

To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

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Related Clinical Coverage Policies

Refer to <https://medicaid.ncdhhs.gov/> for the related coverage policies listed below:

1A-20, *Sleep Studies and Polysomnography Services*
3A, *Home Health Services*
3D, *Hospice Services*
3H-1, *Home Infusion Therapy*
5A-1, *Physical Rehabilitation Equipment and Supplies*
5A-3, *Nursing Equipment and Supplies*
5B, *Orthotics and Prosthetics*
10A, *Outpatient Specialized Therapies*

1.0 Description of the Procedure, Product, or Service

As a subcategory of Durable Medical Equipment and Supplies, the terms Respiratory Equipment and Supplies, Medical Equipment and Supplies, and Durable Medical Equipment and Supplies are used interchangeably throughout this policy.

1.1 Definitions

1.1.1 Durable Medical Equipment

Durable Medical Equipment (DME) is primarily and customarily used to serve a medical purpose, is generally not useful to an individual in the absence of a disability, illness or injury, can withstand repeated use, and can be reusable or removable.

1.1.2 Supplies

Supplies are health care related items that are consumable or disposable or cannot withstand repeated use by more than one individual, that are required to address an individual medical disability, illness, or injury.

1.2 Categories of Durable Medical Equipment and Supplies

Durable Medical Equipment and Supplies refers to the following categories of equipment and related supplies:

a. Inexpensive or Routinely Purchased:

These items are purchased for a beneficiary.

b. Capped Rental or Purchased Equipment:

These items are rented or purchased as follows:

1. The item is **rented** if the physician, physician assistant, or nurse practitioner documents that the anticipated need is six (6) months or less.
2. The item may be **rented** or **purchased** if the physician, physician assistant, or nurse practitioner documents that the anticipated need exceeds six (6) months. Once rental is initiated on an item, a subsequent request for prior approval of purchase of that item will be denied. The item becomes the property of the beneficiary when the accrued rental payments reach NC Medicaid (Medicaid) allowable purchase price.

c. **Equipment Requiring Frequent and Substantial Servicing:**

These items are rented; oxygen and items dealing with oxygen delivery are in this category.

d. **Related Supplies:**

Supplies are covered when they are provided for use with medical equipment owned by the beneficiary.

e. **Service and Repair:**

The service and repair of medical equipment owned by a beneficiary is covered over the useful life of the item. Refer to **Subsection 5.8, Servicing and Repairing Medical Equipment**, for additional information.

f. **Individually Priced Items:**

These items are reviewed on an individual basis and manually priced.

Refer to **Attachment A, Section C: Procedure Code(s)** for a list of HCPCS codes, established lifetime expectancies and quantity limitations for Durable Medical Equipment and Supplies.

For the rates associated with the list of equipment, supplies, and services found in **Attachment A, Section C**, refer to the Durable Medical Equipment fee schedule at <https://medicaid.ncdhhs.gov/>.

In compliance with the Centers for Medicare and Medicaid Services (CMS) Home Health Final Rule Title 42, §440.70, items not listed in **Attachment A, Section C** or in the Durable Medical Equipment fee schedule will be considered for coverage if requested by a provider, or a beneficiary through a provider, and submitted for prior approval review of medical necessity. For beneficiaries under age 21, please request an “EPSDT review” using NCTracks. Refer to section **2.2 Special Provisions** for more information about EPSDT. For beneficiaries aged 21 and older, please submit the request through NCTracks per the procedure detailed in **Attachment D**.

Note: As a subcategory of Durable Medical Equipment and Supplies, the terms Respiratory Equipment and Supplies, Medical Equipment and Supplies, and Durable Medical Equipment and Supplies are used interchangeably throughout this policy.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term “General” found throughout this policy applies to all Medicaid policies)

- a. An eligible beneficiary shall be enrolled in the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*).
- b. Provider(s) shall verify each Medicaid 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.

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

- a. **Medicaid**
None Apply.

2.2 Special Provisions

2.2.1 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.

b. 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/>

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by Medicaid

Medicaid shall cover durable medical equipment and related supplies when the beneficiary meets the following specific criteria:

- 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 non-institutional 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 supplies has occurred no more than six (6) months prior to the initiation of durable medical equipment and supplies; and
- d. the beneficiary's need for durable medical equipment and supplies is reviewed by the ordering physician, physician assistant, or nurse practitioner at least annually.

Refer to **Subsection 1.1** for definitions of Durable Medical Equipment and Supplies.

Refer to **Subsection 5.3, Documenting Medical Necessity**, for specific coverage requirements.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by Medicaid

Medicaid shall not cover devices and supplies:

- a. for beneficiary or caregiver convenience;
- b. for backup or duplication at various locations;

- c. in any setting in which payment is or could be made under Medicaid for inpatient services that include room and board, unless a discharge plan to a residential setting has been established;
- d. covered by another agency;
- e. for diagnoses related to hospice care per clinical coverage policy 3D, Hospice Services.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Medicaid shall require prior approval for certain medical equipment and supplies. Items that require prior approval are identified on the *Durable Medical Equipment Fee Schedule*. The fee schedule is available on Medicaid's website at: <https://medicaid.ncdhhs.gov/>.

Prior approval is valid for the time period approved on the Certificate of Medical Necessity/Prior Approval (CMN/PA) form. If a physician, physician assistant, or nurse practitioner decides that an item is needed for a longer period, a new CMN/PA form must be submitted.

Capped rental items have restrictions on the length of rental. Refer to **Subsection 1.2**, for information on capped rental items.

Note: The CMN/PA form can be found on this webpage: <https://medicaid.ncdhhs.gov/providers/forms/durable-medical-equipment-orthotics-and-prosthetics-forms>.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

- a. the prior approval request; and
- b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.3 Documenting Medical Necessity

Medical necessity must be documented by the prescriber (physician, physician assistant, or nurse practitioner), for every item provided regardless of any requirements for prior approval. A letter of medical necessity written and signed by the physician, physician assistant, or nurse practitioner, or other licensed professional permitted to perform those tasks and responsibilities by their NC state licensing board, may be submitted along with the CMN/PA form.

5.3.1 Oxygen, Oxygen Supplies, and Equipment

Refer to **Attachment A, Section C: Procedure Code(s)** for a list of HCPCS codes, established lifetime expectancies and quantity limitations for Durable Medical Equipment and Supplies. To request a medical necessity review for an item not listed, refer to **sections 1.2, 2.2 and Attachment D** for instructions.

Medicaid shall cover oxygen therapy and related supplies and equipment for a beneficiary who meets the following criteria:

- a. **Ages zero (0) through three (3) years:** arterial oxyhemoglobin saturation (SaO₂) equal to or less than 94% and have a documented supporting diagnosis.
- b. **Ages 4 through 20 years:** SaO₂ equal to or less than 90% and a documented supporting diagnosis.
- c. **Ages 21 and older:** there is documentation from the treating physician that reports ALL of the following:
 1. A diagnosis of severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy,
 2. Alternative treatments have been tried and considered or deemed clinically ineffective,
 3. 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:
 - A. Group I**
 - i. An arterial PO₂ at or below 55 mmHg, or an arterial oxygen saturation at or below 88%, taken at rest, breathing room air.
 - ii. An arterial PO₂ at or below 55 mmHg, or an arterial oxygen saturation at or below 88%, taken during sleep for a beneficiary who demonstrates an arterial PO₂ at or above 56 mmHg, 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 mmHg, 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.
 - iii. An arterial PO₂ at or below 55 mmHg or an arterial oxygen saturation at or below 88%, taken during exercise for a beneficiary who demonstrates an arterial PO₂ at or above 56 mmHg, 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 beneficiary was breathing room air.

B. Group II

An arterial PO₂ of 56–59 mmHg or arterial blood oxygen saturation of 89%, if there is evidence of ONE of the following:

- i. Dependent edema suggesting congestive heart failure;
- ii. 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
- iii. Erythrocythemia with a hematocrit greater than 56%.

Requirements for Qualifying Oxygen Analysis and Coverage

A qualifying oxygen analysis (either arterial blood gas (ABG) or pulse oximetry for SaO₂) must meet the following criteria.

- a. 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
- b. 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.
- c. 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.
- d. 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.
- e. 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.

Prior Approval Requirements

For initial prior approval of oxygen services, the following must be noted on the CMN/PA form or on attached documentation:

- a. Health record documentation from the beneficiary’s prescriber stating why the use of oxygen is indicated.
- b. 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:
 1. The diagnosis of the disease requiring use of oxygen;
 2. The oxygen flow rate needed; and

3. An estimate of the frequency, duration of use, and length of need for the oxygen.
- c. Results of an oxygen analysis (either ABG or pulse oximetry for SaO₂) as noted in the **Requirements for Qualifying Oxygen Analysis and Coverage**.
- d. 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.
- e. 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. 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 reported on the Recertification CMN/PA form. 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. 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.
- f. 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 reported on the most recent prior CMN/PA form.
- g. There is no requirement for a prescriber's visit that is specifically related to the completion of the CMN/PA form for replacement equipment.
- h. When the prescribed maximum flow rate changes from one of the following categories to another, a repeat blood gas study with the beneficiary on 4liters 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:
 1. Less than one (1) LPM,
 2. One (1) to four (4) LPM,
 3. Greater than four (4) LPM

- i. For beneficiary 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 on the most recent CMN/PA form, then the blood gas study can be the most recent study obtained within one (1) month prior to the initial certification date.
- j. When a portable system is added after the initial prior approval 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.

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. Prior approval given at the 36-month renewal period is considered a lifetime prior 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. However, a qualifying test within six (6) months of the renewal date is not required.

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.

Coverage is described as follows:

- a. 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.
- b. 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.
- c. 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.

- d. 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 is 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. Refer to **Attachment A, Section D**, for a list of the modifiers that must be used.

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 a beneficiary requiring oxygen therapy so that appropriate blood gas levels are achieved and maintained.

5.3.2 Respiratory Devices for the Treatment of Respiratory Disorders other than Obstructive Sleep Apnea (OSA)

Refer to **Attachment A, Section C**: Procedure Code(s) for a list of HCPCS codes, established lifetime expectancies and quantity limitations for Durable Medical Equipment and Supplies. To request a medical necessity review for an item not listed, see **sections 1.2, 2.2 and Attachment D** for instructions.

A respiratory assist device (RAD) BiLevel without back-up rate delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs (such as, noninvasive positive pressure respiratory assistance: NIPPRA).

A RAD BiLevel with back-up rate delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs. In addition, it has a timed back-up feature to deliver this air pressure whenever sufficient spontaneous inspiratory efforts fail to occur.

Medicaid shall cover 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 percent 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 H₂O 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:**
 2. Sleep oximetry demonstrating oxygen saturation less than or equal to 88 percent for at least five (5) minutes in total, done while breathing the beneficiary's usual FIO₂; **or**
 3. Prior to initiating therapy, OSA (treatment with CPAP) has been considered and ruled out.

Prior Approval is required for a RAD.

Note: The above criteria qualify the beneficiary for a RAD **without a back-up rate.**

For a beneficiary with COPD who qualifies for a RAD **without** a back-up rate, and the treating physician determines the beneficiary requires a RAD **with** a back-up rate, the device may be covered, if the following criteria are met:

- A. The treating physician documents that a BiLevel device without back-up rate has been initiated and failed to adequately correct the beneficiary's respiratory status; **or**
 - B. An arterial blood gas PaCO₂, repeated no sooner than 61 calendar days after initiation of compliant use of the RAD without a back-up rate, done while awake and breathing the beneficiary's usual FIO₂, remains greater than or equal to 52 mmHg; **and**
 - C. A signed and dated statement from the treating physician, completed no sooner than 61 calendar days after initiation of the RAD without a back-up rate, declaring that the beneficiary has been compliantly using the device an average of four hours per 24-hour period but that the beneficiary is NOT benefiting from its use.
- c. Central sleep apnea:
- The beneficiary shall meet ALL the following criteria:
1. A polysomnogram provided according to requirements listed in Clinical Coverage Policy 1A-20, *Sleep Studies and Polysomnography Services*, 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.

Requirements for Coverage

- a. A polysomnogram must be submitted with the initial request for a RAD with those diagnoses that have a polysomnogram requirement in the criteria.
 1. **Medicaid shall not accept polysomnograms that are performed by a medical equipment provider.** Polysomnograms must be provided according to requirements listed in Clinical Coverage Policy 1A-20, *Sleep Studies and Polysomnography Services*, on Medicaid's website: <https://medicaid.ncdhhs.gov/>.
 2. 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.
- b. 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.
- c. For an item to be covered by Medicaid a written signed and dated order from the "treating physician" must be received by the supplier before the CMN/PA form is submitted for 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.
- d. 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.
- e. A RAD **with** a back-up rate is not medically necessary if the primary diagnosis is OSA.

Initial Prior 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 prior approval for a RAD is given for a period of **six (6) months**.

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.

Renewal Prior Approval: For renewal prior 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 this must be submitted along with the CMN/PA form request 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 Medicaid 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 with the use of a RAD. The treating physician shall specify which type of humidifier the beneficiary is to use.

Respiratory Devices for the Treatment of Obstructive Sleep Apnea

A BiLevel device without back-up rate delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs. This is also called noninvasive positive pressure respiratory assistance (NPPRA).

CPAP therapy is the use of a CPAP device and related equipment to deliver a constant level of positive air pressure into the throat to prevent the collapse of the airway during inhalation. This is done by way of tubing and noninvasive interface such as nasal, oral or face mask.

CPAP and BiLevel devices require prior approval.

Medicaid shall cover CPAP and BiLevel devices, and related accessories, for beneficiaries who demonstrate medical necessity by meeting the following criteria:

- a. Has a diagnosis of OSA; **and**
- b. Has a documented polysomnogram provided according to requirements listed in Clinical Coverage Policy 1A-20, *Sleep Studies and Polysomnography Services* that meets the following criteria:
 1. The AHI is greater than or equal to 15 events per hour; **or**
 2. The AHI is from 5 to 14 events per hour with documented symptoms of:
 - A. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; **or**
 - B. Hypertension, ischemic heart disease, or history of stroke.

Medicaid shall cover the BiLevel device 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.

Note: An 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 CPAP or BiLevel device in each individual case.

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.

Requirements for Coverage:

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

Note: Medicaid shall not accept polysomnograms that are performed by a medical equipment provider.

- b. Polysomnograms must be provided according to requirements listed in Medicaid's Clinical Coverage Policy 1A-20, *Sleep Studies and Polysomnography Services*, on Medicaid's website: <https://medicaid.ncdhhs.gov/>.
- c. 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.

- d. 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.
- e. For an item to be covered by Medicaid, a written signed and dated order from the treating physician must be received by the supplier **before** the CMN/PA form is submitted for prior approval. If the supplier submits a CMN/PA form without first receiving the completed order, the prior approval request is denied as not medically necessary.
- f. 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.
- g. Auto-titrating CPAP devices are billed the same as a CPAP device.
- h. A non-heated or heated humidifier is covered by Medicaid with the use of a CPAP or BiLevel. The treating physician shall specify which type of humidifier the beneficiary is to use.

Initial Prior Approval:

For initial prior 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).

The initial prior 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.

Renewal Prior Approval:

Renewal prior 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.

Other Respiratory Devices

Ventilators

Medicaid shall cover a home ventilator with an **invasive** interface for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Coverage is provided for both positive and negative pressure ventilators.

Medicaid shall cover a home ventilator with a **non-invasive** interface when criteria “a.” through “c.” are met:

- a. Clinical documentation indicates that:
 1. the beneficiary’s condition cannot be successfully managed on a BiLevel device with pressure support, **or**
 2. BiLevel therapy and BiLevel therapy with a backup feature has been initiated and failed to adequately correct the beneficiary’s respiratory status
- b. Documentation indicates that ONE (1) of the following conditions is present:
 1. Restrictive lung disease when the beneficiary meets the following:
 - A. Beneficiary has chronic respiratory failure with:
 - i. Daytime CO₂ retention greater than 50 mmHg, **or**
 - ii. CO₂ retention of 45 to 50 mmHg with symptoms attributable to hypoventilation (such as morning headaches, restless sleep, nightmares, enuresis, or daytime hypersomnolence), **and**
 - iii. Nighttime oxygen desaturation to less than or equal to 88 for five (5) continuous minutes while breathing the beneficiary’s usual FiO₂, **and**
 - iv. Obstructive sleep apnea has been ruled out
 2. Chronic obstructive pulmonary disease (COPD) when the beneficiary meets the following:
 - A. Beneficiary has chronic respiratory failure symptoms with symptoms attributable to hypoventilation, **and**
 - B. **Any** of the following physiologic criteria:
 - i. PaCO₂ greater than or equal to 55mmHg, **or**
 - ii. PaCO₂ 50-54mmHg and nighttime oxygen desaturation less than or equal to 88 percent for five (5) continuous minutes while breathing the beneficiary’s usual FiO₂, **or**
 - iii. PaCO₂ 50-54mmHg and hospitalization related to recurrent (at least two (2) episodes in a 12-month period) hypercapnic respiratory failure.
 3. Progressive neuromuscular disorder such as:
 - A. Amyotrophic Lateral Sclerosis (ALS)
 - B. Muscular dystrophy (MD)
 - C. Multiple Sclerosis (MS)
 - D. Spinal muscular atrophy (SMA)
 - E. Myasthenia gravis
 - F. Primary lateral sclerosis

4. Chest wall deformity;
 5. Acute poliomyelitis;
 6. Spinal cord diseases or conditions; **or**
 7. Central hypoventilation syndrome or obesity hypoventilation
- c. Beneficiary can protect airway and clear secretions adequately.

Secondary Ventilator

A secondary ventilator shall be considered medically necessary if it is required to serve a different purpose than the primary ventilator as determined by the beneficiary's medical needs. Situations where a second ventilator may be medically necessary may include, but are not limited to:

- a. A beneficiary requires one type of ventilator such as a negative pressure ventilator with a chest shell for part of the day and needs a different type of ventilator such as a positive pressure ventilator with a nasal mask during the rest of the day.
- b. A beneficiary who is confined to a wheelchair and requires a ventilator mounted on the wheelchair for use during the day and another ventilator for use while in bed.

Note: Back-up ventilators are not covered by Medicaid. A back-up ventilator is defined as an identical or similar device used to meet the same medical needs as the primary ventilator or provided as a precaution in case of malfunction of the primary ventilator.

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

Intermittent Positive Pressure Breathing (IPPB) machine

An Intermittent Positive Pressure Breathing (IPPB) machine and humidifier are covered 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.

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.

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.

Nebulizers

A nebulizer with compressor and related supplies is considered medically necessary when the beneficiary's ability to breathe is severely impaired.

Self-contained, ultrasonic nebulizer and related supplies are 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.

Prior approval is **not** required for nebulizers.

Sterile saline is deemed medically necessary when used with the above equipment and accessories.

Apnea Monitor and Supplies

For initial and renewal prior approval of an apnea monitor, attach documentation showing that 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.

Prior approval is required.

Percussor

Percussors are covered for mobilizing respiratory secretions when 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. Block 25 on the CMN/PA form must be completed.

Prior approval is required.

Oximeters

Hospital Grade, Table-Top Oximeter for Rental

For initial and renewal prior approval of a **non-recording oximeter** attach documentation that the equipment is for continuous or intermittent use and at least one (1) of the following applies to the beneficiary:

- 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 (7) days.

Prior approval is required. The documentation requirements are the same for requests to renew prior approval.

For initial and renewal prior approval of a **recording oximeter**, attach documentation that:

- a. the beneficiary's condition meets one (1) of the coverage criteria for a non-recording oximeter, and
- b. the recording 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.

Note: Prior approval is required.

Portable Oximeter for Purchase

A portable oximeter shall 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:

- a. To evaluate initial and ongoing medical necessity of an oxygen therapeutic regimen;
- b. To evaluate appropriate home oxygen liter flow for ambulation, exercise, or sleep in an individual with respiratory disease; or

- c. To evaluate an acute change in condition requiring an adjustment to the liter flow of home oxygen.

Prior approval for a portable oximeter is **not** required.

Note: An oximeter for home use shall not be considered an appropriate method of monitoring a beneficiary with asthma or when used alone as a screening or testing technique for suspected obstructive sleep apnea (OSA).

5.3.3 High-Frequency Chest Wall Oscillation Device

Refer to **Attachment A, Section C: Procedure Code(s)** for a list of HCPCS codes, established lifetime expectancies and quantity limitations for Durable Medical Equipment and Supplies. To request a medical necessity review for an item not listed, refer to **sections 1.2, 2.2 and Attachment D** for instructions.

A high-frequency chest wall oscillation (HFCWO) device is an airway clearance device consisting of an inflatable vest connected by tubes to an air-pulse generator. This device is covered for beneficiaries with a diagnosis of cystic fibrosis, bronchiectasis, and some neurological and neuromuscular conditions that compromise the ability to actively clear secretions from the respiratory tract.

This device is covered when the beneficiary's disease is characterized by daily productive cough for at least six (6) continuous months or frequent exacerbations (more than two (2) per year) requiring antibiotic therapy. In addition, there must be well-documented failure of standard treatments (such as chest percussion, positional drainage, deep breathing exercises) to adequately mobilize mucus.

Prior approval is required. The initial prior approval is for a trial period of three (3) months' rental. A request for subsequent purchase of the device shall 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

The oscillatory positive expiratory pressure (PEP) device and the Flutter device facilitate secretion removal. The PEP uses a counterweighted plug and magnet to create air flow oscillation. The Flutter uses a steel ball which vibrates inside a cone, causing air flow vibration. These devices are considered medically necessary when needed to mobilize secretions and assist with airway clearance. They do not require prior approval.

5.3.4 Mechanical Insufflation - Exsufflation Devices

Refer to **Attachment A, Section C: Procedure Code(s)** for a list of HCPCS codes, established lifetime expectancies and quantity limitations for Durable Medical Equipment and Supplies. To request a medical necessity review for an item not listed, refer to **sections 1.2, 2.2 and Attachment D** for instructions.

A mechanical insufflation - exsufflation device is an electric cough-stimulating device that utilizes a blower and a valve to alternately apply positive and then negative pressure to the beneficiary's airway. The shift in pressure produces a high expiratory flow from the lungs, stimulating a cough. This device assists a beneficiary to clear retained bronchopulmonary secretions. Air is delivered to and from the beneficiary via a breathing circuit incorporating a flexible tube, a bacterial filter, and either a facemask, a mouthpiece, or an adapter to a tracheostomy or endotracheal tube.

Medicaid 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 (Refer to **Attachment A, Section B, Diagnosis Codes**, for the specific diagnosis codes required for this device;
- 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;
- d. Has physician-documented evidence that the beneficiary or caregiver is willing and able to use the device as prescribed.

Medicaid shall require prior approval. Initial prior approval shall be granted for six (6) months if the beneficiary meets all the following criteria:

- a. Has a supporting medical diagnosis;
- b. 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);
- c. Has intolerance to, contraindication of, or unavailability of, chest physiotherapy; and
- d. Has had incidents in the past year of respiratory illnesses requiring either physician office visits, emergency room visits, hospitalizations, or antibiotics.

For subsequent prior approvals, continued medical necessity must be reestablished for each successive six (6) months by:

- a. evidence of beneficiary compliance, caregiver compliance, or both; and
- b. improved disease management since beginning the use of the cough-stimulating device (as indicated by fewer infections requiring antibiotics and fewer hospitalizations).

Medicaid shall not cover mechanical insufflation – exsufflations devices for a beneficiary with:

- a. chronic obstructive pulmonary disease (COPD),
- b. bullous emphysema,
- c. susceptibility to pneumothorax or pneumomediastinum, or

- d. recent barotrauma (an injury occurring after exposure to sudden contractions or expansions of air).

Mechanical insufflation – exsufflations devices shall not be covered if the beneficiary tolerates and demonstrates a response to other techniques for cough assistance and secretion removal.

5.3.5 Tracheostomy Supplies

Refer to **Attachment A, Section C: Procedure Code(s)** for a list of HCPCS codes, established lifetime expectancies and quantity limitations for Durable Medical Equipment and Supplies. To request a medical necessity review for an item not listed, refer to **sections 1.2, 2.2 and Attachment D** for instructions. Medicaid 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 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:

- a. 1-plastic tray;
- b. 1-basin;
- c. 1-pair sterile gloves;
- d. 1-tube brush;
- e. 3-pipe cleaners;
- f. 1-pre-cut tracheostomy dressing;
- g. 1-roll gauze;
- h. 4-4x4 sponges;
- i. 2-cotton tip applicators; and
- j. 30 inches-twill tape.

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:

- a. 1-tube brush;
- b. 2-pipe cleaners;
- c. 2-cotton tip applicators;
- d. 30 inches-twill tape; and
- e. 2- 4x4 sponges.

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

Note: A tracheostomy or laryngectomy tube plug or stop is used as an alternative to a tracheostomy laryngectomy tube.

Note: The HCPCS code for tracheostomy tube collar or holder must not be used for twill ties, twill tape or equivalent fabric or plastic supplies.

5.3.6 Miscellaneous Durable Medical Equipment and Supplies

Refer to **Attachment A, Section C: Procedure Code(s)** for a list of HCPCS codes, established lifetime expectancies and quantity limitations for Durable Medical Equipment and Supplies. To request a medical necessity review for an item not listed, refer to **sections 1.2, 2.2 and Attachment D** for instructions.

A manual ventilation bag requires prior approval and is covered when a beneficiary has a life-threatening diagnosis and requires ventilator support.

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.

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.

A respiratory suction pump, catheters, canisters, and tubing are covered if a beneficiary is physically unable to independently expectorate respiratory secretions.

For prior approval requirements refer to the *Durable Medical Equipment and Supply* fee schedule on Medicaid's website at: <https://medicaid.ncdhhs.gov/>. Items that require prior approval are identified on the *Durable Medical Equipment Fee Schedule*.

5.3.7 Provision of DME and Supplies on the Date of Discharge from Specified Facilities

- a. Items listed in **Attachment B** must be provided to a beneficiary, discharged home on the **date of Discharge** from a skilled nursing facility, short term physical disability rehabilitation center or hospital only.
- b. Delivery of DMES on the date of discharge from a skilled nursing facility, short term physical disability rehabilitation center or hospital shall be consistent with Section 5.6 Delivery of Service.
- c. For items that require PA, the DMES provider shall submit a prescriber's order and an admission history and physical note and any supporting documentation electronically via the provider portal on the NC Tracks website.
- d. For items that do not require PA, the DMES provider shall keep the prescriber's order, a history and physical note, and any supporting documentation on file.

5.4 Amount of Service

The amount of service is limited to that which is medically necessary as determined by Medicaid's clinical coverage policies. Refer to **Attachment A, Section C: Procedure Codes**, for a listing of the established lifetime expectancies and quantity limitations for Durable Medical Equipment and Supplies. To request a medical necessity review for an item not listed, refer to **sections 1.2, 2.2 and Attachment D** for instructions.

5.5 Durable Medical Equipment and Supplies Limitations

Medicaid may place appropriate limits, based on medical necessity criteria, on Durable Medical Equipment and Supplies. When the prescribing physician, physician assistant, or nurse practitioner, orders equipment or supplies beyond these limits, the DME provider shall seek prior approval for these items through NCTracks.

A PA request for an override of a quantity limit, or lifetime expectancy must include the usual PA documentation (**Subsections 5.2 and 5.3**) along with the following additional information:

- a. The item being requested for an override clearly marked on the CMN/PA form.
- b. The type of override (quantity limit, or lifetime expectancy) clearly stated.
- c. An explanation of the medical necessity for the override from the physician, physician assistant, nurse practitioner, or therapist.

Override PA requests are reviewed for medical necessity as per usual PA review timelines. Override PA review outcomes are communicated to providers and beneficiaries in the same way as a typical PA request.

Refer to **Attachment A, Section C: Procedure Code(s)** for a listing of the established lifetime expectancies and quantity limitations for Durable Medical Equipment and Supplies. To request a medical necessity review for an item not listed, refer to **sections 1.2, 2.2 and Attachment D** for instructions.

5.6 Delivery of Service

Providers shall dispense Durable Medical Equipment and Supplies as quickly as possible due to the medical necessity identified for an item. However, providers shall not deliver an item requiring prior approval before prior approval has been received. Providers who deliver before receiving prior approval do so at their own risk.

5.6.1 Delivery directly to the beneficiary

When an item is delivered directly to a beneficiary, the delivery slip must be signed by the beneficiary or a designee. The provider shall assemble the equipment and provide teaching and training on the safe use of the equipment. The provider shall ensure the equipment or supply is appropriate for the beneficiary's needs, and the beneficiary will be educated on the lifetime expectancy and the warranty of the item.

5.6.2 Utilizing Delivery or Shipping Service

When a provider utilizes a shipping service or mail order, the provider shall report the shipping date as the date of service on the claim. Proof of delivery is required. The provider's records shall include the shipping service's package identification number for the package sent to the beneficiary. The shipping service's tracking slip must reference each individual package, the delivery address, the corresponding package identification number given by the shipping service, and the delivery date. In case of lost, stolen, damaged or incomplete delivery of specified medical equipment or supplies; it is the provider's responsibility to replace the specified medical equipment or supplies without cost to the beneficiary or Medicaid. It is expected that the replacement occurs within 48 hours.

5.7 Monitoring Care

5.7.1 Assuring Continuing Need for Rental Items and Supplies

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 last signed CMN/PA form, a new CMN/PA form must be completed and signed by the physician, physician assistant, or nurse practitioner, for the continued coverage. The provider shall obtain the signed form before billing for any services beyond 12 months.

5.8 Servicing and Repairing Medical Equipment

Service and repair of medical equipment is handled in one of three ways:

Rental Equipment: Service and repairs are provided as part of the rental arrangement with no additional charge to Medicaid.

Purchased Equipment Warranty: 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 by submitting a completed CMN/PA form with a repair estimate to NCTracks. 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 Medicaid reimbursed parts.

Purchased Equipment Non-Warranty: 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 Medicaid reimbursed parts or for freight or the provider's travel time or expenses. All the following information must be documented in block 30 of the CMN/PA form:

- a. The description and HCPCS code of the item being serviced or repaired.
- b. The age of the item.
- c. The number of times the item has been previously repaired.
- d. The current replacement cost.

Note: Providers shall have emergency repair service available 24-hours a day, seven days a week for any life-sustaining equipment they provide.

Note: Medicaid shall not cover maintenance or service contracts.

5.9 Replacing Medical Equipment

Medicaid may consider replacing the item, when repairing is no longer cost-effective and the item is out of warranty, Refer to **Attachment A, Section C: Procedure Codes(s)**. To request a medical necessity review for an item not listed, see **sections 1.2, 2.2 and Attachment D** for instructions.

Note: When requesting prior approval for the replacement of an item before its usual life expectancy has ended, explain on the CMN/PA form why the replacement is needed.

Specific documentation, in addition to the prescription and CMN/PA form, is required in the following situations:

- a. In cases of equipment loss or damage beyond repair, a letter from the social worker, case manager or child service coordinator explaining the circumstances.
- b. 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.
- c. In cases of equipment destruction by fire, a copy of the fire report.
- d. 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.

5.10 Changing Suppliers

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.

5.10.1 Changing Suppliers for Oxygen and Oxygen Equipment

The steps for transferring responsibility are as follows:

- a. The new provider asks the previous provider for a copy of the current CMN/PA form.
- b. The previous provider corrects the "TO" date on the form to the last date that it is responsible for service.
- c. The previous provider sends a copy of the corrected CMN/PA form to the new provider.
- d. The new provider obtains a new CMN/PA form 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 CMN/PA form.

5.11 Terminating Rentals

The beneficiary, physician, physician assistant, or nurse practitioner, the supplier, Medicaid, 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 becomes the beneficiary’s property when the total rental payments reach the Medicaid r -allowable new purchase price for the item. Providers shall not attempt to reclaim an item after it becomes the beneficiary’s property.

6.0 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 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.

6.1 Provider Qualifications

Providers shall be enrolled with Medicaid as a Durable Medical Equipment and Supplies provider and meet the following conditions to qualify for participation with Medicaid as a provider.

- a. Providers shall not accept prescriptions for Medicaid covered equipment from any physician, physician assistant, or nurse practitioner, who has an ownership interest in their agency.
- b. Providers shall be enrolled and participate in Medicare as a medical equipment supplier.
- c. Service must be provided on an emergency basis, 24 hours per day, 7 days per week, for life-sustaining equipment.
- d. The providing agency shall be located in the state of North Carolina, or within 40 miles of the North Carolina border in a contiguous state from which North Carolina beneficiaries living on the border can use the agency as a general practice. Out-of-state providers more than 40 miles outside of the North Carolina border may enroll with Medicaid when a covered, medically necessary product they supply or manufacture is not reasonably available through an enrolled provider located in the state of North Carolina or within 40 miles of the North Carolina border.
- e. Refer to <http://www.ncbop.org> under the topic *DME Suppliers and Pharmacy Law/Rules* for other rules that may apply to Durable Medical Equipment and Supplies providers.
- f. Providers shall be either:
 1. a business entity authorized to conduct business in the state or in the locality where the business site is located. Proof of authorization shall include a certificate of assumed name, certificate of authority, certificate of good standing, license, permit or privilege license; or
 2. a Medicaid-enrolled home health agency, a state agency, a local health department, a local lead agency for the Community Alternative Program for Disabled Adults (CAP/DA), a local lead agency for the CAP for Individuals with Intellectual/ Developmental Disabilities, or an agency that provides case management for the Community Alternatives Program for Children.

Note: Providers shall be enrolled and meet the provider qualifications on the date that service is provided.

Note: An agency enrolled to provide Home Infusion Therapy (HIT) may provide EN. A HIT provider shall be a home care agency licensed by the Division of Health Service Regulation to provide infusion nursing services and shall have service available 24 hours a day, seven days a week.

6.2 Seeking Other Sources of Payment

Medicaid providers shall take all reasonable measures to determine the legal liabilities of third parties, including Medicare and private insurance, to pay for services. If third party liability is established, providers shall bill the third party before billing Medicaid.

Refer to the *NCTracks Provider Claims and Billing Assistance Guide*:
<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html> for additional information.

6.3 Accepting Payment

Providers shall accept payment in full.

Providers attempting to bill Medicaid recipients must comply with North Carolina Administrative Code *10A NCAC 22J .0106*.

6.4 Disclosing Ownership Information

Providers shall disclose ownership and control information, and information about the provider's agency's owners or employees that have been convicted of criminal offenses against Medicare, Medicaid, and the Title XX services program.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 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 Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by CMS, DHHS, DHHS division(s) or fiscal contractor(s).

7.2 Record Keeping

The provider shall furnish any information that the U.S. Department of Health and Human Services and its designated contractors, Medicaid and its designated contractors or the State Medicaid Fraud Investigation Unit regarding payments received for providing Medicaid.

Providers shall keep the following documentation of their services:

- a. The prescription for the item signed by the physician, physician assistant, or nurse practitioner, specifying the order as much as possible (such as the number being ordered, frequency to be used, duration of prescription).
- b. The original CMN/PA form for Durable Medical Equipment and Supplies.
- c. The original orders signed by the physician, physician assistant, or nurse practitioner, that were used to provide enteral nutrition.
- d. A full description of all item(s) supplied to a beneficiary.
- e. The dates the items were supplied—the delivery date for purchased items or the delivery and pickup dates for rental items, including signed pick-up and delivery slips. The delivery slip must be signed by the beneficiary or the beneficiary’s designee when the delivery is direct to the beneficiary. When utilizing delivery or shipping services, all requirements as outlined under **Subsection 5.6.2** shall apply.
- f. A full description of any service or repairs, including details of parts and labor, applicable warranty information, and the date of the service or repair. If the item is removed from the beneficiary’s environment for service or repair, record the date of removal and the date of return.

Note: All beneficiary information, including the beneficiary’s Medicaid status, shall be kept confidential. Provide this information only to those who are authorized to receive it.

7.3 Coordinating Care

The Durable Medical Equipment and Supplies provider shall be responsible for determining what other services the beneficiary is receiving and for coordinating care to ensure there is no duplication of service.

8.0 Policy Implementation/Revision Information

Original Effective Date: March 1, 2003

Revision Information:

Date	Section Revised	Change
06/01/2003	Section 6.3, 6.4, 6.5	Text pertaining to provider responsibilities for payment and disclosure was added; effective with date of publication 03/01/03.
06/01/2003	Section 5.3.12, Respiratory Devices	Codes E0452 and E0453 were deleted and replaced with codes K0532 and K0533, respectively.
08/01/2003	Attachment B, block 26	The reminder for billing rentals was updated to reflect the implementation of modifiers.
08/01/2003	Attachment C, block 24c	The instruction for block 24c, Type of Service Code, was updated to read "leave blank."
08/01/2003	Attachment C, block 24d	The instruction for block 24d, Procedures, Services, was updated to state that providers must bill with modifiers NU, UE, and RR.
08/01/2003	Attachment C, claim form examples	Claim examples were updated to reflect the use of modifiers NU, UE, and RR.
09/01/2003	Section 5.3.16	Code W4006 was deleted and replaced with codes E0691 and E0692.
09/01/2003	Section 5.3.17	Code W4007, isolette, was deleted.
09/01/2003	Section 5.3.18 through 5.3.21	These sections were renumbered to 5.3.17 through 5.3.20
09/01/2003	Attachment A, block 24	Code W4006 was deleted and replaced with codes E0691 and E0692. The reference to code W4007 was deleted.
10/01/2003	Section 5.3.7	Code W4127 was deleted and replaced with E1037 and E1038.
10/01/2003	Section 5.3.8	Code W4029 was deleted. Subsequent sections were renumbered.
10/01/2003	Section 5.3.10	This section was renumbered to 5.3.9. The references to codes W4040 and W4041 on page 22 were replaced with codes S8120 and S8121. The reference to code W4042 was deleted.
10/01/2003	Section 5.3.12	This section was renumbered to 5.3.11. Codes W4011 and W4121 were deleted and replaced with E0445.
10/01/2003	Attachment A, block 24	Code E0608 was deleted and replaced with E0619.
11/01/2003	Section 5.3.1	Code W4684 was deleted; W4692 and W4693 were deleted and replaced with E0148; W4694 was deleted and replaced with E0149; W4724 and W4725 were deleted and replaced with K0549; W4727, W4728, and W4729 were deleted and replaced with K0549 and K0550; W4679, W4680, W4681, W4682, and W4683 were deleted and replaced by E0168.
01/01/2004	Section 5.3.1	Codes W4685 and W4686 were end-dated and replaced with E0248; W4687 was end-dated and replaced with E0247; K0459 was end-dated and replaced with E0303; K0550 was end-dated and replaced with E0304.
01/01/2004	Section 5.3.6	Codes K0538 was end-dated and replaced with E2042. Codes K0539 and K0540 were end-dated and replaced with A6550 and A6551;

		criteria for these items was deleted from the section because they do not require prior approval.
01/01/2004	Section 5.3.7	Code K0016 was end-dated and replaced with E0973. Codes K0022 and K0029 were end-dated and replaced with E0982. Code K0030 was end-dated and was not replaced. Code K0025 was end-dated and replaced with E0996. Code K0028 was end-dated and replaced E1226. Code K0048 was end-dated and replaced with E0990. Codes KL0054, K0055, K0057, and K0058 were end-dated and were not replaced. Codes K0062 and K0063 were end-dated and replaced with E0967. Codes K0088 was end-dated and replaced with E2366. Code K0089 was end-dated and replaced with E2367.
01/01/2004	Section 5.3.11	Code K0533 was end-dated and replaced with E0471. Code K0532 was end-dated and replaced with E0470.
01/01/2004	Section 5.7	Code W4005 was end-dated and replaced E1340.
02/01/2004	Section 5.3.13	Criteria for coverage of ultrasonic osteogenesis stimulators were added.
02/01/2004	Section 5.3.11	Code E0608 was deleted and replaced with E0619.
03/01/2004	Sections 5.3.1; 5.3.7; 5.3.11	National miscellaneous HCPCS codes were added to state-created codes.
03/01/2004	Section 5.3.13	Criteria were added for Non-Invasive Electrical Osteogenesis Stimulators for Spinal Applications.
03/01/2004	Attachment A, Block 26	Instructions were added on how to complete the CMN/PA form for approval of items with a national miscellaneous code and the CMN/PA example was revised.
03/01/2004	Attachment C, Block 23	Instructions were added on when to include the Service Request Number and the example of the claim form for DME was revised.
03/01/2004	Attachment D	Attachment D was re-numbered to Attachment E and the list of lifetime expectancies for DME items was added as Attachment D.
08/01/2004	Section 5.3.10	Criteria for segmental and non-segmental pneumatic compressors and appliances were clarified.
10/01/2004	Section 5.3.1	HCPCS codes W4698 through W4700 were end-dated and replaced with E2001 and E2202; W4701 through W4703 were end-dated and replaced with E2203 and E2204; W4707 through W4712 were end-dated and replaced with E2340, E2341, E2342, and E2343; K0651 was added.
10/01/2004	Section 5.3.7	HCPCS code E0192 was end-dated and replaced with K0652 through K0657; K0023 and K0024 were end-dated and replaced with K0660 and K0661; W4148 was end-dated and replaced with K0662 through K0665; E0964 was end-dated and replaced with K0650. The code descriptions for K0108/W4117 and K0108/W4118 were updated.
10/01/2004	Attachment A	The example of the CMN/PA form for DME was revised to reflect new codes.
10/01/2004	Attachment D	The list of Lifetime Expectancies and Quantity Limitations for DME was revised to include new codes.
02/01/2005	Sections 5.3.1, 5.3.7, and 5.3.11	HCPCS codes K0059-K0061, K0081, K0650-K0657, K0660-K0665, E0176-E0179, E1091, W4122-W4126, W4128, W4129, and W4134-W4137 were end-dated and replaced with new codes. Code descriptions were updated.
02/01/2005	Attachment D	The list of Lifetime Expectancies and Quantity Limitations for DME

		was revised to include new codes.
07/01/2005	Section 5.3.7	HCPCS codes E2294, K0108/W4138, K0108/W4151, and E2603-E2606 were end-dated and replaced with new codes. Code descriptions were updated.
07/01/2005	Section 5.3.17 and 5.3.18	These sections, related to orthotics and prosthetics, were deleted.
07/01/2005	Section 5.8	Information related to repairing and servicing orthotics and prosthetics was deleted.
07/01/2005	Attachment D	The list of Lifetime Expectancies and Quantity Limitations for DME was revised to include new codes.
08/01/2005	Attachment A	Instructions were updated to comply with revised CMN/PA form.
09/01/2005	Section 2.2	The special provision related to EPSDT was revised.
09/01/2005	Section 5.3.16	HCPCS code E0609 was end-dated and replaced with E2100
10/01/2005	Section 8.7	Information related to co-payments was added.
10/01/2005	Attachment D	Quantity limits were added for A7032 AND A7034 through A7039.
12/01/2005	Section 2.2	The website address for DMA's EDPST policy instructions was added to this section.
12/01/2005	Section 8.3	The information pertaining to crossover claims was updated.
01/01/2006	Section 5.3.1 and Attachment A	HCPCS code W4737 was end-dated and replaced with codes E2371 and E2372; W4721 was end-dated and replaced with codes E0911 and E0912.
01/01/2006	Section 5.3.7 and Attachment A	The description for HCPCS code E1038 was revised. HCPCS codes E1025, E1026, and E1027 were end-dated and deleted from the policy.
01/01/2006	Section 5.3.17 and Attachment A, block 24.	The description for HCPCS code E0935 was revised.
01/01/2006	Attachment D	HCPCS code A4254 was end-dated and replaced with A4233, A4234, A4235, and A4236; E0972 was end-dated and replaced with E0705; K0064 was end-dated and replaced with E2216; K0066 was end-dated and replaced with E2220; K0067 was end-dated and replaced with E2211; K0068 was end-dated and replaced with E2212; K0074 was end-dated and replaced with E2214; K0075 was end-dated and replaced with E2217; K0076 was end-dated and replaced with E2221; K0078 was end-dated and replaced with E2215; K0102 was end-dated and replaced with E2207; K0104 was end-dated and replaced with E2208; and K0106 was end-dated and replaced with E2209.
01/01/2006	Attachment D	The descriptions for HCPCS codes A4215, A6550, A7032, A7033, B4149, and E0971.
01/01/2006	Attachment D	The following HCPCS codes, descriptions and lifetime expectancies were added to the attachment: E1039, E2210, E2213, E2218, E2219, E2222, E2223, E2224, E2225, and E2226.
01/01/2006	Attachment D	HCPCS code A6551 was end-dated and deleted from the policy.
02/01/2006	Attachment B, Step #6	Information pertaining to denied prior approval requests was updated.
04/01/2006	Section 6.1	Information about when an out-of-state provider can enroll with N.C. Medicaid was added to item #4.
04/01/2006	Section 6.1	A permit or letter of exemption from the N.C. Board of Pharmacy was added as a requirement.
05/01/2006	Attachment D	HCPCS code L8501 was added to the table as a covered code.

07/01/2006	Section 5.3.7	Added HCPCS codes E1029 and E1030 as covered codes.
08/01/2006	Attachment D	Added HCPCS codes K0734 through K0737 as covered codes.
09/01/2006	Section 5.3.11	Coverage criteria and requirements for respiratory assist devices and continuous positive airway pressure devices were updated.
09/01/2006	Section 5.3.18	Coverage criteria for high-frequency chest wall oscillation device added to policy effective with date of service June 1, 2006.
09/01/2006	Attachment D	HCPCS codes E0483, A7025 and A7026 were added to the list of codes.
12/01/2006	Section 2.2	The special provision related to EPSDT was revised.
12/01/2006	Sections 3.0, 4.0, and 5.0	A note regarding EPSDT was added to these sections.
01/01/2007	All sections and attachment(s)	HCPCS codes E0164, E0166, E0180, E2320, and K0090 through K0098, W4704 through W4706, K0010, and K0011 were end-dated and removed.
01/01/2007	All sections and attachment(s)	HCPCS code descriptions for E0163, E0165, E0167, 30181, E0182, E0720, E0730, E0967, and E2209 were revised.
01/01/2007	Appendix D, Capped Rental/Purchase tables	Multiple HCPCS codes in the ranges of E2373 through E2396 and K0733 through K0898 were added.
03/01/2007	Section 2.2	EPSDT statement was updated.
03/01/2007	Attachment D	HCPCS procedure codes E2601 through E2608 and K0734 through K0737 were removed from Inexpensive or Routinely Purchased Items and placed in Capped Rental/Purchase. HCPCS procedure codes K0552 and L8501 were removed from Inexpensive or Routinely Purchased Items and placed in DME-Related Supplies. HCPCS procedure codes A4614, A7006, E0424, E0431, E0434, and E0439 were removed from Frequently Serviced Items and placed in Oxygen and Oxygen-Related Items. HCPCS procedure codes A7030 and A7031 were added to DME-Related Supplies.
03/01/2007	Section 5.3.19 and Attachment D	Coverage added for cough-stimulating device, alternating positive and negative airway pressure (E0482).
04/01/2007	Section 5.3.20	Coverage added for Farrell valve enteral gastric pressure relief system.
04/01/2007	Section 5.8	Removed requirement for hourly labor rate to be included in repair estimates.
04/01/2007	Sections 2.2, 3.0, 4.0, and 5.0	EPSDT information was revised to clarify exceptions to policy limitations for beneficiaries under 21 years of age.
05/01/2007	Section 5.3.1	Transferred some power wheelchairs previously designated as "oversize equipment" into the standard wheelchair category (Section 5.3.7).
05/01/2007	Section 5.3.7	Restored the requirements for power wheelchairs, which were inadvertently deleted in the January 1, 2007, version. Reordered the items so that all manual wheelchairs are together, followed by manual wheelchair accessories. The same organization applies to power wheelchairs and their accessories.
06/01/2007	All sections and attachment(s)	Reformatted lists and styles to be consistent with other DMA documents.
06/01/2007	Section 5.3.7, Attachment D	Removed end-dated codes K0108/W4146 and K0108/W4147; added replacement codes E1002 through E1008.

06/01/2007	Section 7.2	Reformatted the section to set off headings more clearly; moved statement about restrictions on HIT and Hospice service to those subsections; moved a general statement to the beginning of the section.
08/01/2007	Section 6.1	Changed the name of Division of Facility Services (DFS) to Division of Health Service Regulation (DHSR).
01/01/2008	Section 5.3.7	HCPCS code update: deleted E2618; changed the description of E2373; added E2312 and E2313
01/01/2008	Section 5.3.8	HCPCS code update: changed the description of E0630
01/01/2008	Section 5.3.9	Updated the oxygen policy to reflect current standards of practice and Medicare's coverage criteria. Added HCPCS codes E1392 and K0738 to fee schedule. Added modifiers to code E1390 for special reimbursement rates.
01/01/2008	Section 5.10	Deleted requirement to perform a new study to change suppliers.
01/01/2008	Section 5.11	Deleted section on changing the type of oxygen equipment.
01/01/2008	old Section 8.0	Billing Guidelines was renamed Claims-Related Information, moved to Attachment A , and reorganized according to a standard outline. The previous Section 9.0 became Section 8.0, and existing attachments were renumbered in sequence.
01/01/2008	Attachment E	HCPCS code update: deleted B4086, E2618, and W4210; changed the description of B4034, E0630, E2205, and E2373; added A7027, A7028, A7029, B4087, B4088, E2227, E2228, E2312, and E2313.
01/01/2008	All sections and attachment(s)	Removed boldface as a designation for Medicare coverage and asterisks as indicators of prior approval requirements.
04/01/2008	Sections 5.2 and 5.3.7, Attachments C and F	EDS took over the prior approval of pediatric mobility devices from Children's Special Health Services. Deleted references to CSHS and instructions for contacting them.
08/11/2008 (eff. 01/01/2008)	Attachment E	Corrected quantity limitation in HCPCS code B4088 from 2 per month to 4 per year. This is a correction to a typographical error, not a change in actual coverage.
01/01/2009	Section 5.3.21	Added this section on canes, crutches, walkers, and gait trainers.
01/01/2009	Attachment E	Revised lifetime expectancies for HCPCS codes A4637, E0100, E0105, E0110, E0111, E0112, E0114, E0130, E0135, E0141, E0143, E0154; added HCPCS codes A4635, A4636, E0113, E0118, E0155, E0156, E0158, E8000, E8001, and E8002; added miscellaneous HCPCS code E1399.
02/01/2009 (eff. 07/01/2008)	Section 5.3.22, Attachment E	Added section and codes on oral nutrition.
02/01/2009	Section 5.3.23	Added section and codes on augmentative and alternative communication devices.
02/01/2009 (eff. 01/01/2009)	Attachment E	HCPCS code update: changed descriptions of A6257 and A6258; added A9284, E1354, E1355, E1356, E1357, E1358, E2231, and E2295. Corrected descriptions of A7520, A7521, and A7522.
05/01/2009	Section 5.3.22	Added URL for Oral Nutrition Request Form.
05/01/2009	All sections and attachment(s)	Corrected URLs to conform to new DMA website organization.
06/01/2009	5.3.14	Revised coverage criteria for external insulin pumps.
11/01/2009	5.3.24	Added section and codes on Standers
02/16/2011	Attachment E	Quantity for code A7000 changed from 1/Month to 10/Month

04/20/2011	Subsection 5.3.11	Added “Pressure support ventilator, with volume control mode, may include pressure control mode, used with invasive interface (e.g., tracheostomy tube) (E0463)”
07/01/2011	Subsection 5.5.1	Added Subsection 5.5.1 Override Process
10/01/2011	Throughout	Updated policy template language and formatting
07/01/2012	Subsection 5.3.6	Added Prior approval criteria on Rental wheelchairs
07/01/2012	Subsection 5.6.1	Added Subsection 5.6.1 Delivery directly to the recipient
07/01/2012	Subsection 5.6.2	Added Subsection 5.6.2 utilizing delivery or Shipping Service.
07/01/2012	Subsection 7.2	Added and referenced Subsection 5.6.1 and 5.6.2 to Subsection 7.2.e Record Keeping
02/01/2013	Attachment A (C)	Attachment E relocated information to Attachment A (C)
02/01/2013	All sections and attachment(s)	Merge Medicaid and NCHC current coverage into one policy.
02/01/2013	All sections and attachment(s)	Replaced “recipient” with “beneficiary.”
03/01/2013	Subsection 5.3.1	Item “d.” Total Electric Hospital Bed – Wording revised to clarify requirements
07/01/2013	Subsection 5.3.9	Replaced “written statement” with “medical documentation” to reflect process changes.
07/01/2013	Subsection 5.3.11	Deleted “The physician, physician assistant, or nurse practitioner shall document in block 11 and 25 of the CMN/PA form and attach the required documentation that the beneficiary meets the medical necessity requirement for RAD therapy along with the results of the polysomnogram (if required based on the diagnosis).”
07/01/2013	Subsection 5.3.11	Deleted “in block 11 and 25 of the CMN/PA form, or on attached documentation,”
07/01/2013	Subsection 5.3.11	Deleted “the physician, physician assistant, or nurse practitioner shall indicate in block 25 of the CMN/PA form or”
07/01/2013	Subsection 5.3.12	Deleted “the physician, physician assistant, or nurse practitioner shall indicate in block 25 of the CMN/PA form or”
07/01/2013	Attachment B	Deleted Attachment B due to those instructions becoming obsolete with new fiscal agent.
07/01/2013	Attachment C&D	Renumbered to now become Attachment B and Attachment C after the deletion of Attachment B. Updated references throughout the policy to reflect this change.
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
11/01/2015	Subsection 5.3.29	Added process change for the provision of DMES on the Date of Discharge from a Hospital.
11/01/2015	Attachment B	Specific codes to be provided on the date of Discharge from a Hospital.
02/15/2016	Subsection 5.3.29	Policy/Section name updated to Provision of DMES on the Date of Discharge from Specified Facilities.
02/15/2016	Subsection 5.3	Guidance for Electronic Signatures added
02/15/2016	Attachment B	Specific codes to be provided on the date of Discharge from Specified Facilities was updated.
11/01/2016	Subsection 5.3.9	Mirror Medicare oxygen recertification policy (Effective 04/25/2016 per the April 2016 Medicaid Special Bulletin)

11/01/2016	Subsection 5.3.11	Simplify recertification on ventilators (Effective 04/25/2016 per the April 2016 Medicaid Special Bulletin)
11/01/2016	Subsection 5.6.2	Mirror Medicare policy when using shipping or delivery service (Effective 04/25/2016 per the April 2016 Medicaid Special Bulletin)
11/01/2016	Attachment A	C: Codes: Annual HCPCS code update; end date code E0450 and E0463 replace and add HCPCS code E0465 – (Effective 01/01/2016)
11/01/2016	Subsection 5.3.9	Added clarifying language to items “d.” and “i.” and returned wording that had inadvertently been dropped during revision process. (Effective 04/25/2016 per the April 2016 Medicaid Special Bulletin)
11/01/2016	Subsection 5.3.9	Added clarifying language to items “i.” and “j.” (Effective 04/25/2016 per the April 2016 Medicaid Special Bulletin)
11/01/2016	Attachment D	Eliminated Carolina Access requirement from box 19 of example claim in Attachment D. (per September 2016 Special Medicaid Bulletin)
11/01/2016	Subsection 5.3.3, 5.3.5	Initial authorization extended from 3 to 6 months (Effective 10/1/16 per the October 2016 Medicaid Bulletin)
11/01/2016	Subsection 5.6.1	Added beneficiary education on useful life and warranty (Effective 10/1/16 per the October 2016 Medicaid Bulletin)
11/01/2016	Attachment B	Specific codes to be provided on the date of Discharge from Specified Facilities was updated. (Effective 10/1/16)
07/01/2017	All Sections and Attachments	Clinical coverage policy 5A, Durable Medical Equipment and Supplies, separated into three categorical policies: 5A-1, Physical Rehabilitation Equipment and Supplies, 5A-2, Respiratory Equipment and Supplies, and 5A-3, Nursing Equipment and Supplies. The technical change resulted in no substantive changes to the existing 5A clinical coverage policy language.
07/01/2017	Subsections 1.1, 1.2, 3.2.1, 5.3.1, 5.3.2, 5.3.4, 5.6.1 & 7.2	Language amended to comply with CMS 42 CFR Part 440.70, Home Health Services, Final Rule.
08/01/2017	All Sections and Attachments	Amended policy posted on this date, with an EFFECTIVE Date of 07/01/2017.
12/01/2017	All Sections	Policy language was amended to clarify compliance with the CMS Home Health Final Rule, 42CFR, Part 440.70. References to requesting items not listed in policy or the corresponding fee schedule were added in multiple locations throughout the policy.
12/01/2017	Attachment D	Added Attachment D: Requesting Unlisted DME and Supplies for Adults.
02/01/2018	Policy 5A-2 only: 5.3.1, 5.3.2, and Attachment A, Section C: Procedure Codes	In 5.3.1, the 30-day and 90-day criteria were changed to one month and three months respectively. In 5.3.2, policy for respiratory assist device (RAD) BiLevel was updated; and ventilator policy was expanded to include criteria for non-invasive interfaces. In Attachment A, Section C: Procedure Codes, the HCPCS code for home ventilators with a non-invasive interface (E0466) was added. Grammatical, style and numbering errors were corrected throughout.
03/16/2018	All Sections and Attachments	Policy posted with an Amended Date of February 1, 2018
03/15/2019	Table of Contents	Added, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after

		November 1, 2019, please contact your PHP.”
03/15/2019	All Sections and Attachments	Updated policy template language.
11/01/2019	Subsection 1.2	Updated to instruct providers to submit PA requests for unlisted items through NCTracks instead of directly to NC Medicaid clinical policy.
11/01/2019	Subsection 5.5	Updated instructions for requesting overrides of quantity or lifetime expectancy limits.
11/01/2019	Subsection 5.9	Updated to allow use of a wider array of entities to fulfill PA documentation requirements when replacing lost/stolen medical equipment and supplies during natural disasters.
11/01/2019	Subsection 6.4	Added language reminding providers attempting to bill Medicaid recipients that they must comply with North Carolina Administrative Code 10A NCAC 22J .0106.
11/01/2019	Attachment A, Section B	ICD-10-CM Code List for Cough Stimulating Device was updated to add G71.00, G71.01, G71.02 and G71.09.
11/01/2019	Attachment A, Section C	Local codes W4047 (miscellaneous for DME) and W4670 (sterile saline, 3 cc vial, each) were added back to code list as they were inadvertently left out during a previous update.
11/01/2019	Attachment D	Attachment D: Requesting Unlisted DME and Medical Supplies for Adults was updated to instruct providers to submit PA requests through NCTracks instead of directly to NC Medicaid clinical policy.
11/01/2019	Attachment A	Updated policy template language: “Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines”.
01/10/2020	Table of Contents	Updated policy template language, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.”
10/15/2020	Related Clinical Coverage Policies	Added reference to clinical coverage policy 1A-20, Sleep Studies and Polysomnography Services.
10/15/2020	Subsection 5.3.1	Clarified age requirements for qualifying oxygen analysis during inpatient hospital stay.
10/15/2020	Subsection 5.3.2	Added reference to clinical coverage policy 1A-20, Sleep Studies and Polysomnography Services to two instances of polysomnogram requirements. Under heading Respiratory Devices for the Treatment of Obstructive Sleep Apnea , criterion b.: “Has a documented, attended by qualified personnel, facility-based polysomnogram that meets the following criteria:” was replaced with: “Has a documented, polysomnogram provided according to requirements listed in Clinical Coverage Policy 1A-20, Sleep Studies and Polysomnography Services that meets the following criteria:” Removed prior approval requirement for ultrasonic nebulizers. Specified existing oximeter criteria is for hospital grade, table-top oximeters for rental, and added qualifying criteria for infants. Added coverage and medical necessity criteria for portable oximeters for purchase.
10/15/2020	Attachment A,	Added ICD-10-CM diagnoses G71.20, G71.21, G71.22, G71.220,

	Section B	G71.228 and G71.29, as acceptable diagnoses for Cough Stimulation Devices
10/15/2020	Attachment A, Section C	Clarified existing row for E0445 (oximeter) as “rental only” and added a second row for E0445 (oximeter) as a purchase option with a lifetime expectancy of 3 years.
10/15/2020		Amended policy posted on this date, with an EFFECTIVE Date of 10/1/2020
05/01/2021	Related Clinical Coverage Policies	Added clinical coverage policies 5A-3, <i>Nursing Equipment and Supplies</i> and 5B, <i>Orthotics & Prosthetics</i>
05/01/2021	Subsection 5.3.4	The subsection heading “Cough Stimulating Device, Alternating Positive and Negative Airway Pressure” was renamed “Mechanical Insufflation – Exsufflation Devices”.
05/01/2021	Subsection 5.3.5	Added medical necessity criteria for tracheostomy supplies.
05/01/2021	Subsections 5.3.5 and 5.3.6	Existing subsections 5.3.5, Miscellaneous Durable Medical Equipment and Medical Supplies and 5.3.6, Provision of DME and Medical Supplies on the Date of Discharge from Specified Facilities were renumbered to 5.3.6 and 5.3.7 respectively.
05/01/2021	Attachment A, Section B	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.
05/01/2021	Attachment A, Section C	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”.
05/01/2021	Attachment C	Removed ICD-9-CM from block 21 and added ICD-10-CM.
05/01/2021		Policy posted 05/12/2021 and has an effective date of 04/01/2021 with an amended date of 05/01/2021
03/15/2022	All Sections and Attachments	Updated the link to the DME Fee Schedule. Updated CMN/PA to CMN/PA form.
03/15/2022	Subsection 5.3.1	In the first instance of criterion c., changed the word “includes” to “reports”.
03/15/2022	Subsection 5.3.2 and 5.8	Updated the reference to the field found on the CMN/PA form.

03/15/2022	Attachment A, Section C	Denoted HCPCS codes E0570, A7003, A7004, A7005, A7006, A7015, A4627 and A4614 as appropriate codes for physicians, physician assistants, or nurse practitioners to issue and receive reimbursement.
03/15/2022	Attachment A, Section C	Effective 2/1/2022, 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.
03/15/2022	Attachment B	Removed the asterisk (*) indicating that an item requires prior approval, as this information can be found in the DME Fee Schedule.
03/15/2022	Attachment C	Removed NCHC from block 1, as this is not a valid selection on the CMS-1500 form. Removed the extraneous word “reported” from the Note.
08/15/2022	Subsection 5.3.2	Added medical necessity criteria for a secondary ventilator.
08/15/2022	Attachment A, Section C	Quantity limits were updated for existing HCPCS codes A7002, A7003, A7013, A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7036, A7037 and A7038. New coverage and quantity limits were added for HCPCS codes A4619, A7014, E0572, E0574, E0585 and E1372.
08/15/2022	Attachment A, Section F	Updated places of service to align with NCTracks: 04-homeless shelter, 12-home, 13-assisted living facility, 14-group home, 33-custodial care facility, 34-hospice.
08/15/2022		Policy has an amended date of 08/15/2022 with an effective date of 08/01/222
12/15/2022	Subsections 5.1 and 5.3.6	Removed the statement that an asterisk (*) identifies equipment and supplies that require PA on the DME Fee Schedule.
06/01/2023	All Sections and Attachments	Updated policy template language due to North Carolina Health Choice Program’s move to Medicaid. Policy posted 6/1/2023 with an effective date of 4/1/2023.
04/01/2025	Throughout	Language updated for clarity and consistency. The terms approval, authorization and prior authorization were changed to prior approval for consistency.
04/01/2025	Related Clinical Coverage Policies	Added clinical coverage policies <i>3D, Hospice Services</i> and <i>3H-1, Home Infusion Therapy</i> .
04/01/2025	Section 1.0	Added clarifying language.
04/01/2025	Subsection 4.2.1	Updated language for clarity.
04/01/2025	Subsection 6.1	Criterion d. updated for clarity.
04/01/2025	Subsection 6.2	Removed outdated references to Federal Laws from policy.
04/01/2025	Attachment A, Section D	Added modifiers NU, UE and RR for clarity.
04/01/2025	Attachment C	Updated instructions for completing claim form. Outdated sample claim form images removed from policy. Instructions about when to submit an invoice with a claim for a manually priced item was updated at the bottom of page 53 to align with current practice.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, Medicaid’s clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

A. Claim Type

Professional (CMS-1500/837P 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.

ICD-10-CM Code(s)			
Mechanical Insufflation - Exsufflation Devices			
B91	G70.2	G71.8	S22.20xA
E74.02	G70.80	G71.9	S22.20xB
G12.0	G70.81	G72.0	S22.21xA
G12.1	G70.89	G72.1	S22.21xB
G12.8	G70.9	G72.2	S22.22xA
G12.9	G71.00	G72.3	S22.22xB
G12.20	G71.01	G72.41	S22.23xA
G12.21	G71.02	G72.49	S22.23xB
G12.22	G71.09	G72.81	S22.24xA
G12.23	G71.11	G72.89	S22.24xB
G12.24	G71.12	G72.9	S22.31xB
G12.25	G71.13	G73.7	S22.31xS
G12.29	G71.14	G73.1	S22.32xB
G12.8	G71.19	G73.3	S22.43xB
G12.9	G71.2	G82.20	S22.43xD
G14	G71.20	G82.21	S22.43xG
G35	G71.21	G82.22	S22.43xS
G61.0	G71.22	G82.50	S22.49xB
G65.0	G71.220	G82.51	
G70.00	G71.228	G82.52	
G70.01	G71.29	G82.53	
G70.1	G71.3	G82.54	

C. Procedure 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.

Refer to the **Durable Medical Equipment Fee Schedule** for the rates associated with the equipment, supplies, and services listed in the table below. The fee schedules are available on Medicaid's website at: <https://medicaid.ncdhhs.gov/>. To a medical necessity review for an item not listed, refer to **sections 1.2, 2.2 and Attachment D** for instructions.

Lifetime Expectancies and Quantity Limitations for Durable Medical Equipment and Supplies

Note: + 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	Mouthpiece	N/A
A4618	Breathing circuits	N/A
A7027	Combination oral/nasal mask, used with continuous positive airway pressure device, each	4 per year
A7028	Oral cushion for combination oral/nasal mask, replacement only, each	2 per month
A7029	Nasal pillows for combination oral/nasal mask, replacement only, pair	2 per month
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

HCPCS Code	Item Description	Lifetime Expectancy or Quantity Limitation
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	4 per year
A7031	Face mask interface, replacement for full face mask, each	1 per month
A7032	Cushion for use on nasal mask interface, replacement only, each	2 per month
A7033	Pillow for use on nasal cannula type interface, replacement only, pair	2 per month
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device with or without head strap	4 per year
A7035	Headgear used with positive airway pressure device	2 per year
A7036	Chinstrap used with positive airway pressure device	2 per year
A7037	Tubing used with positive airway pressure device	4 per year
A7038	Filter, disposable, used with positive airway pressure device	2 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

HCPCS Code	Item Description	Lifetime Expectancy or Quantity Limitation
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		
A4619	Face tent	1 per month
E0570+	Nebulizer, with compressor	3 years
E0572	Aerosol compressor, adjustable pressure, light duty for intermittent use	3 years
E0574	Ultrasonic/electronic aerosol generator with small volume nebulizer	5 years
E0585	Nebulizer, with compressor and heater	5 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	2 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	2 per month
A7014	Filter, nondisposable, used with aerosol compressor or ultrasonic generator	4 per year
A7015+	Aerosol mask, used with DME nebulizer	4 per month
E1372	Immersion External Heater for Nebulizer	3 years
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

HCPCS Code	Item Description	Lifetime Expectancy or Quantity Limitation
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	
A4614+	Peak expiratory flow rate meter, handheld	2 per year
A4627+	Spacer, bag or reservoir, with or without mask, for use with metered dose inhaler	3 per year

HCPCS Code	Item Description	Lifetime Expectancy or Quantity Limitation
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	4 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

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

Provider(s) shall follow applicable modifier guidelines.

NU for items purchased new, UE for items purchased used, RR for rental items.

Oxygen:

If a flow of greater than 4 liters per minute (LPM) is documented as medically necessary, the higher oxygen allowable will be paid to the supplier at one-and-a-half (1.5) times the rate. The modifiers listed below are to be added to the oxygen code being used. If either of these modifiers 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.

QF: Prescribed amount of oxygen is greater than 4 LPM and portable oxygen is also prescribed

QG: Prescribed amount of oxygen is greater than 4 LPM and portable oxygen is not prescribed

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).

F. Place of Service

12-Home, 04-homeless shelter, 13-assisted living facility, 14-group home, 33-custodial care facility, 34-hospice.

G. Co-payments

Medicaid eligible beneficiaries are exempt from co-payments.

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>

Attachment B: Provision of DME and Supplies on the Date of Discharge from Specified Facilities

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

Oxygen Equipment and Supplies For Clinical Coverage and Prior Approval Criteria, refer to Subsection 5.3.1	
E0431	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask and tubing
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
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing
E0439	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask & tubing.
E1390	Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate
E1392	Portable oxygen concentrator, rental
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
W4001	CO2 saturation monitor with accessories, probes
	Respiratory Devices - Nebulizers
E0570+	Nebulizer, with compressor
A7003+	Administration set, with small volume nonfiltered pneumatic nebulizer, disposable
A7005+	Administration set, with small volume nonfiltered pneumatic nebulizer, non-disposable
A7013	Filter, disposable, used with aerosol compressor or ultrasonic generator
A7015+	Aerosol mask, used with DME nebulizer

HCPCS Code	Item Description
Respiratory Devices – Apnea Monitor For Clinical Coverage and Prior Approval Criteria, refer to Subsection 5.3.2	
E0619	Apnea monitor, with recording feature
Respiratory Devices – Percussor For Clinical Coverage and Prior Approval Criteria, refer to Subsection 5.3.2	
E0480	Percussor, electric or pneumatic, home model
Respiratory Devices – Oximeter For Clinical Coverage and Prior Approval Criteria, refer to Subsection 5.3.2	
E0445	Oximeter device for measuring blood oxygen levels non-invasively (rental)

HCPCS Code	Item Description
<p>Cough Stimulating Device For Clinical Coverage and Prior Approval Criteria, refer to Subsection 5.3.4</p>	
E0482	Cough stimulating device, alternating positive and negative airway pressure
<p>Miscellaneous Durable Medical Equipment and Supplies For Clinical Coverage and Prior Approval Criteria, refer to Subsection 5.3.5</p>	
W4002	Manual ventilation bag (e.g. Ambu bag)
A4627+	Spacer, bag or reservoir, with or without mask, for use with metered dose inhaler

Attachment C: Completing a Claim for DME or EN Services

Refer to the following information for completing a CMS-1500 claim form for DME services.

Block #/Description	Instruction
1.	Place an X in the MEDICAID block.
1a. Insured's I.D. Number	Enter the beneficiary's Medicaid ID number (nine digits and the alpha suffix) from the beneficiary's Medicaid ID card.
2. Patient's Name	Enter the beneficiary's last name, first name and middle initial from the Medicaid ID card.
3. Patient's Birth Date/Sex	Enter eight numbers to show the beneficiary's date of birth - MMDDYYYY. The birth date is on the Medicaid ID card. <i>EXAMPLE: November 14, 1949 is 11141949.</i> Place an X in the appropriate block to show the beneficiary's sex.
4. Insured's Name.	Leave blank
5. Patient's Address	Enter the beneficiary's street address, including the city, state and zip code. The information is on the Medicaid ID card. Entering the telephone number is optional.
6. Patient's relationship to insured	Leave blank.
7. Insured's address	Leave blank.
8. Reserved for NUCC use	Leave blank.
9. Other Insurer's Name 9a. Other insured's policy or group number 9b. Reserved for NUCC use 9c. Reserved for NUCC use 9d. Insurance plan name or program name	Enter applicable information.
10. Is Patient's condition related to: 10a. Employment? 10b. Auto Accident? 10c. Other Accident? 10d. Claim codes	Place an X in the appropriate block for each question.
11. Insured's policy group or FECA number 11a. Insured's date of birth 11b. Other claim ID 11c. Insurance plan name or program name 11d. Is there another health benefit plan?	Optional
12. Patient's or authorized person's signature	Optional

Block #/Description	Instruction
13. Insured's or authorized person's signature	Optional
14. Date of current illness, injury, or pregnancy	Optional
15. Other date	Leave blank.
16. Dates patient unable to work in current occupation	Leave blank.
17. Name of referring provider or other source 17a. 17b. NPI	Optional.
18. Hospitalization dates related to current services	Optional.
19. Additional claim information	Leave blank.
20. Outside Lab?	Leave blank.
21. Diagnosis or Nature of Illness or injury	Enter the ICD-10-CM code(s) to describe the primary diagnosis related to the service. You may also enter related secondary diagnoses.
22. Resubmission Code	Leave blank.
23. Prior Authorization Number	Enter the prior approval number here, if applicable.

Note: Blocks 24A through 24K are where you provide the details about what you are billing. There are several lines for listing services. Each line is called a “detail.”

When completing these blocks:

- Use one line for each HCPCS code that you bill on a given date.
- If you provide more than one unit of the same item on one day, include all the items on the same line. For example, if you provide 100 blood glucose strips (A4253) on August 2, include all the strips on one line. Enter 2 units in 24G for that date of service.
- Include only dates of service in the SAME calendar month.
- Include only dates of service for which the beneficiary is eligible for Medicaid

Block #/Description	Instruction
<p>24a. Date(s) of Service</p>	<p>Your entry depends upon the services:</p> <p>Customized Equipment: You may enter either the date of the physician’s prescription or the date of delivery to the beneficiary’s home as the date of service. Place the date in the FROM block. Enter the same date in the TO block.</p> <p>Other Purchased Equipment - DME and EN: Enter the date the item is delivered to the beneficiary in the FROM block. Enter the same date in the TO block.</p> <p>Rental Equipment - DME and EN: For the month being billed, enter the first day in that month that the item is at the beneficiary’s residence in the FROM block. Enter the last day in that month that the item is at the beneficiary’s residence in the TO block. Do NOT span calendar months. <i>EXAMPLE: An enteral pump is provided from 3/25/02 through 5/15/02. Submit three claims. On March’s claim, enter 032502 in the FROM block and 033102 in the TO block. On April’s claim, enter 040102 in the FROM block and 043002 in the TO block. On May’s claim, enter 050102 in the FROM block and 051502 in the TO block.</i></p> <p>Service and Repairs: Enter the date that the item is serviced or repaired in the beneficiary’s home as the date of service. If the item is removed from the beneficiary’s home for service or repairs, enter the date that it is returned. Place the date in the FROM block. Enter the same date in the TO block.</p> <p>DME-Related Supplies: Enter the date that the item is delivered to the beneficiary’s residence in the FROM block. Enter the same date in the TO block.</p> <p>EN Supply Kits: Enter the date in the month that the therapy begins in the FROM block. If the therapy is continued from the prior month, enter the first of the month in the FROM block. Enter the last day of therapy for the month in the TO block. If the therapy extends into the next month, enter the last day of the current month in the TO block. Do NOT span calendar months. See the <i>EXAMPLE</i> under Rental Equipment for guidance.</p> <p>EN Individual Supply Items: Enter the date that the item is delivered to the beneficiary in the FROM block. Enter the same date in the TO block.</p> <p>EN Formulae: Enter the service dates for the formula in the FROM and TO blocks.</p>
<p>24b. Place of Service</p>	<p>See Attachment A, Section F of this policy for appropriate places of service for DME.</p>

Block #/Description	Instruction
24c. EMG	Leave blank.
24d. Procedures, Services or supplies CPT/HCPCS code and modifier	Enter the appropriate HCPCS code and modifier: See Attachment A, Section D of this policy for appropriate modifiers for DME.
24e. Diagnosis pointer	Leave blank.
24f. Charges	Enter the total charge for the items on the line. For rental items, enter the full month's rental charge—do not prorate the charge if the item is provided less than a full month. Note: Providers shall bill their usual and customary rates. Do not automatically bill the established maximum reimbursement rate listed.
24g. Days or Units	Enter the number of units as follows: Purchased Equipment (DME and EN): Enter the number of units provided on the date of service. Rental Equipment (DME and EN)—Other than Oxygen: Enter 1. Oxygen and Oxygen Equipment: Enter the units provided on the date of service. Service and Repair: Enter 1 unit for each 15-minute increment being billed. DME-Related Supplies: Enter the number of units provided on the date of service. EN Supply Kits: Enter the number of consecutive days shown in 24A. EN Individual Supply Items: Enter the number of units provided on the dates of service. EN Formulae: Enter the number of units provided for the dates of service.
24h. EPSDT Family plan	Leave blank.
24i. ID qual.	Leave blank.
24j. Rendering Provider ID #	Optional.
25. Federal Tax ID Number	Optional
26. Patient's Account No.	Optional. You may enter your agency's record or account number for the beneficiary. The entry may be any combination of numbers and letters up to a total of nine characters. If you enter a number, it will appear on your RA. This will assist in reconciling your accounts.
27. Accept Assignment	Leave blank.
28. Total Charge	Enter the sum of the charges listed in Item 24F.
29. Amount Paid	Enter the total amount received from third party payment sources.
30. Rsvd for NUCC Use	Leave blank.
31. Signature of Physician or Supplier including degrees or credentials and date	Leave blank if there is a signature on file with Medicaid. Otherwise, an authorized representative of your agency must sign and date the claim in this block. A written signature stamp is acceptable.
32. Service facility location information	Optional.
33. Billing provider info & PH #	Enter your agency's name, address, including ZIP code, and phone number. The name and address must be EXACTLY as shown on your Medicaid DME participation agreement.

Note: For manually priced items requiring PA, if the maximum allowable reimbursement was based on a quote or estimate, then the invoice must be submitted with the claim. If the invoice was submitted with the PA request, then it is not required again with claim.

Attachment D: Requesting Unlisted DME and Supplies for Adults

In compliance with the Centers for Medicare & Medicaid Services (CMS) Home Health Final Rule, 42 CFR Part 440.70, please follow these guidelines when requesting medical necessity reviews for DME and supplies for adults not listed in **Attachment A, Section C** or the DME fee schedule.

- a. The general requirements and criteria set forth in clinical coverage policy 5A-2 must be met.

This includes, but is not limited to:

1. The item being requested must fit the definition of durable medical equipment or supplies;
 2. The beneficiary must be enrolled in the Medicaid program and be eligible for the item;
 3. The provider must be enrolled in the Medicaid program with an appropriate taxonomy;
 4. The requested item must be safe, effective, economical and not intended for the convenience of the beneficiary, the beneficiary's caregiver, or the provider;
 5. The item must be medical in nature, generally recognized as an accepted method of treatment, and must not be experimental or investigational;
 6. The item must be ordered by a physician, physician assistant, or nurse practitioner; and
 7. The item must be medically necessary to maintain or improve a beneficiary's medical, physical or functional level, and appropriate for use in any non-institutional setting in which normal life activities take place;
 8. 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 the item must have occurred no more than six months prior to the initiation of durable medical equipment or supplies; and
 9. The beneficiary's need for the item must be reviewed by the ordering physician, physician assistant, or nurse practitioner at least annually.
- b. If the provider determines that the applicable requirements and criteria set forth in clinical coverage policy 5A-2 have been met, then the provider may submit a completed Certificate of Medical Necessity/Prior Approval (CMN/PA form) and the usual supportive prior approval documentation, through NCTracks for a medical necessity review.
- c. Providers may request non-covered, unlisted, or restricted items using their identifiable HCPCS code (such as E1012). If no HCPCS code exists, providers may use the miscellaneous combination K0108/W4005 for wheelchair accessories only, and for non-wheelchair items, the miscellaneous combination E1399/W4047.
- d. Items approved by this procedure may be manually priced. Please include the appropriate manual pricing documentation with the prior approval request (see May 2017 Medicaid Bulletin for details).
- e. Providers should expect medical necessity reviews using this procedure to take longer than usual.
- f. Claims for items approved using this procedure should also be submitted through NCTracks.
- g. If denied, the provider and beneficiary will be notified, and normal beneficiary appeal rights will apply.
- h. Providers will be notified if the device requested is covered by a different Medicaid policy area or waiver program.

Additional Resources

For additional information, link to the NC Medicaid Durable Medical Equipment and Supplies web page, or the CMS final rule at 42 CFR Part 440.70.