Advice note for the Evaluation of Temperature Controlled Laminar Airflow (Airsonett®)
(For use in a fully assessed and monitored patient as part of a difficult asthma service)

Scientific basis
Airsonett® is a non-pharmacological treatment for patients with poorly controlled persistent atopic asthma despite medium to high dose pharmacotherapy. It utilises a novel filtered Temperature Controlled Laminar Airflow (TLA), which allows the patient to breath air which is almost totally allergen-free whilst asleep in bed.

Exposure to inhaled allergens is believed to drive ongoing airway inflammation in atopic asthma. Previous efforts to reduce allergen load have not so far been judged to produce cost effective clinical benefits (BTS/SIGN Asthma Guideline 2011; Cochrane Summaries – summaries.cochrane.org), but have generally focussed on removing allergen from a relatively large environment (ie whole room, whole house) with variable outcomes (Sublett, Curr Allergy Asthma Rep 2011).

Airsonett® differs by eliminating allergen from a very limited area in front of the patient’s face (the breathing zone). Movements in the bed (a significant allergen reservoir) and the warm body create a persistent airflow, transporting allergens from the bedding to the breathing zone exposing the patient to inhaled allergens all through the night (Gore et al, Thorax supplement BTS 2010). Airsonett® is able to displace the body convection without creating a draught or dehydration, and thereby reduces and controls allergen exposure in the breathing zone throughout the night (Svensson et al, JACI supplement EAACI 2010).

Clinical outcomes
There is limited evidence for clinical outcomes, with just 2 studies, one an RCT published in Thorax 2011 (Pedroletti et al Respir Med 2009, Boyle et al Thorax 2011). After 1 year of treatment quality of life was improved most clearly in those patients on the most treatment (step 4) and/or with the poorest asthma control (Asthma Control Test <18). There was some improvement in exhaled nitric oxide (FeNO), but no improvement in total IgE or lung function. Airsonett® appeared to minimise the increase in allergen specific IgE (HDM, cat, dog) seen in the placebo group. There was no statistically significant effect on exacerbation rate or medication (though the study was not designed or powered for this). No serious adverse events have been noted. Of note smokers, passive smokers, and those on ICS >1200mcg budesonide / >1000mcg fluticasone were excluded.

Eligibility Criteria
The target population is envisaged to be atopic asthma patients with poorly controlled asthma at BTS/GINA step 4 and above who may be under consideration for long term oral steroid or omalizumab therapy, or may have refused / had no benefit from omalizumab. It may have particular relevance where total IgE >1500 precludes the use of omalizumab. The following specific criteria apply (from RCT Boyle et al Thorax 2011):
• Patient prescribed high dose ICS + LABA and poorly controlled (ACT <18/ACS>2), with or without oral corticosteroids, but not currently on Omalizumab
• Positive skin test/serology (>0.7kU) to at least 1 indoor perennial allergen (house dust mite, cat, dog) and total serum IgE at least 70 IU/ml
• Patient aged 6 and above (providing able to sleep in own bed for most of the night)

Cost Implications
The current cost is £208.80 per calendar month (£174 plus 20% VAT). This is a fully managed scheme and includes the responsibility for all servicing, breakdown cover and consumables (ie filters every 6 months). Billing is on a monthly basis. There is no specific contract. It does not include electricity usage – estimated at 50W/10p per night by the company – which is paid for by the patient with no mechanism for reclaiming costs.

Airsonett, the company which provides Airsonett®, have agreed to refund the first 6 months of treatment if discontinued for any reason, including, but not limited to, failure to show improvement in symptoms and/or quality of life, or patient preference to not continue. There are no strict criteria – simply clinician and/or patient decision. If treatment is successful and continued there is no refund. Patients currently receiving Airsonett® funded by Airsonett (previous agreement) will continue to do so until funding is obtained, or the treatment withdrawn by clinician/patient.

Comparison with Omalizumab: Airsonett® costs £2505.60 per year. Omalizumab varies from approx £3300 to £26600 depending on IgE level and patient weight (this does not include the cost of hospital visits).

Patients wishing to buy privately pay £8500 (including VAT) for the machine. Filters are £143 (including VAT) every 6 months. Servicing is separately chargeable by the company – no quote available.

Governance issues
Airsonett® is CE marked and accepted by the MHRA as a class 1 medical device to be used in the patient’s own home. It adheres to relevant EU directives regarding design, function, safety and health requirements. In the event of machine failure Airsonett will replace it within 2 weeks of notification. In the event of harm to the patient as a result of failure to replace the device Airsonett’s insurance bears all responsibilities. Post-marketing surveillance data is planned to be collected via a database set up through UCL (not yet in operation).
Guide for the assessment of response to treatment with Airsonett

Baseline assessment
Key assessments: Mini-AQLQ, ACT, ACS
Supportive assessments: PEF, medication, unscheduled asthma related Health Care Use in last 12 months (GP visits, A&E attendance, hospital admissions)

26 week/6 months decision to continue
Key response indicators: must achieve at least 2.0 improvement in ACT OR at least 0.5 improvement in mini-AQLQ with no deterioration in the other
Supportive indicators: PEF
Medication changes
Unscheduled HCU

52 week/yearly assessment
Key assessments: Mini-AQLQ change from baseline
ACT/ACS change from baseline
Supportive assessments: PEF change from baseline
Medication change from baseline
Unscheduled HCU since baseline

Could also include spirometry and GETE as part of assessment

Summary

Airsonett® offers a novel therapeutic approach in patients with poorly controlled atopic asthma. Although the evidence is currently less robust, it offers the potential advantages of cost and convenience over omalizumab, and avoids the potential long term adverse health outcomes and associated costs of oral steroids.

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Airsonett® Evaluation Project
Patient Assessment Form

Baseline assessment

- Mini AQLQ score
- ACT score
- PEF
- Medication
- Unplanned GP visits last 12 months
- A&E attendance last 12 months
- Hospital admissions last 12 months

26 Week assessment

- Mini AQLQ score
- ACT score
- PEF
- Medication changes
- Unplanned GP visits since baseline
- A&E attendance since baseline
- Hospital admissions since baseline

52 Weeks assessment

- Mini AQLQ score
- ACT score
- PEF
- Medication changes
- Unplanned GP visits since baseline
- A&E attendance since baseline
- Hospital admissions since baseline