This policy includes the following:
Back-up/Secondary Ventilators
Diapers/Incontinence Products
Electric Breast Pumps

Benefit Coverage

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Description

For all DME items covered in this policy Neighborhood Health Plan of Rhode Island (Neighborhood) utilizes the definitions published by The Centers for Medicare and Medicaid Services (CMS) and our Medical Management team utilizes the following government references to determine medical necessity when medical review is required:
- CMS guidelines https://med.noridianmedicare.com/
- “Rhode Island DHS – Screening List for Durable Medical Equipment” (see reference below)

DME is equipment which:
- can withstand repeated use; i.e., could normally be rented and used by successive patients;
- is primarily and customarily used to serve a medical purpose;
- generally is not useful to a person in the absence of illness or injury; and,
- is appropriate for use in a patient’s home.

DME items available through retail pharmacy include:
- Aerochambers
- Glucometers (Neighborhood Formulary brand name is Accu-Chek®)
- Peak flow metersSyringes

Orthotics are rigid or semi-rigid devices that are used for the purpose of supporting a weak or deformed body part or restricting or eliminating motion in a diseased or injured part of the body. An orthosis can be either prefabricated or custom fabricated.
Clinical Medical Policy

Durable Medical Equipment (DME)- # 018

Last reviewed: 06/05/2019

Prosthetic devices (other than dental), a) replace all or part of an internal or external body organ, or b) replace all or part of the function of a permanently inoperative or malfunctioning internal or external body organ.

Medical supplies include: IV supplies, catheter supplies, suctioning supplies, and wound care supplies that serve a medical purpose and are deemed medically necessary for the treatment of a medical diagnosis.

Coverage Determination

Neighborhood’s day to day oversight of our durable medical equipment (DME) and prosthetics and orthotics (P&O) delivery network is managed through our selected vendor, DMEnsion Benefit Management.

DME items which do NOT require prior authorization are obtained through physician orders directed to contracted DMEnsion’s providers. Before submitting a claim to DMEnsions, the provider must have on file:

- a dispensing order,
- the written order,
- the CMN (if applicable),
- the patient’s diagnosis (if an ICD-10-CM code is required on the claim),
- and any information required for the use of specific modifiers,
- or attestation statements, in accordance with Medicare guidelines.

Neighborhood follows Medicare (CMS) policy guidelines for monthly quantity limits. For miscellaneous supply items, (CMS does not have limits for NOC codes), Neighborhood utilizes the “Neighborhood Quantity List.” If the quantity limit is exceeded, the member/provider is eligible to submit a request for review. The definition of DME included in this policy, along with the criteria below, will be applied.

Because CMS quantity limits may not be appropriate for prosthetics and orthotics for the Pediatric population (all lines of business, under age 19 years), Neighborhood will review medical necessity documentation and give consideration to age, growth, and conditions which may warrant additional prosthetic or orthotic items.

Requests for DME items which do require prior authorization and a medical necessity determination are reviewed by Neighborhood’s Medical Review Nurses, in accordance with Medical Management applicable policies and procedures for utilization review decisions. The Associate Medical Director or his/her designee reviews requests that fail to meet medical necessity criteria, and renders a determination.

Documentation

Submitted documentation expected for medical review decisions includes but is not limited to:

- Appropriate CMS DME Information Form (DIF) or appropriate Certificate of Medical Necessity (CMN)
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Last reviewed: 06/05/2019

☐ Documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable).

☐ The information should include the
  ☐ patient’s diagnosis and other pertinent information including, but not limited to,
  ☐ duration of the patient’s condition,
  ☐ clinical course (worsening or improvement),
  ☐ prognosis,
  ☐ nature and extent of functional limitations,
  ☐ other therapeutic
  ☐ interventions and results, past experience with related items, and impact of physical change such as growth (in the pediatric population only).

Criteria
Neighborhood classifies DME, orthotics and prosthetics, as per CMS descriptions listed above. Additionally, ALL the following criteria must be met:

☐ The equipment is reasonable and necessary to sustain a minimum level of independent daily living.

☐ The equipment can withstand repeated use.

☐ Covered orthotics must be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part.

☐ Strollers may be covered, in addition to previously approved wheelchairs.

☐ Pediatric beds, with features which assure that the patient does not climb or fall out of bed, may be covered if there is a profound "safety unawareness" due to developmental delay or other cognitive dysfunction and if other, more traditional protective measures cannot be implemented because of special circumstances.

Exclusions
- Maintenance and repairs covered under warranty.
- Items intended for sports related purposes, exercise equipment, physiotherapy, personal comfort and convenience items.
- A second piece of equipment for the same or similar medical purpose as existing equipment.
- Devices/appliances considered to be experimental.
- Equipment used to treat sensory integration disorder, including but not limited to weighted vests and blankets, cushions, balls, rockers, mats, swings, chew toys, and scooters are not covered because they are of an unproven medical benefit and there is no peer-reviewed literature documenting their effectiveness.
Back-up/Secondary Ventilators

Definitions

Ventilators are available for continuous rental and all accessories and supplies are included in the rental fee.

Back-up Ventilator - A backup ventilator is defined as an identical or similar device used to meet the same medical needs for the patient but provided at the bedside as a precaution in case of malfunction of the primary ventilator.

Second Ventilator - A second ventilator is one which serves a different purpose than the primary ventilator, as determined by the patient's medical needs.

Coverage Determination

Back-up Ventilator - The DME vendor is responsible for ensuring that the patient's medical needs will be met on a consistent and ongoing basis, and that there is a contingency plan to manage any interruptions in the use of the equipment such as emergency situations or mechanical failures, that would be life threatening to the patient. The expectation is that an acceptable plan would involve input from the treating practitioner and would take into account the severity of the patient’s condition and time restraints in providing emergency support.

Examples (not all-inclusive) of situations in which a second or other multiple piece of equipment would be considered a backup and therefore would not be covered are:

- A ventilator-dependent patient is confined to a bed and a second ventilator of the same or similar type is provided at the bedside as a precaution in case of malfunction of the primary ventilator

Second Ventilator - A second ventilator is considered for authorization and reimbursement when it is required to serve a different purpose than the primary ventilator, as determined by the patient's medical needs, as defined in the criteria below. A Certificate of Medical Necessity is required. Medical documentation must indicate specific medical needs for which the second ventilator will address.
There are several safety reasons that the same vent cannot be used for both stationary and wheelchair mounting purposes:

- Stationary vents are mounted on stands and uniformly are attached to humidifiers. Because they are attached to humidifiers they use one type of circuit.
- Ambulatory humidifiers are mounted on wheelchair platforms, are also attached to a battery power source, and because they uniformly do not involve humidity, they use a different type of circuit.
- In order for a single person to perform a transfer from a bed to a wheelchair with a single vent, they would need to perform manual “bagging” during the disconnection, transfer of patient and transfer of vent.

Criteria for Second Ventilators:
A second ventilator will be considered when the following conditions are met:

- Without both pieces of equipment the member may be prone to certain medical complications, may not be able to achieve certain appropriate medical outcomes, or may not be able to use the medical equipment effectively, and
  - When a member confined to a wheelchair requires a ventilator mounted on the wheelchair for use during the day and needs another ventilator (either same of different type) to be used while in bed
  - Member has other medical needs or mobility requirements that indicate the second ventilator will serve a different purpose than the primary ventilator

Exclusions
Back-up ventilators for convenience of risk of power failure only.

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**Diapers/Incontinence Products**

**Description**
Diapers and absorbent products used for managing urinary incontinence in adults and children over the age of three (3) years old that are considered medically necessary are covered benefits. Diapers for children under the age of three (3) are generally considered a convenience for the parent or guardian, and therefore are usually not medically necessary.

**Definitions & Limits**
Absorbent products are defined as diaper or brief-like garments and underpads or liners used to contain urinary incontinence. Absorbent products may be either disposable or reusable/washable.

Urinary incontinence is defined as unintentional loss of urine due to malfunctions in the lower urinary tract. Incontinence is a symptom associated with a broad range of medical conditions, including but not limited to neurological diseases, congenital anomalies, injuries to the pelvic region or spinal cord, and infections. Correction of underlying factors such as medical illnesses and medication side effects can sometimes improve urinary continence.
Monthly order period is considered to be 30 days.

Disposable underpads are limited to 150 per month (based on 30 day supply).

DME vendors are prohibited from making automatic shipments.

Coverage Determination

Non Auth Required:
Diapers up to 192 for 30 day supply are obtained through physician orders directed to contracted DMEnsion’s providers.

Before submitting a claim to DMEnsions, the provider must have on file:
- a dispensing order,
- the written order,
- information from the treating physician concerning the patient’s diagnosis (if an ICD-9-CM code is required on the claim), AND
- any information required for the use of specific modifiers, or attestation statements, in accordance with Medicare guidelines.

Prior Auth Requirement:
Diaper quantities ordered in excess of 192 per month, up to a maximum of 300, require prior authorization. Requests are submitted to a contracted DMEnsion provider, using the Neighborhood Medical Necessity Review Form for Absorbent Products. DMEnsion forwards the request to Neighborhood’s Utilization Management staff for medical necessity review.

Appeal Rights
Diaper quantities in excess of 300 per month and disposable underpads in excess of 150 per month are non-covered benefits. Benefit Appeal rights are explained in Neighborhood’s Member Handbook.

Criteria
The following information is reviewed when submitted on the Neighborhood Medical Necessity Review Form for Absorbent Products, and a determination is made as to medical necessity and time frame required for the products. For members who are 18 years of age or older, Medical Necessity Review Form is NOT required and a physician prescription alone is acceptable.

☐ The member is over the age of three (3) years and presents ONE of the following signs/symptoms of incontinence that include, but are not limited to:

☐ Stress – urine loss caused by increased intra-abdominal pressure;
☐ Urge – urine loss caused by involuntary bladder contraction;
☐ Mixed – urine loss caused by a combination of stress and urge incontinence;
☐ Overflow – urine loss when urine produced exceeds the bladder’s holding capacity; and
☐ Total – uncontrolled or continuous leakage caused by neurological dysfunction, abdominal surgeries, or anatomical defects.

☐ A history and physical exam has been conducted to detect factors contributing to urinary incontinence, and to identify potentially reversible causes. Such factors include, but are not limited to:
  ☐ Medical conditions, such as delayed developmental skills, fecal impaction, psychosis, or other neurological diseases that affect motor skills;
  ☐ Symptomatic urinary tract infection;
  ☐ Evidence of atrophic urethritis/vaginitis;
  ☐ Medication regimens that include diuretics, drugs that stimulate or block the sympathetic nervous system, or psychoactive medications
  ☐ Environmental conditions (for example, impaired mobility, lack of access to a toilet, restraints, restrictive clothing, or excessive beverage intake); and
  ☐ Social circumstances that prevent personal hygiene (for example, inconsistent caregiver support for toileting).

☐ Tests deemed appropriate by the prescribing clinician have been conducted and results have been reported. Such tests may include, but are not limited to:
  ☐ Developmental assessment and prognosis in children
  ☐ Urinalysis/culture and sensitivity
  ☐ Urological testing and/or consultation
  ☐ Rectal exam
  ☐ Pelvic exam in women

☐ Treatments (for example, behavioral techniques, pharmacologic therapy, and/or surgical intervention) to manage symptoms of incontinence have been tried and failed or partially successful. This must include evidence of documentation on regular monitoring of responsiveness to such treatments.

☐ Urinary incontinence is accompanied by fecal incontinence

☐ Enuresis due to a diagnosis of Global Delay may be considered for limited approval if a toilet training program is in place and is ongoing.

Exclusions

- The patient is using a permanent or temporary device such as a catheter to manage incontinence.
- No examination performed and no information available that supports the need for absorbent products or diapers.
- The history and physical identified possible reversible factors, but no treatment or plan has been initiated to manage the incontinence.
- Products are used solely for the management of nocturnal enuresis.
- Products are used primarily for managing fecal incontinence and no medical or surgical alternatives have been tried to correct or control the fecal incontinence.
- Products are provided solely for the convenience of the member or service provider.
- An excess of 300 diapers per month is not covered.
- An excess of 150 disposable underpads per month is not covered.
### Electric Breast Pumps

**Description**
An electric breast pump is an electronic device that enables a nursing mother to pump her breast milk into a storage container so that it can be refrigerated or frozen for later use.

**Coverage Determination**

#### Non Auth Required:
Neighborhood Health Plan of Rhode Island (Neighborhood) covers Electric Breast Pumps for purchase of personal electric pumps without prior authorization when medically necessary.

- Manual Breast Pumps (HCPC Code E0602)
- Standard Electric Breast Pumps (HCPC Code E0603)

#### Prior Auth Requirement:
Rentals of hospital grade electric breast pumps (HCPC Code E0604) do require prior authorization and medical review. If criteria are met, initial authorization is for a period of one (1) month.

Please note that claims for this equipment can be submitted up to 30 days before the due date.

- Requests for durations beyond two (2) months can be submitted and Neighborhood’s, Utilization Management staff will contact member to determine:
  1. If electric breast pump still being utilized by mom
  2. How much longer mom expects to need the equipment
  3. If mom would like to speak to someone about a lactation consultant

If there is continued need identified by the member, a Medical Review Nurse will contact the attending/ordering practitioner to determine if criteria continue to be met.

#### Criteria
Breast pumps, manual and electric, should be used to promote lactation and to provide lactation support when natural feeding is not possible. When offered for medical reasons, electric breast pumps should be accompanied by consultation with a lactation specialist to insure appropriate use of equipment, storage of milk, transition to natural breast-feeding and other support.

**Rental of Hospital Grade Electric Pumps (E0604)**
Authorization of hospital grade electric breast pumps is contingent upon the following criteria:

- **Lactation cannot be initiated in the normal fashion or with a standard electric pump** because of conditions of the mother or baby, which prevent normal suckling. This includes but is not limited to prematurity, neonatal or maternal illness, neurological abnormalities, and anatomic abnormalities such as oro-facial or breast anomalies. The goal of the hospital grade pump is to simulate as closely as possible the normal maternal physical and physiologic response to suckling to enhance effective lactation and to produce sufficient milk for the infant’s nutrition.
Physician-diagnosed medical/physical conditions, which will only require short term maternal pumping, and therefore there is no need for a purchased standard electric pump. These include mastitis, or maternal need for medications, which require pumping, and discarding the milk. The physician will be required to document the continued need for the pump for the originally specified condition on a monthly basis.

Disclaimer

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's coverage plan; a member's coverage plan will supersede the provisions of this medical policy. For information on member-specific benefits, call member services. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. Neighborhood reserves the right to review and revise this policy for any reason and at any time, with or without notice.

References

**DME, Supplies, Prosthetics, Orthotics**
Centers for Medicare & Medicaid Services (CMS). (04/2015). NHIC (National Heritage Insurance Company) the DME MAC for Region A.


CMS DME Benefit Regulation Definition – 42 CFR 414.202


**Backup/Ventilators**


**Diapers/Incontinence Products**


**Electric Breast Pumps**


Hollister – Ameda HygieniKit Additional Claim, Letter from Department of Health and Human Services confirms FDA approval and ability to market the device.