SPECIFIC COVERAGE CRITERIA

Apnea Monitors

Apnea monitors are cardio-respiratory monitoring devices capable of providing continuous or periodic two-channel monitoring of the heart rate and respiratory rate. Apnea monitors must meet current Food and Drug Administration (FDA) guidelines for products in this class. Apnea monitors must have alarm mechanisms to alert care givers of cardio-respiratory distress or other events which require immediate intervention, and must also record and store events and provide event recording downloads or printouts of such data.

Medical Criteria for Authorization of Payment for Apnea Monitor

Home apnea monitors may be approved for rental or purchase when any of the criteria are met.

Apnea of Prematurity

Apnea of prematurity is the sudden cessation of breathing that lasts for at least 20 seconds or is accompanied by bradycardia or oxygen desaturation cyanosis in an infant younger than 37 weeks gestational age.

Apnea of Infancy

Apnea of infancy is an unexplained episode of cessation of breathing for 20 seconds or longer or a shorter respiratory pause associated with bradycardia, cyanosis, pallor, and/or marked hypotonia. The term apnea of infancy generally refers to infants with gestational age of 37 weeks or more at the onset of apnea. The Medicaid Program defines bradycardia for infants as a resting heartbeat of less than 80 beats per minute at one month of age, less than 70 beats per minute at 2-3 months of age, and less than 60 beats per minute at three months of age or older.

Monitoring for subsequent siblings of Sudden Infant Death Syndrome (SIDS) victims less than eight months of age may be approved for a maximum of eight months.

Following an Apparent Life-Threatening Event

An Apparent Life-Threatening Event (ALTE) is characterized by some combination of central apnea or occasionally obstructive apnea, color change (usually cyanotic or pallid but occasionally erythematous or plethoric), and a marked change in muscle tone (usually marked

limpness), choking, or gagging, which required vigorous intervention or cardiopulmonary resuscitation (CPR).

Children requiring home oxygen therapy, central hypo-ventilator, tracheotomy, and/or home ventilator support will be considered on a case-by-case basis.

Approval following apneic episodes resistant to treatment, such as Ondine's Curse, shall be considered on a case-by-case basis.

Apnea Monitor Initial Authorization Period for Rentals

Authorization of payment for rental of an apnea monitor may be approved for the initial three months without download reports or download summary information with download report, based on clinical data supporting medical necessity. The initial three-month rental includes all apnea monitor initial set up supplies – belt, leads and electrodes.

Apnea Monitor Extensions after Initial Three Months

Any request for extensions after the initial three-month period must be accompanied by documented evidence obtained in the home environment of recurrence of apneic episodes (e.g., cyanosis, resuscitative measures, etc.).

Apnea monitors will not be approved beyond the initial three months without download reports or download summary information with a download report. Family non-compliance and/or physician's refusal to remove the child from the apnea monitor are not acceptable reasons for further approval of payment for rental of the apnea monitor.

Apnea Monitor Emergency Requests

An oral request may be approved in an emergency for a one-month period to avoid prolonged hospitalization. Once documentation has been received indicating medical criteria have been met, the request may be approved for an additional two months.

Artificial Eyes

An artificial eye is approved if an eyeball is removed and replacement is necessary to maintain the contour of the face.

Artificial Larynxes

An artificial larynx is approved only if the larynx is removed and the recipient is unable to use an esophageal voice. Repairs and batteries are included.

Augmentative and Alternative Communication Devices

Augmentative and Alternative Communication (AAC) Devices – electronic or non-electronic aids, devices, or systems that assist a recipient to overcome or ameliorate (reduce to the maximum degree possible) the communication limitations that preclude or interfere with meaningful participation in current and projected medically necessary daily activities. Examples of AAC devices include:

- Communication boards or books, speech amplifiers, and electronic devices that produce speech and/or written output;
- Devices that are constructed for use as communication devices as well as systems that may include a computer, when the primary use of the computer serves as the recipient's communication device; and
- Related components and accessories, including software programs, symbol sets, overlays, mounting devices, switches, cables and connectors, auditory, visual, and tactile output devices, printers, and necessary supplies, such as rechargeable batteries.

NOTE: Meaningful participation refers to effective and efficient communication of messages in any form the recipient chooses.

Speech-Language Pathologist - an individual who has:

- A certificate of clinical competence in speech language pathology from the American Speech Language Hearing Association;
- Completed the equivalent educational requirements and work experience necessary for the certificate; or
- Completed the academic program and is acquiring supervised work experience to qualify for the certificate.

General Provisions

Consideration shall be given for Medicaid reimbursement for AAC devices for recipients of all ages if the device is considered medically necessary, the recipient has the ability to physically and mentally use a device and its accessories, and if criteria are met as listed below. The following medically necessary conditions shall be established for recipients who/whose:

- Have a diagnosis of a significant expressive or receptive (language comprehension) communication impairment or disability;

- Impairment or disability either temporarily or permanently causes communication limitations that preclude or interfere with the recipient's meaningful participation in current and projected daily activities; and

- Had a speech language pathologist (and other health professional, as appropriate):
  - Perform an assessment and submit a report pursuant to the criteria set forth in Assessment/Evaluation (see Assessment/Evaluation below);
  - Recommend speech language pathology treatment in the form of ACC devices and services;
  - Document the mental and physical ability of a recipient to use, or learn to use a recommended AAC device and accessories for effective and efficient communication;
  - Prepare a speech language pathology treatment plan that describes the specific components of the AAC devices and the required amount, duration, and scope of the AAC services that will overcome or ameliorate communication limitations as earlier described; and

- Requested AAC devices constitute the least costly, equally effective form of treatment that will overcome or ameliorate communication limitations as earlier described.

The following are additional general principles relating to medical necessity determinations for AAC devices:

- The cause of the recipient's impairment or disability (e.g., congenital, developmental, or acquired), or the recipient's age at the onset of the impairment or disability, are irrelevant considerations in the determination of medical need;

- Recipient participation in other services or programs (e.g., school, early intervention services, adult services programs, employment) is irrelevant to medical necessity determination for AAC devices;

- No cognitive, language, literacy, prior treatment, or other similar prerequisites must be satisfied by a recipient in advance of a request for AAC devices; and

- The unavailability of an AAC device, component, or accessory for rental will not serve as the basis for denying a prior authorization (PA) request for that device, component or accessory.

Assessment/Evaluation

- An assessment or evaluation of the recipient's functioning and communication limitations that preclude or interfere with meaningful participation in current and projected daily activities must be completed by a speech language pathologist with input from other health professionals, (e.g., occupational therapists and rehabilitation engineers) based on the recommendation of the speech language pathologist and a physician's prescription, as appropriate;

- Requests for AAC devices must include a description of the speech language pathologist's qualifications, including a description of the speech-language pathologist's AAC services training and experience; and

- An assessment (augmentative and alternative communication evaluation) must include the following information about the recipient:

    - Identifying information:
        - Name;
        - Medicaid identification number;
        - Date of the assessment;
        - Medical and neurological diagnoses (primary, secondary, tertiary);
        - Significant medical history;
        - Mental or cognitive status; and
        - Educational level and goals.

- Sensory Status:
  - Vision and hearing screening (no more than one year prior to AAC evaluation);
  - If vision screening is failed, a complete vision evaluation;
  - If hearing screening is failed, a complete hearing evaluation; and
  - Description of how vision, hearing, tactile, and/or receptive communication impairments or disabilities affect expressive communication.

- Postural, Mobility and Motor Status:
  - Gross motor assessment;
  - Fine motor assessment;
  - Optimal positioning;
  - Integration of mobility with AAC devices; and
  - Recipient's access methods (and options) for AAC devices.

- Current speech, language and expressive communication status:
  - Identification and description of the recipient's expressive or receptive (language comprehension) communication impairment diagnosis;
  - Speech skills and prognosis;
  - Language skills and prognosis;
  - Communication behaviors and interaction skills (i.e., styles and patterns);
  - Functional communication assessment, including ecological inventory;
  - Indication of past treatment, if any; and
  - Description of current communication strategies, including use of an AAC device, if any.

NOTE: If an AAC device is currently used, describe the device, when and by whom it was previously purchased, and why it is no longer adequate for communication needs).

- Communication Needs Inventory:
  - Description of recipient's current and projected communication needs;

- Communication partners and tasks including partners' communication abilities limitations, if any; and
- Communication environments and constraints which affect AAC device selection and/or features (e.g., verbal and/or visual output and/or feedback; distance communication needs).

- Summary of Communication Limitations:
  - Description of the communication limitations that preclude or interfere with meaningful participation in current and projected daily activities (i.e., why the recipient's current communication skills and behaviors prevent meaningful participation in the recipient's current and projected daily activities).

- AAC Devices Assessment Components:
  - Vocabulary requirements;
  - Representational system(s);
  - Display organization and features;
  - Rate enhancement techniques;
  - Message characteristics, speech synthesis, printed output, display characteristics, feedback, auditory and visual output;
  - Access techniques and strategies; and
  - Portability and durability concerns, if any.

- Identification of AAC Devices Considered for Recipients:
  - Identification of the significant characteristics and features of the AAC devices considered for the recipient; and
  - Identification of the cost of the AAC devices considered for the recipient (including all required components, accessories, peripherals and supplies as appropriate).

- AAC Device Recommendation:
  - Identification of the requested AAC devices including all required components, accessories, software, peripheral devices, supplies and the device vendor;
  - Identification of the recipient and communication partner's AAC devices preference, if any;

- Assessment of the recipient's ability (physically and mentally) to use, or to learn to use, the recommended AAC device and accessories for effective and efficient communication; and
- Justification stating why the recommended AAC device (including description of the significant characteristics, features and accessories) is better able to overcome or ameliorate the communication limitations that preclude or interfere with the recipient's meaningful participation in current and projected daily activities as compared to the other AAC devices considered; and justification stating why the recommended AAC device (including description of the significant characteristics, features and accessories) is the least costly, equally effective, alternative form of treatment to overcome or ameliorate the communication limitations that preclude or interfere with the recipient's meaningful participation in current and projected daily activities.

- Treatment Plan and Follow Up:
  - Description of short term communication goals (e.g., 6 months);
  - Description of long term communication goals (e.g., one year);
  - Assessment criteria to measure recipient's progress toward achieving short and long term communication goals;
  - Description of amount, duration and scope of AAC services required for the recipient to achieve short and long term communication goals; and
  - Identification and experience of AAC service provider responsible for training (these service providers may include, e.g.: speech language pathologists, occupational therapists, rehabilitation engineers, the recipient's parents, teachers and other service providers).

- Summary of Alternative Funding Source for AAC Device:
  - Description of availability or lack of availability, of purchase of AAC device through other funding sources.

Trial Use Periods

In instances where the appropriateness of a specific AAC device is not clear, a trial use period for an AAC device may be recommended (although it is not required) by the speech-language pathologist who conducts the AAC evaluation.

Prior authorization for rental of AAC devices shall be approved for trial use periods when the speech-language pathologist prepares a request that includes, but is not limited to:

- The characteristics of the recipient's communication limitations;
- Lack of familiarity with a specific AAC device; and
- Whether there are sufficient AAC services to support the recipient's use of the AAC device, or other factors.

If the speech-language pathologist seeks a trial use period, he/she must prepare a trial use period request that includes the following information:

- The duration of the trial period;
- The speech-language pathologist information and the recipient information as required in the Assessment Evaluation;
- The AAC device to be examined during the trial period, including all the necessary components (e.g., mounting device, software, switches, or access control mechanism);
- The identification of the AAC services provider(s) who will assist the recipient during the trial period;
- The identification of the AAC services provider(s) who will assess the trial period; and
- The evaluation criteria, specific to the recipient that will be used to determine the success or failure of the trial period.

Trial use period requests must include Medicaid funding for the rental of all necessary components and accessories of the AAC device. If an accessory is necessary for rental, but the communication device is available for rental for trial use, Medicaid may consider the purchase of the accessory for the trial use of the communication device.

Trial periods may be extended and/or different AAC devices provided, when requested by the speech-language pathologist responsible for evaluating the trial use period.

Results of trial use periods must be included with any subsequent request for prior authorization of the AAC device purchase. Recommendations for the purchase of an AAC device, as a result of a trial use period of the device, must clearly indicate the recipient's ability to use the device during the trial period.

Repairs

Medicaid will cover repairs to keep AAC devices, accessories, and other system components in working condition. Medicaid coverage for repairs will include the cost of parts, labor, and shipping, when not otherwise available without charge pursuant to a manufacturer's warranty.

Providers of AAC devices are expected to comply with the Louisiana New Assistive Devices Warranty Act, R.S § 51:2762 to 2767.

One of the provisions of this law is that all persons who make, sell, or lease assistive devices, including AAC devices, must provide those who buy or lease the equipment with a warranty which lasts at least one year from the time the equipment is delivered to the recipient. If, during the warranty period, the equipment does not work, the manufacturer or dealer must make an attempt to repair the equipment.

Medicaid additionally requires providers to provide the recipient with a comparable, alternate AAC device while repairing the recipient's device during a warranty period. Medicaid coverage may be provided for the rental of an alternate AAC device during a repair period after expiration of the warranty. Medicaid will not cover repairs, or rental of a loaner device, when repairs are made during a warranty period.

When a device is received by the provider for the purpose of repair, the provider will conduct an assessment of the device to determine whether it can be repaired, and if so, prepare a written estimate of the parts, labor, and total cost of the repair, as well as the effectiveness (i.e., estimated durability) of the repair. If the manufacturer or provider concludes that the device is

not repairable and a replacement device is needed, written notice will be provided to the recipient.

Medicaid coverage for repairs greater than $300.00 must be accompanied by a statement from the speech-language pathologist. The statement must indicate whether there have been any significant changes in the sensory status (e.g., vision, hearing, tactile); postural, mobility or motor status; speech, language, and expressive communication status; or any other communication need or limitation of the recipient as earlier described and whether the device remains the speech language pathologist's recommendation for recipient's use.

Replacement or Modification

Modification or replacement of AAC devices will be covered by Medicaid subject to the following limitations:

- Requests for modification or replacement of AAC devices and/or accessories may be considered for coverage after the expiration of three or more years from the date of purchase of the current device and accessories in use;
- Requests for modification or replacement require PA and must include the recommendation of the speech-language pathologist;
- Requests for replacements of AAC devices may be submitted for identical or different devices;
- Requests for replacements of identical AAC devices must be accompanied by a statement from the provider that the current device cannot be repaired or that replacement will be more cost effective than repair of the current device. Data must be provided about the following:
    - Age;
    - Repair history;
        - frequency;
        - duration; and
        - cost; and
    - Repair projections (estimated durability of repairs).

- Requests for modification or replacement of AAC devices with different devices must include the following additional information:

  - A significant change has occurred in the recipient's expressive communication, impairments, and/or communication limitations. Modification or replacement requests due to a change in the recipient's circumstances must be supported by a new assessment of communication limitations by a speech-language pathologist, and may be submitted at any time; or

  - Even though there has been no significant change in the recipient's communication limitations, there has been a significant change in the features or abilities of available AAC devices (i.e., a technological change) that will overcome or permit an even greater amelioration of the recipient's communication limitations as compared to the current AAC device. A detailed description of all AAC device changes and the purpose of the changes must be provided with the results of a re-evaluation by a speech-language pathologist.

  - Requests for replacements of AAC devices due to loss or damage (either for identical or different devices) must include a complete explanation of the cause of the loss or damage and a plan to prevent the recurrence of the loss or damage.

Bath and Toileting Aids

Bathroom and toileting aids are devices used to assist recipients who are unable to use standard facilities.

Elevated Toilet Seats

An elevated toilet seat may be considered when a recipient is unable to go from a sitting to a standing position without assistance.

Bath or Shower Chairs

Bath or shower chairs may be considered only for severe incapacitating problems due to neurological, physiological, or cognitive disorders that impair the recipient's balance, coordination, or physical strength needed to safely sit or stand while bathing or showering.

Safety Guardrails

Safety guardrails may be considered for recipients who are unable to stand up in the tub or get out of the tub without assistance.

Footrest for Use with Toilet

A footrest for a toilet may be considered when the recipient's feet cannot touch the floor and it is needed for balance and support.

Commode Chairs

A commode chair may be considered when the recipient is physically incapable of utilizing regular toilet facilities.

An extra wide/heavy duty commode chair is covered for a recipient weighing 300 pounds or more. If the recipient weighs less than 300 pounds but the basic coverage criteria for a commode chair are met, payment will be based on the least costly medically appropriate alternative.

A request for payment of a mobile commode chair will be denied as not medically necessary if basic coverage criteria for a commode chair are met. Payment will be based on the least costly medically appropriate alternative stationary commode chair.

Commode Chairs with Detachable Arms

A commode chair with detachable arms may be considered if this feature is necessary to facilitate transferring the recipient, or if the recipient has a body configuration that requires extra width. If these additional criteria are not met but the basic coverage criteria for a commode chair are met, reimbursement will be authorized based on the least costly medically appropriate alternative.

Urinals (Hospital Type) and Bed Pans

Urinals (hospital type) and bed pans may be considered if the recipient is capable of using them and is confined to bed.

Environmental Modifications or Environmental Modification Repairs

Environmental Modifications are activities of a major and largely non-recurring nature to improve the safety, sanitation and adaptability of a recipient's home. Installation of equipment is not covered.

Batteries

Batteries are covered for artificial larynxes, insulin pumps, electric wheelchairs and cochlear implants.

Blood Pressure Devices

Blood pressure devices are only covered for recipients receiving hemo-dialysis in the home setting. Hypertension or hypotension is reviewed for recipients under age 21.

Electronic blood pressure devices may be considered for recipients under the age of 21, based on medical necessity.

Breast or Mammary Prostheses

A breast or mammary prosthesis is approved only after breast removal. If one breast is removed, one prosthesis may be approved. Replacement of a prosthesis may be approved if medical need is established and documented.

Abdominal Binder and Hernia Supports or Burn Garments and Stockings

Abdominal binder and hernia supports may be approved with documentation of medical necessity.

Burn garments and stockings are approved only for severe burns and major vascular problems.

Cochlear Implant (Early and Periodic Screening, Diagnosis and Treatment (EPSDT)-Only)

Reimbursement is available for the cochlear implant device(s) for Medicaid recipients with profound-to-total bilateral hearing loss.

Only recipients, ages one through twenty years, who meet the medical and social criteria listed below shall qualify for implantation.

Only one device per lifetime per ear per eligible recipient shall be reimbursed unless the device fails or is damaged beyond repair, in which case reimbursement for another device and re-implantation will be considered.

Simultaneous bilateral cochlear implantation is a covered service for recipients aged 1-20 when prior authorized for recipients with a profound bilateral sensorineural hearing loss with limited or no benefit from the use of hearing aids. Please refer to the Professional Services Provider Manual for complete details.

Recipient Medical and Social Criteria

The following criteria apply to all recipients. Recipients must:

- Have a profound bilateral sensorineural hearing loss which is a pure tone average of 1,000, 2,000 and 4,000 Hz of 90dB HL or greater;
- Be a profoundly deaf child, age one year or older or be a post linguistically deafened adult through the age of 20 years;
- Receive no significant benefit from hearing aids as validated by the cochlear implant team;
- Have high motivation to be part of the hearing community as validated by the cochlear implant team;
- Have appropriate expectations;

- Have had radiologic studies that demonstrate no intracranial anomalies or malformations which would contraindicate implantation of the receiver-stimulator or the electrode array;

- Have no medical contraindications for undergoing implant surgery or post-implant rehabilitation; and

- Show that the candidate and his/her family are well-motivated, possess appropriate post-implant expectations and are prepared and willing to participate in and cooperate with pre and post implementation assessment and rehabilitation programs as recommended by the implant team and in conjunction with Federal Drug Administration (FDA) guidelines.

- Appropriate tests were administered and no significant benefit from a hearing aid was obtained in the best aided condition as measured by age-appropriate speech perception materials. Specific to ages one through nine years; ages 10 through 17; and

- No responses were obtained to Auditory Brainstem Response, Otoacoustic Emission testing, or any other special testing that would be required to determine that the hearing loss is valid and severe enough to qualify for cochlear implantation.

Specific Criteria

In addition to documentation that recipients meet general criteria, additional required documentation for ages 10 – 20 years must include:

- The recipient has received consistent exposure to effective auditory or phonological stimulation in conjunction with oral method of education and auditory training;

- The recipient utilizes spoken language as his primary mode of communication through one of the following: an oral/aural (re)habilitation program or total communications educational program with significant oral/aural training; and

- The recipient has at least six months' experience with hearing aids or vibrotactile device except in the case of meningitis (in which case the 6 month period will be reduced to 3 months).

NOTE: For multi-disabled children, criteria appropriate for the child's age group are applied.

Non-Covered Expenses of Cochlear Device(s)

The following expenses related to the maintenance of the cochlear device(s) are the responsibility of either the recipient or his family or caregiver(s):

- All costs for service contracts and/or extended warranties; and
- All costs for insurance to protect against loss and theft.

Prior Authorization for Cochlear Device(s)

All aspects of the cochlear device (preoperative speech and language evaluation, implantation, device, repairs, supplies, therapy) must be prior authorized. The request to perform surgery must come from the multidisciplinary team which assessed the recipient's disability and determined the recipient to be a possible candidate for implantation.

The multidisciplinary team must consist of:

- A surgeon/otologist;
- An audiologist;
- A speech/language pathologist;
- A psychiatrist; and
- An educator of the deaf with experience in oral/auditory instruction.

Canes and Crutches

Requests for canes (wooden or metal), quad canes (four-prong), and all types of crutches may be approved if the recipient's condition impairs ambulation and there is a potential for ambulation.

Catheters

Catheters are approved only if the recipient's medical condition necessitates the use of a catheter.

Dialysis Equipment and Supplies

Dialysis equipment and supplies are approved only if the recipient is under treatment for chronic renal disease and is trained in the use of the equipment.

All requests must have:

- The diagnosis and prognosis;
- Any other pertinent medical and social data;
- The date the recipient was first dialyzed;
- A statement from the facility that the recipient is capable of operating the equipment;
- A statement from the equipment provider for home dialysis verifying that the recipient has been trained to use the dialysis equipment;
- The name of the provider;
- A prescription for the machine and the supplies; and
- Frequency of dialysis.

Baclofen Therapy

Consideration shall be given for Medicaid reimbursement for implantation of an Intrathecal Baclofen Therapy (IBT) infusion pump if the treatment is considered medically necessary; the candidate is four years of age or older with a body mass sufficient to support the implanted system, and any one or more of the criteria as described below apply.

Inclusive Criteria for Candidates with Spasticity of Cerebral Origin:

- There is severe spasticity of cerebral origin with no more than mild athetosis;
- The injury is older than one year;
- There has been a drop in Ashworth scale of 1 or more;
- Spasticity of cerebral origin is resistant to conservative management; and
- The candidate has a positive response to test dose of Intrathecal Baclofen.

Inclusive Criteria for Candidates with Spasticity of Spinal Cord Origin:

- Spasticity of spinal cord origin that is resistant to oral antispasmodics or side effects unacceptable in effective doses;
- There has been a drop in Ashworth scale of two or more; or
- The candidate has a positive response to test dose of Intrathecal Baclofen.

Caution should be exercised when considering IBT infusion pump implantation for candidates who: have a history of autonomic dysreflexia; suffer from psychotic disorders; have other implanted devices; or utilize spasticity to increase function such as in posture, balance and locomotion.

Exclusion Criteria

Consideration for an implantation of an IBT infusion pump shall not be made if the candidate:

- Fails to meet any of the inclusion criteria;
- Is pregnant, or refuses or fails to use adequate methods of birth control;
- Has a severely impaired renal or hepatic function;
- Has a traumatic brain injury of less than one year pre-existent to the date of the screening dose;

- Has a history of hypersensitivity to oral baclofen;
- Has a systemic or localized infection which could infect the implanted pump; or
- Does not respond positively to a 50, 75 or 100 mcg Intrathecal bolus of Lioresal during the screening trial procedure.

Diagnoses Covered

The following diagnoses are considered appropriate for IBT treatment and infusion pump implantation:

- Meningitis;
- Encephalitis;
- Dystonia;
- Multiple sclerosis;
- Spastic hemiplegia;
- Infantile cerebral palsy;
- Other specified paralytic syndromes;
- Acute, but ill-defined, cerebrovascular disease;
- Closed fracture of base of skull;
- Open fracture of base of skull;
- Closed skull fracture;
- Fracture of vertebral column with spinal cord injury;
- Intracranial injury of other & unspecified nature; and

- Spinal cord injury without spinal bone injury.

Prior Authorization for IBT

Prior authorization for chronic infusion of IBT must be requested after the screening trial procedure has been completed, but **prior** to pump implantation.
The request to initiate chronic infusion must come from the multidisciplinary team that evaluates the recipient. This multidisciplinary team must be a neurosurgeon or an orthopedic surgeon, a psychiatrist and/or neurologist, the recipient's attending physician, a nurse, a social worker and allied professionals (physical therapist, occupational therapist, etc.).

These professionals must have expertise in the evaluation, management and treatment of spasticity of cerebral and spinal cord origin and shall have undergone training in infusion therapy and pump implantation by a recognized product supplier with expertise in Intrathecal Baclofen.

The following documentation must be submitted in one package by the multidisciplinary team:

- A recent history with documentation of assessments in the following areas:
    - Medical and physical;
    - Neurological;
    - Functional; and
    - Psychosocial.
- Ashworth scores taken before and after the administration of IBT test dose(s); and
- Documentation of any other findings about the recipient's condition which would be of interest to or would assist the Medical Review team in making a decision regarding the recipient's need for chronic infusion, i.e., a video tape of the trial dosage.

Ambulatory Equipment

Walkers and Walker Accessories

A standard walker and related accessories are covered if all of the following criteria are met:

- It is prescribed by a physician for a recipient with a medical condition that impairs ambulation;
- Recipient has a potential for ambulation; and
- Recipient has a need for greater stability and security than can be provided by a cane or crutches.

Wheeled Walker

A wheeled walker may be fixed height or adjustable height and may include glide-type brakes (or equivalent). The wheels may be fixed or swivel. A wheeled walker shall be approved only if the recipient is unable to use a standard walker due to severe neurological disorders, debilitating medical condition that may prohibit the use of a standard walker or limited use of one hand. The request must contain supporting documentation from the prescribing physician which substantiates the need for a wheeled walker rather than a standard walker.

Heavy Duty Walker

A heavy-duty walker may be approved for recipients who meet the criteria for a standard walker and weigh more than 300 pounds.

Heavy Duty, Multiple Braking System, Variable Wheel Resistance Walker

A heavy duty, multiple braking system, variable wheel resistance walker is a four-wheeled, adjustable height, folding walker that has all of the following characteristics:

- Capable of supporting recipients weighing more than 350 pounds;
- Hand operated brakes that cause the wheels to lock when the hand levers are released;

- Can be set so that either one or both brakes can lock the wheels;
- Adjust so the recipient can control the pressure of each hand brake;
- Additional braking mechanism on the front crossbar; and
- A minimum of two wheels have brakes that can be independently set through tension adjustability to provide varying resistance.

A heavy duty, multiple braking system, variable wheel resistance walker is considered medically necessary for recipients who weigh greater than 350 pounds, meet coverage criteria for a standard walker, and are unable to use a standard walker due to a severe neurological disorder or other condition causing the restricted use of one hand. Obesity alone is not considered a medically necessary indication for this walker.

Leg Extensions

Leg extensions are considered medically necessary for recipients six feet tall or more.

Arm Rests

Armrest attachments are considered medically necessary when the recipient's ability to grip is impaired.

Non-Covered Walker Items

- Walker with enclosed frame;
- Enhanced accessories (i.e. style, color, hand operated brakes (other than those described above on heavy duty), multiple braking system, variable wheel resistance walker), seat attachments, tray attachments, or baskets (or equivalent); and
- Walking belts.

A walker with enclosed frame is a folding wheeled walker with a frame completely surrounding the recipient and an attached seat in the back. Walkers with enclosed frames are not considered

medically necessary because their medical necessity compared to a standard folding wheeled walker has not been established.

Enhancement Accessories

Medicaid considers enhancement accessories of walkers, canes and crutches not medically necessary. An enhancement accessory does not contribute significantly to the therapeutic function of the walker, cane or crutch. It may include, but is not limited to style, color, hand operated brakes (other than those described in the section above on heavy duty, multiple braking system, variable wheel resistance walker), seat attachments, tray attachments, or baskets (or equivalent).

Walking Belts

Medicaid does not consider walking belts used to support and guide the recipient in walking as medically necessary because they are not primarily medical in nature and are normally used by persons who do not have a disease or injury.

Wheelchairs

Wheelchairs are approved only when the recipient is confined to a bed, chair or room.

Standard Wheelchairs

The request should indicate the recipient's ability to walk unassisted and whether the request is for a first chair or replacement chair. Standard wheelchairs require documentation of medical necessity.

Standard Wheelchair Attachments

- Foot rests
- Brakes
- Arm rests

Wheelchairs, Motorized and/or Custom Motorized

The term ***motorized*** shall have the same meaning as power, electric or any means of propulsion other than manual. A motorized wheelchair must be medically necessary.

A motorized wheelchair is covered if the recipient's condition is such that the requirement for a motorized wheelchair is long term (at least six months).

The recipient must meet all of the following criteria in order to be considered for a motorized wheelchair:

- The recipient is not functionally ambulatory. Not functionally ambulatory means the recipient's ability to ambulate is limited such that without use of a wheelchair, he/she would otherwise be generally bed or chair confined;

- The recipient is unable to operate a wheelchair manually due to severe weakness of the upper extremities due to a congenital or acquired neurological or muscular disease/condition or is unable to propel any type of manual wheelchair because of other documented health problems; and

- The recipient is capable of safely operating the controls for a motorized wheelchair and can adapt to or be trained to use a motorized wheelchair effectively.

Wheelchair Prior Authorization

All wheelchairs and modifications required to meet the needs of a particular recipient are subject to PA. Prior authorization will be made for only one wheelchair at a time. Backup chairs, either motorized or manual, will be denied as not medically necessary. In addition to the required documentation needed for all PA requests, PA requests for motorized wheelchair must include:

- A completed PA-01 form;

- A physician's prescription for a motorized wheelchair;

- Medical documentation from a physician is required to support the provisions set forth regarding recipient criteria as noted above; and

- A seating evaluation performed, signed and dated by the physical therapist or occupational therapist that performed the seating evaluation. The seating evaluation shall:

- Indicate the appropriateness of the specific wheelchair requested and all modifications and/or attachments to the specific wheelchair and its ability to meet the recipient's long term medical needs. Options that are primarily beneficial in allowing the recipient to perform leisure or recreational activities are not covered;
- Include the dated signature of the physician who prescribed the motorized wheelchair is medically necessary; and
- The recipient's diagnosis or condition is such that a motorized wheelchair is medically necessary; and
- He or she has seen the seating evaluation and motorized wheelchair recommendation.

- Documentation indicating that the recipient is capable of safely operating the controls for a motorized wheelchair and can adapt to or be trained to use the motorized wheelchair effectively. It is not sufficient for a Medicaid provider of motorized wheelchairs to indicate that a recipient is capable of safely operating the controls for a motorized wheelchair and can adapt to or be trained to use it effectively. Such documentation shall include:

  - A signed and dated statement from the recipient's physician, physical therapist that he/she has determined that the recipient has the cognitive, motor and perceptual abilities needed to safely operate the controls of a motorized wheelchair. This statement -must be verified by the notes and recommendation of the physician, physical therapist or occupational therapist making such statement; and

  - A signed and dated statement from the recipient's physician or physical therapist that he or she has determined that the recipient can adapt to or be trained to use the motorized wheelchair effectively. This statement must be verified by the notes and recommendation of the physician, physical therapist or occupational therapist making such statement.

Repairs and Modifications

Request for repairs to motorized wheelchairs will be considered for basic repairs only. Basic repairs are those which are requested to repair an existing component of the recipient's current motorized wheelchair.

Requests for modifications or reconstruction of the recipient's current motorized wheelchair shall not be considered basic repairs. Requests for modifications or reconstruction of the recipient's current motorized wheelchair must be submitted in accordance with PA criteria.

Modifications or reconstruction will be denied if it is more cost effective to provide a new motorized wheelchair.

All repairs and modifications of motorized wheelchairs must be completed within one month, unless there is a justifiable reason for a dely. Rental of a manual wheelchair may be prior authorized on a monthly basis as a temporary replacement, if necessary, when the recipient's motorized wheelchair is being repaired or modified.

Standing Frame

A standing frame (also known as a stander, standing aid, standing device) is assistive technology that can be used by a person who relies on a wheelchair for mobility. A standing frame provides alternative positioning to sitting in a wheelchair by supporting the person in the standing position.

Specific Criteria

The criteria to be considered for a standing frame include, but are not limited to, the following. The recipient must:

- Be at a high risk for lower extremity contractures that cannot be improved with other interventions (stretching, medications, serial casting, splinting, and modalities);
- Be able to tolerate a standing or upright position on the foot and ankle;
- Be non-ambulatory or is unable to stand due to conditions such as, but not limited to, neuromuscular or congenital disorders, including acquired skeletal abnormalities;
- Have tried more cost effective alternatives and still requires a stander;
- Not have a walker or gait trainer and it is not anticipated they will require one;

- Have demonstrated improved mobility, function and physiologic symptoms or has maintained status with the use of the requested stander and is able to follow a home standing program with the use of the requested stander; and

- Use the equipment for personal use only. The equipment will not be used at school.

Exclusion Criteria

Non-coverage of the standing frame includes, but is not limited to the following:

- The recipient has complete paralysis of the lower extremities;

- When there is no expected improvement in mobility or maintenance of function;

- The anticipated functional benefits of standing can be achieved through less-costly alternatives;

- Mobile (dynamic) stander – either self-propelled standers or standers with powered mobility;

- Active stander – allows movement of the arms and legs in a standing position.

- In recipients with syncope, orthostatic hypotension, postural tachycardia syndrome, osteogenesis imperfecta, osteoporosis, and other brittle bone diseases, and hip subluxation;

- In recipient's that have hip and knee flexion contractures of more than 20 degrees; and

- A stander will not be purchased for a recipient who has a gait trainer or ambulatory device.

Documentation Requirements

The following documentation must be submitted to support the medical necessity for this equipment:

- Prior Authorization – (PA-01 Form);
- Physician prescription;
- State of Louisiana Medicaid Standing Frame Evaluation (BHSF-SF-Form 1) completed by a Louisiana State license Physician and Physical or Occupational Therapist in its entirety (see Appendix G); and
- Original Manufacture price.

Strollers of a Therapeutic Type

Strollers of a therapeutic type are approved if the recipient is confined to a bed, chair or room, or if they are needed for transportation to a medical or training facility.

Special Needs Car Seat

A special needs car seat is designed for safe transport of the moderately to severely disabled child.

A special needs car seat is covered when all of the following criteria apply:

- The special needs car seat must be medically necessary and appropriate. The physician must submit a full description of the recipient's postural condition including head and trunk control and height and weight. Weight must be between 20-105 lbs;
- The recipient's condition is of such severity that he/she cannot be safely transported using a standard car seat, car seat belts, or modified vest travel restraints;
- There is expected long-term need for the car seat; and

- The special needs car seat must accommodate at least 36 months growth.

If applicable, the car seat must be equipped with leg extensions to allow for growth over the 36-month period. Consideration must be given to the manufacturers' weight limitations.

Diabetic Supplies and Equipment

Durable Medical Equipment, Prosthetics, Orthotics and Supplies Program

Items including glucometers, insulin pumps, and supplies for insulin pumps other than the insulin itself, are covered through the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) program.

Glucometer

Glucose monitors are provided to Medicaid eligible recipients who are insulin-dependent or insulin-requiring, ***or have a diagnosis of gestational diabetes.***

The prescription or letter for the blood glucose monitor must state that:

- The recipient is an insulin-dependent or insulin-requiring diabetic, ***or the recipient's diagnosis is gestational diabetes****;* and

- The recipient or someone on his/her behalf can be trained to use the monitor correctly.

Diabetic supplies for recipients who are insulin-dependent, insulin-requiring ***or who have gestational diabetes*** must present a physician's prescription and current Medicaid card to pharmacies which accept Medicaid for the following diabetic supplies: disposable insulin syringes, blood glucose monitoring strips, urine ketone monitoring strips, auto-lancet devices and auto-lancets.

The prescription for disposable syringes must contain the prescribing physician's written statement that the recipient is insulin-dependent or insulin-requiring.
For Medicaid recipients in long term care facilities, glucose monitors are not reimbursable through the PAU. These monitors are covered in the per diem nursing facility rate.

Continuous Subcutaneous Insulin External Infusion Pumps

A continuous subcutaneous insulin external infusion pump is a portable insulin pump. It is about the size and weight of a small pager. The pump delivers a continuous basal infusion of insulin. Insulin pumps can be automatically programmed for multiple basal rates over a 24-hour time period. This can be useful for such situations as nocturnal hypoglycemia, the dawn phenomenon, and to assist with tight glycemic control.

Before meals or at other times (e.g., hyperglycemia after unanticipated caloric intake), the pump can be set to deliver a bolus of insulin, similar to taking an injection of pre-meal regular insulin for someone using multiple daily injections.

Payment for a continuous subcutaneous insulin external infusion pump and related supplies will be authorized for treatment of Type I diabetes. **Recipients must meet either Criterion A or B as follows**:

> **Criterion A:** The recipient has completed a comprehensive diabetes education program and has 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; and has documented 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 meets two or more of the following criteria while on the multiple daily injection regimen:
>
> - Has a glycosylated hemoglobin level (HbAlc) greater than 7.0 percent;
> - Has a history of recurring hypoglycemia;
> - Has wide fluctuations in blood glucose levels (regardless of A1C);
> - Demonstrated microvascular complications;
> - Recurrent severe hypoglycemia;
> - Suboptimal diabetes control (A1C exceeds target range for age);
> - Adolescents with eating disorders;

- Pregnant adolescents;
- Ketosis-prone individuals;
- Competitive athletes; and
- Extreme sensitivity to insulin in younger children.

OR

Criterion B: The recipient with Type I diabetes has been on a pump prior to enrollment in Medicaid and has documented frequency of glucose self-testing an average of at least four times per day during the month prior to Medicaid enrollment.

In addition to meeting Criterion A or B above, the recipient with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement, ***or*** must be autoantibody positive (e.g. islet cell autoantibodies (ICA), glutamic acid decarboxylase (GAD65), the 40K fragment of tyrosine phosphatase (IA2), insulin autoantibodies (IAA), or zinc transporter 8 autoantibodies (ZnT8).

Updated fasting C-peptide testing requirement:

- Insulinopenia (defined as fasting C-peptide level less than or equal to 110 percent of the lower limit of normal of the laboratory's measurement method); and
- Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose less than 225 mg/dl.

NOTE: Levels only need to be documented once in the medical record.

The pump must be ordered by and follow-up care of the recipient must be managed by a physician who has familiarity with continuous subcutaneous insulin infusion (CSII) and who works closely with a team of nurses, diabetes educators and dietitians who are knowledgeable in the use of CSII.

Non-Covered Items DMEPOS

Continuous subcutaneous insulin external infusion pumps shall be denied as not medically necessary for all Type II diabetics, including insulin requiring Type II diabetics.

Insulin for the continuous subcutaneous insulin external infusion pumps must be obtained through the Pharmacy Program and is not covered in the DMEPOS Program.

The Medicaid Program will not cover the replacement of a currently functioning insulin pump for the sole purpose of receiving the most recent insulin pump technology as this would not be medically necessary.

The Medicaid Program will not cover additional software or hardware required for downloading data to a device such as a personal computer, smart phone, or tablet to aid in self-management of diabetes mellitus.

Special Shoes and Corrections

Please refer to Orthopedics in this section, for information concerning special shoes and corrections for diabetics.

Disposable Incontinence Products (T4521 - T4535 & T4543)

The products below are covered for recipients ages four years through 20 years when specifically prescribed by the recipient's physician and specific criteria are met as described below.

Diapers

The individual has a medical condition resulting in permanent bowel/bladder incontinence, and the individual would not benefit from or has failed a bowel/bladder training program when appropriate for the medical condition.

Pull-on Briefs

There is presence of a medical condition resulting in permanent bowel/bladder incontinence and the recipient has cognitive and physical ability to assist in his/her toileting needs.

Liners/Guards

Liners/guards may be approved if they are cost-effective in reducing the amount of other incontinence supplies needed.

NOTE: Permanent loss of bladder and/or bowel control is defined as a condition that is not expected to be medically or surgically corrected and that is of long and indefinite duration.

Recipients, who have a diagnosis of nocturnal incontinence, including those who do not have a problem in the daytime but are not able to wake up to go to the bathroom at night, may be qualified to receive a diaper or pull-up for nighttime use.

Documentation Requirements

The prescription request form for disposable incontinence products may be completed, or a physician's prescription can be submitted along with the required documentation as listed below.

Documentation must reflect the recipient's current condition and include the following:

- Diagnosis (specific ICD-9-CM code) of condition causing incontinence (primary and secondary diagnosis);
- Item to be dispensed;
- Duration of need (physician must provide);
- Size;
- Quantity of item and anticipated frequency the item requires replacement; and
- Description of mobility/limitations.

To avoid unnecessary delays and need for reconsideration, care should be taken to use the correct HCPC code from among T4521-T4535 and T4543.

Documentation for extraordinary needs must include all of the above and:

- Description of mental status/level of orientation;

- Description of current supportive services; and
- Additional supporting diagnosis to justify increased need for supplies.

The "Prescription Request Form for Disposable Incontinence Supplies" collects this information. (See Appendix D for form.)

Prior Authorization Requirements for Incontinence Supplies

Prior authorization is required for all disposable incontinence supplies. The PA requests shall meet all previously defined criteria for:

- Eligible recipient;
- Eligible provider;
- Covered product; and
- Documentation requirements.

Quantity Limitations

Disposable incontinence supplies are limited to eight per day. Additional supporting documentation is required for requests that exceed the established limit.

Dispensing

Only a one-month supply may be dispensed at any time as initiated by the recipient. Allowable amounts may preclude the purchase of some products. The rate has been established so that the majority of products on the market are obtainable. Providers should always request authorization for the appropriate product for the recipient's current needs.

Providers must provide at the minimum, a moderate absorbency product that will accommodate a majority of the Medicaid recipient's incontinence needs. Supplying a larger quantity of inferior products is not an acceptable practice.

For recipients requesting a combination of incontinence supplies, the total quantity shall not exceed the established limit absent approval of extraordinary needs.

Because payment cannot exceed the number of units prior authorized, providers who choose to have incontinent supplies shipped directly from the manufacturer to the recipient's home shall be responsible for any excess over the number of supplies approved by the PA.

Hearing Aids

Hearing aids are only provided to eligible recipients under the age of 21 (EPSDT eligibles) and approved only when there is a significant hearing loss documented by audiometric data from both an ear specialist (otologist) and a hearing aid provider.

A hearing loss greater than 20 decibels average hearing level in the range 250-2000 hz is considered significant.

Reimbursement is $553 per hearing aid. Hearing aids must have a two year warranty and should normally be expected to last at least three years before replacement.

Repairs are reimbursed at the invoice price up to $40 per hour for labor. Repair and batteries do not require PA.

Hospital Beds

Standard hospital beds are approved if the recipient is confined to a bed and their condition necessitates positioning the body in a way that is not possible in an ordinary bed. Elevation of the head/upper body less than 30 degrees does not usually require the use of a hospital bed.

Prior authorization requests for all covered hospital beds (as described in this section) must include the following:

- The recipient requires positioning of the body in ways not feasible with an ordinary bed due to a medical condition that is expected to last for at least one month;

- The recipient requires the head of the bed to be elevated more than 30 degrees most of the time due to congestive heart failure, chronic pulmonary disease, or problems with aspiration. Pillows or wedges must have been tried and failed; and

- The recipient has a condition that requires special attachments (such as a trapeze, foot board, or traction equipment) that cannot be fixed and used on an ordinary home bed.

NOTE: More specific criteria may apply as described for each covered hospital bed type.

Hospital Beds, Fixed and Variable Height

A fixed height hospital bed is one with manual head and leg elevation adjustments but no height adjustment. A variable height hospital bed is one with manual height adjustment and manual head and leg elevation adjustments.

In addition to the required documentation for PA requests as described under Hospital Beds above, the request must also include that the recipient has a condition that requires special attachments (such as a trapeze, foot board, or traction equipment) that cannot be fixed and used on an ordinary home bed.

Furthermore, requests for a variable height bed must document that the recipient requires a bed height different than a fixed height hospital bed to permit safe transfers to a chair or for adequate bed care.

Hospital Bed, Semi-Electric

A semi-electric hospital bed is one with manual height adjustment and electric head and leg elevation adjustments.

In addition to the required documentation as previously listed under Hospital Beds, the PA request must document that the recipient requires a bed height different than a fixed height hospital bed to permit safe transfers to a chair or for adequate bed care. The PA request must also include that the recipient is alone for extended periods of time, requires frequent and immediate changes in body position and can operate the bed controls independently.

Hospital Bed, Total Electric

A total electric hospital bed is one with electric height adjustment and electric head and leg elevation adjustments.

In addition to the required documentation as previously listed under Hospital Beds, the PA request must document that the recipient requires a bed height different than a fixed height hospital bed to permit safe transfers to a chair or for adequate bed care. The PA request must also include that the recipient is alone for extended periods of time, requires frequent and immediate changes in body position and can operate the bed controls independently.

Documentation submitted on the PA request must also indicate one of the following:

- The recipient has tried multiple means of transfer and can only transfer with a total electric bed; and

- The recipient has a care giver with a documented medical condition stating an inability to use a crank on a semi-electric bed.

Hospital Bed Mattresses

Hospital bed mattresses are considered part of the hospital bed and will only be approved to replace mattresses that are no longer functional, when the recipient meets the criteria to receive a hospital bed.

Egg-Crate Mattresses & Alternating Air Pressure Mattresses/Pads

Egg-crate mattresses and alternating pressure mattresses/pads are devices used to relieve pressure and prevent the occurrence of decubitus ulcers. The pads include: gel, air, dry and water pressure pads for mattresses, and mattress-size pads.

The PA request must include:

- Documentation on the lesions, the recipient's condition, positioning, nutritional status (including serum albumen and total protein levels with the initial request), and detailed descriptions of prior treatments used and the outcomes of the treatments;

- Documentation showing the presence of stage three or stage four decubitus ulcers affecting at least two pressure bearing surfaces; and

- For subsequent PA requests, documentation must show signs of healing. The presence of new decubitus must be explained and may be a basis for denial without extenuating circumstances.

Sheepskins

Sheepskins are approved if the recipient's skin condition necessitates use.

Side Rails

Side rails for beds other than hospital beds are approved only if the recipient's medical condition necessitates use of rails on a regular bed.

Hospital Bed, Pediatric

A pediatric hospital bed allows for the manual, semi-electric, or fully electric adjustment to the head and leg elevation. A pediatric hospital bed is:

- One with a full side rail (360 degrees, up to 24 inches high above the mattress) enclosure; and
- May be manual, semi-electric, or total electric.

Specific Criteria

Hospital Bed, Pediatric without Safety Enclosure

A pediatric hospital bed without an added safety enclosure is covered when **all** of the following criteria are met. The recipient must:

- Be under 21 years of age;
- Meet the criteria for a hospital bed (see Hospital Bed Criteria in this section);
- Have a medical condition that prevents the use of a standard size hospital bed and is best met by a pediatric sized hospital bed;

- Have a medical condition that requires positioning of the body ordered by the physician so that the head of the bed elevation is greater than 30 degrees, or have documented problems with aspirations; and

- Have a medical condition that is expected to last greater than 6 months which requires positioning of the body in ways that are not feasible with an ordinary bed, or hospital bed.

In addition, the following criteria must be met:

- The desired medical benefit is not attainable by the use of an ordinary bed. All alternative methods have been tried and failed;

- An ordinary bed cannot be modified or adapted by commercially available items to meet the medical needs; and

- Pillows and wedges must have been considered and ruled out.

Hospital Bed, Pediatric with Safety Enclosure

A pediatric hospital bed with an added safety enclosure is covered when **all** of the following criteria are met. The absence of a pediatric hospital bed with safety enclosure would result in the recipient being institutionalized.

The recipient must:

- Be under 21 years of age and:

- Have one of the following diagnoses: brain injury, moderate to severe cerebral palsy, seizure disorder (with daily seizure activity taking anti-seizure medication), developmental disability, or severe behavior disorder (this list is not all inclusive):

- Meet the criteria for a hospital bed (see Hospital Bed Criteria in this section);

- Have a medical condition that puts him/her at risk for falling off of or seriously injuring himself/herself while in an ordinary bed, standard size hospital bed, or a pediatric sized hospital bed;

- Have a history of behavior involving unsafe mobility (climbing out of bed - more than standing at the side of the bed) that puts the recipient at risk for serious injury while in an ordinary bed, standard hospital bed, or pediatric hospital bed; and

- Be cognitively impaired and have communication impairments. The recipient is mobile and his/her unrestricted mobility has resulted in documented injuries; and

- Have tried less costly alternatives which were unsuccessful, including any of the following (not all inclusive):
  - Rail protectors;
  - Medications to address seizures and/or behaviors;
  - Helmets for head banging;
  - Baby monitors and bed alarm systems;
  - Behavior modification strategies;
  - Removal of safety hazards and installation of child protection devices (e.g. baby gate, safety door knob) in the recipient's room;
  - Placement of mattress on the floor; and
  - Physical and environmental factors for behavior have been eliminated. These include, but are not limited to, hunger, thirst, toileting, pain, restlessness, fatigue due to sleep deprivation, acute physical illness, temperature, noise levels, lighting, medication side effects, over/under stimulation or a change in caregivers or routine.

Exclusion Criteria

Non-coverage of the pediatric hospital bed includes, but is not limited to the following:

- Lack of caregiver monitoring of recipient's safety;

- The safety enclosure frames are used as a restraint or for the convenience of family or caregiver;

- An ordinary bed, typically sold as furniture, which consists of a frame, box spring, and mattress;

- Institutional type hospital beds (e.g. oscillating beds, spring-base beds, circulating beds, continuous lateral rotation beds, and Stryker frame beds);

- Enclosed beds for recipients with 24-hour care from caregivers who are required to be awake and actively caring for the child;
- Enclosed bed systems that are not approved by the FDA (e.g. Vail Enclosure Bed, Posey Bed Enclosure System); and the
- Hospital beds where manufacturer is not registered and cleared to market with the FDA.

Documentation Requirements

The following documentation must be submitted to support the medical necessity for this equipment:

- Prior Authorization form – (PA-01 Form);
- Physician prescription;
- Louisiana Medicaid Pediatric Hospital Bed Evaluation (BHSF-PHB-Form 1) completed by a Louisiana State licensed physician and physical or occupational therapist in its entirety (see Appendix G); and
- Original manufacturer's price.

High Frequency Chest Wall Oscillation Devices

High frequency chest wall oscillation devices (E0483) are covered for recipients who meet the following criteria:

The recipient must have one of the following:

- A diagnosis of cystic fibrosis.
- A diagnosis of bronchiectasis:
  - Characterized by daily productive cough for at least 6 continuous, months or, frequent (i.e. more than 2/year) exacerbations requiring antibiotic therapy; and
  - Confirmed by high resolution, spiral, or standard CT scan.

- Neuromuscular Disorder

and

- Well-documented failure of standard treatments to adequately mobilize retained secretions with all of the following:
  - Chest physical therapy and flutter device at least twice daily (when age appropriate);
  - A pattern of hospitalizations at least annually or more;
  - Significantly deteriorating clinical condition;
  - Be under the care of a pulmonologist; and
  - Copies of two pulmonary test results that indicate the recipient's condition improved with the use of the vest.

Enteral Nutrition

Enteral therapy or oral nutritional supplements may be provided safely and effectively in the home by non-professional persons who have undergone special training. Medicaid will not pay for any services furnished by non-physician professionals.

Enteral nutritional therapy is considered reasonable and necessary for a recipient when medical documentation, such as hospital records and clinical findings, support an independent conclusion that the recipient has a permanently inoperative internal body organ or function which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with his/her general condition. For purposes of this policy, permanent means an indefinite period of more than one month.

Prescriptions for enteral feedings must be for an average of at least 750 calories per day over the prescribed period and must constitute at least 70 percent of the daily caloric intake to be considered for coverage by Medicaid. Coverage of prescribed feedings of less than an average of 750 calories per day may only be considered with additional physician documentation and justification of the reason for prescribing less than an average of 750 calories per day. Baby food and other regular grocery products than can be used with an enteral system are not covered.

All requests must include the following information:

- Name of the nutrient product or nutrient category;

- Number of calories prescribed by enteral feeding per day (100 calories equals one unit) and whether the prescribed amount constitutes 70 percent or more of the daily caloric intake;
- Frequency of administration per day;
- Method of administration (oral or, if tube, whether syringe, gravity, or pump fed);
- Route of administration, if tube fed (i.e. nasogastric, jejunostomy, gastrostomy, percutaneous enteral gastrostomy, or naso-intestinal tube); and
- Reason for use of a pump, if prescribed.

Enteral nutritional therapy will not be approved for temporary impairments or for convenience feeding via gastrostomy.

Enteral feedings can only be provided for the most economic package equivalent in calories and ingredient content to the needs of the recipient as established by medical documentation. The physician(s) must document the reason for prescribing a formula higher than category I-A (HCPC B415) or category II (HCPC B4152). This includes any formula in categories III through IV (HCPC B4153 through B4155).

Approved requests shall be reviewed at periodic intervals not to exceed six months. Approval may be granted for up to six months at a time. Medicaid, however, will pay for no more than one month's supply of enteral nutrients at any one time.

Enteral Infusion Pump

A standard enteral infusion pump will be approved only with documented evidence that the pump is medically necessary and that syringe or gravity feedings are not satisfactory due to complications such as aspiration, diarrhea, dumping syndrome, etc.

Medicaid will pay for the rental of a standard enteral infusion pump and accessories. Medicaid can pay for repairs not covered by the warranty or lease agreement.

Hyperalimitation - Intradialytic Parenteral Nutrition Therapy

Intradialytic parenteral nutrition therapy (IDPN) is considered for PA when a gastrointestinal disease or condition is present and is the cause of the recipient's inability to sufficiently absorb enough nutrients to maintain their weight and strength. Authorization will not be considered for recipients who only have renal failure or insufficiency and an associated poor appetite or failure to thrive.

Request must include the following information:

- Documentation that the recipient has an inability to sufficiently maintain their weight and strength without the IV nutrition therapy;
- Documentation that adequate nutrition cannot be made possible by dietary adjustment, oral supplements, or enteral nutrition (tube or non-tube fed); and
- Documentation that a clinically significant gastrointestinal disease or conditions that have resulted in the recipient's malnutrition due to the inability of the GI tract to sufficiently absorb enough nutrients. A diagnosis alone is not sufficient to determine coverage.

Lumbar Orthosis and Truss Supports

Lumbar orthosis and truss supports may be approved with documentation of medical necessity.

Patient Lifts

Lifts are approved only if all of the following conditions are met:

- If the recipient is confined to bed, chair or room and is unable to transfer or unable to achieve needed movement with or without assistance;
- If the caregiver is unable without the use of a lift to provide periodic movement necessary to arrest or retard deterioration in the recipient's condition, thus affecting improvement in rehabilitation; and

- When the caregiver is unable to transfer recipient from chair to bed or bath (or vice versa) e.g., because of recipient's size or weight.

NOTE: Medicaid covers hydraulic lifts. **Medicaid does not cover electric lifts**.

Lift Slings

Lift slings or seats, either canvas or nylon, are considered part of the lift and are only covered as replacement items.

Nebulizers

Nebulizers are reimbursed for purchase only. Medications for use with the nebulizer are reimbursed through the Pharmacy Program, not DME.

Orthopedic Shoes and Corrections

Orthopedic shoes and corrections may be approved only when:

- Needed to protect gains from surgery or casting (qualifies as an emergency prior authorization); or
- Medically necessary to prevent clinical deterioration of the foot as with recipients with severe diabetes; or
- Medically necessary to prevent clinical deterioration of the foot as with recipients with severe peripheral vascular disease; or
- Attached to braces.

Diabetics

Special shoes and corrections are covered for diabetics. Coverage is provided for extra-depth or custom molded shoes, as well as inserts or modifications, when the physician:

- Documents that the recipient has diabetes;

- Certifies that the recipient is being treated under a comprehensive plan of care for his/her diabetes and that he/she needs therapeutic shoes; and

- Documents that the recipient has one or more of the following conditions:
  - Previous amputation of the foot or part of the foot due to complications that resulted from diabetes;
  - History of previous foot ulceration;
  - Pre-ulcerative callus formation, or peripheral neuropathy with a history of callus formation;
  - Foot deformity; or
  - Poor circulation.

Shoe Lifts

Shoe lifts are covered only if the lift needed is greater than 1/2 inch. Inserts are only covered for shoes which are attached to braces, or when there is sufficient documentation from the treating physician to justify medical coverage without the attachments to braces.

Reimbursement

Because Medicare requires that the recipient either has diabetes with peripheral complications or the shoe must always be attached to braces, Medicaid will allow PA for consideration of payment when Medicare's criteria are not met. The provider must use a GY modifier when submitting the PA request for consideration or the claim for payment.

NOTE: Cables are not considered braces and are not covered.

Shoes for Minor Orthopedic Problems

Payment will not be made for shoes to correct minor orthopedic problems such as pes planus, metatarsus adductus, and internal tibial torsion.

Orthotic Devices

Orthotic devices include leg braces, neck braces, knee braces and supports, spinal supports, splints, brace attachments and repairs. The request for approval should include the following:

- A complete description of special type brace;
- The recipients mental and physical ability to use the device;
- Whether the device is a replacement;
- Whether training is indicated; and
- The plan of training, when indicated.

Osteogenic Bone Growth Stimulators

Osteogenic bone growth stimulators are used to augment bone repair associated with either a healing fracture or bone fusion. Medicaid coverage is limited to reimbursement for electrical and ultrasonic non-invasive types of bone growth stimulators. Medicaid will not provide reimbursement for invasive types of bone growth stimulators.

This item has not been approved by FDA for rental. Therefore, Medicaid will not approve payment for an osteogenic bone growth stimulator as a rental device.

Non-spinal Non-invasive Electrical Stimulators

Non-spinal noninvasive electrical bone growth stimulators may be considered under the following circumstances:

- The failure of long bone fractures to heal. A period of six months from the initial date of treatment must elapse before failure is considered to have occurred;
- The failure of long bone fusions (a period of nine months from the initial date of treatment must elapse before failure is considered to have occurred); or
- The treatment of congenital pseudoarthroses. There is no minimal time requirement after the diagnosis.

Non-Spinal Non-Invasive Ultrasonic Stimulators

Non-Spinal non-invasive ultrasonic bone growth stimulators may be considered under the following circumstances:

- The failure of a non-union fracture to heal. A period of 90 days following treatment has occurred;
- Documentation consists of two sets of radiographs, one before treatment and the second occurring 90 days after treatment; and
- The radiographs shall include multiple views and be accompanied by a written interpretation by a physician stating that there has been no clinically significant evidence of the fracture healing between the two sets of radiographs.

Spinal Non-Invasive Electrical Stimulators

Spinal non-invasive electrical bone growth stimulators may be considered:

- When a minimum of nine months has elapsed since the recipient had fusion surgery which resulted in a failed spinal fusion;
- When there is a history of a previously failed spinal fusion at the same site following spinal fusion surgery (meaning more than nine months has elapsed since fusion surgery was performed at the same level which is being fused again). As long as nine months has passed since the failed fusion surgery, this repeated fusion attempt requires no minimum passage of time for the application of the device;
- Following a multi-level spinal fusion (i.e., involving three or more contiguous vertebrae, such as L3-L5 or L4-S1). There is no minimum requirement for application after surgery.

Oxygen Concentrators

The attending physician, or a consultant physician who has personally examined the recipient at the request of the attending physician, must have seen the recipient within 30 – 60 days of prescribing oxygen therapy.

Initial requests for oxygen concentrators must include a prescription which is signed and dated by the treating physician and which includes:

- The oxygen flow rate;
- The frequency and duration of use;
- An estimate of the period of need; and
- The results of a current blood gas laboratory report done at rest and at room air (performed no more than 30 days prior to the prescription) from an appropriate facility giving the arterial blood gases (ABGs) and arterial saturation. However, oxygen saturation may be determined by pulse oximetry when ABGs cannot be taken.

The following diagnostic findings support the need for oxygen therapy:

- **Group I**
  - A current ABG with a P02 at or below 55 mm Hg, or arterial oxygen saturation at or below 88 percent or below 88 percent, taken at rest, breathing room air.
  - A current ABG with a P02 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken during sleep; or if there is a significant drop during sleep of more than 10 mm Hg of the arterial P02, or a drop of more than 5 percent of the arterial oxygen saturation, and this drop is associated with symptoms or signs reasonably attributable to hypoxemia.

    Example: PO2 while awake - 75 mm HG
    PO2 while asleep - 64 mm HG
    Symptoms: nocturnal restlessness

  - A current ABG with a P02 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken during exercise for a recipient who demonstrates an arterial P02 at or above 56mm Hg, or an arterial saturation at or below 89 percent while awake at rest. In this case,

supplemental oxygen is provided during the exercise if there is evidence that use of oxygen improves the hypoxemia experienced during exercise while breathing room air.

- **Group II**

  Coverage is available for recipients whose current arterial P02 is 56-59 mm hg or whose arterial blood oxygen saturation is 89 percent, if there is evidence of:

  - Dependent edema suggesting congestive heart failure (CHF) (documentation from the physician must indicate the degree of edema and if it is associated with CHF);
  - "P" pulmonale on a current electrocardiogram (EKG) (documentation from the physician must indicate if the AP@ wave on an EKG taken within the last 30 days was greater than 3 mm in standard leads II, III of AVF); or
  - Erythrocythemia with a current hematocrit greater than 56 percent.

- **Group III**

  Medicaid reimbursement will not be made for recipients with arterial P02 levels at or above 60 mm Hg, or arterial blood saturation at or above 90 percent.

Portable Oxygen

Portable oxygen equipment will be reimbursed for recipients who need continuous oxygen and require portable units while enroute to a doctor's office, hospital or medically necessary appointment.

Documentation of medical necessity as well as the anticipated number of visits per month needed must be submitted by the recipient's treating physician with the prior authorization request. Portable systems will not be approved to be used on a standby basis only. Units will be authorized per month based on review of submitted medical justification. An example of justification for refills includes, but is not limited to, multiple weekly visits for radiation or chemotherapy.

For recipients under age 21 only, portable oxygen may be approved when needed for travel to and from school.

Reimbursement for Oxygen Concentrators

Payment for an oxygen concentrator also includes the cost of providing all routine maintenance and servicing, and monitoring the proper usage in the home by a respiratory therapist. At the time of the initial request for PA, the DME provider must describe a plan for routine checking and servicing of the machine and a plan for monitoring the proper usage in the home by a respiratory therapist as a prerequisite to authorization of purchase or rental of an oxygen concentrator from that provider.

Reimbursement fees for oxygen concentrators are $1,250 for purchase or $150 per month for rental, or billed charges, whichever is the lesser amount. If the item is not available at the established rate, the flat fee that will be utilized is the lowest cost at which the item has been determined to be widely available by analyzing usual and customary fees charged in the community.

Peak Flow Meters and Mucus Clearance (Flutter) Devices

Portable, manual type peak flow meters can be covered for recipients with asthma when prescribed for the measurement of lung function as part of an effective asthma management program and PA is required.

Coverage of small, hand held mucus clearance (flutter) devices is provided when prescribed for recipients with lung diseases or conditions producing retained secretions, such as Chronic Obstructive Pulmonary Disease and Cystic Fibrosis, to facilitate the removal of mucus from the lungs and must be prior authorized.

Pulse Oximeter

Pulse Oximeter **(E0445)** are a covered service for EPSDT eligible individuals who are already approved for supplemental home oxygen systems and/or Vent dependent and whose blood saturation levels fluctuate (submit supporting blood saturation levels), thus requiring continuous or intermittent monitoring to adjust oxygen delivery.

The following criteria for coverage apply to pulse oximeter:

This item is usually approved for a purchase for vent dependent and oxygen dependent recipients. Other diagnoses are usually approved for rental for six months, then recertification is required for purchase.

A non-recording/alarming pulse oximeter is covered when one of the following apply:

- The beneficiary is dependent on a ventilator with supplemental oxygen.
- The beneficiary has a tracheostomy, on oxygen, and requires monitoring of O2 saturation as determined by the physician.
- The beneficiary requires supplemental oxygen and has unstable saturations.
- The beneficiary is on supplemental oxygen and weaning is in process.

A recording/alarming pulse oximeter is covered when **all** of the following apply:

- The beneficiary's condition meets one of the criteria for a non-recording/alarming oximeter;
- The recording/alarming oximeter is being ordered by the physician to monitor the beneficiary during a specific event such as a weaning attempt from oxygen or ventilator; and
- feeding times for an infant, or other times for which the physician needs documentation of the recipient's blood oxygen saturation.

Prosthetic Devices

Prosthetic devices include artificial limbs, body parts, sockets, suspension components, attachment, alignment and finishing. A complete description of the prosthesis is required, such as whether the device is a conventional type, above the knee or a special type. The request should indicate the following:

- Whether the request is for the first prosthesis or a replacement;

- The mental and physical ability of the recipient to use the device; and
- Whether training is required for a replacement.

A plan of training shall always be a part of a first request for prosthesis.

Suction Pumps

Purchase of a respiratory suction pump may be considered for recipients who have difficulty raising and clearing secretions secondary to:

- Cancer or surgery of the throat or mouth;
- Dysfunction of the swallowing muscles;
- Recipient is in an unconscious or obtunded state; or
- Tracheostomy.

Suction machines may be considered only if the machine specified is medically required and appropriate for home use without technical or professional supervision.

Accessories and supplies may be considered when they are medically necessary and used with a medically necessary suction pump.

Sterile suction catheters are considered to be medically necessary only for tracheostomy suctioning.

Support Hose

Support hose are approved only for severe incapacitating vascular problems, such as acute thrombophlebitis, massive venous stasis, or pulmonary embolism.

Surgical Dressings or Bandages (gauze, tape, sponges, cement and disposable gloves)

Surgical dressings and bandages are approved only for wound dressing and post-operative care with documentation of medical necessity.

Surgical Mastectomy Bras

Surgical mastectomy bras are approved only if one or both of the recipient's breasts have been removed. After a mastectomy, two bras may be approved. If the breasts are removed in separate surgeries, two more bras may be approved following the second surgery.

Replacements may be approved after a reasonable length of time.

Tracheostomy Care Supplies

Tracheostomy care supplies are covered for recipients following an open surgical tracheostomy.

Tracheostomy care or cleaning starter kits may be covered for a maximum of two weeks postoperative of an open surgical tracheostomy and must contain the following:

- Plastic tray;
- Basin;
- Pair of sterile gloves;
- Tube brush;
- Pipe cleaners;
- Pre-cut tracheostomy dressing;
- Roll of gauze;
- 4 inch x 4 inch sponges;
- Cotton-tip applicators; and
- One-half inch twill tape.

Tracheostomy care kits for an established tracheostomy may be covered for routine care. One care kit per day is considered normal usage. Additional kits may be considered only with medical necessity documentation.

Tracheostomy care kits for established tracheostomies are expected to contain the following:

- Tube brush;
- Pipe cleaners;
- Cotton-tip applicators;
- One-half inch twill tape;
- 4 inch x 4 inch sponges; and
- Pair of sterile gloves.

Sterile suction catheters are considered medically necessary only for tracheostomy suctioning.

Traction Equipment

Traction equipment is approved only if the recipient has significant orthopedic impairment which prevents ambulation. Cervical traction collars are considered under Orthotic Devices.

Trapeze Bar

Trapeze bars are approved if the recipient requires assistance to sit up in bed because of a respiratory condition or a need to change body position for other medical reasons.

Intravenous (IV) Therapy and Administrative Supplies

Intravenous (IV) therapy or intravenous therapy is a way of taking medicine so that it flows straight into the bloodstream.

IV medicines are given through flexible plastic tubes that are inserted into a vein, usually in the arm or the chest.

Medication that is given through an IV may be given with a syringe as a single dose (push), from a bag that is attached to the end of the tube (gravity infusion) or with a pump.

IV medication is used instead of medicine that is taken by mouth (oral) when:

- The medicine needed is not available in oral form;
- The doctor feels that IV medication will be more effective than oral medicine; and/or
- Recipient is unable to take medication by mouth.

Some of the different devices that are used to give IV medicines are:

- Cannulas;
- Central lines, (Hickman's catheter);
- Picc (Peripheral Intravenous Central Catheter) lines; and
- Portacaths® (Infuse-a-port®, Mediport®).

Syringes and Needles

Syringes and needles are covered only for intravenous (IV) therapy, intramuscular (IM) injections, sub-coetaneous (Sub Q) injections, for dialysis purposes when used to inject heparin into the dialysis system, and for wound care.

Documentation must show that a home health agency is administering and/or monitoring the administration of IV therapy provided in the home in order for these supplies to be approved.

NOTE: Insulin syringes are not covered in the DMEPOS Program, but are covered in the Pharmacy Program. Syringes are not separately reimbursable for enteral and parenteral therapy, as these items are included in the supply kits.

Ventilator Assist Devices

Bi-level Positive Airway Pressure

The following policy guidelines apply to all ventilator assist devices:

All equipment needs, including emergency equipment, must be prior authorized. The PAU will act on emergency requests and give a decision within two working days. If not an emergency, the PAU will act on written requests and give a decision within 25 days. Unless the physician can clearly justify purchase of the equipment, a rental trial period of up to three months can be requested to have an adequate trial period to document appropriateness.

Other equipment, such as low pressure alarms, must be separately documented to show medical necessity. Low pressure alarms will be approved for recipients who are ventilator dependent or at risk for a life threatening event. Pulse oximetry, due to its technology limitations, is not reimbursable for home use.

These guidelines exist to assist the physician and the FI to efficiently approve most applications but allow physicians to request consideration for recipients which for unique reasons fall outside criteria. All medical providers are expected to preserve pertinent information which may periodically be surveyed to evaluate these criteria in the future.

Non-disposable, reusable supplies should be prescribed, if appropriate, for medical care and economical reasons. Periodic exacerbations may increase supply needs, therefore, an extra prescription should be written. The prescription should be written out "As needed" and **not** by using the acronym "prn" so it can be used anytime during a several month span.

The use of oxygen must be considered for those recipients where these devices fail to adequately improve the recipient's condition. There must be documentation of satisfactory clinical improvement such that mechanical ventilation through a tracheotomy tube is justifiably avoided.

Continuous Positive Airway Pressure

A continuous positive airway pressure (CPAP) machine is used to treat recipients who have moderate to severe obstructive sleep apnea.

A respiratory cycle is defined as an inspiration, followed by expiration. Polysomnography is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation, and report. It must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), and electrooculogram (EOG), and a submental electromyogram (EMG).

Polysomnography must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a

whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.
Apnea is defined as the cessation of airflow for at least 10 seconds documented on a polysomnogram.

Hypopnea is defined as an abnormal respiratory event lasting at least 20 seconds associated with at least a 30 percent reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4 percent decrease in oxygen saturation.
The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of two hours of sleep without the use of a positive airway pressure device, reported by Polysomnography using actual recorded hours of sleep (i.e., the AHI may not be extrapolated or projected).

Criteria for Adults

A single level continuous positive airway pressure (CPAP) device is covered if the recipient has a diagnosis of obstructive sleep apnea (OSA) documented by an attended, facility-based polysomnogram and meets either of the following criteria:

The AHI is greater than or equal to 15 events per hour; or,

- The AHI is from 5 to 14 events per hour with documented symptoms of:
    - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or
    - Hypertension, ischemic heart disease, or history of stroke.

For the purpose of this policy, polysomnographic studies must be performed in a facility based sleep study laboratory and not in the home or in a mobile facility. These labs must be qualified providers of Medicare or Medicaid services and comply with all applicable state regulatory requirements.

For the purpose of this policy, polysomnographic studies may not be performed by a DME provider.

Pediatric Criteria (Under Age 21)

A single level continuous positive airway pressure (CPAP) device is covered if the recipient has a diagnosis of obstructive sleep apnea (OSA) documented by an attended, facility-based polysomnogram and there is:

- Documentation of physical exam (including airway) and of any other medical condition, which may be correctable (e.g., tonsillectomy and/or adenoidectomy) prior to the institution of assisted ventilation.

- Documentation of how sleep disturbance reduces the quality of life and affects the activities of daily living.

- Prescription by a physician with training and expertise in pediatric respiratory sleep disorders.
- Documentation of the medical diagnosis, which is known to cause respiratory/sleep disorders.

- Sleep or respiratory study documenting two or more of the following:
  - Oxygen saturation of less than 90 percent pulse oximetry or partial pressure of transcutraneous or arterial of less than 60mm. Hg.;
  - Carbon dioxide greater than 55 mm. Hg. Bye end tidal, transcutaneous, arterial, or capillary blood measurement; and
  - Apnea of 10 to 20 seconds duration on the average of one per hour.

- A follow up plan should be submitted identifying the responsible physician or facility, giving data collected to demonstrate the success or failure of intervention, and showing a visit within the first month of use and a second assessment within the first three months of use.

- Indication of a responsible, committed home environment and of caregivers properly trained in appropriate respiratory care.

- A written plan for home health follow up care.

Humidifiers

Humidifiers are covered if continuous positive airway pressure (CPAP), bi-level positive airway pressure (BIPAP), or oxygen therapy has been prescribed for use in connection with medically necessary DME for purposes of moisturizing the oxygen. Humidifiers are used to prevent dry mouth, stuffy, congested, or runny nose and dry, burning, itching, or bleeding nose.

Heated and non-heated humidification for use with positive airway pressure system devices requires PA. Documentation of medical necessity including the diagnosis and expected outcome must be submitted with the request for PA. Non-heated humidifiers are sufficient for recipients that did not have any particular problems with sinus or dryness prior to going on CPAP.

Non-heated humidifiers make a noticeable difference by allowing a recipient to sleep longer before awaking due to dryness or sleep through the entire night. They are usually smaller, lighter and less expensive than heaters. The process of evaporation lowers the temperature of the air reaching the recipient. Most recipients using non-heated humidifiers without symptoms do not need to use it year around as they tend to get enough humidification whenever their home air conditioning or heater is not on. The effectiveness of a non-heated humidifier is related to its size. Larger non-heated humidifiers are more effective.

If recipients dry out most nights on CPAP or have a history of sinus troubles prior to CPAP, they will benefit from a heated humidifier. Heated humidifiers can warm the air to whatever temperature the user is most comfortable. The warmer the air, the more moisture it carries. A heated humidifier delivers air of the temperature the recipient prefers in addition to humidification.

Vagus Nerve Stimulators

Consideration shall be given for Medicaid reimbursement for implantation of the vagus nerve stimulator (VNS) if the treatment is considered medically necessary, the recipient meets the published criteria, and the recipient has a diagnosis of medically intractable epilepsy.

Criteria for Recipient Selection

The following criteria are used to determine recipient eligibility and approval of the VNS:

- Partial epilepsy confirmed and classified according to the International League Against Epilepsy (ILAE) classification. The recipient may also have associated

generalized seizures, such as tonic, tonic-clonic, or atonic. The VNS may have efficacy in primary generalized epilepsy as well;

- Age 12 years or greater, although case by case consideration may be given to younger children who meet all other criteria and have sufficient body mass to support the implanted system;

- Seizures refractory to medical anti-epilepsy treatment, with adequately documented trials of appropriate standard and newer anti-epilepsy drugs or documentation of recipient's inability to tolerate these medications;

- Recipient has undergone surgical evaluation and is considered not to be an optimal candidate for epilepsy surgery;

- Recipient is experiencing at least four to six identifiable partial onset seizures each month. Recipient must have had a diagnosis of intractable epilepsy for at least two years. The two-year period may be waived if waiting would be seriously harmful to the recipient;

- Recipient must have undergone Quality of Life (QOL) measurements. The choice of instruments used for the QOL measurements must assess quantifiable measures of daily life in addition to the occurrence of seizures; and

- In the expert opinion of the treating physician, there must be reason to believe that QOL will improve as a result of implantation of the VNS. This improvement should occur in addition to the benefit of seizure frequency reduction. The treating physician must document this opinion clearly in the request for prior authorization (PA).

Exclusion Criteria

Regardless of the criteria for recipient selection, **authorization for VNS implantation shall not be given if the recipient has one or more of the following criteria**:

- Psychogenic seizures or other non-epileptic seizures;

- Insufficient body mass to support the implanted system;

- Systemic or localized infections that could infect the implanted system; or
- A progressive disorder contraindicated to VNS implantation, e.g., malignant brain neoplasm, Rasmussen's encephalitis, Landau-Kleffner syndrome and progressive metabolic and degenerative disorders.

Place of Service Restriction

Surgery to implant the VNS is restricted to an outpatient hospital, unless medically contraindicated. If it is medically necessary for the recipient to be hospitalized, the hospital must obtain pre-certification for the stay as well as obtain PA to perform the surgery and purchase the device.

Prior Authorization

Prior Authorization (PA) for implantation of the VNS shall be requested after the recipient evaluation has been completed but prior to stimulator implantation.

This request to initiate implantation shall come from the multi-disciplinary team that evaluates the recipient. The multi-disciplinary team should be comprised of the following:

- A surgeon who has been trained and is familiar with the carotid sheath;
- A psychiatrist or neurologist;
- The recipient's attending physician;
- A nurse;
- A social worker; and
- Allied health professionals (physical therapist, occupational therapist, etc.).

These professionals shall have expertise in the evaluation, management, and treatment of epilepsy and have undergone VNS implantation training by a nationally recognized product supplier with expertise in VNS.

The following documentation shall be labeled and submitted in one package by the multi-disciplinary team:

- A recent history with documentation of assessments in the following areas:
  - Medical and physical including a history of prior drug experience;
  - Neurological information about seizure type and epilepsy syndrome diagnosis, and the results of EEG and/or video EEG monitoring;
  - Functional and psychosocial assessment;
  - Result of evaluation of epilepsy surgery; and

- Documentation of any other findings about the recipient's condition which would be of interest to or would assist the Medical Review team in making a decision regarding the medical necessity for recipient implantation.

Billing for the Cost of the Vagus Nerve Stimulator

The VNS is reimbursable by the Medicaid Program; however, reimbursement of the device is dependent upon approval of the surgeon to perform the procedure. Hospitals should confirm the surgeon has received an authorization for the procedure prior to submitting the claim. Hospitals shall submit the appropriate Healthcare Common Procedure Coding System (HCPCS) code for the VNS generator and VNS leads, to the fiscal intermediary on a CMS-1500 claim form with the words "DME" written in red on the top of the form. The claim will pend to the fiscal intermediary's Medical Review Department for review of the surgeon's approved PA request. If the surgeon's request is approved, the hospital claim will be allowed to process for payment. If there is no valid authorization, the hospital claim will deny with edit 191 (PA required).

Subsequent Implants and Battery Replacement

Battery replacement and subsequent implants require PA. In order to be considered, the request must contain documentation demonstrating the benefits of the original VNS transplant.

Wound Care Supplies

Surgical dressings, bandages, and other wound care supplies may receive PA approval for three months at a time. The PA request must reflect the submitted prescription. The PA request must document the factors below in order to meet criteria.

To request PA for wound care supplies, the following documentation must be provided:

- Accurate diagnostic information pertaining to the underlying diagnosis/condition as well as any other medical diagnoses/conditions, to include the recipient's overall health status;
- Appropriate medical history related to the current wound;
- Wound measurements to include length, width and depth, any tunneling and/or undermining;
- Wound color, drainage (type and amount) and odor, if present;
- The prescribed wound care regimen, to include frequency, duration and supplies needed;
- Treatment for infection, if present;
- The recipient's use of a pressure reducing mattress and/or cushion, when appropriate; and
- Whether or not a home health agency is involved in the care.

The prescription must be updated for any extensions to be granted.
A Medicaid approved home health agency must be involved in the care of the recipient for consideration of approval for wound care supplies. Any routine supplies provided by the home health agency that are not covered by the DMEPOS Program must be provided in the skilled nursing visit rate.

Wound Care Reimbursement

When prior authorized as medically necessary, reimbursement is 70 percent of the Medicare fee schedule or 70 percent of the manufacturer’s suggested retail price (MSRP) amount, or billed charges, whichever is the lesser amount. If an item is not available at 70 percent of the Medicare fee schedule amount or 70 percent of the MSRP amount, the flat fee that will be utilized is the lowest cost at which the item has been determined to be widely available by analyzing usual and customary fees charged in the community.

Wound Care System

Wound care systems may be considered for reimbursement when prior authorized. A wound care system may be considered for reimbursement for recipients with a Stage III or IV chronic, non-healing wound, such as a pressure, venous stasis, and diabetic ulcers, postsurgical wound dehiscence, non-adhering skin grafts, or surgical flaps required for covering such wounds.
Types of wound care systems include the following:

- Thermal wound care system; and
- Sealed suction wound care system.

Portable hyperbaric oxygen chambers that are placed directly over the wound and provide higher concentrations of oxygen to the damaged tissue are not covered.

NOTE: This list of covered services may not be all inclusive (see fee schedule located on the Louisiana Medicaid web site). Refer to the Section 18.5 for information regarding prior authorization.