, sustaining improved asthma control, reducing annual exacerbation rates, and improving quality of life patients with persistent allergic asthma compared with no intervention or with other standardised treatments? Are TCLA devices cost effective in children with persistent allergic asthma?

Based on the inclusion and exclusion criteria detailed in the appendix, 4 studies were selected for full review. This includes a National Institute for Health and Care Excellence (NICE) Medtech Innovation Briefing published in August 2014. There are two Grade 1- studies, including a randomised controlled trial and one cost-effectiveness study which were both funded by Airsonnet AB. There is one Grade 3 case series which addresses clinical effectiveness in addition to quality of life outcomes.

The best current evidence for use of TCLA devices for persistent allergic asthma comes from a single, relatively large, randomised study (Boyle et al 2012). This study was not designed primarily to evaluate the full effects clinical effectiveness of TCLA such as impact on asthma exacerbations, hospitalisation, emergency room visits and use of medication. The history of frequent or severe exacerbations was not an inclusion criterion. In the included study population, the active and placebo groups showed no statistically significant difference in standard asthma medication use and asthma exacerbations. There was no follow-up of the patients post study period to evaluate long term effectiveness. TCLA treatment was associated with a greater decrease in fraction exhaled nitric oxide (FeNO) than placebo during the study period of one year. There was no significant impact on blood eosinophil counts, total IgE level and overall lung function between treatment groups.

Despite the identified limitations in study design, there is some evidence from the study that TCLA can improve quality of life for patients with more severe and uncontrolled asthma.

Of those patients who had at least 1 day of treatment with the Airsonett device, there was a significantly greater proportion with increase in AQLQ score of at least 0.5 points and 1 points compared with the placebo group. Statistically significant improvements using this measure were most noticeably reported in those with poor symptom control (ACT<18) who received high intensity treatment. These differences in improvement of quality of life only reach statistical significance in the subgroup of patients aged below 12 years. The study was powered on subgroup> 12 years.

The other study which specifically addressed questions of clinical effectiveness in addition to quality of life (Schauer et al 2015) is a non-randomized uncontrolled pre and post retrospective observational study to investigate the effect of 12 months' TCLA use in a population of 30 patients (27 finished full 12 month follow-up). Due to small number of patients and the observational study design, the findings from the study cannot be generalised to broader patient population.

Medtech innovation briefing on the Airsonett temperature-controlled laminar airflow device for persistent allergic asthma (NICE, 2014) advises that the device is non invasive and non pharmaceutical. No treatment related adverse events have been identified. Two trials (Boyle et al 2012, Pedroletti et al. 2009) showed statistically significant improvement in asthma related quality of life in people with severe persistent allergic asthma when Airsonett was compared with a placebo device. There was no statistically significant difference in asthma medication usage or exacerbation rates, which were secondary outcome measures in one randomised controlled trial. The second Randomised Control Trial (Pedroletti et al. 2009) was identified as a crossover study with a very small sample size, and no details were reported on the methods of randomisation or blinding. All other studies reviewed had small sample sizes and provided insufficient information to assess their quality.

There is currently very limited published evidence on how the use of the Airsonett device, or similar TCLA would affect NHS resources by either reducing the use of Omalizumab and other alternative treatment options or reducing asthma exacerbations.

The Medtech review advises that the average cost of long term treatment with Airsonett is £5.72 per patient per day. The estimated cost of an add on therapy currently used in NHS practice, Omalizumab, is £23 per day.

The only study on cost-effectiveness of TCLA (Brodtkorb et al 2010) is based on Markov model of QALYs for next 5 year using data from Pedroletti et al (2011). The study concludes that Airshower strategy could result in a mean gain of 0.25 QALYs per patient in Sweden, thus yielding an approximate cost per QALY gained of under £25,571 as long as the cost of Airshower is below £5991 [Original figures provided in euros and converted to the nearest full pound based on conversion rate on 19/10/2015 of £1 to 1.37 euros and is provided as a guideline for comparison only]. The study does not include comparative cost effectiveness with existing comparator interventions such as Omalizumab, immunosuppressant therapy and bronchial thermoplasty.

The UK LASER Trial (Laminar Airflow in Severe Asthma for Exacerbation Reduction) currently underway could provide conclusive evidence regarding the clinical and comparative cost effectiveness of TCLA in patients with Persistent Allergic Asthma.

7. Documents which have informed this policy

NICE MIB Report - Airsonnet Temperature-Controlled Laminar Airflow Device 2014
NICE Technology Appraisal Guidance - Omalizumab for treating severe persistent allergic asthma [TA 278] 2013

8. Date of review

This document will lapse upon publication by NHS England of a commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned (expected by June 2016)