

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No.	A14/S/b
Service	Specialised Respiratory Services (adult) – Severe Asthma
Period	12 months

1. Population Needs

1.1 National/local context and evidence base

Patients with **severe asthma** are a separate entity from the majority of asthmatics with mild to moderate disease.

They require systematic assessment and specialist care in tertiary respiratory centres.

Severe asthma has an estimated prevalence of 140 patients/million population with an annual incidence of approximately 14 patients/million.

One of the key roles of the specialist centres **is to improve outcomes for people with severe asthma** and to act as gatekeepers for the use of bronchial thermoplasty, **mepolizumab** and omalizumab, as well as other high cost novel biological agents currently in development, to prevent inappropriate use, unnecessary risk to patients and spiralling costs to the NHS.

Over **4** million people are prescribed asthma therapies in the UK and it remains responsible for more than **500** deaths per year. Asthma exacerbations lead to over **65,000** hospital admissions with an annual spend of **£901** million on pharmaceutical costs alone. In addition, it is estimated that asthma leads to a direct cost to the NHS of £1 billion and an indirect cost to society, due to time off work and loss of productivity, of **£1.2 billion** (1).

The vast majority of patients with asthma have mild to moderate disease and have the potential to be well controlled with existing therapies, assuming that well established national guidelines are followed (2). A small proportion of patients, estimated at less than 5% of all asthmatics, have **severe asthma**. These patients have ongoing daily symptoms despite maximal medical therapy and **significant side effects and co-morbidities secondary to their requirement for oral corticosteroids** (3).

There is a common misconception that **severe asthma** patients are an extreme example of

the milder version of the disease. There is a growing body of evidence to support the presence of several different phenotypes of severe asthma, some of which have markedly different mechanisms driving their symptoms. It is therefore essential to differentiate severe from milder versions of the disease and to consider it as a separate condition that requires specialist services to improve the health of this patient group, which continues to have a clear unmet need.

In a publication attempting to calculate individual patient costs, it was estimated that a patient controlled at the mildest end of the spectrum (Step 1 British Thoracic Society (BTS) guidelines, with no exacerbations), would cost 50 times less to provide their package of care than a patient with **severe asthma** (Step 5 BTS guidelines, having exacerbations) (4). **Data from the British Thoracic Society Difficult Asthma Registry has been used to estimate direct healthcare costs and the annual mean treatment costs among severe refractory asthma patients were £2912 (SD £2212) to £4127 (SD £2449) (3).**

The above calculated costs do not include the long term morbidity due to the side effects of frequent rescue or maintenance oral corticosteroids, which will affect the majority of patients with **severe asthma**. The side effects include diabetes, **hypertension**, cataracts, osteoporosis, glaucoma, skin disease, reflux oesophagitis, **non-alcoholic fatty liver disease** and obesity. The additional health care costs required to manage these side effects are currently unquantified and not included in the costs calculated above. Hence, the quoted values are likely to be significant under-estimates of current costs.

No gold standard diagnostic test exists for **severe asthma**. The condition is more akin to a syndrome with multiple different causes, rather than a single disease entity. This has hampered the production of a clear definition of severe asthma. In the BTS/Scottish Intercollegiate Guidelines Network (SIGN) asthma guidelines, “difficult asthma” is defined as patients having symptoms despite being prescribed step 4 drug therapy. This definition is vague and will include a significant proportion of patients for whom appropriate care could be provided in secondary care if attention were paid to co-morbidities, therapy adherence and alternative diagnoses that mimic asthma.

The most up to date definition is provided by an international consensus statement from the **European Respiratory and American Thoracic Societies (5)**. The subgroup with truly severe refractory asthma can be defined and distinguished from patients with ‘problematic’ or ‘difficult’ asthma. The term ‘problematic severe asthma’ includes all asthma and asthma-like symptoms that remain uncontrolled despite the prescription of high-intensity asthma treatment. It is an umbrella term that comprises patients with ‘difficult’ asthma as well as patients with ‘severe refractory’ asthma. The term ‘difficult asthma’ is reserved for asthma that remains uncontrolled despite the prescription of high-intensity asthma treatment due to:

- persistently poor medication adherence

- psychosocial factors, dysfunctional breathing, vocal cord dysfunction
- persistent environmental exposure to allergens or toxic substances
- untreated or under treated co morbidities such as chronic rhinosinusitis, reflux disease or obstructive sleep apnoea syndrome

The term **severe asthma** should be reserved for patients with asthma in whom alternative diagnoses have been excluded; co morbidities have been treated; trigger factors have been removed (if possible); and adherence with treatment, including inhaler technique has been checked, but still have poor **symptom control (Asthma Control Questionnaire > 1.5 or Asthma Control Test < 20)**, or frequent severe exacerbations **(2 or more bursts of systemic corticosteroids in the previous year)**, or serious exacerbations **(at least one hospitalisation, ICU stay or mechanical ventilation in the previous year)** despite the prescription of high-intensity treatment **(step IV/V of the asthma guidelines)**, or those patients with controlled asthma that worsens on tapering of high doses of inhaled or systemic corticosteroids.

Previous studies have demonstrated the difficulty in making an accurate diagnosis in this patient population, which in combination with psychological and social interaction on health care beliefs and self management, make a systematic assessment essential in order to accurately target therapy when standard asthma inhaler therapy and add-on drugs have failed (6, 7).

Given the above, there is a clear consensus that patients with **severe asthma** should be systematically evaluated by a dedicated multi-disciplinary service utilising a team experienced in the assessment and management of **severe asthma** (BTS/SIGN Asthma guidelines 2009 Section 7.1 Difficult asthma (2)). The benefits of systematic assessment include confirmation of the diagnosis, improved adherence with prescribed therapies, treatment of co-morbidities or alternative diagnoses and a reduction in important healthcare outcomes, specifically hospital admission, unscheduled healthcare visits and rescue courses of oral steroids (8); **as well as improvements in patient reported outcomes such as quality of life and asthma control (9)**.

There is limited evidence to help define the number of patients with **severe asthma** in England. A study by Roberts et al, examined a questionnaire sent to all BTS members with a 50% response rate. This identified 7,027 patients with severe asthma, 50% of these patients were under the care of a consultant who stated that they had an interest in difficult asthma.

In the North West of England, with a referral population of approximately 5 million, currently 120 patients per year are referred to the Manchester severe asthma service. Of these, 45% fulfil the definition of severe asthma on the basis of steroid requirements, 5% on previous intensive care unit admission, 40% on FEV₁ criteria and approximately 30% on 2 hospitalisations in the previous 12 months (9). Extrapolating this to the population of England would suggest approximately 1,000 new referrals per year. These annual

referrals represent approximately 0.001% of the total asthma population. This data suggests an annual incidence of 14 patients/million and prevalence of 140 patients/million.

Severe asthma is recognised as an area of unmet therapeutic need and multiple high cost novel biological therapies are currently in multinational phase III studies. These treatments are likely to be expensive and will require careful monitoring to ensure that they are prescribed to the correct patient population with specialist assessment of efficacy to prevent inappropriate prescribing.

Omalizumab **has been reviewed** by the National Institute for Health and Care Excellence (NICE) and is recommended as an option for treating severe persistent allergic asthma as an add on to optimised standard therapy in patients who need continuous or frequent courses of oral corticosteroids.

<http://www.nice.org.uk/guidance/TA278>

Bronchial thermoplasty has also been reviewed by NICE and the details of all patients undergoing this procedure need to be submitted to the BTS severe asthma registry.

IPG 419 Bronchial thermoplasty for severe asthma: <http://guidance.nice.org.uk/IPG419>

Mepolizumab for treating severe eosinophilic asthma will shortly undergo a NICE HTA with an anticipated publication date of July 2016.

<https://www.nice.org.uk/guidance/indevelopment/gid-tag519>

Without specialist assessment the targeting of omalizumab, **mepolizumab** and other high cost novel therapies for severe asthma will not be possible, leading to the potential of inappropriate use, unnecessary risk to patients and spiralling costs.

The **severe asthma** service will be based at pre-existing regional specialist units. The service will provide a multi-disciplinary diagnostic, assessment and treatment service for individuals with severe asthma. It is anticipated that the service will reduce inequalities in asthma care and will lead to reductions in hospitalisations and death for individuals with severe asthma.

Successful implementation of existing policy will depend on these specialist units. Without them it will not be possible to meet the commitment of the chronic obstructive pulmonary disease (COPD) and Asthma Outcomes strategy to address the needs of people with the most severe asthma and provide appropriate care for them. As the strategy acknowledges, these people need multidisciplinary support and face lack of recognition in non-specialist health services.

<http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPol>

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2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	X
Domain 2	Enhancing quality of life for people with long-term conditions	X

Domain 3	Helping people to recover from episodes of ill-health or following injury	X
Domain 4	Ensuring people have a positive experience of care	X
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	X

Key Service Outcomes (Domains 1,2,3,4 and 5)

Outcome	Measurable output
To improve asthma control	Measure the number of patients with a minimally clinically important difference improvement in ACQ-7 questionnaire scores 12 months after entry into specialist services
To improve measurement of asthma related lung function	Number of patients with recorded FEV1 (or recorded contraindication to spirometry) 12 months after entry into specialist services
To improve adherence to prescribed asthma therapy	Measure the number of patients in whom concordance with prescribed therapy has been formally assessed
To improve access to high cost biologics and bronchial thermoplasty	Measure the number of patients for whom the decision to offer thermoplasty or start a biologic agent was taken in a severe asthma MDT
To ensure patients have a positive experience of care in specialist centres	Measure the results of 'Friends and Family' test and compare across specialist centres
To ensure that decisions on patient specific therapies and outcomes are accurately recorded	Measure the number of patients who have a record in the BTS severe asthma registry

3. Scope

3.1 Aims and objectives of service

The core aims of the severe asthma service will be to improve patient outcomes, including decreased exacerbation frequency, measured by reductions in emergency visits, hospital admissions and oral steroid courses, as well as improved mortality, improved lung function and improved quality of life.

These aims will be met by the following core objectives of the severe asthma service:

- To confirm the diagnosis and severity of individuals referred with suspected **severe asthma**.
- To identify and remove aeroallergen and occupational triggers.
- To diagnose alternative conditions mimicking severe asthma and refer to the appropriate specialist team.
- To diagnose and appropriately treat co-morbidities contributing to severity of asthma (e.g. allergic bronchopulmonary aspergillosis or Churg Strauss syndrome/Eosinophilic granulomatosis with polyangiitis).
- To improve adherence to prescribed therapies using patient education and clinical health psychology when required.
- To diagnose and treat, or refer to the appropriate service, co morbidities associated with severe asthma, such as gastroesophageal reflux disease (GORD) and obstructive sleep apnoea.
- To treat and where possible prevent the complications of long term oral and high dose inhaled corticosteroids.
- To decrease exacerbation frequency and improve patient quality of life through effective self management and appropriate patient support, including telephone clinics, rapid access review and other appropriate support when required.
- To optimise disease management by using existing therapies in a patient specific fashion by quantifying each patient's asthma phenotype.
- To use measures of airway inflammation to guide therapy where appropriate.
- To use omalizumab, **mepolizumab** and other novel therapies for the correct patient groups and objectively assess response to new treatments/interventions and stop treatment when not effective.
- To enhance research and education in this area of unmet clinical need.

3.2 Service description/care pathway

Full multi-disciplinary assessment spread over 2 day case visits.

Pre-planned investigations to include measures of airway inflammation and airways hyper reactivity, which are only available at specialist centres.

Assessment to include allergy, ENT and physiotherapy review in all cases.

Review of adherence in all cases including measurement of blood levels of prednisolone and cortisol, as well as review of prescription refills and pick up from primary care and FeNO suppression testing if appropriate.

Following initial assessment the decision will be made regarding the patient's suitability for bronchial thermoplasty, omalizumab, **mepolizumab** or high cost novel biological therapies, as they become available.

Majority (approximately 70%) of patients will stay under long term follow up at the specialist centre or under shared care.

The following investigations will be required, assuming that they have not already been performed by the referring centre:

- Full pulmonary function tests (PFT) and bronchodilator reversibility (BDR).
- Airways hyper-reactivity measured by histamine or methacholine challenge if appropriate.
- Induced sputum for measurement of eosinophils and/or measurement of exhaled nitric oxide to quantify airway inflammation.
- High resolution computed tomography (HRCT) thorax.
- Skin prick tests to common aeroallergens and those identified as relevant from the history.
- Bone densitometry (DEXA).
- Full Blood Count (FBC), Immunoglobulin E (IgE), Aspergillus IgE and Immunoglobulin G (IgG), Total immunoglobulins and vaccine responses.
- Measurement of adherence including serum theophylline and prednisolone and cortisol levels.
- Assessment in upper airway clinic.
- Oesophageal function studies, if indicated after clinical assessment.

During this period of assessment the patients will require a full multi-disciplinary assessment including review by a physiotherapist, asthma nurse specialist, clinical health psychologist, dietician, respiratory pharmacist and allergist.

Each service will be run by a minimum of two service-dedicated respiratory physicians with appropriate expertise and training in severe asthma. They will require access to the members of the multi-disciplinary team listed above and also be able to refer patients to a consultant in occupational lung disease and consultant psychiatrist when required. Each service will require the facilities to provide patients with omalizumab, mepolizumab and other high cost novel biological therapies that are currently in clinical trials. Other treatment options that will be available at the specialist centres will include access to bronchial thermoplasty, antifungal agents for severe asthma with fungal sensitisation, long term macrolide therapy for neutrophilic asthma and administration and monitoring of steroid sparing agents such as methotrexate.

The specialist centre will act as an advisory lead on omalizumab, mepolizumab and other high cost novel biological therapies for the region they serve. The decision to treat and the initial assessment of efficacy will occur at the specialist centre. If the trial is successful then the drug may be delivered locally in the longer term. The specialist centre will continue to oversee this process via outpatient review every 6 months. Regular specialist review will allow decisions on duration of therapy and switch to alternative options to be made when required.

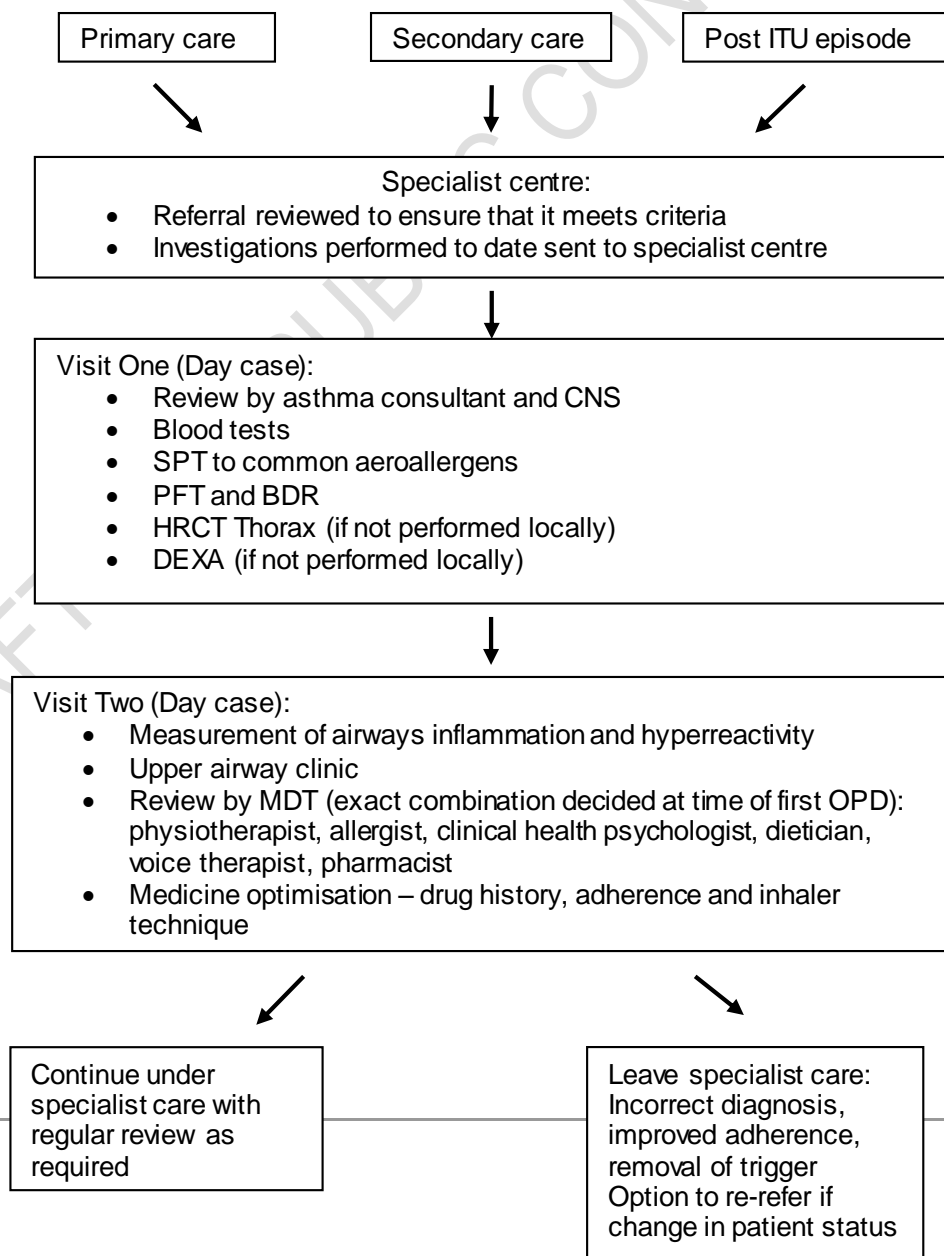
Every centre will require the capacity to review patients on a day unit or similar to provide expert care at the start of an exacerbation in an attempt to prevent hospital admission. Every centre will need the capacity to admit patients in an emergency or planned fashion for intravenous hydrocortisone, aminophylline and antibiotics when

required. Individual patients will continue to have access to their geographically closest hospital for acute admission when required through the use of a shared care model. Each centre will have an identified bronchoscopist that is competent to perform diagnostic bronchoscopies in patients with severe asthma.

Patients will initially be reviewed 3 months after their initial assessment and then every 6 months if clinically stable.

The majority of patients with confirmed severe asthma will need to stay under the long term follow up of the specialist centres. Those who remain under long-term care of specialist centres will receive ongoing patient education and support to self-manage and to improve their quality of life via the most appropriate services. However, a significant percentage of patients, approximately 20 to 30%, will be able to return to primary or secondary care after their initial assessment, when they turn out to have a different disease, poor adherence to prescribed therapies or after removal of triggers, such as aero or occupational allergen

Figure 1: Patient journey:





Treatment options:

- Bronchial thermoplasty, omalizumab, mepolizumab, steroid sparing agents, antifungal agents for SAFS, macrolides for neutrophilic asthma, entry into ongoing clinical trials with high cost novel biological agents
- Patient-centred education and support to improve self management, including of asthma exacerbations
- Prevention and treatment of comorbidities and prednisolone related side effects
- Continued input from MDT as required

The specialist centres will also play a wider role in education of primary and secondary care physicians as well as other members of the multidisciplinary team and liaise closely with patient support organisations to ensure that they are providing the services that the patients want. The centres will continue their successful research collaborations, which have already led to key publications in the area and generated successful research funding. The centres will provide national leadership on severe asthma and continue to train specialist respiratory trainees in this important part of their Joint Royal Colleges of Physicians Training Board (JRCPTB) curriculum.

The specialist centres will form a resource to improve the care of all asthma patients that do not fulfil the specific criteria listed above. The centres will develop regional MDT meetings arranged geographically to provide national coverage of patients with moderate to severe disease.

Specialist asthma services will not be delivered using precisely the same model in all areas of the country. Different approaches are likely to be required depending on the geography, population, and concentration of facilities in each region. It is important that individuals receive safe, expert care but also that excessive travelling for investigations and treatment is avoided. It is also valuable to patient care for specialist centres and other NHS services in that region to share data and expertise.

Network approaches have been successful in delivering high-quality care in areas such as burns, trauma, and neonatal critical care. They have also been central to NHS-supported research and dissemination through Local Comprehensive Research Networks and Academic Health Sciences Networks. A specialist centre supported by (and supporting) a network has the potential to provide high-quality care closer to the patient, facilitating initial and specialist investigations and the delivery of high-cost treatments. There is clear potential for a network model to raise standards across a region.

It is envisaged that a commissioned centre could engage with a small number (one or two) other sites within the region to:

- reduce travel time
- reduce waiting times for appointments, investigations, and treatments

- reduce inappropriate referrals
- ensure high-cost therapies are delivered in a safe protocolised manner close to the patient's home whenever possible

Networked centres would be contracted to undertake activities to an agreed high standard and have the following members of staff:

- at least one respiratory consultant with a clinical focus on severe asthma (i.e. runs a dedicated severe asthma clinic in outpatients on at least a weekly basis)
- at least one specialist respiratory nurse with a focus on severe asthma
- a specialist respiratory pharmacist
- a specialist respiratory physiotherapist

The capacity to carry out the following screening investigations:

- skin prick testing to common aeroallergens
- full lung function testing including bronchodilator reversibility and measurement of airways hyperreactivity
- HRCT thorax
- Induced sputum for measurement of eosinophils and/or measurement of exhaled nitric oxide to quantify airway inflammation
- adherence measures such as testing serum prednisolone and cortisol levels

3.3 Population covered

The service outlined in this specification is for patients ordinarily resident in England*; or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP practice in England.

Access to the specialist service will be for all adults and adolescents over 16 years old with asthma fulfilling the criteria described in section 3.4.

Data published by the BTS severe asthma network has demonstrated a variation in referral patterns to specialist care across England. This initiative with its clear referral pathway will enable the correct referral of patients to specialist care across the whole of England.

3.4 Any acceptance and exclusion criteria and thresholds

Referrals will originate primarily from Respiratory Physicians in secondary care. Primary care physicians will also be able to refer patients as long as they meet the criteria defined below. All patients discharged from ITU following an admission with an acute exacerbation of asthma will be referred either by an intensive care or respiratory physician. Consultant paediatricians will be able to refer patients to the service to allow transitional care of adolescents with severe asthma.

The service will only be for individuals that meet the criteria defined below. Individuals who do not fulfil the criteria or who have chronic obstructive pulmonary disease will not be covered by the service.

The receiving service will confirm that the patient meets the specified criteria before accepting the referral.

The BTS Specialist Advisory Group on Asthma and the BTS Difficult Asthma Network has proposed the following pragmatic and targeted definition, which will be used to determine which patients can be referred to the specialist centres:

Patients fulfilling the ERS/ATS definition of severe asthma **and** one of the following:

- An event of acute severe asthma which is life threatening, requiring invasive ventilation with elevated inflation pressures within the last 10 years.
- Continuous or frequent treatment with oral corticosteroids (defined as 2 or more courses in the previous year).
- Fixed airflow obstruction, with a post bronchodilator forced expiratory volume in 1 second (FEV₁) less than 70% of predicted normal.
- Referred as an adolescent transition patient from a paediatric severe asthma service.

Patients will be referred to the centre that is geographically most convenient for them.

3.5 Interdependencies with other services/providers

Co-located services:

- Immediate onsite access to critical care.
- Advanced diagnostics including lung physiology, bronchial provocation testing and measurement of airways inflammation.
- Day unit available for patient assessment, omalizumab, mepolizumab and other high cost novel biological agent administration and challenge testing.
- In patient beds available for management of acute exacerbations of asthma.
- Upper airway assessment for diagnosis of upper airway dysfunction mimicking asthma at time of acute attack.
- Physiotherapy for acute management of breathing pattern dysfunction.

Interdependent services:

- Allergy
- Clinical Immunology
- ENT
- Physiotherapy for exercise and pulmonary rehabilitation
- Voice therapy
- Clinical health psychology
- Liaison psychiatry
- Dietetics
- Metabolic medicine for osteoporosis management
- Pharmacy
- Smoking cessation services

Related services:

- Occupational lung disease

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

Each service will see at least 100 new referrals per year and be staffed by a minimum of two service-dedicated respiratory physicians with appropriate expertise and training in severe asthma to allow for cross cover and service resilience.

Each service will have access to a consultant respiratory physician fully competent to perform bronchial thermoplasty independently and performing at least 10 procedures per annum.

Every centre will participate in weekly MDTs involving consultant respiratory physicians, clinical nurse specialists, radiologist, physiotherapists, voice therapists, dieticians, pharmacists and clinical health psychologists.

Each centre will enter patient data into a national severe asthma registry. The BTS severe asthma network has a fully functional web based database, which will be used to facilitate this process and enable bench marking between centres, data submission to this database will be a routine requirement for all centres.

These are addressed in the current NICE guidance and the National COPD and Asthma

Outcomes strategy. Statement 11 of the NICE quality standards for asthma state that people with difficult asthma are offered an assessment by a multidisciplinary difficult asthma service.

An outcomes strategy for people with chronic obstructive pulmonary disease (COPD) and asthma in England : Department of Health - Publications

NICE quality standards for Asthma:
<http://publications.nice.org.uk/quality-standard-for-asthma-qs25>

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

BTS/SIGN Asthma guidelines 2009 Section 7.1 Difficult asthma

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

To be agreed with commissioners.

6. Location of Provider Premises

The Provider's Premises are located at:

No formal designation process in place

7. Individual Service User Placement

Not applicable

Appendix Two

Quality standards specific to the service using the following template:

Quality Requirement	Threshold	Method of Measurement	Consequence of breach
Domain 1: Preventing people dying prematurely			
To improve adherence to prescribed asthma therapy	Measure the level of adherence with prescribed therapy measured by prednisolone and cortisol levels, prescription refills or FeNO suppression testing.	Annual audit	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 2: Enhancing the quality of life of people with long-term conditions			
To improve asthma control	Measure improvement in ACQ-7 questionnaire scores 12 months after entry into specialist services	Annual audit	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 3: Helping people to recover from episodes of ill-health or following injury			
To decrease annual exacerbation frequency	Measure the number of asthma exacerbations in the 12 months prior and after referral to specialist services	Annual audit	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 4: Ensuring that people have a positive experience of care			
To increase the percentage of patients with severe asthma who are discussed in a severe asthma MDT	Measure the number of patients discussed in a severe asthma MDT 12 months after entry into specialist services	Annual audit	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan
Domain 5: Treating and caring for people in a safe environment and protecting them from avoidable harm			
To ensure patients have a positive experience of care in specialist centres	Measure the results of 'Friends and Family' test and compare across specialist centres	Annual audit	As per Standard NHS Contract General Conditions Clause 9 (GC9) Remedial Action Plan