DRAFT FOR CONSULTATION

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	E03X07		
Policy Title	Temperature-controlled laminar airflow device for persistent allergic asthma (children)		
Accountable Commissioner	Julia Grace	**Clinical Lead**	John Warner
Finance Lead	Shekh Motin	**Analytical Lead**	Ceri Townley
Section K - Activity Impact			
Theme	**Questions**		**Comments** (Include source of information and details of assumptions made and any issues with the data)
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?		K1.1 This policy proposes that temperature-controlled laminar airflow devices (TCLA) will **not be routinely commissioned** for children with severe persistent allergic asthma. The prevalence of asthma in the UK is estimated at 1:12 in adults and 1:11 in children. In England, this relates to a population of 3.6m adults and 1.1m children receiving treatment for asthma. [i]

	K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	K.1.2 Under the policy, TCLA is indicated in relation to children with severe persistent allergic asthma. The prevalence of severe difficult to control asthma is approximately 140 per million.[ii] Based on this, the number of children that could be eligible for TCLA is estimated at around 1,600 in 2014/15.[iii]
	K1.3 What age group is the treatment indicated for?	K1.3 This treatment is indicated for children (under 18).
	K1.4 Describe the age distribution of the patient population taking up treatment.	K1.4 Amongst children, prevalence of asthma is highest in those aged 5 to 15.[iv]
	K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 There were an estimated 2,900 **hospital admissions** in 2014/15 relating to children with mixed and allergic asthma.[v] There is **other activity in the system** around management of severe asthma which includes outpatient attendances, visits to specialist centres and asthma clinics and emergency attendances. However, the volume of these for the target population is not confirmed.[vi] TCLA is not routinely commissioned by NHS England. Around five patients may have started using the device last year through individual funding requests (IFRs).[vii] TCLA is considered to be additive treatment, not specifically displacing other activity relating to management of this condition.

	K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	K1.6 No growth in the underlying prevalence rate of the condition is expected.[viii] As such, the eligible population is estimated to grow due to general population growth. The number of children affected by severe difficult to control asthma is estimated to be in the region of: [ix] • ~1,630 in 2016/17 • ~1,630 in 2017/18 • ~1,650 in 2020/21
	K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2, 5 and 10 years?	K1.7 Historically, the growth rate in non-elective admissions for those with allergic asthma averaged c.9% per annum.[x] If this were to continue, activity in future years is estimated at around: • ~3,450 in 2016/17 • ~3,750 in 2017/18 • ~4,800 in 2020/21
	K1.8 How is the population currently distributed geographically?	K1.8 More children are admitted to hospital with asthma in the North West, West Midlands, and parts of East Anglia.[xi] These areas have rates of hospital admissions of over 260 per 100,000 children aged under 19.
K2 Future Patient Population & Demography	K2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	K2.1 This policy establishes a non-routine commissioning position.
	K2.2 Please describe any factors likely to affect growth in the	K2.2 Environmental factors could trigger

	patient population for this intervention (e.g. increased disease prevalence, increased survival). K2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details. K2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?	asthma, including air pollution, chemicals and other factors as per the NHS.[xii] Increases in these factors could affect growth. K2.3 None identified. K2.4 The policy establishes a "not routinely commissioned position" for the eligible population. The number of patients who fall outside of the cohort covered by the proposed policy, or for whom exceptionality might be demonstrated is likely to be very small. There is therefore likely to be no change in the number of patients who would access the treatment.
K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet. K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet. K3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please provide details in accompanying excel sheet.	K3.1 The current activity is set out in K1.5. K3.2 The new activity levels are set out in K1.7 and K2.4. K.3.3 The activity would be as set out in 3.2 as the policy is to not routinely commission.
K4 Existing Patient Pathway	K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.	K4.1 Children with persistent allergic asthma are currently treated with omalizumab once any other contributing factors such as smoke and

	K4.2. What are the current treatment access criteria? K4.3 What are the current treatment stopping points?	the effectiveness of conventional asthma therapies are ruled out. K4.2. Available to patients with severe persistent confirmed allergic IgE-mediated asthma whose doctors believe that omalizumab is appropriate. K4.3 None.
K5 Comparator (next best alternative treatment) Patient Pathway	K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity. K5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	K5.1 Long term oral steroids or bronchial thermoplasty. K5.2 Information not collected.
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy. K6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	K6.1-6.2 Not applicable.
K7 Treatment Setting	K7.1 How is this treatment delivered to the patient? o Acute Trust: Inpatient/Daycase/Outpatient o Mental Health Provider: Inpatient /Outpatient o Community setting o Homecare delivery	K7.1 The TCLA device is in the patient's home, as it is intended to be installed over the child's bed.

	K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	K7.2 Not applicable.
K8 Coding	K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded? K8.2 How will this activity related to the new patient pathway be identified? (e.g. ICD10 codes/procedure codes)	K.8.1 Not applicable. K.8.2 Not applicable.
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule? K9.2 If this treatment is a drug, what pharmacy monitoring is required? K9.3 What analytical information /monitoring/ reporting is required? K9.4 What contract monitoring is required by supplier managers? What changes need to be in place? K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring? K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy? K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in M1 below*	K9.1-9.7 Not applicable.

Section L - Service Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised? (i.e. tertiary centres, networked provision) L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.1 Service is provided in tertiary respiratory and allergenic centres. L1.2 No change anticipated, as the policy is to not routinely commission, consistent with current practice.
L2 Geography & Access	L2.1 Where do current referrals come from? L2.2 Will the new policy change / restrict / expand the sources of referral? L2.3 Is the new policy likely to improve equity of access? L2.4 Is the new policy likely to improve equality of access / outcomes?	L2.1 Referrals to specialist centres can come from primary care, secondary care and post-intensive care units. L2.2-2.4 The policy standardises the approach to commissioning.
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed? L3.2 Is there a change in provider physical infrastructure required? L3.3 Is there a change in provider staffing required? L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	L3.1-3.8 Not applicable.

	L3.5 Are there changes in the support services that need to be in place? L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor) L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers? L3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	L4.1 No
Section M - Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which? M1.2 Is this treatment excluded from national prices? M1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services? M1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is	M1.1 No. M1. TCLA is not explicitly excluded from national tariff. M1.3 No local price arrangements were identified. M1.4 No new price has been proposed.

	not additionally / double charged through existing routes? M1.5 is VAT payable (Y/N) and if so has it been included in the costings? M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	 M1.5 Not applicable. M1.6 Not applicable.
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1? M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.1 The revenue cost is estimated at nil as the policy is not to commission. For reference, the cost per patient in the first year is estimated at £2,088. [xiii] M2.2. The revenue cost in subsequent years would be the same as in year 1.
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England. M3.2 Where this has not been identified, set out the reasons why this cannot be measured.	M3.1 Cost neutral. The policy does not involve routine commissioning. M3.2 Not applicable.
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs). M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole. M4.3 Where this has not been identified, set out the reasons why this cannot be measured. M4.4 Are there likely to be any costs or savings for non NHS	M4.1 No costs to other parts of the NHS were identified. M4.2 Cost neutral. M4.3 Not applicable.

	commissioners / public sector funders?	M4.4 No costs or savings for other funders were identified.
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified *e.g. decommissioning less clinically or cost-effective services.*	M5.1 Not applicable.
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy? M6.2 Can these be mitigated, if so how? M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	M6.1 Not applicable. M6.2 Not applicable. M6.3 Not applicable.
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature*	M7.1 There is currently no published evidence on how the use of temperature-controlled laminar airflow devices would affect NHS resources by either reducing the use of omalizumab and other alternative treatment options or reducing asthma exacerbations. The only study on cost-effectiveness of TCLA (Brodtkorb et al 2010) is based on a 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 a cost per QALY gained of under €35,000 as long as the cost of Airshower is below €8,200 per year. The study does not include comparative cost effectiveness with

		existing comparator interventions such as Omalizub, immunosuppressant therapy and bronchial thermoplasty.
	M7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	M7.2 There is very limited evidence on cost effectiveness of TCLA and the evidence that does exist is model-based and does not include cost effectiveness comparisons with comparator interventions.
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs*	M8.1 Not applicable.
	M8.2 If so, confirm the source of funds to meet these costs.	M8.2. Not applicable.

[i] The upper end of the range is drawn from Asthma UK. This higher number could indicate a higher number of patients who may have the condition but are not actively receiving any treatment. Source: Asthma UK. Asthma facts and statistics. [Online] Available from http://www.asthma.org.uk/asthma-facts-and-statistics [Accessed: 11/11/2015]. The prevalent population is based on 2015 Office for National Statistics (ONS) estimates for the 2014 population in England for those aged 18 +(adults) and for those aged under 18 (children), multiplied by the prevalence rate for each group (1:12 for adults and 1:11 for children). The numbers cited on asthma UK correlate approximately to slightly different age groups given the 2015 UK population figures (children aged up to ~15 16). The figures noted here consider 16-17 year olds to be closer to children than older adults to align to the population under the policy

[ii] This is based on the NHS service specifications for treatment of severe asthma and refers to adult rates [Source: NHS Commissioning board.(2013), A14/S/b 2013/14 NHS Standard Contract for Respiratory Care: Severe Asthma (adult) Particulars, Schedule 2- The Services, A- Service Specifications. [Online] Available from https://www.england.nhs.uk/wp-content/uploads/2013/06/a14-respiratory-sev-asthma.pdf [accessed: 06/11/2015]]. Similar specific statistics were not available for children; however as the prevalence of asthma is relatively similar to the adult rate (see K1.1), the adult rate has been used.

[iii] This estimate is based on the stated prevalence rate of 'severe difficult to control asthma' in the population, (see foonote ii) multiplied by the Office for National Statistics (ONS) population estimate for those aged under 20 in 2014/15 [Source: ONS (2015). Population Estimates for UK, England and Wales, Scotland and Northern Ireland, Mid-2014]. It was not possible to specifically identify the number of children living with severe persistent allergic asthma in England in the literature, Secondary Uses Service (SUS) data or through publically available audits.

[iv] Asthma UK, Astma facts and FAQs. [Online] Avaliable from http://www.asthma.org.uk/asthma-facts-and-statistics [Accessed: 10/11/2015]; and NICE (2013). Omalizumab for treating severe persistent allergic asthma. [Online] Available form: https://www.nice.org.uk/guidance/ta278/chapter/2-Clinical-need-and-practice [Accessed: 10/11/2015].

[v] This is based on SUS data for non-elective admissions for those with a diagnosis recorded in the first three positions relating to allergic asthma or mixed asthma (ICD-10 codes J450 and J458), average activity from 2011/12 to September 2015, taking into account the growth in such admissions over the time period (also see K1.7).

[vi] Management of severe allergic asthma includes a daily dose of corticosteroid tablets and Omalizumab. In addition there are other options that include bronchial thermoplasty and immunosuppressants such as methotrexate and cyclosporine. These require visits to specialist centres. Source: NICE (2013). Omalizumab for treating severe persistent allergic asthma. [Online] Available from: https://www.nice.org.uk/guidance/ta278/chapter/2-Clinical-need-and-practice [Accessed: 10/11/2015]; and NICE (2014). The Airsonett temperature-controlled laminar airflow device for persistent allergic asthma. [Online] Available from: http://www.nice.org.uk/advice/mib8/resources/the-airsonett-temperaturecontrolled-laminar-airflow-device-for-persistent-allergic-asthma-1763872211653 [Accessed: 16/12/2015].

[vii] Five IFRs were submitted in 2014/15 for paediatric patients.

[viii] Asthma prevalence in the UK is considered to have plateaued in the late 1990s (Asthma UK). Source: http://www.asthma.org.uk/asthma-facts-and-statistics. Accessed: 11/11/2015

[ix] Specific growth rates for persistent allergic asthma were not identified. As the policy focuses on children, the ONS baseline projections for the population below age 20 over the next ten years have been used to calculate yearly growth rates. These growth rates are applied to the prevalence figures set out in K1.2 to estimate the eligible population in future years.

[x] Based on an analysis of SUS data from 2011/12 to 2014/15. For non-elective admissions for those with a diagnosis in the first three positions relating to allergic asthma or mixed asthma. The level of future activity for the eligible population could not be estimated as the population of those with *persistent* allergic asthma could not be uniquely identified in the SUS data, and the figures were unavailable even when asking clinicians or from public sources.

xi Public Health England. *Hospital admissions for asthma (age under 19 years) (2013/14).* [Online] available from: http://atlas.chimat.org.uk/IAS/dataviews/report/fullpage?viewId=501&reportId=546&geoId=56&geoReportId=4631&indicator=i4509 [Accessed: 09/11/2015].

[xii] NHS Choices (2014). Asthma-Causes. [Online] Available at http://www.nhs.uk/Conditions/Asthma/Pages/Causes.aspx [Accessed: 12/11/2015].

[xiii] NICE (2014). The Airsonett temperature-controlled laminar airflow device for persistent allergic asthma. [Online] Available from: https://www.nice.org.uk/advice/mib8/chapter/Evidence-review [Accessed: 10/11/2015].