Clinical Policy: Respiratory Equipment and Supplies

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See Important Reminder at the end of this policy for important regulatory and legal information.

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description[1]

This policy describes the medical necessity criteria for Respiratory Equipment and Supplies.

Policy/Criteria[1]

I. WellCare of North Carolina® shall cover durable medical equipment and related medical supplies when **ALL** the following requirements are met:

A. The item is ordered by a Physician, Physician Assistant, or Nurse Practitioner;
B. The item is medically necessary to maintain or improve a beneficiary's medical, physical or functional level, and appropriate for use in any noninstitutional setting in which normal life activities take place;
C. A documented face-to-face encounter with the beneficiary and the ordering Physician, Physician Assistant, or Nurse Practitioner related to the primary reason the beneficiary requires durable medical equipment and medical supplies has occurred no more than six (6) months prior to the initiation of durable medical equipment and medical supplies; **and**
D. The beneficiary's need for durable medical equipment and medical supplies is reviewed by the ordering Physician, Physician Assistant, or Nurse Practitioner at least annually.

II. WellCare of North Carolina® shall cover **oxygen therapy and related supplies and equipment** for a beneficiary who meets the following criteria:

A. Age Specific
   1. **Ages zero (0) through three (3) years**
      a. Arterial oxyhemoglobin saturation (SaO2) equal to or less than 94% and have a documented supporting diagnosis.
   2. **Ages 4 through 20 years**
      a. SaO2 equal to or less than 90% and a documented supporting diagnosis.
   3. **Ages 21 and older** - There is documentation from the treating physician that reports **ALL** the following:
      a. A diagnosis of severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy;
      b. Alternative treatments have been tried and considered or deemed clinically ineffective;
      c. The beneficiary has a qualifying blood gas study (either arterial blood gas (ABG), or pulse oximetry for SaO2) that meets the criteria for **ONE** of the following groups:
         i. *Group I*

a) an arterial PO2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken at rest, breathing room air.
b) an arterial PO2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken during sleep for a patient who demonstrates an arterial PO2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, while awake; or a greater-than-normal fall in oxygen level during sleep (a decrease in arterial PO2 more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5%) associated with symptoms or signs reasonably attributable to hypoxemia (such as, impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided only for use of oxygen during sleep, and then only one type of unit will be covered. Portable oxygen, therefore, would not be covered in this situation.
c) an arterial PO2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, taken during exercise for a patient who demonstrates an arterial PO2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, during the day while at rest. In this case, supplemental oxygen is provided during exercise if there is evidence the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

ii. *Group II*

a) an arterial PO2 of 56–59 mm Hg or arterial blood oxygen saturation of 89%, if there is evidence of **ONE** of the following:
1) dependent edema suggesting congestive heart failure;
2) pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF); **or**
3) erythrocythemia with a hematocrit greater than 56%.

B. A **qualifying oxygen analysis** (either arterial blood gas (ABG) or pulse oximetry for SaO2) must meet the following criteria:
1. For beneficiaries **21 years of age and older**, if the oxygen analysis is performed during an inpatient hospital stay, the reported test must be one obtained closest to, but no earlier than two (2) calendar days prior to the hospital discharge date. For beneficiaries **under 21 years of age**, the reported test may be one obtained at any time during the inpatient hospital stay; **or**
2. If the qualifying oxygen analysis is not performed during an inpatient hospital stay, the reported test must be performed while the beneficiary is in a chronic stable state—that is, not during a period of acute illness or exacerbation of their underlying disease.
3. The oxygen analysis used to determine medical necessity must not be performed by a medical equipment supplier or a related corporation. In addition, the oxygen analysis must not be performed by a physician with a significant ownership interest in the medical equipment supplier or the laboratory performing such tests. These provisions include relationships through blood or marriage. A referring physician may perform the test in his office as part of routine care.

4. The oxygen analysis must be performed by a clinician that does not have a vested interest in the company that supplies the oxygen, equipment and supplies.
5. In cases where treatment is for *nocturnal hypoxemia*, a new ABG or pulse oximetry result is not required for reauthorization once the beneficiary has had greater than 2 oxygen concentrator approvals;
6. The initial oxygen analysis must be performed within a one (1) month period before the approved start date of treatment. Otherwise, the approved start date of treatment is the date of the initial qualifying analysis.

C. **Approval Requirements** - For initial prior approval of oxygen services, the following must be noted in the documentation:
1. Health record documentation from the beneficiary's prescriber stating why the use of oxygen is indicated.
2. Health record documentation from the beneficiary's prescriber showing that the beneficiary has had an examination within one (1) month of the start of oxygen therapy. The documentation must list **ALL** the following:
   a. The diagnosis of the disease requiring use of oxygen;
   b. The oxygen flow rate needed; **and**
   c. An estimate of the frequency, duration of use, and length of need for the oxygen.
3. Results of an oxygen analysis (either ABG or pulse oximetry for SaO2).
4. Initial prior approval is given for *12 calendar months* for a beneficiary **under age 21 years of age**, or who qualifies for oxygen under *Group I* criteria. Continuation prior approval for this beneficiary is required at the end of the 12 calendar months. If approved, continuation is granted for an *additional 24 months*. For a beneficiary **under 21 years of age**, repeat testing is not required for continuation prior approval.
5. Initial prior approval is given for *three (3) calendar months* for a beneficiary who qualifies for oxygen therapy under *Group II* criteria. Continuation prior approval for this beneficiary is required at the end of the three (3) months. If approved, continuation is granted for an *additional nine (9) months*.
6. For a beneficiary initially meeting *Group II* criteria, the most recent blood gas study that was performed between the 61st and 90th day following initial certification must be documented. If a qualifying test is not obtained between the 61st and 90th day of oxygen therapy, but the beneficiary continues to use oxygen and a test is obtained at a later date, if that test meets *Group I or II* criteria, coverage would resume beginning with the date of that test.
7. For a beneficiary initially meeting *Group I or II* criteria, the beneficiary must be seen and re-evaluated by the treating prescriber within three (3) months prior to the date of any recertification. If the prescriber's visit is not obtained within the three (3) month window, but the beneficiary continues to use oxygen, and the visit is obtained at a later date, coverage would resume beginning with the date of that visit. If the beneficiary meets the *Group II* criteria, the second continuation prior approval is given for an additional 24 months.
8. Repeat testing is not required in cases where equipment is replaced. Enter the most recent qualifying value and test date. This test does not have to be within one (1) month prior to the initial certification date, but could be the test result documented.
9. When the prescribed maximum flow rate changes from one of the following categories to another, a repeat blood gas study or oximetry with the beneficiary on 4

liters per minute (LPM) must be performed and this must be the most recent study obtained within one (1) month prior to the initial certification date:
   a. Less than one (1) LPM,
   b. One (1) to four (4) LPM,
   c. Greater than four (4) LPM

10. For beneficiaries **21 years of age and older** who initially qualified under *Group I* criteria, when the length of need expires – if the prescriber specified less than lifetime length of need in the documentation, then the blood gas study can be the most recent study obtained within one (1) month prior to the initial certification date.
11. When a portable system is added after the initial authorization of a stationary system, there is not a requirement for a repeat blood gas study unless the initial qualifying study was performed during sleep, in which case a repeat blood gas study must be performed while the beneficiary is at rest while awake or during exercise within one (1) month prior to the revised date.
12. *At the end of 36 months,* **all** beneficiaries shall be recertified. The provider shall submit a new prior approval request for the continuation of oxygen therapy. This request must contain documentation of continued medical need reported by the treating prescriber along with a qualifying test within six (6) months of the renewal date. **Approval given at the 36-month renewal period is considered a lifetime approval**.

Note: Continuation prior approval for oxygen therapy is not required when initially approved for use with a continuous positive airway pressure (CPAP) device or a respiratory assist device (RAD) for obstructive sleep apnea (OSA), or ventilator dependency for respiratory failure.

Special Reimbursement Explanation: Oxygen contents are approved only for beneficiary-owned equipment. This includes portable tanks, liquid oxygen, and oxygen tanks that are used on an ongoing basis based on prior approval and medical necessity.

D. Coverage Descriptions

1. For a beneficiary receiving oxygen therapy delivered by an oxygen concentrator and also prescribed a portable oxygen system, reimbursement is for rental on the oxygen concentrator and portable oxygen tank. There is no separate coverage for contents that are used by the portable system, regardless of the amount of portable oxygen contents used in that month, as rental for the oxygen systems include contents.
2. For a beneficiary who is on a stationary liquid oxygen system and portable liquid oxygen system, coverage is for rental at the published rate for both a stationary liquid oxygen system and a portable system. Contents are covered in the published rate, and no additional contents are separately approved for a monthly rental.
3. Portable oxygen systems—A beneficiary who meets the clinical coverage criteria for medical necessity may qualify for coverage of a portable oxygen system either by itself or to use in addition to a stationary system. The qualifying health record documentation must indicate that the beneficiary is mobile and would benefit from the use of the portable oxygen system. Portable oxygen systems that are used on a standby basis are not covered except in instances of a fragile infant with a tracheostomy.
4. If basic oxygen coverage criteria have been met, a higher allowance for a stationary system for a flow of greater than four (4) LPM will be paid only if a blood gas study

performed while the beneficiary is on four (4) LPM meets Group I or II criteria. If a flow rate greater than four (4) LPM is billed and the coverage criterion for the higher allowance is not met, payment will be limited to the standard fee schedule allowance. The higher oxygen allowable will be paid to the supplier at one-and-a-half (1.5) times the rate. A modifier must be added to the oxygen code being used. If a modifier is used, then only the one-and-a-half (1.5) times the rate will be reimbursed and there will be no payment for the portable oxygen system.

5. A Carbon Dioxide (CO2) Saturation Monitor with Accessories and Probes is considered medically necessary when it is required to monitor carbon dioxide (CO2) levels in beneficiary's requiring oxygen therapy so that appropriate blood gas levels are achieved and maintained.

III. WellCare of North Carolina® shall cover **respiratory assist devices (RADs) and related accessories** for beneficiaries with **ANY** of the following respiratory disorders who demonstrate medical necessity for each disorder:

A. *Restrictive thoracic disorders* - The beneficiary shall meet any **one** of the following criteria:
   1. Documentation of the beneficiary's progressive neuromuscular disease or severe thoracic cage abnormality and an arterial blood gas PaCO2, done while awake and breathing the beneficiary's usual fraction of inspired oxygen (FIO2), that is greater than or equal to 45 mmHg;
   2. Sleep oximetry demonstrating oxygen saturation less than or equal to 88% for at least five (5) continuous minutes, done while breathing the beneficiary's FIO2; **or**
   3. For a progressive neuromuscular disease (only), maximal inspiratory pressure is less than 60cm H20 or forced vital capacity is less than 50% predicted; and chronic obstructive pulmonary disease does not contribute significantly to the beneficiary's pulmonary limitation.

B. *Severe chronic obstructive pulmonary disease (COPD)* - The beneficiary must meet the following criteria:
   1. Documentation of the beneficiary's severe COPD and an arterial blood gas study, done while awake and breathing the beneficiary's usual FIO2, demonstrating a PaCO2 that is greater than or equal to 52 mmHg; and **one** of the following:
      a. sleep oximetry demonstrating oxygen saturation less than or equal to 88% for at least five (5) minutes in total, done while breathing the beneficiary's usual FIO2; **or**
      b. prior to initiating therapy, OSA (treatment with CPAP) has been considered and ruled-out.

C. *Central sleep apnea* - The beneficiary shall meet **ALL** the following criteria:
   1. A polysomnogram documenting the Central Sleep Apnea (CSA)
   2. Exclusion of Obstructive Sleep Apnea (OSA) as the predominant cause of sleep-associated hypoventilation;
   3. Ruling out of CPAP as effective therapy of OSA is a component of the sleep-associated hypoventilation;
   4. Oxygen saturation less than or equal to 88% for at least five (5) continuous minutes, done while breathing the beneficiary's usual FIO2; **and**

5. Significant improvement of the sleep-associated hypoventilation with the use of a RAD without a back-up rate on the settings that will be prescribed for initial use, while breathing the beneficiary's usual FIO2

Note: For **beneficiaries ages 0 through 18** with CSA, an apnea-hypopnea index (AHI) of 5 to 10 is acceptable if the physician who is a sleep specialist provides appropriate documentation on the physician's letterhead stationery of medical necessity for the RAD in each individual case.

D. *Obstructive sleep apnea (OSA)* - The beneficiary shall meet the following criteria:
   1. Has a diagnosis of OSA; **and**
   2. Has a documented polysomnogram provided that meets the following criteria:
      a. the AHI is greater than or equal to 15 events per hour; **or**
      b. The AHI is from 5 to 14 events per hour with documented symptoms of:
         i. excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; **or**
         ii. hypertension, ischemic heart disease, or history of stroke.
   3. Coverage for a **BiLevel** device is allowed for a beneficiary who meets the criteria listed above and the prescribing Physician, Physician Assistant, or Nurse Practitioner documents that the beneficiary meets **one** of the following conditions:
      a. has had an unsuccessful six (6) month trial on a CPAP device;
      b. is unable to tolerate CPAP;
      c. has special needs that have been documented on the physician's letterhead stationery by a physician who is a sleep specialist.

E. Requirements for Coverage - **RAD**
   1. A polysomnogram must be submitted with the initial request for a RAD with those diagnoses that have a polysomnogram requirement in the criteria.
      a. WellCare of North Carolina® shall not accept polysomnograms that are performed by a medical equipment provider.
      b. The polysomnogram must be based on a minimum of two (2) hours of recorded sleep time without the use of a CPAP or RAD device, reported by the polysomnogram. The polysomnogram must include sleep staging and other sleep parameters such as airflow, respiratory effort, and oxygen saturation by oximetry.
   2. If the polysomnogram criteria listed above are not met, claims submitted for reimbursement of a RAD and related accessories are denied as not medically necessary.
   3. For an item to be covered by Wellcare of North Carolina® a written signed and dated order from the "treating physician" must be received by the supplier before requesting prior approval. The treating physician is one who is qualified by virtue of experience and training in non-invasive respiratory assistance, to order and monitor the use of the respiratory assist devices.
   4. If there is a discontinuation of the RAD at any time, the provider is expected to determine that the RAD has been discontinued and stop billing for the equipment and related accessories.
   5. A RAD with a back-up rate is not medically necessary if the primary diagnosis is OSA.

F. Approval Details - **RAD**

1. *Initial Approval*: For a RAD to be covered, the treating physician, physician assistant, or nurse practitioner, shall fully document in the beneficiary's clinical health record those symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, or dyspnea, etc. Initial approval for a RAD is given for a period of **six (6)** months.
2. *Renewal Approval*: For renewal approval and continued coverage of the RAD beyond the first six (6) months of therapy, no sooner than the fifth (5th) month after initiating therapy:
   a. The provider shall obtain a statement of compliance from the treating physician declaring that the beneficiary is using the device an average of four (4) hours per 24-hour period which must be submitted for renewal. Failure of the beneficiary to be consistently using the RAD for an average of four (4) hours per the 24-hour period by the time of the reevaluation would represent non-compliant use and constitute reason for WellCare of North Carolina® to deny continued coverage as not medically necessary; **and**
   b. A statement must be submitted by the physician, physician assistant, or nurse practitioner indicating the progress of relevant symptoms and that the RAD is still medically necessary.

Note: A non-heated or heated humidifier is covered by Medicaid and NCHC with the use of a RAD. The treating physician shall specify which type of humidifier the beneficiary is to use.

Note: A RAD without a back-up rate is reimbursed as a rental only and not to exceed a total of monthly rental payments equal to the purchase price. A RAD with a back-up rate is reimbursed as a continuous rental item.

G. Requirements for Coverage - **CPAP or BiLevel**

1. A polysomnogram must be submitted with the initial request for prior approval of a CPAP or BiLevel device.

Note: WellCare of North Carolina® shall not accept polysomnograms that are performed by a medical equipment provider.

2. Polysomnograms must be provided according to requirements.
3. The polysomnogram must be based on a minimum of two (2) hours of recorded sleep time without the use of the CPAP or BiLevel device, reported by the polysomnogram. The polysomnogram must include sleep staging and other sleep parameters such as airflow, respiratory effort, and oxygen saturation by oximetry.
4. If the polysomnogram criteria listed above are not met, claims submitted for reimbursement of the CPAP or BiLevel device and related accessories are not medically necessary, and therefore not covered.
5. For an item to be covered by WellCare of North Carolina®, a written signed and dated order from the treating physician must be received by the supplier before the request for prior approval.
6. If there is discontinuation of the CPAP or BiLevel device at any time, the provider is expected to determine this, and stop billing for the equipment and related accessories.
7. Auto-titrating CPAP devices are billed the same as a CPAP device.

8. A non-heated or heated humidifier is covered by WellCare of North Carolina® with the use of a CPAP/ BiLevel. The treating physician shall specify which type of humidifier the beneficiary is to use.

H. Approval Details - **CPAP or BiLevel**

1. *Initial Approval*:
   a. Document that the beneficiary has OSA and meets the medical necessity requirements for CPAP therapy.
   b. Submit results of the non-titrated polysomnogram summary (preferably in the non-narrative form).
   c. The initial approval and coverage for a CPAP or BiLevel device is for a period of *six (6) months*.

Note: A CPAP or BiLevel device is reimbursed as rental only. Reimbursement is not to exceed a total of monthly rental payments equal to the purchase price.

2. *Renewal Approval*: Renewal approval and continued coverage of the CPAP or BiLevel device beyond the first six (6) months of therapy, requires that, no sooner than the fifth (5th) month after initiating therapy the provider shall:
   a. determine from the treating physician that the beneficiary is continuing to use the CPAP or BiLevel device; **and**
   b. submit a statement from the Physician, Physician Assistant, or Nurse Practitioner indicating that the CPAP or BiLevel device is still medically necessary. This information is acceptable in lieu of a polysomnogram for prior approval renewal only.

If the criteria listed above are not met, continued coverage of a CPAP or BiLevel device and related equipment and accessories is not medically necessary.

IV. WellCare of North Carolina® shall cover **ventilators** when the following criteria is met**:**

A. Home ventilator with an **invasive** interface

1. Covered for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.
2. Coverage is provided for both positive and negative pressure ventilators.

B. Home ventilator with a **non-invasive** interface - when **all** criteria is met:

1. Clinical documentation indicates that:
   a. the beneficiary's condition cannot be successfully managed on a BiLevel device with pressure support, **or**
   b. BiLevel therapy and BiLevel therapy with a backup feature has been initiated and failed to adequately correct the beneficiary's respiratory status.
2. Documentation indicates that **ONE** of the following conditions is present:
   a. *restrictive lung disease* when the beneficiary meets the following:
      i. beneficiary has chronic respiratory failure with:
         a) daytime CO2 retention greater than 50 mm Hg, **or**
         b) CO2 retention of 45 to 50 mm Hg with symptoms attributable to hypoventilation (such as morning headaches, restless sleep, nightmares, enuresis, or daytime hypersomnolence), **and**
         c) nighttime oxygen desaturation to less than or equal to 88% for five (5) continuous minutes while breathing the beneficiary's usual FiO2, **and**
         d) obstructive sleep apnea has been ruled out.

b. *chronic obstructive pulmonary disease (COPD)* when the beneficiary meets the following:
   i. beneficiary has chronic respiratory failure symptoms with symptoms attributable to hypoventilation, **and**
   ii. **any** of the following physiologic criteria:
      a) PaCO2 greater than or equal to 55mm Hg, **or**
      b) PaCO2 50-54mm Hg and nighttime oxygen desaturation less than or equal to 88% for five (5) continuous minutes while breathing the beneficiary's usual FiO2, **or**
      c) PaCO2 50-54mm Hg and hospitalization related to recurrent (at least two (2) episodes in a 12-month period) hypercapnic respiratory failure.

c. *progressive neuromuscular disorder* such as:
   i. Amyotrophic Lateral Sclerosis (ALS)
   ii. Muscular dystrophy (MD)
   iii. Multiple Sclerosis (MS)
   iv. Spinal muscular atrophy (SMA)
   v. Myasthenia gravis
   vi. Primary lateral sclerosis

d. *chest wall deformity*;
e. *acute poliomyelitis*;
f. *spinal cord diseases/conditions*; **or**
g. central hypoventilation syndrome or obesity hypoventilation

3. Beneficiary can protect airway and clear secretions adequately.

C. Prior approval is required for home ventilators. Recertification is at 12 months. A lifetime PA may be considered at recertification if medical necessity is demonstrated.

V. WellCare of North Carolina® shall cover an **Intermittent Positive Pressure Breathing** (IPPB) machine and humidifier if the beneficiary's ability to breathe is severely impaired because of **any** of the following:

A. The beneficiary has unstable hyperventilation with CO2 retention that can be reduced or prevented from rising with frequent mechanical assistance; **or**
B. The beneficiary requires intermittent or constant use of assisted or controlled ventilation to maintain adequate respiration because of chronic hypoventilation.
C. Prior approval is required for an IPPB machine. To renew prior approval, a statement is needed from the physician, physician assistant, or nurse practitioner, indicating the beneficiary's overall condition has not changed and the IPPB remains medically indicated. This information is acceptable in lieu of a repeat pulmonary function test for renewal of prior approval only. An air power source requires prior approval and is covered if it is required for use with medically necessary medical equipment for purposes of operating equipment that is not self-contained, or cylinder driven.
Note: The beneficiary shall have pulmonary function test evidence of difficulty removing bronchial secretions or reversible bronchial constriction that is better after IPPB. In the absence of medical indication, reimbursement is limited to compressor-driven nebulization.

VI. WellCare of North Carolina® shall consider a self-contained, ultrasonic **nebulizer** and related supplies as considered medically necessary when:

A. The beneficiary's ability to breathe is severely impaired; **and**

B. The prescribing physician, physician assistant, or nurse practitioner states that the ultrasonic nebulizer is medically necessary for the beneficiary to receive a smaller particle size than an ordinary nebulizer will provide.
C. Prior approval is **not** required for nebulizers. Sterile saline is deemed medically necessary when used with the above equipment and accessories.

VII. WellCare of North Carolina® shall consider an **apnea monitor and supplies** as medically necessary when any **one** of the following applies to the beneficiary:
A. There has been an observed or recorded episode of prolonged apnea (greater than 10 seconds) within the last three (3) months that is documented by medical personnel and associated with bradycardia, reflux, cyanosis or pallor;
B. The beneficiary is a sibling of a sudden infant death syndrome (SIDS) child. If the sibling was three (3) months of age or less at the time of death, the beneficiary is covered up to six (6) months of age. If the sibling was four (4) months of age or older at the time of death, the beneficiary is covered up to three (3) months beyond the sibling's age at death;
C. The beneficiary has had an event or events requiring vigorous stimulation or resuscitation within the past three (3) months;
D. The beneficiary is an infant with bronchopulmonary dysplasia who requires oxygen and displays medical instability; **or**
E. The beneficiary is less than two (2) years of age and has a tracheostomy. After two (2) years of age, additional documentation from the prescribing physician, physician assistant, or nurse practitioner justifying extended medical necessity for the apnea monitor must be attached.
F. Prior approval is required.

VIII. WellCare of North Carolina® shall consider a **percussor** as medically necessary when:
A. Necessary for mobilizing respiratory secretions
B. The beneficiary or operator of the powered percussor has received appropriate training by a physician, physician assistant, or nurse practitioner or a therapist, and no one competent or able to administer manual therapy is available.
C. Prior approval is required.

IX. WellCare of North Carolina® shall consider **oximeters** as medically necessary when the following criteria is met:
A. For initial and renewal approval, attach documentation that:
1. The equipment is for continuous or intermittent use;
2. The beneficiary's condition meets **one (1)** of the coverage criteria below:
a. the beneficiary is dependent on both a ventilator and supplemental oxygen;
b. the beneficiary has a tracheostomy and is dependent on supplemental oxygen;
c. the beneficiary requires supplemental oxygen and has unstable saturations;
d. the beneficiary is a premature infant or an infant less than one (1) year of age with a lung disease such as bronchopulmonary dysplasia;
e. the beneficiary is on supplemental oxygen and weaning is in process;
f. the beneficiary has an appropriately documented respiratory diagnosis and requires short-term oximetry to rule out hypoxemia. In this case coverage is allowed for a maximum of **seven** days; **and**

3. The oximeter is required to monitor the beneficiary during a specific event such as a weaning attempt from oxygen or ventilator, feeding times for an infant, or other times for which documentation of the beneficiary's oxygen saturation rate is needed.
4. Prior approval is required.

B. A **portable oximeter** may be considered medically necessary for beneficiaries who are required by their medical provider to independently monitor and report their blood oxygen levels noninvasively from home for any one of the following indications:
1. To evaluate initial and ongoing medical necessity of an oxygen therapeutic regimen;
2. To evaluate appropriate home oxygen liter flow for ambulation, exercise, or sleep in an individual with respiratory disease; **or**
3. To evaluate an acute change in condition requiring an adjustment to the liter flow of home oxygen.
4. Prior approval is **not** required.

X. WellCare of North Carolina® shall cover a **high-frequency chest wall oscillation device** when the beneficiary's disease (diagnosis of *cystic fibrosis*, *bronchiectasis*, and some *neurological and neuromuscular conditions that compromise the ability to actively clear secretions from the respiratory tract*) is characterized by:
A. Daily productive cough for at least six (6) continuous months or frequent exacerbations (more than two (2) per year) requiring antibiotic therapy;
B. Well-documented failure of standard treatments (e.g. chest percussion, positional drainage, deep breathing exercises) to adequately mobilize mucus.
C. Prior approval is required. The initial approval is for a trial period of **three (3) months'** rental. A request for subsequent purchase of the device may be considered based on the following documented results of the initial trial period:
1. Beneficiary compliance with device use and established plan of care;
2. Significant improvement of symptoms with use of the HWFCO device; **and**
3. Decreased hospitalizations for the qualifying diagnosis during the initial trial period.

Note: The oscillatory positive expiratory pressure (PEP) device and the Flutter device facilitate secretion removal and **do not** require prior approval.

XI. WellCare of North Carolina® shall cover a **mechanical insufflation – exsufflation device** for a beneficiary who is unable to cough and clear secretions effectively and who meets **all** the following criteria:
A. A diagnosis of a neuromuscular disease or high-level spinal cord injury;
B. Has a significant impairment of chest wall or diaphragmatic movement, resulting in an inability to effectively cough and clear retained secretions;
C. Lack of success with other standard respiratory treatments such as chest percussion and postural drainage, IPPB, incentive spirometry, inhalers, PEP therapy, or flutter devices; **and**
D. Has physician-documented evidence that the beneficiary or caregiver is willing and able to use the device as prescribed.
E. Prior approval is required. Initial approval may be granted for **six (6) months** if the beneficiary meets all the following criteria:
1. Has a supporting medical diagnosis;
2. There is evidence that the beneficiary has tried other methods to control secretions, such as chest percussion and postural drainage, IPPB, incentive spirometry, inhalers,

PEP mask therapy, or flutter devices, without significant response (methods should be described);
3. Has intolerance to, contraindication of, or unavailability of, chest physiotherapy; **and**
4. Has had incidents in the past year of respiratory illnesses requiring either physician office visits, emergency room visits, hospitalizations, or antibiotics.

F. For subsequent approvals, continued medical necessity must be reestablished for each successive **six (6) months** by:
1. Evidence of beneficiary compliance, caregiver compliance, or both; **and**
2. Improved disease management since beginning the use of the coughstimulating device (as indicated by fewer infections requiring antibiotics and fewer hospitalizations).

G. Cough-stimulating devices are not covered for beneficiaries with:
1. COPD
2. Bullous emphysema,
3. Susceptibility to pneumothorax or pneumomediastinum, or
4. Recent barotrauma (an injury occurring after exposure to sudden contractions or expansions of air).

A cough-stimulating device may not be covered if the beneficiary tolerates and demonstrates a response to other techniques for cough assistance and secretion removal.

XII. WellCare of North Carolina® shall consider supplies for the care of a **tracheostomy** site medically necessary following an open surgical tracheostomy which has been opened or is expected to remain open for at least three months.

A. A tracheostomy care kit for a **new** tracheostomy is considered medically necessary during the first two (2) postoperative weeks. The following supplies should be included in the kit:
1. 1-plastic tray
2. 1-basin
3. 1-pair sterile gloves
4. 1-tube brush
5. 3-pipe cleaners
6. 1-pre-cut tracheostomy dressing
7. 1-roll gauze
8. 4-4x4 sponges
9. 2-cotton tip applicators
10. 30 inches-twill tape

B. A tracheostomy care kit for an **established** tracheostomy is considered medically necessary after the first two postoperative weeks. The following supplies should be included in the kit:
1. 1-tube brush
2. 2-pipe cleaners
3. 2-cotton tip applicators
4. 30 inches-twill tape
5. 2- 4x4 sponges

C. Quantities included in a tracheostomy care kit are to provide ALL necessary supplies for the care of the tracheostomy site. Additional supplies may be considered medically necessary ONLY for the care of another site, such as a speaking valve.

D. A tracheostomy or laryngectomy tube plug or stop is used as an alternative to a tracheostomy laryngectomy tube.
E. The HCPCS code for tracheostomy tube collar or holder should **not** be used for twill ties, twill tape or equivalent fabric or plastic supplies.

XIII. WellCare of North Carolina® shall consider the following **miscellaneous durable medical equipment and medical supplies** as medically necessary when criteria is met**:**

A. A **manual ventilation bag** requires prior approval and is covered when a beneficiary has a life-threatening diagnosis and requires ventilator support.
B. **Peak flow meters** are covered when a beneficiary's physician deems it medically necessary for the beneficiary to monitor his peak expiratory flow rate on a regular basis.
C. Supplies for use with **metered dose inhalers** are covered when ordered by the physician who has also ordered a medically necessary metered dose inhaler for the beneficiary.
D. A **respiratory suction pump, catheters, canisters, and tubing** are covered if a beneficiary is physically unable to independently expectorate respiratory secretions.

Additional Guidelines

I. Monitoring Care

A. Assuring Continuing Need for Rental Items and Supplies
1. Providers are expected to be alert to changes in the beneficiary's needs for rental items and supplies, and work with the physician, physician assistant, or nurse practitioner, to implement the changes. At a minimum, the continuing need to provide a rental item (one that is not subject to prior approval) or a supply must be verified with the attending physician, physician assistant, or nurse practitioner, at least every 12 months. If there is a need for one of these items beyond 12 months from the date of authorization, a new authorization must be completed by the physician, physician assistant, or nurse practitioner, for the continued coverage. The provider shall obtain the authorization before billing for any services beyond 12 months.

II. Servicing and Repairing Medical Equipment

A. Rental Equipment
1. Service and repairs are provided as part of the rental arrangement with no additional charge to WellCare of North Carolina®.

B. Purchased Equipment Warranty
1. Service and repairs are handled under any warranty coverage an item may have. If there is no warranty, providers may request prior approval to perform the needed service and repairs. The estimate must show a breakdown of charges for parts and the number of hours of labor. No charge is allowed for pick-up or delivery of the item or for the assembly of WellCare of North Carolina® reimbursed parts.

C. Purchased Equipment Non-Warranty
1. Service or repair is covered if the equipment is owned by the beneficiary and if the repair is not covered under the warranty. A repair estimate must be provided. The estimate must show a breakdown of charges for parts and the number of hours of labor. No charge is allowed for pick-up or delivery, for the assembly of WellCare of North Carolina® reimbursed parts or for freight or the provider's travel time or expenses.
Note: Providers shall have emergency repair service available 24-hours a day, seven days a week for any life-sustaining equipment they provide.
Note: WellCare of North Carolina® shall not cover maintenance or service contracts.

III. Replacing Medical Equipment

A. WellCare of North Carolina® may consider replacing the item, when repairing is no longer cost-effective and the item is out of warranty.

B. When requesting prior approval for the replacement of an item before its usual life expectancy has ended, explaination on why the replacement is needed must be documented.

1. In cases of equipment loss or damage beyond repair, a letter from the social worker, case manager or child service coordinator explaining the circumstances.
2. In cases of theft, a copy of the police report or a letter from the appropriate person with knowledge of the occurrence, such as the school principal, social worker, etc.
3. In cases of equipment destruction by fire, a copy of the fire report.
4. In cases of wide-spread natural disasters, documentation is accepted from any of the entities listed above or from the NC Division of Emergency Management, Federal Emergency Management Agency, American Red Cross, the National Guard or other appropriate state or local authorities and agencies on the ground in the affected areas.

IV. Changing Suppliers

A. A change in suppliers may occur for various reasons, such as a beneficiary exercising their freedom of choice of suppliers. When the change involves a transfer of responsibility for providing a rental item or oxygen and oxygen equipment, the transfer must be coordinated with the new supplier and the prescribing physician, physician assistant, or nurse practitioner. For the new provider to get prior approval to provide rental equipment that has been supplied by the previous provider, the new provider shall submit a pick-up ticket from the first provider showing the equipment has been picked-up and new equipment is needed. The previous provider shall submit a pick-up ticket that includes the provider's name, beneficiary's name, item picked up, and date item was picked up. Failure to submit a pick-up ticket to the new provider within 30 calendar days will result in an investigation and possible recoupment of funds.

B. Changing Suppliers for Oxygen and Oxygen Equipment - The steps for transferring responsibility are as follows:

1. The new provider asks the previous provider for a copy of the prior authorization.
2. The previous provider corrects the "TO" date on the form to the last date that it is responsible for service.
3. The previous provider sends a copy of the corrected authorization to the new provider.
4. The new provider obtains a new authorization signed by the physician, physician assistant, or nurse practitioner, and forwards it to the address listed on the form along with a copy of the old authorization.

V. Terminating Rentals

A. The beneficiary, physician, physician assistant, or nurse practitioner, the supplier, or WellCare of North Carolina® may terminate the rental of an item during the rental period. If the rental is terminated, providers may reclaim the equipment from the beneficiary within 30 calendar days.

Note: Medical equipment rented under the "capped rental" rules become the beneficiary's property when the total rental payments reach the WellCare of North Carolina® allowable new purchase price for the item. Providers shall not attempt to reclaim an item after it becomes the beneficiary's property.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2019, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Lifetime Expectancies and Quantity Limitations for Durable Medical Equipment and Supplies

+ indicates that physicians, physician assistants or nurse practitioners may issue and be reimbursed for the specified asthma supplies.

HCPCS Code	Item Description	Lifetime Expectancy or Quantity Limitation
	Oxygen Equipment and Supplies	
A4615	Cannula, nasal	N/A
A4616	Tubing (oxygen), per foot	N/A
A4617	Mouth piece	N/A
A4618	Breathing circuits	N/A
A7027	Combination oral/nasal mask, used with continuous positive airway pressure device, each	2 per year
A7028	Oral cushion for combination oral/nasal mask, replacement only, each	2 per year
A7029	Nasal pillows for combination oral/nasal mask, replacement only, pair	2 per year
A9284	Spirometer, non-electronic, includes all accessories	2 per year
E0424	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask and tubing.	N/A
E0431	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask and tubing	N/A

E0433	Portable liquid oxygen system, rental; home liquefier used to fill portable liquid oxygen containers, includes portable containers, regulator, flowmeter, humidifier, cannula or mask and tubing, with or without supply reservoir and contents gauge	N/A
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing	N/A
E0439	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask & tubing.	N/A
E0441	Stationary oxygen contents, gaseous, 1 month's supply = 1 unit	N/A
E0442	Stationary oxygen contents, liquid, 1 month's supply = 1 unit	N/A
E0443	Portable oxygen contents, gaseous, 1 month's supply = 1 unit	N/A
E0444	Portable oxygen contents, liquid, 1 month's supply = 1 unit	N/A
E0550	Humidifier, durable for extensive supplemental humidification during IPPB treatments or oxygen delivery	2 years
E0555	Humidifier, durable, glass or auto-clavable plastic bottle type, for use with regulator or flowmeter	2 years
E1354	Oxygen accessory, wheeled cart for portable cylinder or portable concentrator, any type, replacement only, each	5 years
E1355	Stand/rack	5 years
E1356	Oxygen accessory, battery pack/cartridge for portable concentrator, any type, replacement only, each	1 year
E1357	Oxygen accessory, battery charger for portable concentrator, any type, replacement only, each	1 year
E1358	Oxygen accessory, DC power adapter for portable concentrator, any type, replacement only, each	1 year
E1390	Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate	N/A
E1392	Portable oxygen concentrator, rental	N/A
K0738	Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing	N/A
S8120	Oxygen contents, gaseous, 1 unit equals 1 cubic foot	N/A
S8121	Oxygen contents, liquid, 1 unit equals 1 pound	N/A

W4001	CO_2 saturation monitor with accessories, probes	N/A
	Respiratory Devices	
E0470	Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)	5 years
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)	N/A
E0561	Humidifier, non-heated, used with positive airway pressure device	2 years
E0562	Humidifier, heated, used with positive airway pressure device	2 years
E0601	Continuous airway pressure (CPAP) device	5 years
A4604	Tubing with integrated heating element for use with positive airway pressure device	4 per year
A7030	Full face mask used with positive airway pressure device, each	2 per year
A7031	Face mask interface, replacement for full face mask, each	2 per year
A7032	Cushion for use on nasal mask interface, replacement only, each	2 per year
A7033	Pillow for use on nasal cannula type interface, replacement only, pair	2 per year
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device with or without head strap	2 per year
A7035	Headgear used with positive airway pressure device	2 per year
A7036	Chinstrap used with positive airway pressure device	1 per year
A7037	Tubing used with positive airway pressure device	2 per year
A7038	Filter, disposable, used with positive airway pressure device	1 per month
A7039	Filter, non-disposable, used with positive airway pressure device	6 per year
A7046	Water chamber for humidifier, used with positive airway pressure device, replacement, each	2 per year
	Respiratory Devices - Other	
E0465	Home ventilator, any type, used with invasive interface, (e.g., tracheostomy tube)	N/A

E0466	Home ventilator, any type, used with noninvasive interface, (e.g., mask, chest shell)	N/A
E0500	IPPB machine, all types, with built-in nebulization; manual or automatic valves; internal or external power source	N/A
E0550	Humidifier, durable for extensive supplemental humidification during IPPB treatments or oxygen delivery	2 years
E0565	Compressor, air power source for equipment which is not self-contained, or cylinder driven	2 years
E0600	Respiratory suction pump, home model, portable or stationary, electric	5 years
A4483	Moisture exchanger, disposable, for use with invasive mechanical ventilation	60 per month
A4611	Battery, heavy duty; replacement for patient owned ventilator	N/A
A4612	Battery cables; replacement for patient-owned ventilator	N/A
A4613	Battery charger; replacement for patient-owned ventilator	N/A
	Respiratory Devices - Nebulizers	

E0570+	Nebulizer, with compressor	3 years
E0575	Nebulizer, ultrasonic, large volume	1 year ages 0-20 2 years ages 21 and over
A7003+	Administration set, with small volume nonfiltered pneumatic nebulizer, disposable	1 per month
A7004+	Small volume nonfiltered pneumatic nebulizer, disposable	4 per month
A7005+	Administration set, with small volume nonfiltered pneumatic nebulizer, non-disposable	2 per year
A7006+	Administration set, with small volume filtered pneumatic nebulizer	1 per month
A7007	Large volume nebulizer, disposable, unfilled, used with aerosol compressor	3 per month
A7010	Corrugated tubing, disposable, used with large volume nebulizer, 100 feet	1 per month
A7012	Water collection device, used with large volume nebulizer	3 per month
A7013	Filter, disposable, used with aerosol compressor or ultrasonic generator	1 per month
A7015+	Aerosol mask, used with DME nebulizer	4 per month
	Respiratory Devices – Apnea Monitor	

E0619	Apnea monitor, with recording feature	N/A
A4556	Electrodes (e.g., apnea monitor), per pair	2 per month
A4557	Lead wires (e.g., apnea monitor), per pair	2 per month
	Respiratory Devices – Percussor	
E0480	Percussor, electric or pneumatic, home model	2 years
	Respiratory Devices – Oximeter	
E0445	Oximeter device for measuring blood oxygen levels non-invasively	N/A (rental only)
E0445	Oximeter device for measuring blood oxygen levels non-invasively	3 years (portable for purchase)
	High Frequency Chest Wall Oscillation	
E0483	High frequency chest wall oscillation air-pulse generator system, (includes hoses and vest), each	Lifetime
E0484	Oscillatory positive expiratory pressure device, non-electric, any type, each	2 per lifetime
A7025	High frequency chest wall oscillation system vest, replacement for use with patient owned equipment, each	Lifetime
A7026	High frequency chest wall oscillation system hose, replacement for use with patient owned equipment, each	Lifetime
S8185	Flutter device	2 per lifetime
	Cough Stimulating Device	
E0482	Cough stimulating device, alternating positive and negative airway pressure	5 years
A7020	Interface for cough stimulating device, includes all components, replacement only	2 per year
	Tracheostomy Supplies	
A4481	Tracheostomy filter, any type, any size, each	62 per month
A4623	Tracheostomy, inner cannula	62 per month

A4624	Tracheal suction catheter, any type, other than closed system, each	720 per month
A4625	Tracheostomy care kit for new tracheostomy	90 per month ages 0-20; 30 per month ages 21 and over
A4626	Tracheostomy cleaning brush, each	2 per month
A4629	Tracheostomy care kit for established tracheostomy	90 per month ages 0-20; 30 per month ages 21 and over
A7501	Tracheostoma valve, including diaphragm, each	1 per month
A7502	Replacement diaphragm/faceplate for tracheostoma valve, each	1 per month
A7503	Filter holder or filter cap, reusable, for use in a tracheostoma valve, each	2 per year
A7504	Filter for use in tracheostoma heat and moisture exchange system, each	62 per month
A7505	Housing reusable without adhesive, for use in heat and moisture exchange system and/or with a tracheostoma valve, each	8 per year
A7506	Adhesive disc for use in a heat and moisture exchange system and/or with tracheostoma valve, any type	62 per month
A7507	Filter holder integrated filter without adhesive, for use in a tracheostoma heat and moisture exchange system, each	62 per month
A7508	Housing and integrated adhesive, for use in tracheostoma heat and moisture exchange system and/or with a tracheostoma valve, each	62 per month
A7509	Filter holder and integrated filter housing, and adhesive, for use as a tracheostoma heat and moisture exchange system, each	62 per month
A7520	Tracheostomy/laryngectomy tube, non-cuffed, polyvinylchloride (PVC), silicone or equal, each	4 per month
A7521	Tracheostomy/laryngectomy tube, cuffed, polyvinylchloride (PVC) silicone or equal, each	4 per month
A7522	Tracheostomy/laryngectomy tube, stainless steel or equal (serializable and reusable), each	1 per year
A7524	Tracheostomy stent/stud/button, each	4 per year

A7525	Tracheostomy mask, each	4 per month
A7526	Tracheostomy tube collar/holder, each	31 per month
L8501	Tracheostomy speaking valve	7 per month
W4153	Tracheostomy ties, twill	2 per day
	Miscellaneous Durable Medical Equipment and Supplies	
A4614+	Peak expiratory flow rate meter, hand held	2 per year
A4627+	Spacer, bag or reservoir, with or without mask, for use with metered dose inhaler	3 per year
A4628	Oropharyngeal suction catheter, each	4 per month
A7000	Canister, disposable, used with suction pump, each	10 per month
A7001	Canister, non-disposable, used with suction pump, each	2 per year
A7002	Tubing, used with suction pump, each	2 per month
W4002	Manual ventilation bag (e.g. Ambu bag)	2 per year
W4047	Miscellaneous for DME	N/A
W4120	Disposable bags for Inspirease inhaler system, set of 3	4 per year
W4670	Sterile saline, 3 cc vial, each	400/month
W4678	Replacement battery for portable suction pump	2 years

ICD-10-CM Diagnosis Codes that Support Coverage Criteria
+ Indicates a code(s) requiring an additional character

ICD-10-CM Code	Description
B91	Sequelae of poliomyelitis
E74.02	Pompe disease
G12.0	Infantile spinal muscular atrophy, type I [Werdnig-Hoffman]
G12.1	Other inherited spinal muscular atrophy
G12.20	Motor neuron disease, unspecified
G12.21	Amyotrophic lateral sclerosis
G12.22	Progressive bulbar palsy
G12.23	Primary lateral sclerosis
G12.24	Familial motor neuron disease
G12.25	Progressive spinal muscle atrophy
G12.29	Other motor neuron disease
G12.8	Other spinal muscular atrophies and related syndromes
G12.9	Spinal muscular atrophy, unspecified
G14	Postpolio syndrome
G35	Multiple sclerosis
G61.0	Guillain-Barre syndrome
G65.0	Sequelae of Guillain-Barre syndrome
G70.00	Myasthenia gravis without (acute) exacerbation
G70.01	Myasthenia gravis with (acute) exacerbation
G70.1	Toxic myoneural disorders
G70.2	Congenital and developmental myasthenia
G70.80	Lambert-Eaton syndrome, unspecified
G70.81	Lambert-Eaton syndrome in disease classified elsewhere
G70.89	Other specified myoneural disorders
G70.9	Myoneural disorder, unspecified
G71.00	Muscular dystrophy, unspecified
G71.01	Duchenne or Becker muscular dystrophy
G71.02	Facioscapulohumeral muscular dystrophy
G71.09	Other specified muscular dystrophies
G71.11	Myotonic muscular dystrophy
G71.12	Myotonia congenita
G71.13	Myotonic chondrodystrophy
G71.14	Drug induced myotonia
G71.19	Other specified myotonic disorders
G71.2	Congenital myopathies
G71.20	Congenital myopathy, unspecifed
G71.21	Nemaline myopathy
G71.22	Centronuclear myopathy
G71.220	X-linked myotubular myopathy
G71.228	Other centronuclear myopathy
G71.29	Other congenital myopathy
G71.3	Mitochondrial myopathy, not elsewhere classified

G71.8	Other primary disorders of muscles
G71.9	Primary disorder of muscle, unspecified
G72.0	Drug-induced myopathy
G72.1	Alcoholic myopathy
G72.2	Myopathy due to other toxic agents
G72.3	Periodic paralysis
G72.41	Inclusion body myositis [IBM]
G72.49	Other inflammatory and immune myopathies, not elsewhere classified
G72.81	Critical illness myopathy
G72.89	Other specified myopathies
G72.9	Myopathy, unspecified
G73.1	Lambert-Eaton syndrome in neoplastic disease
G73.3	Myasthenic syndromes in other diseases classified elsewhere
G73.7	Myopathy in diseases classified elsewhere
G82.20	Paraplegia, unspecified
G82.21	Paraplegia, complete
G82.22	Paraplegia, incomplete
G82.50	Quadriplegia, unspecified
G82.51	Quadriplegia, C1-C4 complete
G82.52	Quadriplegia, C1-C4 incomplete
G82.53	Quadriplegia, C5-C7 complete
G82.54	Quadriplegia, C5-C7 incomplete
S22.20xA	Unspecified fracture of sternum, initial encounter for closed fracture
S22.20xB	Unspecified fracture of sternum, initial encounter for open fracture
S22.21xA	Fracture of manubrium, initial encounter for closed fracture
S22.21xB	Fracture of manubrium, initial encounter for open fracture
S22.22xA	Fracture of body of sternum, initial encounter for closed fracture
S22.22xB	Fracture of body of sternum, initial encounter for open fracture
S22.23xA	Sternal manubrial dissociation, initial encounter for closed fracture
S22.23xB	Sternal manubrial dissociation, initial encounter for open fracture
S22.24xA	Fracture of xiphoid process, initial encounter for closed fracture
S22.24xB	Fracture of xiphoid process, initial encounter for open fracture
S22.31xB	Fracture of one rib, right side, initial encounter for open fracture
S22.31xS	Fracture of one rib, right side, sequela
S22.32xB	Fracture of one rib, left side, initial encounter for open fracture
S22.43xB	Multiple fractures of ribs, bilateral, initial encounter for open fracture
S22.43xD	Multiple fractures of ribs, bilateral, subsequent encounter for fracture with routine healing
S22.43xG	Multiple fractures of ribs, bilateral, subsequent encounter for fracture with delayed healing
S22.43xS	Multiple fractures of ribs, bilateral, sequela
S22.49xB	Multiple fractures of ribs, unspecified side, initial encounter for open fracture

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date	04/21	06/21
Covered diagnosis codes added to section "High-frequency chest wall oscillation device". The section heading "Cough Stimulating Device, Alternating Positive and Negative Airway Pressure" was renamed "Mechanical Insufflation – Exsufflation Devices". Added medical necessity criteria for tracheostomy supplies. ICD-10 CM code list for mechanical insufflation – exsufflation devices was updated to add E74.02, G12.23, G12.24, G12.25, G12.8, G12.9, G71.12, G71.13, G71.14, G71.19, G71.3, G71.8, G71.9, G72.0, G72.1, G72.2, G72.3, G72.49, G72.81, G72.89, G72.9 and G73.7. New coverage and quantity limits were added for HCPCS codes A4481, A7501, A7502, A7503, A7504, A7505, A7506, A7507, A7508, A7509 and A7524. Quantity limits were updated for existing HCPCS codes A4623, A4626, A7520, A7521, A7522, A7525 and A7526. HCPCS codes A4623, A4624, A4625, A4626, A4629, A7520, A7521, A7522, A7525, A7526, L8501 and W4153 were moved from the "Miscellaneous Durable Medical Equipment and Supplies" category to the new category "Tracheostomy Supplies".	07/21	08/21
Deleted diagnosis codes: S22.32xS, S22.39xB, S22.39xS, S22.41xB-S22.42xS, S22.49xD-S22.49Xs. Quantity limits were updated for existing HCPCS codes A7520, A7521 and A7525 and new coverage and quantity limits were added for HCPCS codes A4604 and A7046. Deleted HCPCS code W4153.	04/22	

References

1. State of North Carolina Medicaid. Medicaid and Health Choice Clinical Coverage Policy No: 5A-2 Respiratory Equipment and Supplies. https://medicaid.ncdhhs.gov/providers/clinical-coverage-policies. Published March 15, 2022. Accessed April 7, 2022.

North Carolina Guidance

Eligibility Requirements

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise); or
   2. the NC Health Choice (NCHC is NC Health Choice program, unless context clearly indicates otherwise) Program on the date of service and shall meet the criteria in this policy.

b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.

c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:

NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
EPSDT provider page: https://medicaid.ncdhhs.gov/

EPSDT does not apply to NCHC beneficiaries.

Provider(s) Eligible to Bill for the Procedure, Product, or Service
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid or NCHC qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance
Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information
Provider(s) shall comply with the, NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

a. Claim Type - as applicable to the service provided:
Professional (CMS-1500/837P transaction)
Institutional (UB-04/837I transaction)
Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
b. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) - Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
c. Code(s) - Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report

the procedure, product or service using the appropriate unlisted procedure or service code.
Unlisted Procedure or Service
CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.
HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service

d. Modifiers - Providers shall follow applicable modifier guidelines.
e. Billing Units - Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
f. Co-payments -
For Medicaid refer to Medicaid State Plan:
https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan
For NCHC refer to NCHC State Plan:
https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan
g. Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or

regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.