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

3H-1, Home Infusion Therapy

3A, Home Health Services

5A-1, Physical Rehabilitation Equipment and Supplies

5A-2, Respiratory Equipment and Supplies

5B, Orthotics and Prosthetics

11C, Ventricular Assist Devices

1.0 Description of the Procedure, Product, or Service

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 Medical Supplies

Medical 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 Medical Supplies

Durable Medical Equipment and Medical 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 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 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) or NC Health Choice's (NCHC) 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 Medical 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 Medical 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 <u>https://medicaid.ncdhhs.gov/</u>.

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 authorization (PA) review of medical necessity. For a beneficiary under age 21, please request an "EPSDT review" using NCTracks. Refer to section **2.2 Special Provisions** for more information about EPSDT. For a beneficiary aged 21 and older, please submit the request through NCTracks per the procedure detailed in **Attachment D**.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term "General" found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 - 1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 - 2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(*The term "Specific" found throughout this policy only applies to this policy*) a. <u>Medicaid</u>

None Apply.

b. <u>NCHC</u> 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/providermanuals.html

EPSDT provider page: https://medicaid.ncdhhs.gov/

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

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 and NCHC 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 both Medicaid and NCHC

Medicaid and NCHC cover durable medical equipment and related medical supplies when ALL the following requirements are met:

- a. the item is ordered by a physician, physician assistant, or nurse practitioner;
- b. the item is medically necessary to maintain or improve a beneficiary's medical, physical or functional level, and appropriate for use in any 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 medical supplies has occurred no more than six (6) months prior to the initiation of durable medical equipment and medical supplies; and

d. the beneficiary's need for durable medical equipment and medical supplies is reviewed by the ordering physician, physician assistant, or nurse practitioner at least annually.

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

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

- **3.2.2 Medicaid Additional Criteria Covered** None Apply.
- **3.2.3 NCHC 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 and NCHC 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 both Medicaid and NCHC Medicaid and NCHC shall not cover convenience items or features.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

- a. NCHC beneficiaries are excluded from preconception care, pregnancy, and gestational diabetes services. If eligible, NCHC beneficiaries who become pregnant shall be enrolled in a Medicaid eligibility category that includes pregnancy coverage
- b. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 - 1. No services for long-term care.
 - 2. No nonemergency medical transportation.
 - 3. No EPSDT.

Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."
 Note: Subsection 4.2.3(b) applies to NCHC only.

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 and NCHC shall require prior approval (PA) for some medical equipment and supplies. Items that require prior approval are identified for the item identified on the *Durable Medical Equipment Fee Schedule* by an asterisk (*). The fee schedule is available on NC Medicaid's website: at: <u>https://medicaid.ncdhhs.gov/</u>.

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 of time, 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: <u>https://medicaid.ncdhhs.gov/providers/forms/durable-medical-equipment-orthotics-and-prosthetics-forms</u>.

5.2 **Prior Approval Requirements**

5.2.1 The 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 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 Negative Pressure Wound Therapy Electrical Pump, Stationary or Portable, and Related 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 Medical Supplies. To request a medical necessity review for an item not listed, see sections 1.2, 2.2 and Attachment D for instructions.

Negative pressure wound therapy (NPWT) is the use of an electrical pump to convey sub-atmospheric pressure to a specialized wound dressing and thereby promote wound healing.

The NPWT pump and wound care set are covered when they are medically necessary for the beneficiary. These items require prior approval. Initial authorization is given for a maximum of six consecutive months.

For initial approval, the following criteria must be met:

The beneficiary has a chronic Stage III or Stage IV pressure ulcer, neuropathic ulcer, venous or arterial insufficiency ulcer, or chronic (present for at least 30 calendar days) ulcer of mixed etiology.

A complete wound therapy program, as described below, must have been considered and ruled out, or tried, prior to application of NPWT:

- a. For all ulcers or wounds:
 - 1. Documentation in the beneficiary's health record of evaluation, care, and wound measurement by a licensed medical professional permitted to perform those tasks and responsibilities by their NC state licensing board;
 - 2. Application of dressings to maintain a moist wound environment;
 - 3. Debridement of necrotic tissue if present; and
 - 4. Evaluation of and provision for adequate nutritional status.
- b. For Stage III or Stage IV ulcers:
 - 1. The beneficiary has been appropriately turned and positioned.
 - 2. A group 2 or 3 support surface has been used for pressure ulcers on the posterior trunk or pelvis (Note: A Group 2 or 3 support surface is not required if the ulcer is not on the trunk or pelvis).
 - 3. Moisture and incontinence have been appropriately managed.
- c. For neuropathic (for example, diabetic) ulcers:
 - 1. The beneficiary has been on a comprehensive diabetic management program, and
 - 2. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities.
- d. For venous insufficiency ulcers:
 - 1. Compression bandages or garments have been consistently applied; or if contraindicated to Peripheral Artery Disease (PAD);
 - 2. Lower extremity elevation and ambulation have been encouraged.

NPWT pumps must be capable of accommodating more than one wound dressing set when a beneficiary has multiple wounds. Therefore, more than one NPWT pump per beneficiary for the same time period is not covered.

An NPWT pump and supplies is not medically necessary when any of the following are present:

- a. The presence in the wound of necrotic tissue with eschar, if debridement is not attempted;
- b. Untreated osteomyelitis within the vicinity of the wound;
- c. Cancer present in the wound; or
- d. The presence of a fistula to an organ or body cavity within the vicinity of the wound.

For coverage to continue beyond the initial prior approval period, a licensed medical professional shall:

- a. Directly assess the wound(s) treated with the NPWT pump;
- b. Supervise or directly perform the NPWT dressing changes; and
- c. On a **monthly** basis, document changes in the ulcer's dimension and characteristics.

Note: For the purposes of this policy, a licensed medical professional can be a physician, physician's assistant, registered nurse, licensed practical nurse or physical therapist. The practitioner shall be licensed to assess wounds and administer wound care within the state where the beneficiary is receiving NPWT.

Re-authorizations for continued coverage are given for a maximum of one month. If the criteria are not fulfilled, continued coverage of the NPWT pump and supplies are not medically necessary and therefore not covered.

Lack of improvement of a wound, as used within this policy, is defined as a lack of progress in quantitative measurements of wound characteristics, including wound length and width (surface area) or depth measured serially and documented over a specified time interval. Wound healing is defined as improvement occurring in either surface area or depth of the wound.

Note: The staging of pressure ulcers used in this policy is as follows:

- Stage I non-blanchable erythema of intact skin
- Stage II partial-thickness skin loss involving epidermis, dermis, or both
- **Stage III** full-thickness skin loss involving damage or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia
- **Stage IV** full-thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures

5.3.2 External Insulin Infusion Pump

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 Medical Supplies. To request a medical necessity review for an item not listed, see sections 1.2, 2.2 and Attachment D for instructions.

An external insulin infusion pump is used in a beneficiary with diabetes to provide continuous subcutaneous insulin infusion to implement intensive diabetes management with the goal of achieving near-normal levels of blood glucose. Prior approval is required for the infusion pump, gray adapter, and

piston rod. An external insulin infusion pump and related supplies are covered for a beneficiary who demonstrates medical necessity by meeting one of the following criteria:

Adult Beneficiary (21 years of age or older)

An adult beneficiary shall have a diagnosis of diabetes mellitus and be insulin dependent. Additionally, a beneficiary shall fulfill the requirements in a, or b, **and** c or d, below.

a. C-peptide testing requirement

The beneficiary shall meet criterion 1 or 2, and criterion 3:

- 1. The C-peptide level is less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method.
- 2. For a beneficiary with renal insufficiency and creatinine clearance (actual or calculated from age, weight, and serum creatinine) less than or equal to 50 ml/minute, the **fasting** C-peptide level is less than or equal to 200 percent of the lower limit of normal of the laboratory's measurement method.
- 3. A fasting blood sugar obtained at the same time as the C-peptide level is less than or equal to 225 mg/dl.

or

b. The beneficiary's beta cell autoantibody test shall be positive.

and

The beneficiary shall also fulfill either criteria c or d below.

- c. The beneficiary must have completed a comprehensive diabetes education program; been on a program of multiple daily injections of insulin (at least three injections per day), with frequent self-adjustments of insulin dose, for at least six months prior to initiation of the insulin pump; documented his or her frequency of glucose self-testing (an average of at least four times per day during the two months prior to initiation of the insulin pump); and experienced one or more of the following events or conditions while on the multiple injection regimen:
 - 1. Glycosylated hemoglobin level (HbA1C) greater than 7 percent
 - 2. History of recurring hypoglycemia
 - 3. Wide fluctuations in blood glucose before mealtime
 - 4. Dawn phenomenon (fasting blood sugar frequently exceeding 200 mg/dl)
 - 5. History of severe glycemic excursions

or

d. The beneficiary has been on an external insulin infusion pump prior to enrollment in Medicaid, and that pump is no longer functional, there is documentation from the DME provider that the pump cannot be repaired, and the warranty has expired. These beneficiaries shall document their frequency of glucose self-testing (an average of at least four times per day during the month prior to enrollment). (Refer to **Subsections 5.8, Servicing and**

Repairing Durable Medical Equipment, and 5.9, Replacing Durable Medical Equipment.)

Beneficiaries age 0 through 20

External insulin infusion pumps are covered for beneficiaries aged 0 through 20 who meet one of the following criteria:

- a. The beneficiary has a diagnosis of diabetes mellitus, is insulin dependent, and has an HbA1C greater than 6.5 percent, with medical record documentation that justifies the medical necessity for the insulin pump. Except for neonatal diabetes, a diagnosis of diabetes for six weeks is required before the pump is approved; or
- b. The beneficiary has been on an external insulin infusion pump prior to enrollment in Medicaid or NCHC, when health record documentation justifies the medical necessity for the insulin pump and that pump is no longer functional, there is documentation from the DME provider that the pump cannot be repaired, and the warranty has expired.

(Refer to Subsections 5.8, Servicing and Repairing Durable Medical Equipment, and 5.9, Replacing Durable Medical Equipment.)

Beneficiaries with Gestational Diabetes

External insulin infusion pumps are covered for beneficiaries who have a diagnosis of gestational diabetes and are insulin dependent when there is either a health record documentation of erratic blood glucose readings, despite maximum compliance, or other documented evidence that adequate control is not being achieved. Refer to Attachment A, Section B: ICD-10-CM Code(s), for the specific diagnosis requirements for coverage for an external insulin infusion pump.

Prior Approval Requirements for All Beneficiaries

For prior approval, the physician, physician assistant, or nurse practitioner experienced in pump therapy who orders the pump shall document all of the following:

- a. The beneficiary's status shall be monitored during the time he or she uses the pump
- b. The beneficiary (or caregiver, if applicable) has demonstrated the ability and commitment to comply with:
 - 1. the regimen of pump care,
 - 2. frequent self-monitoring of blood glucose,
 - 3. careful attention to diet and exercise; and
 - 4. has completed a comprehensive diabetes education program.

The external insulin infusion pump is covered as a purchase item for all beneficiaries meeting coverage criteria except for those with gestational diabetes. For gestational diabetes, Medicaid beneficiaries meeting coverage criteria, the external insulin infusion pump is provided only as a rental through the end of the

delivery month. If the Medicaid beneficiary requires continued use of the external insulin infusion pump post-partum, prior approval is required. If approved, payments will continue until the combined payments for gestational and post-partum use cap at the purchase price.

Replacement Pumps

Medicaid and NCHC may cover a replacement external insulin infusion pump if the pump is no longer functional, and there is documentation from the DME provider indicating that:

- a. the pump cannot be repaired; and
- b. the warranty has expired.

A replacement pump is *not* medically necessary simply because the pump is out of warranty or is no longer being manufactured. Replacement of a functioning external insulin infusion pump with a newer advanced model is *not* covered

Refer to Subsections 5.8, Servicing and Repairing Durable Medical Equipment, and 5.9, Replacing Durable Medical Equipment.

5.3.3 Standard Blood Glucose Monitors, Continuous Glucose Monitors and Related 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, see **sections 1.2, 2.2 and Attachment D** for instructions.

- a. **Standard blood glucose monitors** (BGMs), syringes, strips, lancets, and other related supplies may be considered medically necessary when all the following coverage criteria are met:
 - 1. The beneficiary has a diagnosis of insulin dependent diabetes mellitus, non-insulin dependent diabetes, gestational diabetes, or glycogen storage disease which is being treated by a physician, physician assistant, or nurse practitioner;
 - 2. The BGM and related supplies have been ordered by the practitioner treating the beneficiary's diabetes;
 - 3. The beneficiary or the beneficiary's caregiver has completed sufficient training or is scheduled to begin training in self-monitoring of blood glucose (SMBG) using the monitor, test strips and lancets; and
 - 4. The beneficiary or the beneficiary's caregiver is willing and able to use the test results to assure optimal glycemic control.

Note: Standard BGMs and preferred brand BGM supplies do not require prior authorization. However, prior authorization is required for non-preferred brand BGM supplies. For the National Drug Codes (NDCs) of preferred brand BGM supplies, refer to the DME fee schedule on the NC Medicaid website at https://medicaid.ncdhhs.gov/.

b. BGMs with an **integrated voice synthesizer** may be considered medically necessary when all the coverage criteria for a standard BGM have been met, plus these additional criteria:

The beneficiary's physician, physician assistant, or nurse practitioner documents that:

- 1. the beneficiary has a severe visual impairment; and
- 2. the beneficiary's best corrected visual acuity is 20/200 or worse.

Note: BGMs with an integrated voice synthesizer **do not** require prior authorization.

Continuous Glucose Monitoring Systems and Related Supplies

A Continuous Glucose Monitoring (CGM) system continuously measures glucose values in the interstitial fluid and consists of a glucose sensor, transmitter and receiver. Some CGM systems integrate with an insulin pump while others are designed to stand alone.

Therapeutic CGM systems are approved by the FDA for use as non-adjunctive devices to replace information obtained from standard BGMs in making diabetes treatment decisions.

Note: Therapeutic CGM systems are covered under the Pharmacy benefit. Outpatient Pharmacy prior approval criteria for therapeutic CGM systems and related supplies can be found on this webpage: https://www.nctracks.nc.gov/content/public/providers/pharmacy/pa-drugscriteria-new-format.html

Non-therapeutic CGM systems are approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from standard BGMs in making diabetes treatment decisions. Non-therapeutic CGM systems must be intermittently calibrated with fingerstick blood glucose measurements.

Note: Non-therapeutic CGMs are covered under the DME benefit (this policy).

Initial medical necessity determination: A non-therapeutic CGM system and related supplies may be considered medically necessary when criteria **one through six (1-6) below, or one and seven (1 and 7) below** are met, and a face-to-face encounter is performed. Medical necessity documentation must contain the brand and model of the CGM system provided:

- 1. the beneficiary has a diagnosis of insulin-dependent diabetes mellitus;
- 2. the beneficiary has been using a standard BGM and testing four (4) or more times daily;
- 3. the beneficiary requires two (2) or more insulin injections daily;
- 4. the beneficiary's insulin treatment regimen requires frequent adjustment based on standard BGM testing;
- 5. the beneficiary or caregiver(s) is willing and able to use the CGM system as prescribed;
- 6. the beneficiary has had a face-to-face encounter with the treating practitioner to evaluate the beneficiary's glycemic control and determine that criteria one

through five (1-5) above have been met, within six (6) months of the initiation of non-therapeutic CGM use;

7. the beneficiary uses an external insulin pump.

First medical necessity redetermination: After the first six (6) months of non-therapeutic CGM use, continuation may be considered medically necessary if:

- 1. the beneficiary has been using the CGM system as prescribed; and,
- 2. the beneficiary has been able to improve glycemic control; or,
- 3. the beneficiary continues to use an external insulin pump.

Annual medical necessity redeterminations: After the initial determination and first redetermination of medical necessity, the following criteria must be met annually:

- the beneficiary has had a face-to-face encounter with the ordering practitioner to evaluate the efficacy of the CGM system no more than three (3) months prior to the annual redetermination; and,
- 2. the beneficiary has been using the CGM system as prescribed; and,
- 3. the beneficiary has been able to maintain or further improve glycemic control; **or**,
- 4. the beneficiary continues to use an external insulin pump.

Prior authorization for non-therapeutic CGM systems and supplies is **not** required. In addition to the typical documentation requirements described in subsection **7.2**, **Record Keeping**, documentation of the medical necessity determinations outlined above must also be kept on file.

Note: The beneficiary must meet the FDA age limits and other restrictions or requirements for the specific device prescribed.

Note: Simultaneous coverage for a standard BGM and supplies, and a non-therapeutic CGM system **is** permitted.

Note: For the specific diagnosis requirements for coverage of glucose monitors and supplies, refer to **Attachment A**, **Section B: ICD-10-CM Code(s)**.

5.3.4 Phototherapy

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 Medical Supplies. To request a medical necessity review for an item not listed, see sections 1.2, 2.2 and Attachment D for instructions.

Medicaid covers Phototherapy (bilirubin) light therapy. Bilirubin light therapy is covered for the treatment of hyperbilirubinemia within the first 31 calendar days of life for a maximum of seven consecutive days. The family members or caregivers must be trained in the use of the equipment.

Prior approval is not required.

Block 24 on the CMN/PA form kept on file, must be checked, indicating that the beneficiary's status will be monitored by the physician, physician assistant, or nurse practitioner, while the equipment is provided.

Medicaid and NCHC cover Ultraviolet light therapy. Ultraviolet light therapy requires prior approval and is covered when **all** the following criteria are met:

- 1. the severity of the beneficiary's condition is such that it has **not** been significantly improved by conventional treatment;
- 2. the beneficiary has involvement over more than 20 percent of his or her body; and
- 3. a trial period of light treatment in a clinical setting has been successful.

5.3.5 Farrell Valve Enteral Gastric Pressure Relief System

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 Medical Supplies. To request a medical necessity review for an item not listed, see sections 1.2, 2.2 and Attachment D for instructions.

The Farrell valve is a vented, closed, disposable system used for gastric pressure relief with some enterally fed beneficiaries. It is used to eliminate the buildup of gastric reflux and gas in the stomach and around the outside of a feeding tube. The Farrell valve is not indicated or required for all enterally fed beneficiaries. Medicaid and NCHC shall cover the Farrell valve when all the following criteria are met:

- a. the beneficiary is receiving continuous enteral feedings via gravity or pump;
- b. there is documented evidence of disorders or complications with enteral feedings, such as gastric dysmotility, abdominal distention, aspiration pneumonia, anti-reflux surgery, gastric pseudo-obstruction, tracheoesophageal fistula, or atresia repair; and
- c. other attempted gastric decompression measures have failed.

The Farrell valve is not covered when clinical documentation demonstrates that the beneficiary is tolerating continuous enteral feedings without difficulty or complications.

Prior approval is required for the Farrell valve. Initial prior approval is for a maximum of one valve per day per beneficiary for a maximum period of six months. For additional approvals, medical necessity must be re-established for each successive six months.

The health record must contain documentation by the physician, physician assistant, or nurse practitioner substantiating the medical necessity requirement. A starting date and expected duration for the use of the Farrell valve must be reported. The medical necessity must specifically address the beneficiary's complicating factors, such as gastric dysmotility, distention, reflux, aspiration risk, excessive gastric residuals, pain, neurological impairments, and dates of any anti-reflux procedures. The inability of the beneficiary to tolerate enteral feedings without the Farrell valve must be documented.

Note: The Farrell valve is not provided under routine enteral feeding supply kits.

5.3.6 Nutrition

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 Medical Supplies. To request a medical necessity review for an item not listed, see **sections 1.2, 2.2 and Attachment D** for instructions.

Oral Nutrition Products - Metabolic Formulas

Oral Nutrition products are covered for beneficiaries' ages 0 through 20 when required to ameliorate a medical condition, prevent severe health complications, prevent worsening health outcomes, or improve clinical and functional benefits. Refer to **Subsection 2.1** for specific age eligibility for NCHC.

Metabolic Formulas are covered for beneficiaries aged 0 through 115 for in-born errors of metabolism diagnosed at birth and before the age of 10 years. Refer to **Subsection 2.1** for specific age eligibility for NCHC.

Oral nutrition products and metabolic formulas include formulas, such as Peptamen, Peptamen Jr., and PhenylAde; modular components, such as thickening agents and single nutrients (used in treatment of inborn errors of metabolism); and feeding systems, such as Pigeon feeding systems.

Some conditions that may indicate a need for oral nutrition products are: inborn errors of metabolism, such as phenylketonuria (PKU) or galactosemia; history of prematurity, very low birth weight (VLBW), or low birth weight (LBW); cystic fibrosis; human immunodeficiency virus (HIV); necrotizing enterocolitis (NEC); short bowel syndrome; cleft lip or cleft palate; central nervous system disorders resulting in dysphagia; and Crohn's disease.

Oral nutrition products are considered medically necessary when **all** the following conditions are met:

- a. There is a documented diagnosis in which caloric or dietary nutrients cannot be safely or adequately consumed, absorbed, or metabolized; and
- b. The oral nutrition product is an integral component of a documented medical treatment plan and is ordered in writing by the treating physician, physician's assistant, or nurse practitioner.

Medical necessity of the oral nutrition product is substantiated by documented physical findings, and laboratory data if available, that demonstrate malnutrition or risk of nutritional depletion.

Requirements for coverage

- a. A beneficiary shall be under the care of the ordering physician, physician's assistant, or nurse practitioner who develops a medical treatment plan that incorporates oral nutrition products.
- b. The prescriber may order a nutritional assessment to aid if it aids in the development of a comprehensive oral nutrition therapy plan.
- c. If a nutritional assessment is ordered, it must be conducted by a licensed dietitian/nutritionist (LDN) or registered dietitian (RD).
- d. The prescriber may order a feeding or swallowing evaluation performed by a licensed therapist (SLP-CCC or OTR/L).

The above-mentioned assessments must be maintained within the health record as supporting documentation to substantiate medical necessity.

Medical necessity of oral nutrition product use must be re-established at specific intervals:

- a. For beneficiaries with a diagnosed inborn error of metabolism, the provider shall complete and keep on file a new CMN/PA form every 12 months.
- b. For beneficiaries with other medical conditions necessitating oral nutrition supplementation, the provider shall complete and keep on file a new CMN/PA form every six months with documentation supporting the effectiveness of the oral nutrition supplementation.
- c. For beneficiaries receiving modular components and feeding devices, the provider shall submit a new CMN/PA form at either the 6-month or 12-month interval, depending on the approved certification period.

Note: Oral nutrition products are not covered when medical necessity is not established, or when they are used as convenient food substitutes.

Note: Oral nutrition products must be billed using a second modifier. Refer to **Attachment A, Section D: Modifiers** for information about the correct modifier to use.

Enteral Nutrition

Enteral nutrition (EN) refers to the medical equipment, supplies, formulae or solutions ordered by a physician, physician assistant, or nurse practitioner, and provided according to standards of practice. The allowance for all items includes delivery to the beneficiary.

Enteral nutrition includes the following equipment, supplies, formulae or solutions:

a. Medical equipment includes the pump used for EN and the IV pole. The equipment is rented if the physician, physician assistant, or nurse practitioner documents that the anticipated need is six months or less. The equipment may be rented or purchased if the physician, physician assistant, or nurse practitioner documents that the anticipated need exceeds six months. Once rental is initiated on an item, a subsequent request for purchase of that item is denied. The item becomes the property of the beneficiary when the accrued rental payments reach the Medicaid or NCHC allowable purchase price.

For home infusion therapy nutrition, refer to Clinical Coverage Policy 3H-1, *Home Infusion Therapy*, on NC Medicaid's website: <u>https://medicaid.ncdhhs.gov/</u>.

For EN to be covered the beneficiary shall be under the care of the referring physician, physician assistant, or nurse practitioner, who prescribes EN therapy, establishes a plan of care for EN, and monitors the therapy's progress.

A beneficiary shall meet **all** the following criteria:

- a. Require infusion therapy on an ongoing basis that is medically indicated for the treatment of his or her condition;
- b. Have a clinical status that allows EN to be safely administered in his or her environment;
- c. Be unable to tolerate nutrients orally sufficient to maintain life. The beneficiary is either unable to take oral nutrition or unable to tolerate oral intake. EN is considered reasonable and necessary for a beneficiary with a functioning gastrointestinal tract who, due to non-function of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Some conditions that may indicate the need for EN include dysphagia or aphagia due to a cerebrovascular accident, a comatose condition, myasthenia gravis causing inability to swallow due to paralysis of the structure that permits swallowing, or a brain tumor with neurological deficit resulting in the lack of a gag reflex;
- d. Understand the purpose and need for the therapy, accepts the associated requirements, and wants to pursue the treatment. When the beneficiary is unable to comprehend all that is involved, there must be a primary caregiver responsible for the beneficiary and acting in the beneficiary's behalf to meet this requirement;
- e. Be in an environment conducive to the provision of EN—that is, a clean environment with electricity, water, telephone access, refrigeration, and enough space to support EN;
- f. Be capable of self-administering EN or have a primary caregiver who is adequately trained, capable, and willing to administer EN safely and effectively; and
- g. Be psychologically stable—the prospect of adhering to a disciplined medical regimen and coping with infusion therapy is realistic.

Infusion Pumps

Enteral and parenteral nutrition infusion pumps are covered by Medicaid and NCHC when a beneficiary requires medically necessary covered enteral and parenteral nutrition.

In-line Digestive Enzyme Cartridges

In-line digestive enzyme cartridges, such as Relizorb, may be considered medically necessary when all the following criteria are met:

- a. <u>Beneficiary is at least five years of age;</u>
- b. Beneficiary has a diagnosis of exocrine pancreatic insufficiency (EPI); and
- <u>Beneficiary meets the criteria for enteral nutrition as documented in this</u> policy.

Note: If the above medical necessity criteria are met, then prior authorization is not required.

5.3.7 Automatic External Defibrillator, With Integrated Electrocardiogram Analysis, Garment Type (also known as wearable cardioverter defibrillator)

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 Medical Supplies. To request a medical necessity review for an item not listed, see **Subsections 1.2**, **2.2 and Attachment D** for instructions.

A wearable cardioverter defibrillator (WCD) is an external device (vest-like garment) that contains the following components:

- a. cardiac monitor;
- b. electrodes;
- c. alarm system; and
- d. cardioverter-defibrillator.

The WCD monitors cardiac (heart) rhythm and delivers an electrical shock if a life-threatening ventricular arrhythmia is detected. The WCD is worn continuously, 24 hours per day.

A WCD requires prior approval and is considered medically necessary and covered for a beneficiary who is at risk for sudden cardiac death, is not a suitable candidate for immediate internal cardiac defibrillator (ICD); and meets **any one** of the following criteria:

- a. A documented episode of ventricular fibrillation or sustained run of ventricular tachycardia lasting 30 seconds or longer. These dysrhythmias may either be spontaneous or induced during an electrophysiologic (EP) study, but may not be due to a transient or reversible cause and not occurring during the first 48 hours of an acute myocardial infarction;
- b. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhthymias such as long QT syndrome, hypertrophic cardiomyopathy;
- c. Either a documented prior myocardial infarction or a dilated cardiomyopathy and measured left ventricular ejection fraction less than or equal to 35 percent;
- d. Documentation of a previously implanted defibrillator that due to infection, injury or illness requires a waiting period before ICD reinsertion; **or**
- e. Documentation of an infection or other temporary medical condition that prevents the initial implantation of an ICD.

The FDA has **not** approved use of the WCD for the indications listed below. Therefore, the WCD is **not medically necessary and not covered** for a beneficiary who meets **any one** of the following:

- a. Meets the criteria for an ICD or already has an ICD implanted and operating;
- b. Has a vision or hearing problem that may interfere with reading or hearing the WCD messages;
- c. Is taking medication that would interfere with pushing the response buttons on the WCD alarm module;
- d. Is unwilling or unable to wear the device continuously, except when bathing or showering;

- e. Is pregnant or breast feeding;
- f. Is of childbearing age and not attempting to prevent pregnancy; or
- g. Is exposed to excessive electromagnetic interference (EMI) from machinery, such as powerful electric motors, radio transmitters, power lines or electronic security scanners, EMI can prevent the WCD from detecting an abnormal heart rhythm.

Note: The WCD must be ordered by a physician who is experienced in management of a beneficiary at risk for sudden cardiac death, agrees to closely monitor the beneficiary during the coverage period, and is willing to obtain documentation of beneficiary's compliance with the WCD.

Note: The beneficiary shall meet the FDA and manufacturer's requirements for the specific device prescribed, including but not limited to age, weight and chest circumference.

Note: WCD is for rental only and the initial prior approval is given for a time period of three months when the beneficiary meets all medical necessity and coverage criteria.

5.3.8 Incontinence, Ostomy, and Urinary Catheter 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 Medical Supplies. To request a medical necessity review for an item not listed, see Subsections 1.2, 2.2 and Attachment D for instructions.

Medicaid and NCHC shall reimburse medical equipment providers for the provision of incontinence, ostomy and urinary catheter supplies to beneficiaries only when they are medically necessary due to a disease, illness or injury. The supplies must be prescribed by a physician, physician assistant, or nurse practitioner, and the amount delivered must be supported by the beneficiary's actual medical needs. Medical equipment providers shall obtain the written, signed, and dated prescription for the supplies prior to submitting their claim for reimbursement. If the provider submits a claim for reimbursement before obtaining the completed prescription, the supplies are considered not medically necessary. Claims paid for supplies issued before the date of the prescription are subject to recoupment.

The prescription must document the type(s) of supplies ordered and the quantity to be used for a specified time (such as per month). All requests for specialty supplies (such as silicone catheter instead of regular latex catheters) must have medical necessity documentation from the physician, physician assistant, or nurse practitioner stating the medical necessity for the specialty supply.

Incontinence supplies (such as diapers) are only covered for beneficiaries three years of age and older who are incontinent due to disease, illness or injury.

Incontinence supplies must comply with industry-wide quality standards for rate acquisition, rewet and capacity.

Prior approval is not required for incontinence, ostomy, and urinary catheter supplies; however, the medical equipment provider shall have on file a CMN/PA form (completed and signed by the provider as well as the physician, physician assistant, or nurse practitioner,) which is valid for no more than 12 consecutive months. If the need for the supplies continues beyond 12 consecutive months from the date of the last signed CMN/PA form, a new completed and signed CMN/PA form must be obtained and kept on file. The DME provider shall obtain the signed CMN/PA form before billing for the supplies.

These quantity limitations do not reflect minimum quantities to which the beneficiary is entitled. These limitations are the maximum quantities allowed for the beneficiary. The quantities billed must be the quantities that are documented as medically necessary to meet the beneficiary's needs and the quantity prescribed by the physician, physician assistant, or nurse practitioner. The medical equipment provider shall make every effort, in coordination with the beneficiary or their caregiver (such as the Adult Care Home staff), to ensure the quantity of supplies ordered each month remains medically necessary, prior to providing them. This is necessary to eliminate stockpiling of excessive supplies, waste, abuse and the excess cost of unused supplies. Claims that have been paid for supplies that have been stockpiled, wasted or abused are subject to recoupment by Medicaid or NCHC.

Note: Pre-moistened incontinence wipes must not be billed using A4335 or any other HCPCS code without prior authorization based on EPSDT guidelines or, for beneficiaries over age 21, the procedure outlined in Attachment D: Requesting Unlisted DME and Medical Supplies for Adults. NC Medicaid's Program Integrity Unit and its authorized agents continue to monitor DME provider billing of A4335 for pre-moistened incontinence wipes to ensure compliance with this policy. Any future review revealing non-compliance with Medicaid regulation, rule, and policy may be subject to recoupment.

Note: Home health agencies shall provide supplies to beneficiaries receiving other home health services. Please refer to Clinical Coverage Policy 3A, *Home Health Services*, on NC Medicaid's website: <u>https://medicaid.ncdhhs.gov/</u>.

5.3.9 Manual Pump-Operated Enema System

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 Medical Supplies. To request a medical necessity review for an item not listed, refer to Subsections **1.2**, **2.2 and Attachment D** for instructions.

A manual pump-operated enema system, such as the Peristeen® Anal Irrigation System, may be considered medically necessary when all the following coverage criteria are met:

- a. Beneficiary has a diagnosis of neurogenic bowel dysfunction. Refer to Attachment A, Section B for the required ICD-10 diagnosis code;
- b. Beneficiary is two years of age and older;
- c. Beneficiary suffers from fecal incontinence, chronic constipation, and timeconsuming bowel management procedures; and

d. Initial management involving diet, bowel habit, laxatives, or constipating medication has failed.

Note: If the above medical necessity criteria are met, then prior authorization is not required.

5.3.10 <u>Electric Breast Pumps</u>

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 Medical Supplies. To request a medical necessity review for an item not listed, refer to Subsections 1.2, 2.2 and Attachment D for instructions.

A breast pump is a device used to extract milk from the breast of a lactating mother for infant feeding when the mother cannot be present at feeding time or when the infant is too sick or too weak to suckle.

An electric breast pump requires prior authorization and is considered medically necessary when one of the following criteria is met:

- a. <u>During the time when a newborn is detained in the hospital after the mother</u> is discharged; or
- b. <u>The newborn has a congenital anomaly that interferes with feeding (such as</u> cleft palate, neuromuscular disease or congenital heart defect); or
- c. <u>A medical condition that causes low milk production is present (such as prematurity, thyroid conditions, polycystic ovarian syndrome, diabetes, or obesity).</u>

Note: If a rental hospital grade breast pump is medically necessary, then the PA may be limited to one (1) month at a time.

5.3.11 Miscellaneous Durable Medical Equipment and Medical 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 Medical Supplies. To request a medical necessity review for an item not listed, see **Subsections 1.2**, **2.2** and **Attachment D** for instructions.

An **IV pole** is covered when a beneficiary receives either parenteral or enteral fluids.

Sterile and non-sterile gloves may be considered medically necessary when used with covered Durable Medical Equipment and Medical Supplies by the beneficiary or to protect the beneficiary from infection. Gloves used by an outside agency for the caregiver's protection, are considered the agency's overhead cost and must not be billed to Medicaid.

An **ambulatory infusion pump** is covered when a beneficiary requires covered IV medications.

Automatic blood pressure (BP) monitors may be considered medically necessary for beneficiaries who are required by their medical provider to independently monitor and report their blood pressure from home due to

conditions such as hypertension, hypotension, renal failure, or complications of pregnancy.

A **floor scale**, regular capacity or extra capacity, may be considered medically necessary for beneficiaries who are required by their medical provider to independently monitor and report their body weight from home due to conditions such as heart failure, renal failure, or complications of pregnancy.

Covered **wound care supplies** may be considered medically necessary for a beneficiary who is required by their medical provider to independently perform dressing changes at home, due to conditions such as the presence of an open wound, surgical site or ventricular assist device driveline site.

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

5.3.12 Provision of DME and Medical 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 **Subsection 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 NC 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 Medical Supplies. To request a medical necessity review for an item not listed, see **Subsections 1.2, 2.2 and Attachment D** for instructions.

5.5 Durable Medical Equipment and Medical Supplies Limitations

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

A PA request for an override of a quantity limit, or lifetime expectancy must contain 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 Medical Supplies. To request a medical necessity review for an item not listed, see Subsections 1.2, 2.2 and Attachment D for instructions.

5.5.1 Diabetic Supply Override Process

An override process is available for beneficiaries who are not able to obtain reliable results with diabetic supplies from the designated preferred manufacturer's product(s). The provider furnishing the product for this beneficiary shall be a medical equipment provider.

The provider shall comply with **Subsection 5.5** above. A request for an override may be considered if the beneficiary meets **one** of the following:

- a. The designated preferred manufacturer's glucose meter is incompatible with the beneficiary's current insulin pump; **or**
- b. The beneficiary has diabetes mellitus and is now being referred by his or her healthcare provider because of the ongoing inability to obtain reliable results that cannot be resolved with user education.

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 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 and NCHC. 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

Provider(s) 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.

5.7.2 Monitoring Enteral Nutrition (EN)

The provider and the physician, physician assistant, or nurse practitioner, shall ensure sufficient monitoring to protect a beneficiary's health and well-being. The Physician, physician assistant, or nurse practitioner orders any other service, such as Home Health skilled nursing visits, that are needed for the beneficiary.

The provider's responsibilities for monitoring EN include the following:

- a. Supplies, equipment, and formulae must be provided according to orders from the physician, physician assistant, or nurse practitioner. Problems must be resolved immediately without delay. Defective equipment must be repaired or replaced so that there is no lapse in treatment.
- b. The beneficiary's physician, physician assistant, or nurse practitioner shall be notified when the ordered services do not appear appropriate, there are problems with their provision, or there are concerns about administration.

Note: Medicaid and NCHC do not cover infusion nursing services for EN. When RN monitoring is needed, refer the beneficiary to Home Health Services. The provider may not bill Medicaid or NCHC for RN monitoring.

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 or NCHC.

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 or NCHC 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 or NCHC reimbursed parts or for freight or the provider's travel time or expenses. All the following information must be entered in block 25 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: Provider(s) shall have emergency repair service available 24-hours a day, seven days a week for any life-sustaining equipment they provide.

Note: Medicaid and NCHC shall not cover maintenance or service contracts.

5.9 Replacing Medical Equipment

Medicaid or NCHC may consider replacing the item, when repairing is no longer costeffective 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 his 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 Rental Items Other than Oxygen Equipment

The new provider shall obtain a new completed and signed CMN/PA form and a pick-up slip from the former provider. Failure to provide a pick-up ticket to the new provider within 30 calendar days may result in investigation and possible recoupment of funds from the previous provider. If the item needs prior approval, the new provider sends the CMN/PA form to the address listed on the form. A new prior approval number is issued for the item and assigned to the new supplier.

Note: The allowable rental period on capped rental items carries over from the old to new supplier. The new supplier is able to get rental payments for only the balance of the rental period before the item becomes the property of the beneficiary.

5.11 Terminating Rentals

The beneficiary, physician, physician assistant, or nurse practitioner, the supplier, Medicaid, or NCHC may terminate the rental of an item during the rental period. If the rental is terminated, provider(s) may reclaim the equipment from the beneficiary within 30 calendar days.

Note: Medical equipment rented under the "capped rental" rules become the beneficiary's property when the total rental payments reach the Medicaid or NCHC-allowable new purchase price for the item. Provider(s) may not 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 or NCHC qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 **Provider Qualifications**

Provider(s) shall be enrolled with Medicaid as a Durable Medical Equipment and Supplies provider and meet the following conditions to qualify for participation with Medicaid and NCHC as a provider.

- a. Provider(s) shall not accept prescriptions for Medicaid or NCHC covered equipment from any physician, physician assistant, or nurse practitioner, who has an ownership interest in their agency.
- b. Provider(s) shall be enrolled and participate in Medicare as a medical equipment supplier. When the beneficiary is insured under NC Health Choice, the NCHC provider is exempt from the requirement to be enrolled and participate in Medicare.
- 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 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 provider(s) more than 40 miles outside of the North Carolina border may enroll with NC Medicaid when the medically necessary product they supply or manufacture is not reasonably available through an enrolled provider located within 40 miles of the North Carolina border.
- e. Refer to <u>https://www.ncbop.org</u> under the topic *DME Suppliers and Pharmacy Law/Rules* for other rules that may apply to Durable Medical Equipment and Supplies providers.
- f. Provider(s) 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 must 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: Provider(s) 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 Federal Laws

Provider(s) shall comply with the following requirements in addition to the laws specifically pertaining to Medicaid and NCHC:

- a. **Title VI of the Civil Rights Act of 1964,** which states that "no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation under any program or activity receiving federal financial assistance."
- b. Section 504 of the Rehabilitation Act of 1973, as amended, which states that "no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance."

c. The Americans with Disabilities Act of 1990, which prohibits exclusion from participation in or denial of services because the agency's facilities are not accessible to individuals with a disability.

6.3 Seeking Other Sources of Payment

Medicaid provider(s) 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, provider(s) shall bill the third party before billing Medicaid. NC Health Choice is the sole insurer and sole payer. NC Health Choice providers are exempt from identifying and billing third party payers.

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

6.4 Accepting Payment

Providers shall accept payment in full.

Providers billing Medicaid beneficiaries shall comply with North Carolina Administrative Code *10A NCAC 22J.0106*.

6.5 Disclosing Ownership Information

Provider(s) 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 or NCHC, 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 NC 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(s) shall furnish any information that the U.S. Department of Health and Human Services and its designated contractor(s), NC Medicaid and its designated contractor(s), or the State Medicaid Fraud Investigation Unit regarding payments received for providing Medicaid or NCHC services.

Provider(s) 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 or NCHC status, must 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.

DRAFT 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.

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Date	Section Revised	Change
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.

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Date	Section Revised	Change	
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.	

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Date	Section Revised	Change
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 E220; 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 E2212; 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.

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Date	Section Revised	Change	
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	

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Date	Section Revised	Change		
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 per month to 10 per month		

		Amended Date:	
Data	Section Derriged	DRAFT	
Date	Section Revised	Change	
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©	Attachment E relocated information to Attachment A©	
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.	

DRAFT Amended Date:			
Date	Section Revised	Change	
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	
11/01/2016	Subsection 5.3.9	Specified Facilities was updated. Mirror Medicare oxygen recertification policy (Effective	
11/01/2016	Subsection 5.3.11	04/25/2016 per the April 2016 Medicaid Special Bulletin) 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 polic language.	
07/01/2017	Subsections 1.1, 1.2, 3.2.1, 5.3.3, 5.3.6, 5.3.7, 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 E	Added Attachment E: Requesting Unlisted DME and Supplies for Adults.	

DRAFT			
Date	Section Revised	Change	
12/01/2017	Attachment A,	HCPCS code T4544 added to code list as it was inadvertently	
	Section C:	left out during a previous update.	
	Procedure Code(s)		
06/15/2018	Attachment A,	HCPCS code K0606 added to code list as it was inadvertently	
	Section C:	left out during a previous update. Policy posted on	
	Procedure Code(s)	06/15/2018, but no change to Amended Date.	
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	Updated policy template language.	
	Attachments		
10/01/2019	Subsection 1.2	Updated to instruct providers to submit PA requests for	
		unlisted items through NCTracks instead of directly to NC	
		Medicaid clinical policy.	
10/01/2019	Subsection 5.3.2	Eliminated requirement for manufacturer's documentation	
		when submitting PA requests to replace non-functional	
		external insulin infusion pumps.	
10/01/2019	Subsection 5.3.3	Language was updated for clarity, and physician assistants and	
		nurse practitioners were added as allowable treating	
		practitioners.	
10/01/2019	Subsection 5.3.3	This note was added:	
		Note: Standard BGMs and preferred brand BGM supplies do	
		not require prior authorization. However, prior authorization is	
		required for non-preferred brand BGM supplies. For the	
		National Drug Codes (NDCs) of preferred brand BGM	
		supplies, refer to the DME fee schedule on the NC Medicaid	
		website at https://medicaid.ncdhhs.gov/.	
10/01/2019	Subsection 5.3.6	Deleted language requiring an Oral Nutrition Product Request	
		Form be submitted with PA requests for oral nutrition	
		products.	
		Renumbered from 5.3.7 to 5.3.6.	
10/01/2019	Subsection 5.3.8	Added language to indicate that pre-moistened incontinence	
		wipes must not be billed using A4335 or any other HCPCS	
		code without prior authorization based on EPSDT guidelines	
		or, for recipients over age 21, the procedure outlined in	
		Attachment D: Requesting Unlisted DME and Medical	
		Supplies for Adults.	
		Renumbered from 5.3.9 to 5.3.8.	
10/01/2019	Subsection 5.3.9	Updated language to clarify medical necessity for utilization	
		of sterile and non-sterile gloves.	
		Renumbered from 5.3.6 to 5.3.9.	
10/01/2019	Section 5.5	Updated instructions for requesting overrides of quantity or	
		lifetime expectancy limits.	
10/01/2019	Section 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.	

DRAFT Amended Date:				
Data				
10/01/2019	Section 6.4	Change Added language reminding providers billing Medicaid		
10/01/2019	Section 0.4	beneficiaries that they must comply with North Carolina		
		Administrative Code 10A NCAC 22J .0106.		
10/01/2019	Attachment A,	HCPCS codes E0776 (IV pole), A4435 (ostomy pouch,		
10/01/2019	Section C:	drainable, high output) and local code W4047 (miscellaneous		
	Procedure Code(s)	for DME) were added back to code list as they were		
		inadvertently left out during a previous update.		
10/01/2019	Attachment A,	Lifetime expectancies updated for HCPCS codes A9277 and		
	Section C	A9278.		
		Monthly allowable quantity for A9276 changed from 30-day		
		supply to 31-day supply per calendar month.		
		Quantity limits added for HCPCS codes A4927 and A4930.		
		Coverage added for HCPCS code A7048.		
		Corrected clerical error in quantity limits for T4543 and		
		T4544.		
10/01/2019	Attachment C	Attachment C: Oral Nutrition Product Request Form became		
10/01/0010		outdated and was deleted.		
10/01/2019	Attachment D	Attachment D: Completing a Claim for DME or EN Services		
10/01/2010		was re-lettered to Attachment C.		
10/01/2019	Attachment E	Attachment E: 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, and was re-lettered to		
		Attachment D.		
01/10/2020	Table of Contents	Updated policy template language, "To all beneficiaries		
01/10/2020		enrolled in a Prepaid Health Plan (PHP): for questions about		
		benefits and services available on or after implementation,		
		please contact your PHP."		
01/10/2020	Attachment A	Added, "Unless directed otherwise, Institutional Claims must		
		be billed according to the National Uniform Billing		
		Guidelines. All claims must comply with National Coding		
		Guidelines".		
10/15/2020	Subsection 5.3.3	Removed prior authorization requirement for blood glucose		
		monitors with an integrated voice synthesizer.		
		Removed 0-20 age limit for continuous glucose monitoring		
		(CGM) systems, updated medical necessity criteria, and		
		removed prior authorization requirement.		
		Added language indicating therapeutic CGM systems are		
		covered under the Pharmacy benefit and non-therapeutic CGM		
		systems are covered under the DME benefit.		

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Date	Section Revised	Change	
10/15/2020	Subsection 5.3.7	Removed criterion requiring users of wearable cardioverter defibrillators be 18 years of age or older. The prescriber for WCDs was changed from cardiologist to physician. Added Note: The beneficiary must meet the FDA and manufacturer's requirements for the specific device prescribed, including but not limited to age, weight and chest circumference. Clarified that the initial prior approval is for a time period of	
10/15/2020	Subsection 5.3.9	three months. Added medical necessity criteria for automatic blood pressure monitors and floor scales.	
10/15/2020	Attachment A, Section C	Removed age limit from HCPCS code K0606 and added "N/A (Rental only)". Added "Rental Only" to lifetime expectancies of HCPCS codes E0691, E0692 and E0781. Updated quantity limitation for HCPCS code A4244 (Alcohol or peroxide, per pint) from 100 per month to 4 pints per month. Updated quantity limitation for HCPCS code A4217 (Sterile water/saline, 500 ml) from 300 per month to 100 per month. Updated language for quantity limit description for HCPCS code A4252, from "100 per calendar month" to "100 test strips per calendar month". Updated language for quantity limit for HCPCS code A9999, from "1 per day" to "31 per month." Updated language for quantity limit for HCPCS code A4456, from "1 box of 50 per month" to "50 wipes per month." Coverage and lifetime expectancies added for HCPCS codes A4670 and E1639.	
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-1, Physical Rehabilitation Equipment and Supplies, 5A-2, Respiratory Equipment and Supplies, 5B, Orthotics and Prosthetics and 11C, Ventricular Assist Devices	
05/01/2021	Subsection 5.3.6	Language updated for clarity.	
05/01/2021	Subsection 5.3.9	Added medical necessity criteria for wound care supplies.	
05/01/2021	Attachment A, Section C	Coverage and quantity limits were added for HCPCS codes A4245, A4247, A4248, A4333, A6207, A6228, A6259 and A6402.	
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	
05/15/2022	Throughout	Updated "CMN/PA" to "CMN/PA form."	

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Date	Section Revised	Change	
05/15/2022	Subsection 5.3.4	Removed prior authorization requirement for HCPCS code E0202 (Phototherapy (bilirubin) light with photometer). Updated 30 calendar days to 31 calendar days. Revision is effective 11/1/2021.	
05/15/2022	Subsection 5.3.9 Attachment A, Section C	Clinical criteria, coverage and quantity limits were added for Manual Pump-operated Enema Systems, HCPCS codes A4453 and A4459. Revision is effective 10/1/2021.	
05/15/2022	Attachment A, Section C	Effective 12/31/2021, HCPCS code A4397 was end dated. Effective 1/1/2022, HCPCS codes A4436 and A4437 replaced A4397.	
05/15/2022	Attachment B	Removed the asterisk (*) indicating that an item requires prior approval, as this information can be found in the DME Fee Schedule. Removed note stating that BOLD indicates Medicare is primary payer for an item.	
05/15/2022	Attachment C	Removed NCHC from block 1, as this is not a valid selection on the CMS-1500 form. Removed the extraneous word "reported".	
05/15/2022	Attachment A, Section B	Added K59.2 (neurogenic bowel, not elsewhere classified) as the required ICD-10 diagnosis code for a Manual Pump- operated Enema System.	
05/15/2022	Attachment A, Section C	Updated language for quantity limit for HCPCS codes A4450 and A4452 from "80 units" to "80 units per month".	
	Subsections 5.1 and 5.3.11 Subsection 5.3.6	Updated the phrase "Items that require prior approval are identified on the Durable Medical Equipment Fee Schedule by an asterisk (*)" to "Items that require prior approval are identified on the Durable Medical Equipment Fee Schedule". Added medical necessity criteria for in-line digestive enzyme	
		cartridges.	
	Subsection 5.3.10Attachment A,Section B	Added medical necessity criteria for electric breast pumps. Added K86.81 (exocrine pancreatic insufficiency) as the required ICD-10 diagnosis code for in-line digestive enzyme cartridges.	
	Attachment A. Section C	Coverage and quantity limits were added for HCPCS codes, A4281, A4282, A4283, A4284, A4285, A4286, A4315, A4434, A5081, A5082, A5083, A5112, B4105, E0603, E0604, K1005, A4238 and E2102. Updated "over" to "older." Revised the descriptions for HCPCS codes A9276, A9277 and A9278.	

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Date	Section Revised	Change		
	<u>Attachment A,</u> <u>Section C</u>	Updated quantity limitation for HCPCS codes A5056 (Ostomy pouch, drainable, with extended wear barrier attached, with filter, (one piece), each) and A5057 (Ostomy pouch, drainable, with extended wear barrier attached, with built in convexity, with filter, (one piece), each) from 20 per month to 40 per month. Updated quantity limitation for HCPCS code A4371 (Ostomy skin barrier, powder, per oz.) from 2 oz. per month to 10 oz. per month.		
	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.		

Attachment A: Claims-Related Information

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

A. Claim Type

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)				
Blood Glucose Mor	nitor <u>s</u> and Related	Supplies and Extern	al Insulin Pump <u>s</u>		
E10.10	E10.618	E11.359	E13.01	E13.610	
E10.11	E10.620	E11.36	E13.10	E13.618	
E10.21	E10.621	E11.39	E13.11	E13.620	
E10.22	E10.622	E11.40	E13.21	E13.621	
E10.29	E10.628	E11.41	E13.22	E13.622	
E10.311	E10.630	E11.42	E13.29	E13.628	
E10.319	E10.638	E11.43	E13.311	E13.630	
E10.321	E10.641	E11.44	E13.319	E13.638	
E10.329	E10.649	E11.49	E13.321	E13.641	
E10.331	E10.65	E11.51	E13.329	E13.649	
E10.339	E10.69	E11.52	E13.331	E13.65	
E10.341	E10.8	E11.59	E13.339	E13.69	
E10.349	E10.9	E11.610	E13.341	E13.8	
E10.351	E11.00	E11.618	E13.349	E13.9	
E10.359	E11.01	E11.620	E13.351	E74.00	
E10.36	E11.21	E11.621	E13.359	E74.01	
E10.39	E11.22	E11.622	E13.36	E74.02	
E10.40	E11.29	E11.628	E13.39	E74.03	
E10.41	E11.311	E11.630	E13.40	E74.04	
E10.42	E11.319	E11.638	E13.41	E74.09	
E10.43	E11.321	E11.641	E13.42	O24.410	
E10.44	E11.329	E11.649	E13.43	O24.414	
E10.49	E11.331	E11.65	E13.44	O24.419	
E10.51	E11.339	E11.69	E13.49	O24.911	
E10.52	E11.341	E11.8	E13.51	O24.912	
E10.59	E11.349	E11.9	E13.52	O24.913	
E10.610	E11.351	E13.00	E13.59	O24.919	
				O99.810	

DRAFT ICD-10-CM Code(s)

Manual Pump-Operated Enema System

K59.2

ICD-10-CM Code(s)

In-line Digestive Enzyme Cartridges K86.81

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 NC Medicaid's website: <u>https://medicaid.ncdhhs.gov/</u>. To request a medical necessity review for an item not listed, see **sections 1.2, 2.2 and Attachment D** for instructions.

HCPCS Code	Item Description	Lifetime Expectancy or Quantity Limitation
	Negative Pressure Wound Therapy	
E2402	Negative pressure wound therapy electrical pump, stationary or portable	N/A (Rental only)
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories	15 per month

Lifetime Expectancies and Quantity Limitations for Durable Medical Equipment and Supplies

HCPCS	Item Description	Lifetime Expectancy or
Code		Quantity Limitation
	External Insulin Infusion Pump	
E0784	External ambulatory infusion pump, insulin	5 years
A4230	Infusion set for external insulin pump, non-needle cannula type	16 per month
A4231	Infusion set for external insulin pump, needle type	16 per month
A6257	Transparent film, sterile, 16 sq. in. or less, each dressing	16 per month
A6258	Transparent film, sterile, more than 16 sq. in. but less than or equal to 48 sq. in., each dressing	16 per month
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories	16 per month
K0552	Supplies for external drug infusion pump, syringe type cartridge, sterile, each	16 per month
K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each	18 per year

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Amended Date:			
HCPCS	DRAFT	I fetting Francester or or	
Code	Item Description	Lifetime Expectancy or Quantity Limitation	
K0602	Replacement battery for external infusion pump owned by patient, silver oxide, 3 volt, each	18 per year	
K0603	Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each	18 per year	
K0604	Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each	18 per year	
K0605	Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each	18 per year	
	External Defibrillator		
K0606	Automatic external defibrillator, with integrated electrocardiogram	N/A (Rental only)	
	analysis, garment type		
	Glucose Monitors and Supplies		
E0607	Home blood glucose monitor	2 years	
E2100	Blood glucose monitor with integrated voice synthesizer	3 years	
A4215	Needle, sterile, any size, each	200 per month	
A4233	Replacement battery, alkaline (other than J cell), for use with medically necessary home blood glucose monitor owned by patient, each	8 per year	
A4234	Replacement battery, alkaline, J cell, for use with medically necessary home blood glucose monitor owned by patient, each	8 per year	
A4235	Replacement battery, lithium, for use with medically necessary home blood glucose monitor owned by patient, each	8 per year	
A4236			
<u>A4238</u>	Supply allowance for adjunctive continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service	<u>l per month</u>	
A4244	Alcohol or peroxide, per pint	4 pints per month	
A4250	Urine test or reagent strips or tablets (100 tablets or strips)	1 per month	
A4252	Blood Ketone test or reagent strip, each	100 test strips per calenda month	
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips	6 per month ages 0-20 4 per month age 21 and over older	
A4256	Normal, low and high calibrator solution/chips	4 per year	
A4258	Spring-powered device for lancet, each	2 per year	
A4259	Lancets, per box of 100	2 per month	
A9276	Sensor; invasive (e.g. subcutaneous), disposable, for use with <u>non-durable</u> <u>medical equipment</u> interstitial continuous glucose monitoring system, one unit = 1 day supply	Allow a 31-day supply pe calendar month	
A9277	Transmitter; external, for use with <u>non-durable medical equipment</u> interstitial continuous glucose monitoring system	Per manufacturer's warranty	
A9278	Receiver (monitor); external, for use with <u>non-durable medical equipment</u> interstitial continuous glucose monitoring system	Per manufacturer's warranty	
<u>E2102</u>	Adjunctive continuous glucose monitor or receiver	Per manufacturer's warranty	
S5560	Insulin delivery device, reusable pen; 1.5 ml size	3 years	
S5561	Insulin delivery device, reusable pen; 3 ml size	3 years	
S8490	Insulin syringes (100 syringes, any size)	2 per month	
	Phototherapy		
E0202	Phototherapy (bilirubin) light with photometer	7 days max. Ages birth to 1 month on	

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HCPCS	DRAFT	I fotime Free ester or or	
Code	Item Description	Lifetime Expectancy or Quantity Limitation	
E0691	Ultraviolet light therapy system, includes bulbs/lamps, timer, and eye protection; treatment area 2 square feet or less	N/A (Rental only)	
E0692	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 4-foot panel	N/A (Rental only)	
	Farrell Valve		
A9999	Miscellaneous DME supply or accessory, not otherwise specified (For use with Farrell Valve only)	31 per month	
T 0 6 0 0	Electric Breast Pumps		
<u>E0603</u>	Breast pump, electric (ac and/or dc), any type	1 per pregnancy	
E0604	Breast pump, hospital grade, electric (ac and / or dc), any type	<u>N/A (Rental only)</u>	
<u>A4281</u>	Tubing for breast pump, replacement	<u>2 per year</u>	
<u>A4282</u>	Adapter for breast pump, replacement	<u>2 per year</u>	
<u>A4283</u>	Cap for breast pump bottle, replacement	<u>2 per year</u>	
<u>A4284</u>	Breast shield and splash protector for use with breast pump, replacement	<u>2 per year</u>	
<u>A4285</u>	Polycarbonate bottle for use with breast pump, replacement	<u>2 per year</u>	
<u>A4286</u>	Locking ring for breast pump, replacement	<u>2 per year</u>	
<u>K1005</u>	Disposable collection and storage bag for breast milk, any size, any type, each	200 per month	
	Miscellaneous Durable Medical Equipment and Supplies		
A4927	Gloves, non-sterile, per 100	4 boxes/month	
A4930	Gloves, sterile, per pair	75 pair/month	
E0781	Ambulatory infusion pump, single or multiple channels electric or battery operated with administrative equipment, worn by patient	N/A (Rental only)	
A4213	Syringe, sterile, 20cc or greater, each	50 per month	
A4217	Sterile water/saline, 500 ml	100 per month	
A4245	Alcohol wipes, per box	1 box per month	
A4246	Betadine or pHisoHex solution, per pint	10 per month	
A4247	Betadine or iodine swabs/wipes, per box	1 box per month	
A4248	Chlorhexidine containing antiseptic, 1 ml	80 per month	
A4333	Urinary catheter anchoring device, adhesive skin attachment, each	10 per month	
A4456	Adhesive remover, wipes, any type, each	50 wipes per month	
A6207	Contact layer, sterile, more than 16 sq. in but less than or equal to 48 sq. in., each dressing	36 per month	
A6228	Gauze, impregnated, water or normal saline, sterile, pad size 16 sq. in. or less, without adhesive border, each dressing	75 per month	
A6259	Transparent film, sterile, more than 48 sq. in., each dressing	10 per month	
A6402	Gauze, non-impregnated, sterile, pad size 16 sq. in. or less, without adhesive border, each dressing	300 per month	
A7048	Vacuum drainage collection unit and tubing kit, including all supplies needed for collection unit change, for use with implanted catheter, each	31 per month	
E0776	IV pole 3 yet		
W4047	Miscellaneous for DME	N/A	
A4670	Automatic blood pressure monitor	3 years	
E1639	Scale, each	3 years	
	Nutrition – Formula and Supplies	ž	
B4034	Enteral feeding supply kit; syringe fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape	31 per month	
B4035	Enteral feeding supply kit; pump fed, per day, includes but not limited to 31 per month feeding/flushing syringe, administration set tubing, dressings, tape		

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HCPCS Code	Item Description	Lifetime Expectancy or Quantity Limitation	
B4036	Enteral feeding supply kit; gravity fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape	31 per month	
B4081	Nasogastric tubing with stylet	3 every 3 months, not to exceed 12 per year	
B4082	Nasogastric tubing without stylet	3 every 3 months, not to exceed 12 per year	
B4083	Stomach tube—Levine type	3 every 3 months, not to exceed 12 per year	
B4087	Gastrostomy/jejunostomy tube, standard, any material, any type, each	1 every 3 months, not to exceed 4 per year	
B4088	Gastrostomy/jejunostomy tube, low-profile, any material, any type, each	1 every 3 months, not to exceed 4 per year	
B4100	Food thickener, administered orally, per ounce	N/A	
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), $500 \text{ ml} = 1 \text{ unit}$	Maximum allowed per calendar month is 100 units	
B4104	Additive for enteral formula (e.g., fiber)	N/A	
<u>B4105</u>	In-line cartridge containing digestive enzyme(s) for enteral feeding each	<u>62 units per month</u>	
B4149	Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories=1 unit	Monthly limits depend on the individual beneficiary's medical/nutritional needs and physician's orders not to exceed 775 units per calendar month	
B4150	Enteral formulae, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins, and minerals, may include fiber, administered through an enteral feeding tube, 100 calories= 1 unit	Monthly limits depend on the individual beneficiary's medical/nutritional needs and physician's orders not to exceed 775 units per calendar month	
B4152	Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories=1 unit	Monthly limits depend on the individual beneficiary's medical/nutritional needs and physician's orders not to exceed 775 units per calendar month	
B4153	Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories=1 unit	Monthly limits depend on the individual beneficiary's medical/nutritional needs and physician's orders not to exceed 775 units per calendar month.	
B4154	Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories=1 unit	Monthly limits depend on the individual beneficiary's medical/nutritional needs and physician's orders not to exceed 775 units per calendar month.	

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HCPCS Code	Item Description	Lifetime Expectancy or Quantity Limitation	
B4155	Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g. glucose polymers), proteins/amino acids (e.g. glutamine, arginine), fat (e.g. medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories= lunit	Monthly limits depend on the individual beneficiary's medical/nutritional needs and physician's orders not to exceed 775 units per calendar month.	
B4157	Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit	Monthly limits depend on the individual beneficiary's medical/nutritional needs and physician's orders not to exceed 775 units per calendar month.	
B4158	Enteral formula, for pediatric nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit	Monthly limits depend on the individual beneficiary's medical/nutritional needs and physician's orders not to exceed 775 units per calendar month.	
B4159	Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 Cal = 1 unit	Monthly limits depend on the individual beneficiary's medical/nutritional needs and physician's orders not to exceed 775 units per calendar month.	
B4160	Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 Cal = 1 unit	Monthly limits depend on the individual beneficiary's medical/nutritional needs and physician's orders not to exceed 775 units per calendar month.	
B4161	Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 Cal = 1 unit	Monthly limits depend on the individual beneficiary's medical/nutritional needs and physician's orders not to exceed 775 units per calendar month.	
B4162	Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 Cal = 1 unit	Monthly limits depend on the individual beneficiary's medical/nutritional needs and physician's orders not to exceed 775 units per calendar month.	
B9002	Enteral nutrition infusion pump - with alarm	2 years	
B9004	Parenteral nutrition infusion pump, portable	2 years	
B9006	Parenteral nutrition infusion pump, stationary	2 years	
S8265	Haberman Feeder for cleft lip/palate	N/A	
W4211	Low profile gastrostomy extension/replacement kit tubes for cont. feed.	2 per month	
W4212	Low profile gastrostomy extension/replacement kit for bolus feeding Incontinence, Ostomy, and Urinary Catheter Supplies	2 per month	
A4310	Insertion tray without drainage bag and without catheter (accessories only)	2 per month	
A4311	Insertion tray without drainage bag and without canteer (accessories only) Insertion tray without drainage bag with indwelling catheter, Foley type, two-way latex with coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.)	l per month	

DRAFT Amended Date:			
HCPCS	Item Description	Lifetime Expectancy or	
Code		Quantity Limitation	
A4313	Insertion tray without drainage bag with indwelling catheter, Foley type,	1 per month	
11.010	three-way, for continuous irrigation	r per monu	
A4314	Insertion tray with drainage bag with indwelling catheter, Foley type, two-	1 per month	
	way latex with coating (Teflon, silicone, silicone elastomer, or hydrophilic,	- Per monu	
	etc.)		
<mark>A4315</mark>	Insertion tray with drainage bag with indwelling catheter, Foley type, two-	1 per month	
111010	way, all silicone		
A4316	Insertion tray with drainage bag with indwelling catheter, Foley type, three-	1 per month	
111010	way, for continuous irrigation	i per monui	
A4320	Irrigation tray with bulb or piston syringe, any purpose	3 per month	
A4321	Therapeutic agent for urinary catheter irrigation	2 per month	
A4322	Irrigation syringe, bulb or piston, each	2 per month	
A4328	Female external urinary collection device; pouch, each	31 per month	
A4331	Extension drainage tubing, any type, any length, with connector/adapter,	2 per month	
A4331	for use with urinary leg bag or urostomy pouch, each	2 per monui	
A4334		2 man month	
	Urinary catheter anchoring device, leg strap, each	2 per month	
A4335	Incontinence supply; miscellaneous	2 per month	
A4338	Indwelling catheter; Foley type, two-way latex with coating (Teflon,	1 per month	
	silicone, silicone elastomer, or hydrophilic, etc.), each		
A4340	Indwelling catheter; specialty type (e.g., coude, mushroom, wing, etc.),	1 per month	
	each		
A4344	Indwelling catheter, Foley type, two-way, all silicone, each	1 per month	
A4349	Male external catheter, with or without adhesive, disposable, each	35 per month	
A4351	Intermittent urinary catheter; straight tip, with or without coating (Teflon,	200 per month	
	silicone, silicone elastomer, or hydrophilic, etc.), each		
A4352	Intermittent urinary catheter; coude (curved) tip, with or without coating	200 per month	
	(Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each		
A4353	Intermittent urinary catheter, with insertion supplies	200 per month	
A4354	Insertion tray with drainage bag but without catheter	2 per month	
A4357	Bedside drainage bag, day or night, with or without anti-reflux device, with	2 per month	
	or without tube, each		
A4358	Urinary drainage bag, leg or abdomen, vinyl, with or without tube, with	2 per month	
	straps, each	-	
A4361	Ostomy faceplate, each	3 per 6 months	
A4362	Skin barrier; solid, 4X4 or equivalent; each	20 per month	
A4364	Adhesive, liquid or equal, any type, per oz.	4 oz. per month	
A4367	Ostomy belt, each	1 per month	
A4368	Ostomy filter, any type, each	60 per month	
A4369	Ostomy skin barrier, liquid (spray, brush, etc.), per oz.	2 oz. per month	
A4371	Ostomy skin barrier, powder, per oz.	$\frac{2}{2} \frac{10}{10}$ oz. per month	
A4372	Ostomy skin barrier, solid 4X4 or equivalent, standard wear, with built-in	20 per month	
11-13/2	convexity, each	20 per monun	
A4373	Ostomy skin barrier, with flange (solid, flexible, or accordion), with built-in	20 per month	
1173/3	convexity, any size, each	20 per monui	
A4375	Ostomy pouch, drainable, with faceplate attached, plastic, each	15 per month	
A4376	Ostomy pouch, drainable, with faceplate attached, plastic, each Ostomy pouch, drainable, with faceplate attached, rubber, each	3 per month	
A4377	Ostomy pouch, drainable, for use on faceplate, plastic each	10 per month	
A4378	Ostomy pouch, drainable, for use on faceplate, rubber, each	3 per month	
A4379	Ostomy pouch, urinary, with faceplate attached, plastic, each	15 per month	
A4380	Ostomy pouch, urinary, with faceplate attached, rubber, each	3 per month	
A4381	Ostomy pouch, urinary, for use on faceplate, plastic each	10 per month	
A4382	Ostomy pouch, urinary, for use on faceplate, heavy plastic, each	3 per month	
A4383	Ostomy pouch, urinary, for use on faceplate, rubber, each	3 per month	
A4384	Ostomy faceplate equivalent, silicone ring, each	3 per 6 months	

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HCPCS	Item Description	Lifetime Expectancy of		
Code	item Description	Quantity Limitation		
A4385	Ostomy skin barrier, solid 4X4 or equivalent, extended wear, without built-	20 per month		
111505	in convexity, each	20 per monui		
A4388	Ostomy pouch, drainable, with extended wear barrier attached (1 piece),	20 per month		
	each	- 1		
A4389	Ostomy pouch, drainable, with barrier attached, with built-in convexity (1	20 per month		
	piece), each	-		
A4390	Ostomy pouch, drainable, with extended wear barrier attached, with built-in	20 per month		
	convexity (1 piece), each			
A4391	Ostomy pouch, urinary, with extended wear barrier attached (1 piece), each	20 per month		
A4392	Ostomy pouch, urinary, with standard wear barrier attached, with built-in	20 per month		
	convexity (1 piece), each			
A4393	Ostomy pouch, urinary, with extended wear barrier attached, with built-in	20 per month		
1 1 2 0 1	convexity (1 piece), each	16 1		
A4394	Ostomy deodorant, with or without lubricant, for use in ostomy pouch, per	16 oz. per month		
A 4205	fluid ounce	100		
A4395	Ostomy deodorant, for use in ostomy pouch, solid, per tablet	100 per month 1 per month		
A4436	Irrigation supply; sleeve, reusable, per month Irrigation supply; sleeve, disposable, per month			
A4437 A4398	Ostomy irrigation supply; bag, each	1 per month 2 per 6 months		
A4398 A4399	Ostomy irrigation supply, oag, each Ostomy irrigation supply; cone/catheter, with or without brush	2 per 6 months		
A4400	Ostomy irrigation supply, concreatively, with of without brush	2 per 6 month		
A4402	Lubricant, per ounce	4 oz. per month		
A4404	Ostomy ring, each	10 per month		
A4405	Ostomy skin barrier, non-pectin based, paste, per ounce	4 oz. per month		
A4406	Ostomy skin barrier, pectin-based, paste, per ounce	4 oz. per month		
A4407	Ostomy skin barrier, with flange (solid, flexible, or accordion), extended	20 per month		
111107	wear, with built-in convexity, 4X4 inches or smaller, each	20 per montai		
A4408	Ostomy skin barrier, with flange (solid, flexible, or accordion), extended	20 per month		
	wear, with built-in convexity, larger than 4X4 inches, each	1		
A4409	Ostomy skin barrier, with flange (solid, flexible, or accordion), extended	20 per month		
	wear, without built-in convexity, 4X4 inches or smaller, each	1		
A4410	Ostomy skin barrier, with flange (solid, flexible, or accordion), extended	20 per month		
	wear, without built-in convexity, larger than 4X4 inches, each			
A4411	Ostomy skin barrier, solid 4X4 or equivalent, extended wear, with built-in	20 per month		
	convexity, each			
A4414	Ostomy skin barrier, with flange (solid, flexible, or accordion), without	20 per month		
	built-in convexity, 4X4 inches or smaller, each			
A4415	Ostomy skin barrier, with flange (solid, flexible, or accordion), without	20 per month		
	built-in convexity, larger than 4X4 inches, each	(0) 1		
A4416	Ostomy pouch, closed, with barrier attached, with filter (1 piece), each	60 per month		
A4417	Ostomy pouch, closed, with barrier attached, with built-in convexity, with	60 per month		
A // 10	filter (1 piece), each	60		
A4418	Ostomy pouch, closed, without barrier attached, with filter (1 piece), each	60 per month		
A4419	Ostomy pouch, closed; for use on barrier with non-locking flange, with filter (2 piece), each	60 per month		
A4423	Ostomy pouch, closed; for use on barrier with locking flange, with filter (2	60 per month		
ATT2J	piece), each	oo per monui		
A4424	Ostomy pouch, drainable, with barrier attached, with filter (1 piece), each	20 per month		
A4425	Ostomy pouch, drainable; for use on barrier with non-locking flange, with	20 per month		
	filter (2 piece system), each	20 per monui		
A4426	Ostomy pouch, drainable; for use on barrier with locking flange (2 piece	20 per month		
	system), each	= ° r • · · · · · · · · · · · · · · · · · ·		
A4427	Ostomy pouch, drainable; for use on barrier with locking flange, with filter	20 per month		
	(2 piece system), each	*		

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HCPCS	Item Description	Lifetime Expectancy or	
Code	item Description	Quantity Limitation	
A4428	Ostomy pouch, urinary, with extended wear barrier attached, with faucet-	20 per month	
11120	type tap with valve (1 piece), each	20 per monui	
A4429	Ostomy pouch, urinary, with barrier attached, with built-in convexity, with	20 per month	
11129	faucet-type tap with valve (1 piece), each	20 per monu	
A4430	Ostomy pouch, urinary, with extended wear barrier attached, with built-in	15 per month	
	convexity, with faucet-type tap with valve (1 piece), each	F	
A4431	Ostomy pouch, urinary; with barrier attached, with faucet-type tap with	20 per month	
-	valve (1 piece), each	- 1	
A4432	Ostomy pouch, urinary; for use on barrier with non-locking flange, with	20 per month	
	faucet-type tap with valve (2 piece), each	1	
A4433	Ostomy pouch, urinary; for use on barrier with locking flange (2 piece),	20 per month	
	each	1	
<mark>A4434</mark>	Ostomy pouch, urinary; for use on barrier with locking flange, with faucet-	20 per month	
	type tap with valve (two piece), each		
A4435	Ostomy pouch, drainable, high output, with extended wear barrier (one-	20 per month	
	piece system), with or without filter, each	-	
A4450	Tape, non-waterproof, per 18 square inches	80 units per month	
A4452	Tape, waterproof, per 18 square inches	80 units per month	
A4455	Adhesive remover or solvent (for tape, cement or other adhesive), per	16 oz. per 6 months	
	ounce	-	
A4554	Disposable under pads, all sizes	150 per month	
A5051	Ostomy pouch, closed; with barrier attached (1 piece), each	60 per month	
A5052	Ostomy pouch, closed; without barrier attached (1 piece), each	60 per month	
A5053	Ostomy pouch, closed; for use on faceplate, each	60 per month	
A5054	Ostomy pouch, closed; for use on barrier with flange (2 piece), each	60 per month	
A5055	Stoma cap	31 per month	
A5056	Ostomy pouch, drainable, with extended wear barrier attached, with filter, (<u>1 one</u> piece), each	<mark>20</mark> <u>40</u> per month	
A5057	Ostomy pouch, drainable, with extended wear barrier attached, with built in convexity, with filter, (¹ / ₄ one piece), each	<mark>20</mark> <u>40</u> per month	
A5061	Ostomy pouch, drainable; with barrier attached, (1 piece), each	20 per month	
A5062	Ostomy pouch, drainable; without barrier attached (1 piece), each	20 per month	
A5063	Ostomy pouch, drainable; for use on barrier with flange (2 piece system), each	20 per month	
A5071	Ostomy pouch, urinary; with barrier attached (1 piece), each	20 per month	
A5072	Ostomy pouch, urinary; without barrier attached (1 piece), each	20 per month	
A5073	Ostomy pouch, urinary; for use on barrier with flange (2 piece), each	20 per month	
A5081	Stoma plug or seal, any type	<u>31 per month</u>	
A5082	Continent device; catheter for continent stoma	1 per month	
A5083	Continent device, stoma absorptive cover for continent stoma	150 per month	
A5093	Ostomy accessory; convex insert	10 per month	
A5102	Bedside drainage bottle with or without tubing, rigid or expandable, each	2 per 6 months	
A5112	Urinary drainage bag, leg or abdomen, latex, with or without tube, with	<u>1 per month</u>	
	straps, each		
A5120	Skin barrier, wipes, or swabs, each	150 per 6 months	
A5121	Skin barrier; solid, 6X6 or equivalent, each	20 per month	
A5122	Skin barrier; solid, 8X8 or equivalent, each	20 per month	
A5126	Adhesive or non-adhesive; disk or foam pad	20 per month	
A5131	Appliance cleaner, incontinence and ostomy appliances, per 16 oz.	1 per month	
A6216	Gauze, non-impregnated, non-sterile, pad size 16 sq. in or less, without	60 per month	
-	adhesive boarder, each dressing	1	
T4521	Adult sized disposable incontinence product, brief/diaper, small, each	192 per month	
T4522	Adult sized disposable incontinence product, brief/diaper, medium, each	192 per month	
T4523	Adult sized disposable incontinence product, brief/diaper, large, each	192 per month	

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HCPCS Code	Item Description	Lifetime Expectancy or Quantity Limitation		
T4524	Adult sized disposable incontinence product, brief/diaper, extra-large, each	192 per month		
T4525	Adult sized disposable incontinence product, protective underwear/pull on, small size, each	200 per month		
T4526	Adult sized disposable incontinence product, protective underwear/pull on, 200 per month medium size, each			
T4527	Adult sized disposable incontinence product, protective underwear/pull on, large size, each	200 per month		
T4528	Adult sized disposable incontinence product, protective underwear/pull on, extra-large size, each	200 per month		
T4529	Pediatric sized disposable incontinence product, brief/diaper, small/ medium size, each	192 per month		
T4530	Pediatric sized disposable incontinence product, brief/diaper, large size, each	192 per month		
T4531	Pediatric sized disposable incontinence product, protective underwear/pull 200 per 1 on, small/medium size, each			
T4532	Pediatric sized disposable incontinence product, protective underwear/pull on, large size, each	200 per month		
T4533	Youth sized disposable incontinence product, brief/diaper, each	192 per month		
T4534	Youth-sized disposable incontinence product, protective underwear/pull on, 200 per each			
T4543	Disposable incontinence product, brief/diaper, bariatric, each	192 per month		
T4544	Adult sized disposable incontinence product, protective underwear/pull-on, above extra large, each	200 per month		
	Manual Pump-Operated Enema System			
A4453	Rectal catheter for use with the manual pump-operated enema system, 90 units per 3 replacement only			
A4459	Manual pump-operated enema system, includes balloon, catheter and all accessories, reusable, any type	4 per year		
	Equipment Service and Repair			
K0739	Repair or non-routine service for durable medical equipment other than oxygen equipment requiring the skill of a technician, labor component, per 15 minutes	N/A		

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.

Oral Nutrition:

Oral nutrition products must be billed using a second modifier, the BO modifier.

E. Billing Units

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

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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

For Medicaid refer to the NC Medicaid State Plan: https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

For NCHC refer to NCHC State Plan: https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

Medicaid and NCHC eligible beneficiaries are exempt from co-payments.

H. Reimbursement

Providers shall bill their usual and customary charges. For a schedule of rates, see: <u>https://medicaid.ncdhhs.gov/</u>

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

Farrell Valve For Clinical Coverage and Prior Approval Criteria, refer to Subsection 5.3.5	
A9999 Miscellaneous DME supply or accessory, not otherwise specified (For use with	
	Farrell Valve only)

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 ID	Enter the beneficiary's Medicaid or NCHC ID number (nine digits and the
	Number	alpha suffix) from the beneficiary's Medicaid or NCHC ID card.
2.	Beneficiary's	Enter the beneficiary's last name, first name and middle initial from the
	Name	Medicaid or NCHC ID card.
3.	Beneficiary's	Enter eight numbers to show the beneficiary's date of birth - MMDDYYYY.
	Birth Date/Sex	The birth date is on the Medicaid or NCHC ID card.
		EXAMPLE: November 14, 1949 is 11141949 .
		Place an X in the appropriate block to show the beneficiary's sex.
4.	Insured's Name.	Leave blank
5.	Beneficiary's	Enter the beneficiary's street address, including the city, state and zip code.
	Address	The information is on the Medicaid or NCHC ID card. Entering the telephone
		number is optional.
6.—8.		Leave blank.
9.	Other Insurer's	Enter applicable private insurer's name or the appropriate Medicare override
	Name	statement if you know that Medicare will not cover the billed item, using the
		EXACT wording shown below:
		This is a Medicare non-covered service.
		Service does not meet Medicare criteria.
		Medicare benefits are exhausted.
		REMEMBER: You must have documentation to support the use of any of
		these statements.
9a.—9		Enter applicable insurance information.
10.	Is Beneficiary's	Place an X in the appropriate block for each question.
11 1	Condition?	
11.—1		Optional.
15.—1		Leave blank.
	7a. and 18.	Optional.
19.	Reserved for	Leave blank.
20	Local Use	T 11 1
20.	Outside Lab	Leave blank.
21.	Diagnosis or	Enter the ICD-10-CM code(s) to describe the primary diagnosis related to the
	Nature of Illness	service. You may also enter related secondary diagnoses. Entering written
22.	Madiadd	descriptions is optional. Leave blank.
22.	Medicaid Resubmission	Leave blank.
23.	Code Prior	When hilling a national missellaneous as do enter the 11 disit Commission
23.	Prior Authorization	When billing a national miscellaneous code, enter the 11-digit Service
	Authorization	Request Number (SRN) from block 26 (Prior Approval No.) on the CMN/PA form. For all other codes, leave this block blank.
	number	Iorm. For an other codes, leave this block blank.

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:

- $\hfill\square$ 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 of the strips on one line. Enter 2 units in 24G for that date of service.
- \Box Include only dates of service in the SAME calendar month.
- □ Include only dates of service for which the beneficiary is eligible for Medicaid or NCHC.

Block #/Description		Instruction
24a.	Date(s) of	Your entry depends upon the services:
	Service, From/To	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.
		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.
		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.
		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.
		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.
		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.
		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.
		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.
		EN Formulae: Enter the service dates for the formula in the FROM and
		TO blocks.
	Place of Service	Enter 12 to show the items are provided at the beneficiary's residence.
24c. T	Type of Services	Leave blank.

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Bloc	k #/Description	Instruction
24d.	Procedures,	Enter the appropriate HCPCS code and modifier:
	Services	NU for new purchase
		UE for used purchase
		RR for rental
	Diagnosis Code	Leave blank.
24f.	5	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.
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	—24i.	Leave blank.
24j.–	–24k.	Optional.
25.	Federal Tax ID Number	Optional
26.	Beneficiary's	Optional. You may enter your agency's record or account number for the
	Account No.	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.	Balance Due	Subtract the amount in Item 29 from the amount in Item 28 and enter the result here.
31.	Signature of	Leave blank if there is a signature on file with Medicaid and NCHC.
	Physician or	Otherwise, an authorized representative of your agency must sign and date the
	Supplier	claim in this block. A written signature stamp is acceptable.
32.	Name and Address of Facility	Optional.
33.	Physician's/ Supplier's Billing Name	Enter your agency's name, address, including ZIP code, and phone number. The name and address must be EXACTLY as shown on your Medicaid and NCHC DME participation agreement.
PIN#		Leave blank.
GRP	#	Enter your seven-digit Medicaid and NCHC DME provider number.

Remember: When submitting a claim for other manually priced items such as external insulin pumps, an invoice must also be attached to the claim.

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DO NOT				Claim Form	for	MF			
N THIS			Example of	Claim Form	TOL	1.112			
				URANCE CL		RM	PICA		
1. MEDICARE MEDICAID CHA	MPUS CHAN	IPVA GROUP HEALTH PLAN File #) (SSN or ID)	FECA OTHER BLK LUNG (SSN) (ID)	1a. INSURED'S I.D. NUN		(FOF	PROGRAM IN ITEM 1		
(Medicare #) (Medicaid #) (Spor 2. PATIENT'S NAME (Last Name, First Name, N	·	3. PATIENT'S BIRTH DATE		4. INSURED'S NAME (La	ist Name, Firs	Name, Midd	dle Initial)		
Recipient Joe A 5. PATIENT'S ADDRESS (No., Street)	۱	6. PATIENT RELATIONSHI	P TO INSURED	7. INSURED'S ADDRES	3 (No., Street)				
123 Any Street	ST	Self Spouse C	Child Other	CITY			STATE		
Any Town	E (Include Area Code)	IC Single Married	I Other	ZIP CODE	TEL	EPHONE (IN	CLUDE AREA CODE)		
12345 (919)	123 - 1234	Employed Full-Time Student	Student	11. INSURED'S POLICY	GBOUP OB F	() ECA NUMB	ER		
9. OTHER INSURED'S NAME (Last Name, Firs	t Name, Middle Initial)	10. IS PATIENT'S CONDIT							
a. OTHER INSURED'S POLICY OR GROUP N	UMBER	a. EMPLOYMENT? (CURR	ENT OR PREVIOUS)	a. INSURED'S DATE OF	BIRTH	м [SEX		
b. OTHER INSURED'S DATE OF BIRTH MM DD YY	SEX	b. AUTO ACCIDENT?	PLACE (State)	b. EMPLOYER'S NAME	OR SCHOOL	NAME			
C. EMPLOYER'S NAME OR SCHOOL NAME	F	c. OTHER ACCIDENT?		C. INSURANCE PLAN N	AME OR PRO	GRAM NAM	E		
d. INSURANCE PLAN NAME OR PROGRAM	NAME	10d. RESERVED FOR LOC	X NO CAL USE	d. IS THERE ANOTHER					
		ETING & SIGNING THIS FORM.		YES NO <i>If yes</i> , return to and complete item 9 a-d. 13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for					
 PATIENT'S OR AUTHORIZED PERSON'S to process this claim. I also request payment 			er information necessary accepts assignment	payment of medical t services described b	enetits to the elow.	undersigned	physician or supplier ic		
below. SIGNED		DATE		SIGNED					
14. DATE OF CURRENT: ILLNESS (First	ent) OR	15. IF PATIENT HAS HAD SAME GIVE FIRST DATE MM	E OR SIMILAR ILLNESS.	16. DATES PATIENT UN	ABLE TO WO	RK IN CURI			
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		17a. I.D. NUMBER OF REFERR		18. HOSPITALIZATION MM D FROM 20. OUTSIDE LAB?	DATES RELA	TED TO CU	RRENT SERVICES		
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Recipient, Ja			A PATIENT'S BIRTH DATE		7 INSURED'S A		- Dimoi				
5. PATIENT'S ADDRESS (No., SI			6. PATIENT BELATIONSHIP TO Sat Spouse Child		7. INSURED'S A	IDDHE80 (M	0., pines)				
456 Any Stree	et	st	ATE 8. PATIENT STATUS		CITY	8.6			_	5	TATE
Anywhere		NC	Single Married	Other	ZIP CODE		TEL	EPHONE	ETINCLU	JDE AREA	CODE)
ZIP CODE	TELEPHONE (Inclu		Employed Full-Time Student	Parl-Time				()		
54321 9. OTHER INSURED'S NAME (LI	(999)123 ast Name, First Name	, Middle Instal)	10. IS PATIENT'S CONDITION	RELATED TO:	11. INSURED'S	POLICY GP	OUP OR F	FECA NU	MBER		0
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	The second se		b. AUTO ACCIDENT?	PLACE (State)	b. EMPLOYER:	B NAME OR	SCHOOL	NAME			
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 PATIENT'S OR AUTHORIZE to process this claim. I also re below. 	ED PERSON'S SIGN aquest payment of gov	emment benefits	sither to myself or to the party who accurate to	spin assignment	services de	scribed below	ı.	and an Adda			
SIGNED			DATE		SIGNED						
14. DATE OF CURRENT:	LLNESS (First symple NJURY (Accident) OF PREGNANCY(LMP)	om) OR	15. IF PATIENT HAS HAD SAME OF	R SINILAR ILLNESS. D YY	16. DATES PA		LE TO WO	ORK IN C TC	MM	DD	YY YY
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Attachment D: Requesting Unlisted DME and Medical Supplies for Adults

In compliance with the Centers for Medicare & Medicaid Services (CMS) Home Health Final Rule, <u>42</u> <u>CFR Part 440.70</u>, please follow these guidelines when requesting medical necessity reviews for DME and medical 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-3 must be met. This includes, but is not limited to:
 - 1. The item being requested must fit the definition of durable medical equipment or medical supplies;
 - 2. The beneficiary must be enrolled in the NC Medicaid program and be eligible for the item;
 - 3. The provider must be enrolled in the NC 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 medical 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-3 have been met, then the provider may submit a completed Certificate of Medical Necessity/Prior Approval (CMN/PA form) and the usual supportive prior authorization 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 authorization request (refer to <u>May 2017 Medicaid Bulletin</u> for details).
- e. Providers should expect medical necessity reviews using this procedure to be 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 NC Medicaid policy area or waiver program.

Additional Resources

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