

Equality Analysis
(Health Inequalities, Human Rights, Social Value)

Policy for use of domiciliary Non-Invasive Ventilation

Before completing this equality analysis it is recommended that you:

- ✓ Contact your equality and diversity lead for advice and support
- ✓ Take time to read the accompanying policy and guidance document on how to complete an equality analysis

1. Background

EA Title	Policy for use of domiciliary Non-Invasive Ventilation		
EA Author	David King	Team	Equality and Diversity Team
Date Started		Date Completed	
EA Version	1	Reviewed by E&D	
What are the intended outcomes of this work? Include outline of objectives and function aims			
Why is Non-Invasive Ventilation (NIV) used and what is it?			
<p>When we breathe in, we take oxygen out of the air to keep us alive - this oxygen is transferred to our blood in our lungs. The body then uses the oxygen and produces a waste gas called carbon dioxide, which we breathe out. The process of this exchange is ventilation.</p> <p>Some people with severe lung disease, have problems getting sufficient oxygen into the body, which results in hypoxaemia. If their oxygen level drops below a certain level, it is relatively easy to give extra oxygen for them to breathe, which is called oxygenation. However, in some severe cases of obstructive lung conditions, muscle weakness or neurological impairment, the extra effort of trying to keep the oxygen at a satisfactory level in the blood and to expel carbon dioxide results in the person tiring and leading to hypoventilation and hypercapnia causing respiratory failure.</p> <p>Respiratory failure is more difficult to deal with. It is a particular problem with diseases that cause obstruction to our airways, such as chronic obstructive pulmonary disease (COPD). In COPD, the airways are narrowed, making it harder to get oxygen into the lungs and carbon dioxide out. Patients who have weak or denervated respiratory muscles in neuromuscular/neurological conditions are also unable to take in a sufficient volume of air to expel carbon dioxide. In all these conditions, a person can develop type 2 respiratory failure which cannot be corrected with oxygenation as the person needs help to ventilate to expel carbon dioxide. Type 2 respiratory failure can lead to high heart rate and cardiac complications.</p> <p>The aim of using Non-Invasive ventilation (NIV) is not only to obtain satisfactory oxygen levels, but also to expire carbon dioxide. It is often first used at night when the patient is asleep and carbon dioxide levels increase, but as the patient's condition progresses, NIV may be required in the day when the patient has diurnal respiratory failure. It is also important to ease the work of breathing associated with respiratory failure as when a patient with respiratory failure becomes overly tired, this can lead to fatigue, further respiratory compromise and potential respiratory arrest. NIV also aims to take some of the effort out of breathing because the patient's chest muscles don't have to work as hard, so it helps to ease the feelings of breathlessness.</p> <p>People receiving NIV need to wear a cushioned mask or use a mouthpiece, which is connected to an air pump machine. This mask fits either over the nose alone, or over both the nose and mouth; a strap holds the mask firmly in place, but it can be easily removed, to enable, for example, the patient to eat and drink.</p>			

Types of Non-Invasive Ventilation

Non-invasive ventilation (NIV) refers to the administration of ventilatory support without using an invasive artificial airway (endotracheal tube or tracheostomy tube). The use of noninvasive ventilation has markedly increased over the past three decades, and noninvasive ventilation has now become an integral tool in the management of both acute and chronic respiratory failure, in both the home setting and in critical care.

In its simplest terms, noninvasive ventilation differs from invasive ventilation by the interface between the patient and the ventilator. Invasive ventilatory support is provided via either an endotracheal tube or tracheostomy tube. Non-invasive ventilatory support uses a variety of interfaces, and these have continued to evolve with modifications based on patient comfort and efficacy. Many of the interfaces or masks were initially used in patients with obstructive sleep apnea before they were adapted for use in patients to provide non-invasive ventilatory support.

Nasal masks and orofacial masks were the earliest interfaces, with subsequent development and use of full-face masks, mouthpieces, nasal pillows, and helmets. Nasal masks and orofacial masks are still the most commonly used interfaces. Orofacial masks are used almost twice as frequently as nasal masks. Both have advantages and disadvantages in the application of non-invasive ventilation.

Non-invasive positive-pressure ventilation

Positive-pressure ventilation delivered through a mask, has become the predominant method of providing non-invasive ventilatory support. Early bedside physiologic studies in healthy patients and in patients with respiratory conditions document successful ventilatory support (ie, reduction in respiratory rate, increase in tidal volume, decrease in dyspnea) with reduction in diaphragmatic electromyography (EMG), transdiaphragmatic pressures, work of breathing and improvement in oxygenation with a reduction in hypercapnia.

Ventilatory support can be achieved through a variety of interfaces (mouth piece or nasal, face, or helmet mask), using a variety of ventilatory modes (eg, volume ventilation, pressure support, bilevel positive airway pressure [BiPAP], proportional-assist ventilation [PAV], continuous positive airway pressure [CPAP]) with either ventilators dedicated to non-invasive ventilation (NIV) or those capable of providing support through an endotracheal tube or mask. Older models of non-invasive ventilators required oxygen to be bled into the system, but current models incorporate oxygen blenders for precise delivery of the fraction of inspired oxygen (FIO₂).

Non-invasive negative-pressure ventilation

Negative-pressure ventilators provide ventilatory support using a device that encases the thoracic cage starting from the neck, and devices range from a whole-body tank to

a cuirass shell. The general principle is the same with a vacuum device, which lowers the pressure surrounding the thorax, creating sub-atmospheric pressure and thereby passively expanding the chest wall with diaphragmatic descent, all leading to lung inflation. Exhalation occurs with passive recoil of the chest wall.

This was the predominant technology during the polio epidemics, but these devices were bulky and cumbersome to use. Upper airway obstruction was also a problem. These ventilators have been largely supplanted by the more widespread positive-pressure non-invasive ventilators; however, some patients continue to be treated with this modality. While the bulk of the experience lies in patients with chronic respiratory failure, specifically neuromuscular respiratory failure, reports described successful application in patients with acute respiratory failure.

Current use of Non-invasive Ventilation devices.

With respect to the two modes, positive-pressure ventilation has supplanted negative-pressure ventilation as the dominant mode of delivery of non-invasive ventilation. Positive-pressure ventilation is more effective than negative-pressure ventilation in unloading the respiratory muscles, at least under investigational conditions. The primary focus of this policy is domiciliary positive-pressure non-invasive ventilation, and the mention of "non-invasive ventilation" will refer to positive-pressure delivery.

Many patients who are assessed as requiring non-invasive ventilation are provided support with pressure ventilation, i.e. continuous positive airway pressure (CPAP), which is the most basic level of support. CPAP pumps a steady flow of air at constant pressure through the nose to prevent the narrowing or collapse of air passages or to help the lungs to expand. CPAP may be especially useful in patients with congestive heart failure or obstructive sleep apnea.

Bilevel positive airway pressure (BiPAP) is probably the most common mode of noninvasive positive pressure ventilation and requires provisions for inspiratory positive airway pressure (IPAP) and expiratory positive airway pressure (EPAP). The difference between IPAP and EPAP is a reflection of the amount of pressure support ventilation provided to the patient, and EPAP is synonymous with positive end-expiratory pressure (PEEP). Some noninvasive ventilation is provided using proportional-assist ventilation (PAV), which provides flow and volume assistance with each breath.

Clinical trials have not demonstrated a significant difference between PAV and pressure-support ventilation with BiPAP. ^{15, 16} However, BiPAP is the most commonly available and more frequently used modality for non-invasive ventilation. PAV remains available on many ventilator models, but use is much less common than BiPAP.

National context

National Guidance for the provision of aspects of specialist non-ventilation services to patients exists for some individual patient groups e.g. Motor Neurone Disease (MND), Duchene's Muscular Dystrophy; and for broader categories of patients e.g. weaning guidance; and around specific technologies e.g. diaphragmatic pacing and

tracheostomies. There are some national standards (NICE, 2010; 2016) available and some specialist society guidance (BTS/ICS 2016).

Provision of complex home ventilation services also falls within the NHS Outcomes Framework Domain 1 - preventing people from dying prematurely where Improvement Area 1a specifically identifies reducing mortality from respiratory disease, and Domain 2 – enhancing quality of life for patients with long term conditions.

Guidance supports delivery of care by respiratory specialists working within MDTs. For example, the National Institute for Health and Clinical Excellence (NICE) clinical guideline (CG) around use of NIV in MND states that “multidisciplinary teams (MDT) should coordinate and provide on-going management and treatment for patients with MND, including regular respiratory assessment and provision of non-invasive ventilation.

The team should include a neurologist, a respiratory physician, an MND specialist nurse, a respiratory specialist nurse, a specialist respiratory physiotherapist, a respiratory physiologist, a specialist in palliative care and a speech and language therapist.

The guidance also outlines the support and training which need to be provided to the patient and their family and carers: “support and assistance to manage non-invasive ventilation which should include training on using non-invasive ventilation and ventilator interfaces, for example emergency procedures, night-time assistance if the patient is unable to use the equipment independently (for example, emergency removal or replacement of interfaces), how to use the equipment with a wheelchair or other mobility aids if required, what to do if the equipment fails, assistance with secretion management, information on general palliative strategies, an offer of on-going emotional and psychological support for the patient and their family and carers”.

Ensuring NIV is delivered by competent respiratory professionals is emphasised in NICE MND guidance and also in the National Patient Safety Agency (NPSA) alert which identified cases where problems with administering NIV were stated as causing at least moderate harm: key issues included shortage of staff skills or staff time to set up and monitor NIV.

Local context

The CCG, on the basis of strong supporting evidence for the clinical effectiveness of the intervention, will commission the use of domiciliary non-invasive ventilation in the following clinical conditions where the patient’s individual clinical circumstances meet the relevant clinical eligibility criteria outlined in Sections A; B; C; D & E respectively:

- Chronic Obstructive Pulmonary Disease (Section A)
- Neuro-dependent Patients (Section B)
- Obstructive Sleep Apnoea (Section C)
- Thoracic cage deformities (Section D) – awaiting CPAG Scorecard
- Obesity-Related Respiratory failure (Section E – awaiting CPAG Scorecard)

Commented [KD1]: To be added in once CPAG have reviewed via scorecards in August 2019

Please note the provision of non-invasive ventilation for cystic fibrosis patients is a specialised service commissioned by NHSE.

NIV – Section A – Chronic Obstructive Pulmonary Disease (COPD)

Chronic obstructive pulmonary disease (COPD) is the collective name for a group of lung conditions that may cause breathing difficulties.

It includes:

emphysema – damage to the air sacs in the lungs
chronic bronchitis – long-term inflammation of the airways

COPD is a common condition that mainly affects middle-aged or older adults who have a smoking history. The breathing problems tend to get gradually worse over time and can limit the patient's normal activities, although treatment can help keep the condition under control.

Symptoms of COPD

The main symptoms of COPD are:

- increasing **breathlessness**, particularly when the patient is active
- a persistent chesty **cough** with phlegm
- frequent **chest infections**
- persistent wheezing

Without treatment, the symptoms usually get slowly worse. There may also be periods when they get suddenly worse, known as a flare-up or exacerbation.

Causes of COPD

COPD occurs when the lungs become inflamed, damaged and narrowed. The main cause is smoking, although the condition can sometimes affect people who have never smoked.

The likelihood of developing COPD increases the more a patient smokes and the longer the patient has smoked. Some cases of COPD are caused by long-term exposure to harmful fumes, or dust or occur as a result of a rare genetic problem that means the lungs are more vulnerable to damage.

The damage to the lungs caused by COPD is permanent, but treatment can help slow down the progression of the condition.

Treatments include:

- **smoking cessation** – if a patient is diagnosed with COPD still smokes, stopping smoking is the most important thing a patient can do
- **inhalers and medications**
- **pulmonary rehabilitation** – a specialised programme of exercise and education
- **surgery or a lung transplant** –an option for a very small number of people

Chronic obstructive pulmonary disease (COPD) is characterized by recurrent exacerbations that can cause intermittent periods of severe clinical deterioration requiring hospitalization and ventilator support. Although treating patients with COPD and acute respiratory failure with non-invasive ventilation improves outcomes, persistent hypercapnia after an exacerbation is associated with excess mortality and early rehospitalization. In 2013, the 28-day COPD readmission rate was around 20%,⁶ (Suh et al. 2015).

NIV – Section B – Neuro-Muscular Patients

A number of chronic neuromuscular disorders, for example muscular dystrophy and motor neurone disease lead to progressive respiratory muscle dysfunction, which in turn can lead to respiratory failure and death. Nocturnal and daytime Non-Invasive Ventilation (NIV) is becoming the preferred method of treatment for these disorders¹.

Non-invasive ventilation as a treatment for neuromuscular disease has several benefits. It has been shown to^{1,5,6}:

- Improve blood gases
- Decrease work of breathing
- Improve symptoms of fatigue
- Reduce daytime sleepiness
- Improve morning headaches
- Improve survival in Duchenne muscular dystrophy (DMD) and amyotrophic lateral sclerosis (ALS) patients^{7,8}

Patients with one of the following conditions will be considered for funding when the patient also meets the eligibility criteria outlined below.

- Motor Neurone Disease
- Spinal Muscular Atrophy
- Spinal cord injury
- Multiple Sclerosis
- Guillain-Barre Syndrome
- Post polio syndrome with respiratory impairment
- Syringomyelia
- Tuberculosis infection with respiratory impairment
- Other neuromuscular disease which is known to cause respiratory muscle weakness or upper airway functional impairment.

NIV – Section C – Obstructive Sleep Apnoea Hypopnea Syndrome (OSAHS)

Obstructive Sleep Apnoea Hypopnea Syndrome (OSAHS)

Apnoea is defined as a temporary absence or cessation of breathing. **Obstructive Sleep Apnoea** hypopnea syndrome (OSAHS) is a condition in which a person experiences repeated episodes of apnoea because of a narrowing or closure of the pharyngeal airway during sleep. This is caused by a decrease in the tone of the muscles supporting the airway during sleep. Complete closure (obstruction) stops airflow (apnoea) whereas partial obstruction decreases airflow (hypopnoea). OSAHS results in episodes of brief awakening from sleep to restore normal breathing.

Moderate to severe OSAHS can be diagnosed from patient history and a sleep study using oximetry or other monitoring devices carried out in the person's home. In some cases, further studies that monitor additional physiological variables in a sleep laboratory or at home may be required, especially when alternative diagnoses are being considered. The severity of OSAHS is usually assessed on the basis of both severity of symptoms (particularly the degree of sleepiness) and the sleep study, by using either the apnoea/hypopnoea index (AHI) or the oxygen desaturation index. OSAHS is considered mild when the AHI is 5–14 in a sleep study, moderate when the AHI is 15–30, and severe when the AHI is over 30. In addition to the AHI, the severity of symptoms is also important.

The symptoms of OSAHS include impaired alertness, cognitive impairment, excessive daytime sleepiness, snoring, nocturia, morning headaches and sexual dysfunction. The sleep quality of partners may also be affected. Excessive daytime sleepiness can adversely affect cognitive function, mood and quality of life. OSAHS is associated with high blood pressure, which increases the risk of cardiovascular disease and stroke. OSAHS has also been associated with an increased risk of road traffic accidents.

Major risk factors for developing OSAHS are increasing age, obesity and being male. OSAHS is also associated with certain specific craniofacial characteristics (such as retrognathia), enlarged tonsils and enlarged tongue. Use of alcohol or sedatives can also increase the risk or severity of the condition. OSAHS has been reported to affect up to 4% of middle-aged men and 2% of middle-aged women in the UK. It is estimated that 1% of men in the UK may have severe OSAHS.

The use of Non-Invasive Ventilation in OSAHS.

Treatment for OSAHS aims to reduce daytime sleepiness by reducing the number of episodes of apnoea/hypopnoea experienced during sleep. The type of non-invasive ventilation most commonly used in the clinical management of sleep apnoea is continuous positive airway pressure (CPAP).

The alternatives to CPAP are:

- lifestyle management,
- dental devices
- surgery.

Lifestyle management involves helping people to lose weight, stop smoking and/or decrease alcohol consumption.

Dental devices are designed to keep the upper airway open during sleep. The efficacy of dental devices has been established in clinical trials, but these devices are traditionally viewed as a treatment option only for mild and moderate OSAHS.

Surgery involves resection of the uvula and redundant retrolingual soft tissue. However, there is a lack of evidence of clinical effectiveness, and surgery is not routinely used in clinical practice.

A CPAP device consists of a unit that generates airflow, which is directed to the airway via a mask. Positive pressure is generated by the airflow, which prevents upper airway collapse. For CPAP treatment to be effective the patient must always wear their device when they go to sleep.

Reasons for not adhering to CPAP treatment include poor mask fit, pressure intolerance and, more commonly, upper airway symptoms such as nasal dryness, nasal bleeding and throat irritation. Humidification devices are now commonly used in conjunction with CPAP devices in order to reduce these side effects. Masks should be replaced at least annually, and long-term follow-up of patients is critical to ensure adherence.

There are two types of CPAP devices. Fixed CPAP devices deliver air at constant pressure throughout the night, and the person will continue to receive this pressure until a further titration study is performed to determine whether the set pressure is still appropriate. Auto-titrating CPAP devices continually adjust the pressure delivered throughout the night, with the aim of improving comfort and thus adherence.

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

NIV – Section A – Chronic Obstructive Pulmonary Disease (COPD)

Eligibility Criteria: Restricted

For patients with chronic COPD the CCG will commission the use of domiciliary non-invasive ventilation in the following clinical circumstances:

The patient has a diagnosis of COPD, identified by post bronchodilator Forced Expiratory Volume (FEV)₁ / Forced Vital Capacity (FVC) <0.70

AND

The patient must have an awake, non-acute, stable paCO₂ level equal to or greater than 6.5kpa

AND the patient must have **ONE** of the following:

A reduction in quality of life identified by symptoms consistent with sleep disordered breathing problems

If the patient has reduced quality of life, then overnight oximetry should be undertaken to demonstrate that the patient meets ONE of the following criteria:

- An apnoea/hyponoea index >10/hour on polysomnography
- Four or more episodes of SpO₂ <92%
- Drops in SpO₂ of at least 4% per hour of sleep)

OR

- A co-morbidity secondary to hypoxemia
- Pulmonary Hypertension
- Heart Failure

If the patient has co-morbidities secondary to Hypoxemia then the patient should also meet the following criteria:

- Recurrent NIV admissions (2 or more in a 12 month period OR difficulty weaning / unable to tolerate weaning)

AND

- Acute use of NIV has been well tolerated

N.B. Symptoms consistent with Sleep disordered breathing problems are defined as:

- Excessive daytime somnolence (a state of strong desire for sleep, or sleeping for unusually long periods)
- Headache
- Confusion
- Increased shortness of breath
- Resting tremor

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient with COPD meets the above clinical criteria:

- One NIV machine
- +/- Humidifier as required
- 1-2 lengths of tubing per year
- 1-2 masks per year

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

NIV – Section B – Neuro-Muscular Patients

Eligibility Criteria: Restricted

Patients with one of the following conditions will be considered for funding when the patient also meets the eligibility criteria outlined below.

- Motor Neurone Disease
- Spinal Muscular Atrophy
- Spinal cord injury
- Multiple Sclerosis
- Guillain-Barre Syndrome
- Post polio syndrome with respiratory impairment
- Syringomyelia
- Tuberculosis infection with respiratory impairment
- Other neuromuscular disease which is known to cause respiratory muscle weakness or upper airway functional impairment.

For patients diagnosed with a neuromuscular condition as outlined above, the patient must meet the following criteria for funding for non-invasive ventilation to be approved:

Nocturnal Ventilation

The patient must meet ONE of the following criteria:

- Signs (<50% predicted/<1l) or symptoms of hypoventilation
- MIP< 60cmH₂O
- A baseline SpO₂ <95%
- Blood or end tidal pCO₂ >45mmHg whilst awake
- Four or more episodes of SpO₂ <92%
- Drops in SpO₂ of at least 4% per hour of sleep

Daytime Ventilation (in addition to meeting the above criteria the patient must also meet ONE of the following criteria):

- Abnormal deglutition due to dyspnea, which is relieved by ventilatory assistance
- Inability to speak in full sentences without breathlessness
- Symptoms of hypoventilation with baseline SpO₂ <95%
- Blood or end tidal pCO₂ >45mmHG whilst awake
- Symptoms of awake dyspnoea are present

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient meets the above clinical criteria:

Below 14 hours of ventilation required.

- One NIV machine
- +/- Humidifier as required
- 1-2 lengths of tubing per year
- 1-2 masks per year

Above 14 hours / 24 hour period of ventilation required.

- Two NIV machine
- +/- ONE Humidifier as required
- 2-4 lengths of tubing per year
- 2-4 masks per year

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

NIV – Section C – Obstructive Sleep Apnoea Hypopnea Syndrome (OSAHS)

Eligibility Criteria: Restricted

1. Continuous positive airway pressure (CPAP) is commissioned as a treatment option for adults with moderate or severe symptomatic obstructive sleep apnoea/hypopnoea syndrome (OSAHS).
2. CPAP is only recommended as a treatment option for adults with mild OSAHS if:
 - a. The OSAHS is causing severe functional impairment, which is impacting on the patient's ability to carry out activities of daily living

AND

- b. lifestyle advice and any other relevant treatment options have been unsuccessful or are considered inappropriate

The diagnosis and treatment of OSAHS, and the monitoring of the response, should always be carried out by a specialist service with appropriately trained medical and support staff.

N.B. The definition of OSAHS following a sleep study is as follows:

Mild OSAHS= Apnoea–Hypopnoea Index (AHI) 5–14.

Moderate OSAHS = AHI is 15–30.

Severe OSAHS = AHI is over 30.

Functional impairment is defined as preventing activities of daily living to be undertaken independently, i.e. sleeping; eating; walking, driving.

Exclusion criteria:

- Inability to remove mask independently (with no waking night carer)
- Cognitive / behavioural limitation affecting ability to comply safely with NIV
- Intolerance of acute NIV
- Multiple co-morbidities limiting utility of NIV

Funding will be provided for the following if the patient meets the above clinical criteria:

- One CPAP machine
- 1-2 lengths of tubing per year
- 1-2 masks per year

In a small proportion of OSA patients, CPAP proves insufficient to control apnoeas and it becomes necessary to use bi-level NIV. If a patient has failed treatment with CPAP, but continues to meet the eligibility criteria outlined above, a further funding application will be considered for:

- One Bi-level NIV machine
- 1-2 lengths of tubing per year
- 1-2 masks per year

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

2. Research

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

Research/Publications	Working Groups	Clinical Experts
<p>Guidance: Non-Invasive Ventilation</p> <ol style="list-style-type: none"> 1. Corrado A, Gorini M, Melej R, et al. Iron lung versus mask ventilation in acute exacerbation of COPD: a randomised crossover study. <i>Intensive Care Med.</i> 2009 Apr. 35(4):648-55. 2. Parke RL, McGuinness SP. Pressures delivered by nasal high flow oxygen during all phases of the respiratory cycle. <i>Respir Care.</i> 2013 Oct. 58 (10):1621-4. 		

<ol style="list-style-type: none"> 3. Spoletini G, Alotaibi M, Blasi F, Hill NS. Heated Humidified High-Flow Nasal Oxygen in Adults: Mechanisms of Action and Clinical Implications. <i>Chest</i>. 2015 Jul. 148 (1):253-61. 4. Ozsancak A, Sidhom S, Liesching TN, Howard W, Hill NS. EVALUATION OF THE TOTAL FACE MASKTM FOR NONINVASIVE VENTILATION TO TREAT ACUTE RESPIRATORY FAILURE. <i>Chest</i>. 2011 Feb 17. 5. Wysocki M, Richard JC, Meshaka P. Noninvasive proportional assist ventilation compared with noninvasive pressure support ventilation in hypercapnic acute respiratory failure. <i>Crit Care Med</i>. 2002 Feb. 30 (2):323-9. 6. Fernández-Vivas M, Caturla-Such J, González de la Rosa J, Acosta-Escribano J, Alvarez-Sánchez B, Cánovas-Robles J. Noninvasive pressure support versus proportional assist ventilation in acute respiratory failure. <i>Intensive Care Med</i>. 2003 Jul. 29 (7):1126-33. 7. Hoo, G. 2018. Noninvasive Ventilation. Medscape. https://emedicine.medscape.com/article/304235-overview#a5 8. British Thoracic Society/Intensive Care Society Acute Hypercapnic Respiratory Failure Guideline Development Group. 2016. BTS/ICS Guidelines for the Ventilatory Management of Acute Hypercapnic Respiratory Failure in Adults. Journal of the British Thoracic Society. http://thorax.bmj.com/site/about/guidelines.xhtml#open 9. 18. National Institute for Health and Clinical Excellence (NICE). Motor neurone disease: assessment and management. NICE guideline [NG42] Published date: February 2016 Last updated: July 2019 10. 19. National Institute for Health and Clinical Excellence (NICE). <i>Chronic Obstructive Pulmonary Disease in Over 16s: Diagnosis and Management [CG101]</i>. London, England: NICE; 2010. https://www.nice.org.uk/guidance/ng42 		
<p>Guidance – Section A: COPD</p> <ol style="list-style-type: none"> 1. Brochard L, Mancebo J, Wysocki M, et al. Noninvasive ventilation for acute exacerbations of chronic obstructive pulmonary disease. <i>N Engl J Med</i>. 1995;333(13):817-822. 2. Bott J, Carroll MP, Conway JH, et al. Randomised controlled trial of nasal ventilation in acute ventilatory failure due to chronic obstructive airways disease. <i>Lancet</i>. 1993;341(8860):1555-1557. 3. Connors AF Jr, Dawson NV, Thomas C, et al; SUPPORT Investigators (Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments). Outcomes following acute exacerbation of severe chronic obstructive lung disease. <i>Am J Respir Crit Care Med</i>. 1996;154(4 pt 1): 959-967. 4. Murray I, Paterson E, Thain G, Currie GP. Outcomes following non-invasive ventilation for 		

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3. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

3. Impact and Evidence:

Age: Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

NIV – Section A – Chronic Obstructive Pulmonary Disease (COPD)

Long term lifestyle choices (smoking) in most cases is the most common reason for diagnoses, as such COPD is a common condition that mainly affects middle aged or older people who smoke.

It is recognised that genetic conditions can predispose younger people to developing such conditions as COPD.

NIV – Section B – Neuro-Muscular Patients

Depending upon the diagnosed condition of the patient if it's an inherited genetic condition this will be present at birth which may or may not show symptoms until later in life.

However, the condition may link to age in cases of motor neurones disease where cells in the brain and nerves stop working over-time, and mainly affects people in their 60's and 70s, but it can affect adults of all ages.

NIV – Section C – Obstructive Sleep Apnoea Hypopnea Syndrome (OSAHS)

It has been recognised that there is a link to developing OSAHS due to increasing age and alongside other conditions such as obesity. It is also noted that certain specific craniofacial characteristics (such as retrognathia), enlarged tonsils and enlarged tongue are associated with the condition and therefore may be prevalent from birth.

Disability: Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

A link can be made with degenerative conditions where the person experiencing is likely to have a disability. Restricting this procedure may have an impact on this group as a result.

However, an individual can discuss the impact with their GP and has the option for an individual funding request (IFR) request to be made.

3. Impact and Evidence:
<p>Gender reassignment (including transgender): Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment:</p> <p style="text-align: center;">No Impact identified</p>
<p>Marriage and civil partnership: Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:</p> <p style="text-align: center;">No impact identified</p>
<p>Pregnancy and maternity: Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:</p> <p>If any of those conditions are present, then the pregnancy must be managed as the condition may worsen throughout pregnancy.</p>
<p>Race: Describe race related impact and evidence. This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:</p> <p style="text-align: center;">No impact identified</p>
<p>Religion or belief: Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:</p> <p style="text-align: center;">No impact identified</p>
<p>Sex: Describe any impact and evidence on men and women. This could include access to services and employment:</p> <p>Depending on the diagnosis of the patient some conditions are more commonly seen in one gender over the other.</p> <p>For example, motor neurone disease although a rare condition is more likely to effect males than females. Obstructive sleep apnoea hypopnea syndrome (OSAHS) is slightly more evident in males who are obese than females due to how fat is stored in the body. Where the condition has arisen from long term lifestyle choices this could affect either gender.</p>

3. Impact and Evidence:
<p>Sexual orientation: Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:</p> <p style="text-align: center;">No impact identified</p>
<p>Carers: Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:</p>
<p>Other disadvantaged groups: Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)</p> <p>Health inequalities are present in an area of deprivation – which combines factors such as income, employment, health and education which has the greatest impact on someone's likelihood of smoking.</p>

4. Health Inequalities	Yes/No	Evidence
Could health inequalities be created or persist by the proposals?	Yes	This condition could be linked to a health inequality due to the prevalence of smoking. As the procedures remains available it is not anticipated that a health inequality will be made worse.
Is there any impact for groups or communities living in particular geographical areas?	Yes	A possible link between smoking and areas of high deprivation has been made.

Is there any impact for groups or communities affected by unemployment, lower educational attainment, low income, or poor access to green spaces?	Yes	A possible link between the likelihood of someone smoking and unemployment, low income and education has been made. Due regard to this will need to be given in supporting such patients.
<p>How will you ensure the proposals reduce health inequalities?</p> <p>The intention of the policy is to support patients with ventilatory support without using an invasive artificial airway method. For those patients where the condition has been a result of a long-term lifestyle choice, as in smoking, support should be provided to those patients through a number of interventions to help the patient stop smoking.</p>		

5. FREDA Principles/ Human Rights	Question	Response
Fairness – Fair and equal access to services	How will this respect a person's entitlement to access this service?	Yes, this decision has been made in line with clinical recommendation and NICE.
Respect – right to have private and family life respected	How will the person's right to respect for private and family life, confidentiality and consent be upheld?	No discrimination identified
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have their needs met and identified?	No discrimination identified
	How will this affect a person's right to freedom of thought, conscience and religion?	No discrimination identified
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	Policy will be applied with due regard to this consideration.

Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	An individual can discuss the impact with their GP and has the option for an IFR request to be made
Right to Life	Will or could it affect someone's right to life? How?	No discrimination identified
Right to Liberty	Will or could someone be deprived of their liberty? How?	No discrimination identified

6. Social Value	
Consider how you might use the opportunity to improve health and reduce health inequalities and so achieve wider public benefits, through action on the social determinants of health.	
Marmot Policy Objective	What actions are you able to build into the procurement activity and/or contract to achieve wider public benefits?
Enable all people to have control over their lives and maximise their capabilities	
Create fair employment and good work for all	
Create and develop health and sustainable places and communities	
Strengthen the role and impact of ill-health prevention	

7. Engagement, Involvement and Consultation		
If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:		
Engagement Activity	Protected Characteristic/ Group/ Community	Date
For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us So we will):		
As part of the process further targeted engagement is planned with representative groups from among Sandwell, Birmingham and Solihull Patients. In addition, it has been identified that patient and clinician information is key in ensuring that the harmonised treatment policies review delivers effective outcomes. To this end an information briefing sheets on each procedure will be developed to give more information on the procedure, eligibility criteria and signposting to further information sources, such as NHS Choices. These information sheets are also designed to help facilitate discussions between GPs and patients. Information briefing sheets have already been tested and uploaded onto the GP systems for the first 45 harmonised treatment policies for Birmingham and Solihull. Due regard will be given to both the		

accessible information standard and the potential need to translate such leaflets into relevant local languages.

8. Summary of Analysis

Considering the evidence and engagement activity you listed above, please summarise the impact of your work:

The restriction of this policy will have an impact on those who would wish to receive the treatments, this must be balanced against the need to adhere to NICE guidelines and the clinical effectiveness evidence. The opportunity for any exceptional cases to be considered via IFR remains and will ensure treatment is available in an exceptional case.

9. Mitigations and Changes :

Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the **recommendations** and any **changes** to the proposal arising from the equality analysis.

Consideration will need to be given to what additional support patients from a low socio economic background will require and how due regard can be given to reasonable adjustments in approach for disabled persons.

10. Contract Monitoring and Key Performance Indicators

Detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract (refer to NHS Standard Contract SC12 and 13):

This policy is not linked to a contract however, prospective providers remain bound by their contracts with the CCG.

11. Procurement

Detail the key equality, health inequalities, human rights, and social value criteria that will be included as part of the procurement activity (to evaluate the providers ability to deliver the service in line with these areas):
N/A

12. Publication
How will you share the findings of the Equality Analysis?
This can include: reports into committee or Governing Body, feedback to stakeholders including patients and the public, publication on the web pages. All Equality Analysis should be recommended for publication unless they are deemed to contain sensitive information.
Published on CCG website
Following approval all finalised Equality Analysis should be sent to the Communications and Engagement team for publication: bsol.comms@nhs.net

13. Sign Off		
The Equality Analysis will need to go through a process of quality assurance by the Senior Manager for Equality Diversity and Inclusion or the Manager for Equality Diversity and Inclusion prior to approval from the delegated committee		
	Name	Date
Quality Assured By:		
Which Committee will be considering the findings and signing off the EA?		
Minute number (to be inserted following presentation to committee)		

Please send to Balvinder Everitt or Michelle Dunne, Equality, Diversity and Inclusion for Quality Assurance.

Once you have committee sign off, please send to Caroline Higgs, Communications & Engagement Team for publication: bsol.comms@nhs.net