

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	9 th April 2015 (reviewed 1 st September 2020)
Appraisal & Details	<p>Airsonett® laminar flow device for treatment of uncontrolled asthma</p> <p>The Northern (NHS) Treatment Advisory Group considered an appraisal of Airsonett® (Airsonett UK Ltd) laminar flow device for patients with persistent allergic asthma that has not responded adequately to high-intensity pharmacotherapy.</p>
Recommendation	<p>The Northern (NHS) Treatment Advisory Group does not recommend the use of the Airsonett® laminar flow device for the treatment of uncontrolled allergic asthma in adults</p> <p>Although a number of trials have been conducted, the bulk of the clinical data relates to quality of life changes and there is no data showing any improvement in patient orientated outcomes such as a reduction in exacerbations, hospitalisation or medication use.</p> <p>The LASER RCT showed there were some improvements in health-related quality of life at the 6-month follow-up and in peak expiratory flow, but the magnitude of these differences was not sufficient to make the device cost-effective.</p> <p>Noted that not routinely commissioned by NHS England for use in Children as per Clinical Commissioning Policy: 16013/P July 2016.</p>
Clinical evidence summary	<p>The pivotal study (n=282) is a randomised double-blind trial with change in quality of life scores as the primary outcome. A significant improvement in quality of life, as measured by the mini asthma related quality of life questionnaire (AQLQ) or paediatric AQLQ, was more common with Airsonett than placebo (76% vs. 61%). The effect was more pronounced in the people with poorly controlled asthma at baseline. However, this pre-specified subgroup was small, and there is no evidence that pharmacotherapy was optimised prior to starting treatment with Airsonett. There was a high response rate in the placebo arm, suggesting a response bias may be present.</p> <p>The LASER Study (n=489) between May 2014 and January 2016, was a multicentre, randomised, double-blind, placebo-controlled, parallel-group study. The mean [standard deviation (SD)] rate of severe exacerbations did not differ between groups [active 1.39 (1.57), placebo 1.48 (2.03); risk ratio 0.92, 95% CI 0.66 to 1.27; p = 0.616]. There were no significant differences in secondary outcomes for lung function, except for a reduction in mean daily peak expiratory flow [mean (SD) difference 14.7 l/minute (7.35 l/minute), 95% CI 0.32 to 29.1 l/minute; p = 0.045) for those in the active device group. There were no differences in asthma control or airway inflammation and no serious harms related to the device. No significant difference between the groups in quality-adjusted life-years gained over 1 year was observed. In addition, there was no difference in generic or disease-specific health-related quality of life overall, although statistically significant higher quality of life at month 6 was observed. Increases in quality of life were not sufficient to offset the annual costs associated with use of the TLA device.</p>



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Safety	No safety concerns were raised. While adverse events were reported commonly, none were considered to be related to study treatment. A small proportion of people discontinued treatment due to the draught or sound produced by the device causing a disturbance.
Patient Perspective	The Airsonett device is large, and is designed to be installed in a bedroom and left in situ. Patients are therefore unable to use it during trips away from home, making it potentially unsuitable for patients who travel frequently. It is also not clear how frequently the device must be used to achieve a good treatment effect. The cost of running the Airsonett device will likely be borne by the patient, but should be reasonably low. Assuming an electricity cost of 14p per kWh, power consumption of 60-90W and average of 8 hours use per night, estimated running costs are approximately £25-34 per year.
Cost analysis summary	A cost-effectiveness analysis estimates that due to decreased healthcare costs the net cost to the NHS will be approximately £535, with a corresponding ICER of less than £10,000 per QALY. However, this analysis is based on data from a small, uncontrolled, unpublished study conducted in Germany, whose applicability to the UK population cannot be fully assessed.
Financial impact PbR: In-tariff	The annual rental cost of Airsonett is £2,088, including routine servicing and filter replacement. Additional costs may be incurred if damage occurs due to misuse. The financial impact of this recommendation is expected to be nil.