1303 POLICY

1303.1 DURABLE MEDICAL EQUIPMENT, PROSTHETIC DEVICES, ORTHOTIC DEVICES, DISPOSABLE MEDICAL SUPPLIES (DMEPOS) PROGRAM

A. GENERAL INFORMATION

1. DMEPOS Program coverage areas include parenteral and enteral nutrition (PEN), medical foods, and oxygen and oxygen equipment, all of which must meet the definition of durable medical equipment, a prosthetic device, an orthotic device or disposable medical supply.

2. Durable Medical Equipment (DME) of a medical nature, needed as a result of a medical condition and which lasts a considerable time without significant deterioration and appropriate for use where normal life activities take place, is covered by the DHCFP and NCU for eligible recipients. New equipment, repairs or replacement requires medical documentation and are subject to limitations of model, cost and frequency, which are deemed reasonable by the program.

3. Disposable medical supplies are covered by the DHCFP and NCU for eligible recipients only if they are necessary for the treatment of a medical condition and would not generally be useful to a person in the absence of an illness, disability or injury.

4. All DMEPOS products (including all parts to build a product) and services must be medically necessary, safe and appropriate for the course and severity of the condition, using the least costly and equally effective alternative to meet the recipient's medical needs. Any DMEPOS products and services within other DHCFP programs that meet the same medical purpose will be processed as duplicative.

   For purposes of this Chapter, a covered service or item meets the definition of medical necessity if each of the following criteria have been satisfied:

   a. It meets all qualifications of medical necessity outlined in section 103.1 under Medicaid Services Manual (MSM) Chapter 100;
   b. It is the lowest cost alternative that is equally effective and safe to address the recipient's medical condition; and
   c. It is not provided only as a convenience to the recipient, caregiver, or provider.

5. Deluxe equipment (definition or clarification of deluxe can be located within the DME billing guide) will not be authorized when it is determined that a standard model will meet the basic medical needs of the recipient. The recipient must have

a medical need for each component of the item(s) requested. This includes accessory items and features not included in the standard models of the product.

6. Equipment which the program determines is principally for education or rehabilitation will not be approved.

7. Refer to Appendix A of this Chapter for non-covered services, and for special coverage considerations that are based on medical necessity outside of the DMEPOS Program or that is considered under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Healthy Kids Program.

8. Refer to Appendix B of this Chapter, for Coverage and Limitation Policies regarding specific coverage information, qualifications, documentation requirements and miscellaneous information.

4. A DMEPOS provider must adhere to all Federal Rules and Regulations applicable to their provider type including, but not limited to, 42 CFR Part 440 for enrollment.
   i.e. not limited to: storefront, background checks, etc.

5. A Medicaid-contracted DMEPOS provider may be reimbursed for services rendered to Medicaid eligible recipients when provided in accordance with established policies, guidelines and timeframes.

6. The provider is responsible for ensuring the equipment is appropriate for the recipient and the recipient's location of normal life activities prior to billing the DHCFP.

7. The provider is responsible for providing a cost or a manufacturer's suggested retail pricing (MSRP) invoice for certain items, where no rate has been established.

8. The DMEPOS provider must comply with additional requirements as specified throughout this Chapter and its Appendices, Medicaid Services Manual (MSM) Chapter 100, the Provider Type (PT) 33 DMEPOS Fee Schedule, the Provider Billing Manual and DMEPOS Billing Guidelines.

9. The provider is responsible for teaching ~~to teach~~ the recipient, caregivers or authorized representative(s) about the operation, proper use, maintenance requirements~~, and~~ any unacceptable use of the medical equipment and proof of documented teachings were provided, including in the recipient's records.~~.~~

C. RECIPIENT RESPONSIBILITY

The eligible Nevada Medicaid or NCU recipient and/or their authorized representative will:

1. Make and keep appointments necessary for securing medical services/equipment.~~;~~

2. Present current verification of Nevada Medicaid or NCU eligibility.~~;~~

3. Present any forms or identification necessary to utilize other health insurance coverage.~~;~~

4. Contact and return to the provider of services/equipment for any necessary adjustment within the time allotted for such adjustments.~~;~~

5. Maintain the equipment provided by routinely cleaning and caring for the devices according to user information and supplier's guidance. Provide safe, secure storage for item(s) when not in use to protect item(s) from loss or theft.~~;~~

6. Not misuse, abuse or neglect purchased or rented item(s) in a way that renders the item(s) unsafe, non-usable or shortens the lifetime of the item (ie: using power mobility devices as a form of transportation, leaving equipment out in the weather , not properly charging power equipment etc.).

7. Return all rented equipment to the DMEPOS provider when no longer being used, or upon the DME provider's request. Failure to return rented equipment could result in a recipient's financial responsibility for the retail price of the rented equipment, even if the equipment is lost/stolen, the recipient has moved, or they are no longer eligible for Nevada Medicaid/NCU.

8. Comply with additional requirements as specified throughout this Chapter and its Appendices and MSM Chapter 100.

1303.2 DOCUMENTATION REQUIREMENTS

A. Supplier/provider records must substantiate the medical necessity for all DMEPOS items dispensed to recipients. The following describes the requirements for specific types of documentation associated with DMEPOS.

1. ORDERS/PRESCRIPTIONS

a. All DME items, Prosthetics, Orthotics or Disposable Supplies (POS) dispensed must have an order/prescription from the treating physician or practitioner, (To determine included practitioners, refer to MSM Chapter 600 – Physician's Services), such as a Physician's Assistant (PA) or Advanced Practitioner of Nursing (APN), when within their scope of practice and in accordance with federal and state laws governing that entity, prior to dispensing the item.

In accordance with the Patient Protection and Affordable Care Act (PPACA) (The Affordable Care Act) of 2010 (Public Law 111-148), all orders for DMEPOS items as required by CMS, whether verbal or written, must be incidental/relevant to the treating physician-documented face-to-face encounter between the recipient and the prescribing physician/practitioner (as allowed by The Act) no more than six~~6~~ months~~within 30 - 60 days~~ prior to the approved PA start date~~date of the~~

~~order/script~~. The encounter must be clearly documented and relevant to the need for the prescribed DMEPOS.

Refer to Appendix B of this Chapter for additional order/documentation requirements on specific products.

General standards of care/practice mandate that if an order is not clear, a clarification of the order must be obtained from the ordering practitioner prior to acting on it.

b. Verbal Orders:

1. Verbal orders from the prescribing physician/practitioner may be accepted for DMEPOS items that do not require prior authorization;

d. —New Orders Are Required When:

1. There is a change in the recipient~~sident~~'s condition that warrants a change in the order, a change in the treating physician/practitioner or DMEPOS supplier;

2. An item is replaced for any reason; or

3. An ongoing unchanged order continues to be medically necessary one year after the original order (orders are only valid for up to one year, unless documented with a shorter length of time).

2. DETAILED PRODUCT DESCRIPTION

The detailed product description must contain the Healthcare Common Procedure Coding System (HCPCS) code, manufacturer, make and model and the provider's/supplier's invoice for each item supplied. The warranty information must also be included. This may be completed by the provider/supplier but can also be documented by the physician.

3. INVOICE

All requirements below must be met when submitting an invoice.

a. Itemized bill listing Manufacturer's Cost or Manufacturer's Suggested Retail Price (MSRP) invoice for DME items.
b. Name and address of the manufacturer providing item.
c. Invoice number, date and identification of the equipment utilizing the Healthcare Common Procedure Coding system (HCPCs) code, including any miscellaneous HCPCs codes, if appropriate.
d. Name, address, and National Provider Identifier (NPI) of the DME provider submitting the invoice.
e. Cannot be older than six months prior to the date of authorization request.

~~3.~~4. PROOF OF DELIVERY (POD)

A POD is a supplier's delivery receipt, which is dated and timed.

NOTE: Item(s) ordered must be delivered within 120 days of the date of the order.

~~4.~~5. ADDITIONAL MISCELLANEOUS MEDICAL RECORDS

The recipient's medical records must contain sufficient documentation of the recipient's medical condition to substantiate the necessity for the type and quantity of items ordered and the frequency of the use or replacement. The information must include the recipient's diagnosis and other pertinent information, including but not limited to: duration of recipient's condition, clinical course (deteriorating or improving), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. The records must include physician's office records, hospital, nursing home or home health records, records from other professionals including but not limited to: nursing, physical and occupational therapists, prosthetists and orthotists, although medical necessity for item(s) requested must be stated by the prescribing physician/practitioner.

~~5.~~6. ADVANCED DETERMINATION OF MEDICARE COVERAGE (ADMC)

When Medicare is the primary payer, for all items requiring an ADMC (refer online to the DME MAC Jurisdiction D, Supplier Manual, Chapter 9). The ADMC determination must be submitted to the Quality Improvement Organization (QIO)-like vendor at the same time the prior authorization is submitted.

B. PROVIDER RESPONSIBILITY

1. The provider must obtain the required documentation in a timely manner as described under each section listed previously.

2. The provider must maintain records at the physical location of their business for each item billed to, and paid by, the DHCFP for at least six years from the Remittance Advice (RA) date. At a minimum, this includes the original signed order/prescription, all supporting medical documentation, ~~and~~ proof of delivery, proof of any recipient/prescriber training as noted in this chapter, choice of rental or purchase options, and warranty information given to the recipient. ~~.~~

3. The provider must maintain records in a readily accessible location and, for audit and investigation purposes, to make available upon request by Medicaid staff or its contractors, all supporting information related to prior authorizations, dispensed

items and/or paid clams for DMEPOS items, complaints, and resolution accounts filed. ~~for DMEPOS items.~~

1303.3 RENTAL AND PURCHASE OPTIONS

Items identified in the DMEPOS Fee Schedule with an RR modifier for rental and an NU modifier for purchase (for some items to purchase no modifier may be listed on the fee schedule) option may require prior authorization to determine if the recipient's needs justify rental or purchase based on the item prescribed, the individual's anticipated length of need and prognosis (as determined by the prescriber) and cost effectiveness to the DHCFP and NCU. Recipients must be given the option of rental or purchase when policy allows. If a Nevada Medicaid rate has not been assigned, a cost or ~~-~~an MSRP invoice is ~~-are-~~required to be submitted with the prior authorization (PA) request or claim, if a PA is not already required for that item.

b. The DHCFP will only purchase equipment when, in addition to all other requirements and qualifications for the item:

1. the recipient meets the criteria for purchase of new equipment;

2. the item was new when placed in the recipient's use and has been used for less than three months; and

3. the item is currently being used by the same recipient during a trial period and it has been determined the length of need will now be indefinite.

c. A prior authorization must be submitted to request purchase of a rented piece of equipment with all supportive medical documentation to show the date the item was initially issued to the recipient and that the recipient continues to have an ongoing need for the item.

1303.4 PRIOR AUTHORIZATION

A. Prior authorization is a review conducted by the Quality Improvement Organization (QIO)-like vendor's medical professionals who review the prior authorization form and any additional information submitted to evaluate medical necessity, appropriateness, location of service and compliance with the DHCFP's policy, prior to delivery of service. Reference MSM Chapter 100 and the general Billing Manual for detailed information on prior authorizations and Medicaid eligibility for all providers at: http://www.medicaid.nv.gov/providers/BillingInfo.aspx.

1. Submission:

a. Prior authorizations must be completed and submitted by a current Medicaid provider (requestor), and the approval must be received prior to delivery of services. The exception to this is if the recipient is determined eligible for Medicaid retroactively or if number four of this section applies.

b. A Pprior authorization is required for most durable medical equipment, prosthetics, orthotics, and oxygen.

c. A Medicaid provider may submit the prior authorization electronically using the QIO-like vendor's on-line prior authorization system or may fax or mail the prior authorization to the QIO-like vendor. For more information, refer to the prior authorization section posted at: https://www.medicaid.nv.gov.

d. Requestors must submit a prior authorization with the most appropriate HCPCS code available and may not unbundle items included in the HCPCS code description. If an item has a designated code available, the miscellaneous code cannot be used. Providers may contact the Medicare Pricing, Data Analysis and Coding (PDAC) contractor or the DME MAC for guidance on correct coding.

e. Documentation requirements are the same regardless of which mode of submission is used (e.g. the on-line prior authorization system, faxed or mailed). Documentation submitted for consideration of athe request must include the physician's order that entails clear coverage qualification and medical necessity for the specific equipment/supplies. must clearly support coverage qualifications and recipient's medical need for the equipment. Failure to provide all of the supporting medical documentation in its entirety, and within the required timeframes, will result in a denial of the prior authorization request, regardless of mode of submission.

f. Unless otherwise stated in policy, a prior authorization may be submitted to request authorization to exceed established quantity limitations when the medical documentation supports medical necessity for the increased quantity or frequency.

6. Denied Prior Authorization Requests:

a. There are various processing levels associated with prior authorization requests which do not support medical necessity. These may include but are not limited to: a contact to the provider by the QIO-like vendor, a system generated technical denial, a system generated denial or reduction of services, a provider-requested reconsideration, a provider-requested peer-to-peer review with the physician. For additional information on the below time limits and an explanation of each, refer to the general Billing Manual for all providers at: https://www.medicaid.nv.gov/providers/billinginfo.aspx.

1. If a prior authorization request is denied or reduced, the provider and recipient will be sent a Notice of Decision (NOD) with a citation/reason to provide a general explanation of the denial.

a. The provider may request a peer-to-peer review within 10 days of the date of decision via phone contact to the QIO-like vendor.

b. The provider may request consideration of the denial by submitting additional medical documentation and requesting a reconsideration electronically ~~in writing via fax~~ within 30 days of denial.

c. If a reconsideration is not appropriate or is also denied, the recipient may be entitled to request a hearing within 90 days from the date of decision. Refer to MSM Chapter 3100 – Hearings.

B. COVERAGE AND LIMITATIONS

1. Coverage and limitations are explained throughout this Chapter, including its appendices. Appendix B details coverage qualifications, prior authorization documentation requirements, and limitations for specific items.

4. The recipient and/or their authorized representative must present proof of identity and provide documentation of Medicaid coverage and any form of identification necessary to utilize other health insurance coverage.

1303.5 DISPENSING AND DELIVERY OF DMEPOS

A. Dispensing/Duration of Orders

Medical supply orders must be dispensed at a monthly interval. DMEPOS is dispensed according to the physician's orders~~, subject to coverage limitations~~ and not listed quantity limits. The physician's order for medical supplies is valid up to one year. Suppliers may not ship items on a regular, monthly basis without documentation from the recipient, family member or authorized representative that the supply is needed. Documentation of this need must be kept on file. It is acceptable for the supplier to contact the recipient ONLY to verify a re-order and not for solicitation.

B. Delivery of DMEPOS

1. Delivery Method 1. Supplier delivering items directly to the recipient or authorized representative:

   a. The delivery receipt must include the signature and the signature date which must match the date the DMEPOS item was received by the recipient or their authorized representative to verify the DMEPOS item was received.

   b. The delivery receipt must include the recipient's name, quantity, a detailed description of the item(s) delivered, brand name, make and model, serial number (if applicable) and date and time of delivery.

   c. The date of service (DOS) on the claim must be the date the DMEPOS item was received by the recipient or their authorized representative. An exception to this would be when an item must be billed using a date span and the quantity dispensed crosses over into the next month.

2. Delivery Method 2. Suppliers utilizing a delivery/shipping service to deliver items (this is not considered mail order):

   a. An acceptable delivery/shipping service receipt POD includes the supplier's shipping invoice (Bill of Lading (BOL or BL)).

   b. The supplier's BOL must include the recipient's name, delivery address, quantity, detailed description of the item(s) delivered, HCPCs code, brand name, make and model, serial number (if applicable), date and time of delivery/shipment and delivery service package identification number associated with recipient's package(s).

B. Prosthetics and Orthotics

Prosthetics and Orthotics: Are included in the all-inclusive per-diem if provided to a patient during an inpatient hospital prior to discharge and the patient uses item for medically necessary inpatient treatment or rehabilitation. (e.g. after spinal surgery).

C. DME that cannot be utilized by another recipient due to its unique custom features (e.g. custom fabricated molded seating systems etc.) needed for the recipient's permanent, full-time use, are not part of the institution's inclusive rate.

1. All DME must be prior authorized for exception to inclusive facility rates.

2. Hospital and nursing facility patients may be approved for wheelchairs in preparation for discharge. The DHCFP may approve power chairs one month in advance of discharge. Physician documentation to substantiate discharge date may be required. Place of service must reflect the actual place of delivery.

3. Specialized or custom-made items which will be needed by the patient upon discharge may be requested during the inpatient stay. However, approval of the items may be restricted to delivery to the patient at the time of discharge to his home or other place of residence. Providers of requested items will be paid directly only if the required prior authorization has been approved. Facilities will not be paid for items supplied by another provider.

1303.10 SECTION RESERVED FOR FUTURE USE

1303.11 SECTION RESERVED FOR FUTURE USE

1303.12 SECTION RESERVED FOR FUTURE USE

1303.13 SECTION RESERVED FOR FUTURE USE

1303.14 SECTION RESERVED FOR FUTURE USE

1303.15 UTILIZATION CONTROL

A. Pre-Service

The coverage, limitations and exclusions outlined in this chapter constitute pre-service controls on over-utilization.

B. Pre-Payment

The QIO-like vendor will screen each claim for existence and/or application of prior resources, correct coding of services and appropriate authorization form. In addition, each claim will be screened for accuracy in computation and compliance with published procedures.

APPENDIX A

NON-COVERED SERVICES

1. The DHCFP's DMEPOS program does not cover items if they ~~either~~ do not meet the definition of durable medical equipment, prosthetic, orthotic or disposable medical supplies. A request for convenience or comfort of a recipient or their caregiver is not a consideration of medical necessity and is non-covered. Items that~~; or~~ are not considered primarily medical in nature; or are not FDA approved or the approved use by the FDA are ~~is~~ also not applicable when determining coverage under the DME program. ~~Because~~If a provider prescribes, orders and/or recommends a service or supply does not, of itself, make it an eligible benefit.

2. The DHCFP has the authority to establish reasonable standards, consistent with the objectives of the Medicaid statute, for determining the extent of such coverage (42 U.S.C. § 1396(a)) based on such criteria as medical necessity or utilization control (42 CFR 440.230 (d)). The DHCFP has an approved list of covered DMEPOS items. The Provider Type 33 – DMEPOS Fee Schedule is available on the DHCFP website at: http://dhcfp.nv.gov/Resources/Rates/FeeSchedules/.

   a. The DHCFP is required to have a process and criteria for seeking modifications or exceptions to established coverage policies. Some non-covered items requested may require budget authority. Administrative exceptions ~~This process is~~are available to recipients on a case-by-case basis for DMEPOS items excluded from the DMEPOS Fee Schedule with written request via the fiscal agent. ~~Because a provider prescribes, orders and/or recommends a service or supply does not, of itself, make it an eligible benefit.~~

   b. Consideration will be made on a case-by-case basis using the following criteria:

      1. The item must meet the definition of durable medical equipment, prosthetic, orthotic or disposable medical supply as defined in Section 1302 – the ~~Addendum~~ Medicaid Services Manual (MSM) Definitions and MSM Chapter Addendum;

      2. The prescribing physician/practitioner must submit supporting documentation identifying the individual's specific medical needs that meet the standard definition of medical necessity as defined in MSM Chapter 100 (e.g. physical assessment indicating the limitations to be ameliorated by the use of the item(s), peer review documentation indicating this is an accepted standard of care within Nevada's medical community); and

      3. The prescribing physician/practitioner must document that other items have been used and were found ineffective. The requested item(s) must be the most cost-effective alternative, medically necessary service, provided at the most appropriate level to meet the medical needs of the recipient, that it is reasonable and accessible to the recipient.

c. Review chapter and fee schedule for coverage. If not located under this provider type but possibly might be covered under other programs i.e.: EPSDT, nursing home, etc. please review the coverage criteria and fee schedule for that specific provider type.

Policy: INTRODUCTION AND GENERAL INFORMATION

Introduction

1. Appendix B is a supplement to the main body of Chapter 1300 and provides: specific coverage qualifications, forms and documentation requirements, and miscellaneous policies related to specific items of durable medical equipment, prosthetic devices, orthotic devices or disposable medical supplies (DMEPOS).
2. For DMEPOS where coverage and limitations have not been addressed in this Chapter, its Appendices or the DMEPOS Fee Schedule, the Division of Health Care Financing and Policy (DHCFP) may defer to the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) Jurisdiction D, Local Coverage Determinations (LCD) and Policy Articles for coverage and limitations information. This information is available at https://www.noridianmedicare.com.

QUALIFICATIONS	FORMS AND DOCUMENTATION REQUIREMENTS	MISCELLANEOUS POLICY STATEMENTS
1. Qualifications identified for each specific item listed within this Appendix must all be met for coverage by the DHCFP. 2. All requests must meet the definition of DME per CMS. ~~1.~~3. All DME must be primarily medical in nature. ~~2.~~4. All DMEPOS products (including all parts to build a product) and services must be medically necessary, safe and appropriate for the course and severity of the condition, using the least costly equally effective alternative to meet the recipient's medical needs. Items intended to meet the same medical need as other services will be processed as a duplicate service. ~~3.~~5. If all qualifications are not met, refer to Appendix A for other possible coverage options.	1. Refer to the Documentation section and/or the Prior Authorization section in Chapter 1300 for detailed requirements for each type of form. Additional form completion requirements are found in the Form Release Memorandums or Instructions on the QIO-like vendor's website at: http://www.medicaid.nv.gov/providers/forms/forms.aspx 2. All documentation, reports, evaluations and testing must support medical necessity as specified under the Qualifications section. Requirements must be met for each specific item listed within this Appendix and as specified for that item. a. Physician's/Practitioner's Order/Prescription. b. Prior authorization form (when indicated) - Durable Medical Equipment Prior Authorization Forms are available on the QIO-like vendor's website at the above link. There are specific forms for certain items of DMEPOS. Refer to policies to determine if a specific form is required. Prior authorization is required to exceed program limitations. c. All services provided in an institutional facility require a prior authorization. d. Detailed Product Description. e. Proof of Delivery. f. Additional Miscellaneous Medical Records. g. Manufacturer's Suggested Retail Price (MSRP) Invoice (to determine pricing) for certain items, where the DHCFP rate has not been established.	Refer to the main body of Chapter 1300 for general DMEPOS policies. 1. For all items, documentation must support all criteria in the Qualifications section, as specified in each category. 2. Providers must submit an approved prior authorization and claim using the most appropriate available HCPCS code and may not unbundle items included in the HCPCS code description. 3. Rented devices are to be considered purchased by the DHCFP once the purchase price has been reached. The exception to this is when the item is deemed as a rental only by the DHCFP. Refer to main body of Chapter 1300 and the DMEPOS Fee Schedule. 4. Inclusion of a HCPCS code in this Appendix is not an indication of coverage. Refer to the DMEPOS Fee Schedule, ~~and~~ Appendix A, and billing guides. 5. The DHCFP will not reimburse providers who supply DMEPOS prior to PA approval except in certain situations, such as retro eligibility.

Policy: CARDIOVERTER DEFIBRILLATOR			
EQUIPMENT OR ITEM	**QUALIFICATIONS**	**FORMS AND DOCUMENTATION REQUIREMENTS**	**MISCELLANEOUS POLICY STATEMENTS**
Wearable Cardioverter defibrillator (WCD) vest **(K0606)** **Supplies:** **K0607** (Replacement battery for automated external defibrillator, garment type only), **K0608** (Replacement garment for use with automated external defibrillator, each) and **K0609** (Replacement electrodes for use with the automated external defibrillator, garment type only)	Covered for High risk of sudden cardiac death (SCD): 1. 1. A documented episode of ventricular fibrillation or a sustained, ventricular tachyarrhythmia. These dysrhythmias may be spontaneous; and/or must be reproducible during an electrophysiologic (EP) study but a) may not be due to a transient or reversible cause, b) not within the first 48 hours of an acute myocardial infarction, c) not within the first 72 hours post coronary bypass, d) not within 5 days of a transplant 2. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrhythmia such as long QT syndrome or hypertrophic cardiomyopathy 3. Either documented prior myocardial infarction or dilated cardiomyopathy, Endomyocardial eosinophilic dz-Endocardial fibroelastosis or Alcoholic cardiomyopathy--drug or other agent cardiomyopathy) and a measured left ventricular ejection fraction less than or equal to 0.35; or	1. The provider and ordering practitioner have assured that all less costly medically appropriate alternatives have been explored. If the alternatives are not adequate the ordering practitioner is required to provide clear documentation as to why the alternatives are not adequate 2. The ordering practitioner of the wearable defibrillator is a cardiologist and experienced in the management of patients at risk for SCD.	1. Initial evaluation will be for the first 3 months only. 2. Subsequent evaluations may be allowed if medically necessary up to the purchase price. 3. Supplies are only purchased after K0606 is recipient owned. Note: Non-Covered Indications The wearable cardioverter defibrillator (WCD) is not medically necessary, medically contraindicated, and not covered for all other indications, including but not limited to, the following: • Patients with a history of an acute myocardial infarction (MI) within 30 days; • Patients with drug-refractory class IV congestive heart failure (CHF) who are not candidates for heart transplantation. • Patients with a history of psychiatric disorders that interfere with the necessary care and follow-up. • Patients in whom a reversible triggering factor (by drug therapy, definitive therapy, ablation) for VT/VF can be definitely identified, such as ventricular

	4. A previously implanted defibrillator has had mechanical breakdown, infection, and inflammatory reaction due to cardiac valve prosthesis or documentation that severe infection is not due to poor patient compliance.		tachyarrhythmias in evolving acute myocardial infarction or electrolyte abnormalities. • Patients with terminal illnesses other disease processes that clearly and severely limits the patient's life expectancy.

Policy: COMMUNICATION DEVICES

EQUIPMENT OR ITEM	QUALIFICATIONS	FORMS AND DOCUMENTATION REQUIREMENTS	MISCELLANEOUS POLICY STATEMENTS
Speech Generating Device (SGD) *(also known as Augmentative Communication Device (ACD) or Augmentative and Alternative Communication (AAC) Device* **(E2500 – E2510)** **Digitized Speech Devices: (E2500, E2502, E2504, E2506)** **Synthesized Speech Devices: (E2508, E2510)**	1. A dedicated speech generating device (SGD) may be covered when it is medically necessary to restore the function of speech to an individual with a functional disability caused by a long term (lasting more than one year) and severe speech impairment; and 2. When **all** of the following are met: a. The recipient has had a formal written evaluation of their cognitive and communication abilities by a speech-language pathologist (SLP) (not employed by the DME provider) which contains all of the items specified in the Forms/Documentation column; b. The recipient's medical condition is one resulting in a long term (lasting more than one year) and severe expressive speech impairment; c. The recipient's speaking needs cannot be met using natural communication methods; d. Other forms of treatment have been considered and ruled out; e. The recipient's speech impairment will benefit from the device ordered; and f. A copy of the SLP's written evaluation and recommendation was forwarded to the recipient's treating physician/ practitioner and the prescribing physician/ practitioner agreed with, and ordered the specific device and accessories as recommended.	1. Physician's/Practitioner's Order/Prescription. 2. Prior Authorization. 3. Detailed Product Description. 4. Additional Miscellaneous Medical Records (if needed); and: 5. Speech and Language Pathologist (SLP)'s formal written evaluation which includes, at a minimum, all of the following: a. Current communication impairment, including the type, severity, language skills, cognitive ability and anticipated course of the impairment; b. An assessment of whether the recipient's daily communication needs could be met using other natural modes of communication or with low-technology devices; c. A description of the functional communication goals expected to be achieved and treatment options; d. Rationale for selection of a specific device and any accessories; e. Demonstration that the recipient possesses a treatment plan that includes a training schedule for the selected device; f. The cognitive and physical abilities to effectively use the selected device and any accessories to communicate; and g. An attestation statement from the SLP performing the recipient evaluation and/or recommending the product(s) indicating they are not an employee of,	1. For all items, documentation must support all criteria in the Qualifications section. 2. Providers must submit prior authorizations and claims using the most appropriate available HCPCS code and may not unbundle items included in the HCPCS code description. 3. Codes E2500 – E2510 perform the same essential function - speech generation and may not be issued in conjunction with E2511. 4. Code E2511 – SGD software program for Personal Computers (PC) or Personal Digital Assistant (PDA) may not be issued in conjunction with E2500 – E2510. 5. Computer-based and PDA-based AAC devices/speech generating devices are covered when they have been modified to run only AAC software and will not be reimbursed in conjunction with another SGD. Laptop computers, desktop computers, personal digital assistants (PDAs), tablets or other devices that are not dedicated SGDs do not meet the definition of durable medical equipment (DME). 6. Expected lifespan of SGD E2500-E2510 or E2511 is considered 60 months and are limited accordingly. ~~Replacement equipment may be authorized prior to the 60 months based on medical necessity~~. **Note: A trial period of 3 months may be required to ensure appropriate item.**

Policy: DIABETIC SERVICES

EQUIPMENT OR ITEM	QUALIFICATIONS	FORMS AND DOCUMENTATION REQUIREMENTS	MISCELLANEOUS POLICY STATEMENTS
External Ambulatory Infusion Pump, Insulin (E0784)	Covered ICD codes: Diabetes Mellitus Gestational Diabetes All of the following conditions must be met: 1. Fasting serum C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method or as an alternative must be beta cell autoantibody positive. 2. Recipient has completed a comprehensive diabetic education program within the last year. 3. Recipient is motivated to achieve and maintain improved glycemic control. 4. Recipient has been on a program of multiple daily injections of insulin (e.g., at least three injections per day), with frequent self-adjustments of insulin doses for at least six months prior to request for the insulin pump. 5. Documented frequency of glucose self-testing is an average of at least four times per day during the two months prior to starting the insulin pump. 6. Glycosylated hemoglobin level (HbA1C) > 7.0% In addition, one or more of the following indications must be present: 1. History of recurring hypoglycemia; 2. Wide fluctuations in blood glucose before mealtime (e.g., preprandial blood glucose level commonly exceeds 140 mg/dl; 3. Dawn phenomenon with fasting blood sugars frequently >200 ml/dl;	1. A prescription from a physician who manages recipients with insulin pumps and who works closely with a team including nurses, diabetes educators and dietitians. 2. Prior authorization is required for the insulin pump with all of the following documentation: a. Certification of Diabetic Education Class with first time request. b. Signed statement from the physician acknowledging medical necessity and the following: 1. Recipient is motivated to achieve and maintain improved glycolic control, indicated by showing documented finger sticks (at least four times per day) with multiple injections. 2. Recipient has been on a program of multiple injections of insulin (at least three times per day) with frequent self- adjustment of insulin doses at least six months prior to initiation of the insulin pump. 3. Cognitive ability to operate pump and calculate insulin dosages. 3. Qualifying lab results per qualifications. 4. Physician current history and physical including one or more of the additional indications listed in the qualification column. 5. Documentation requirements for recipients using the insulin pump prior to Medicaid eligibility requires a PA with the following documentation: a. A HbA1C level (within last 60 days). b. Signed narrative from the physician documenting the recipient's compliance.	1. External ambulatory infusion pump recipients with Gestational Diabetes who~~m~~ do not meet conditions one through six but do meet qualifications under Gestational Diabetes approval of the insulin pump will be on a rental basis until the end of the pregnancy. 2. Insulin Pump-related Supplies through the DMEPOS program: E0784 - External Ambulatory Infusion pump, Insulin ~~A4230 Infusion set for external pump, non-needle cannula type~~ ~~A4231 Infusion set for external pump, needle type~~ ~~A4232 Syringe with needle for external insulin pump, sterile, 3cc~~ A4224 Supplies for insulin infusion catheter (per/week) A4225 Supplies for external infusion pump-syringe type cartridge (each) Note: Available under DHCFP Pharmacy Program, billed through point of sale (POS).

Policy: DIABETIC SERVICES			
EQUIPMENT OR ITEM	**QUALIFICATIONS**	**FORMS AND DOCUMENTATION REQUIREMENTS**	**MISCELLANEOUS POLICY STATEMENTS**
(continued) **External Ambulatory Infusion Pump, Insulin (E0784)**	4. Extreme insulin sensitivity; or 5. Gestational diabetes or when pregnancy occurs or is anticipated within three months in a previously diagnosed diabetic with ANY of the following indications: a. Erratic blood sugars in spite of maximal recipient compliance and split dosing; or b. Other evidence that adequate control is not being achieved. Qualifications for recipients on the external ambulatory infusion pump prior to Medicaid eligibility: 1. A Glycosylated hemoglobin level (HbA1C) within the last 60 days. 2. Recipient has been compliant with using the insulin pump and has the ability of self-adjusting the insulin pump according to glucose levels.	and ability to self adjust the insulin pump according to glucose levels. 6. An MSRP Invoice if there is no rate established by the DHCFP.	
Diabetic Equipment and Supplies		1. Physician's/Practitioner's Order / Prescription	1. Diabetic shoes, fitting, and modification A5500 – A5507, A5512 – A5513 2. Diabetic equipment and supplies, such as Glucometers, Test strips, Lancet Device, Lancets, Insulin syringes for self-injection, Insulin systems and Continuous Glucose Monitors are not covered under the DHCFP's DME program. These items are covered under the DHCFP's pharmacy program and must be billed through the Point of Sale (POS). Refer to MSM Chapter 1200, Pharmacy Services.

Policy: DISPOSABLE SUPPLIES

EQUIPMENT OR ITEM	QUALIFICATIONS	FORMS AND DOCUMENTATION REQUIREMENTS	MISCELLANEOUS POLICY STATEMENTS
Disposable Incontinent Supplies	1. Disposable briefs/diapers, pull-ons/protective underwear, liners/ shields/ guards/ pads/ undergarments and underpads may be covered for individuals age four years and older with a medical diagnosis (1) of a neurological or neuromuscular disorder or other diagnosis of a medical condition that causes urinary or bowel incontinence, and (2) a diagnosis of urinary and/or bowel incontinence. 2. Diagnoses must be supported by medical documentation which includes other recent (within past six months) interventions used to treat or ameliorate the incontinence, such as but not limited to a bowel and bladder training/retraining program, other toileting programs, exercise and strengthening regimens. 3. The individual's weight, waist/girth measurements and belt-to-belt measurements must be consistent with manufacture's recommendations for the sizing of their products. 4. Recipients with waist size greater than 60 inches may be considered for Bariatric size briefs/diapers. 5. Individuals under four years of age must have a diagnosis of Human Immune Deficiency Virus (HIV) positive or Acquired Immune Deficiency Syndrome (AIDS) with an accompanying gastrointestinal abnormality causing frequent or intractable diarrhea which is documented by the prescribing practitioner.	1. A physician's order. In addition to other requirements for written orders, the prescriber must indicate on the written order all of the following: a. Diagnosis of medical condition causing incontinence with a diagnosis of urinary and/or bowel incontinence; b. The specific item (diaper/brief, pull-on, liner/ shield/ guard/ pad, underpads) and the order must specify the recipient's measurements for the ordered item; c. Frequency of replacement and/or changes needed and monthly quantity of each item to be dispensed; d. The size of the item to be dispensed including the individual's current weight, waist/girth and belt to belt measurements to support the size of product needed. The size of the product supplied must be consistent with the manufacturer's recommendation for their product. 2. Documentation of other interventions tried or currently in progress to treat or ameliorate the incontinence. 3. Documentation must be included in the medical record and must be part of the treatment plan for the individual. The supplier must retain copies of all supporting documentation for audits. 4. Prior authorization is always required for code T4543, Bariatric size brief/diapers or to exceed established quantity limitations, or for ages less than four years old.	1. Use of diapers and related products for individuals under the age of four years are considered age appropriate and are non-covered, unless the individual meets the qualifications and the order was a result of an Early and Periodic Screening, Diagnosis and Treatment (EPSDT) screening. These would require prior authorization. 2. Refer to the DMEPOS Fee Schedule. Prior authorization may be submitted to exceed established limits for these products when medical documentation clearly indicates a greater quantity is medically necessary. 3. Use of multiple types of briefs, diapers, pull-ons or protective underwear in any size combination cannot exceed the maximum limit (listed in the billing guide~~either 100 units or 186 units per month depending on the item~~) without PA. Liners, shields, guards, pads and underpads in any combination cannot exceed the maximum limit of 100 units per month without prior authorization and may be in addition to diapers, briefs, pull-ons or protective underwear. 4. Gloves, sterile or non-sterile and disposable wipes/washcloths are not considered medically necessary for use with incontinence care and are non-covered. 5. Underpads used for tube feedings or other procedures not related to incontinence are

Policy: MOBILITY ASSISTIVE EQUIPMENT (MAE)

EQUIPMENT OR ITEM	QUALIFICATIONS	FORMS AND DOCUMENTATION REQUIREMENTS	MISCELLANEOUS POLICY STATEMENTS
(continued) **Walkers** **Walker Accessories**	a. is *unable* to safely use appropriately fitted canes or crutches to resolve functional mobility deficits; and b. is *able* to safely use the walker; and c. has a functional mobility deficit that can be sufficiently resolved with use of a walker. 1. In addition to #1 and #2 in the MAE General Information Qualification section and #1 of this section, a heavy-duty walker may be covered if the recipient's weight is greater than 300 pounds.		1. Walker accessory items may be provided as replacement items for recipient-owned MAE. When the walker HCPCS description includes the accessory item, these items cannot be billed separately with the initial purchase.
Gait Trainers: **E8000** **E8001** **E8002**	1. EPSDT only. 2. Mobility Assistive Device for moderate to maximum support for walking. 3. Functional mobility deficit cannot be resolved using a walker.	1. Physician's/Practitioner's Order/Prescription. 2. Prior authorization documenting recipient's inability to utilize a standard or reverse walker and how the gait trainer will meet the recipient's needs. 3. Must demonstrate the capability of independently walking with the use of a gait trainer. ~~3.~~ **Note**: Trial and medical necessity must come from the prescribing physician or physical or occupational therapist that specializes in mobility. 4. An MSRP Invoice if there is no rate established by the DHCFP.	Note: Rehab equipment and physical/ occupational therapy equipment for home use is not covered under the DME benefit. Please review policies applicable to therapies and rehabilitation.
~~T5001~~ POSITIONING SEAT FOR PERSONS WITH SPECIAL ORTHOPEDIC NEEDS **T5001**	EPSDT only **Adaptive Car Seats** 1. The recipient's diagnosis(es)/clinical condition(s) support the need for a specialized vehicle positioning seat due to decreased seated postural control that would immediately result in an adverse medical outcome. 2. A commercially available vehicle positioning seat has been trialed and	1. Complete valid Physician's/Practitioner's Order/Prescription. 2. Ordering practitioner clinical that discusses the medical necessity for the requested equipment. 3. Complete qualified health care professional evaluation that meets the following criteria: a. Is performed by a licensed physician, physician's assistant, occupational therapist, or physical therapist.	1. Duplication of services/equipment will not be approved. 2. Deluxe equipment will not be approved if there are less costly alternatives. 3. Products must have received approval from the federal Food and Drug Administration (FDA) and be consistent with the approved use. Products or usage considered experimental or investigational are not covered services. Consideration may be made on a case-by-case basis for items

	demonstrated to not meet recipient's medical needs. 3. The recipient can only be safely transported in a specialized vehicle positioning seat. 4. If the recipient has a mobility base, the recipient cannot be transported in a motor vehicle in the mobility base (for example, the recipient's primary caregiver does not drive an adaptive van equipped to transport the recipient in the mobility base). 5. The growth capacity of the positioning seat will accommodate the recipient ~~member's~~ growth. 6. The positioning seat and components and/or accessories (if necessary) comply with federal safety standards. In addition to submitting the information required with all PA requests for positioning seats, providers are required to also submit **all** of the following information with a PA request for a positioning seat for motor vehicle use: 1. Description of how the recipient ~~member~~ is currently transported in a motor vehicle and 2. Accessibility of the recipient's ~~member's~~ primary caregiver's vehicle. **Activity/Feeder/Corner Chairs** In addition to submitting the information required with all PA requests for positioning seats, providers are required to also submit **all** of the following information with a PA request for a positioning seat for home use: 1.Accessibility of the recipient's residence; 2. All commercially available or special adaptive equipment or items owned and/or used by the recipient in all environments regardless of the pay source of that equipment; and 3. Th recipient's current or anticipated use of a mobility base	b. Includes detailed assessments in the relevant areas that pertain to the specific CRT (complex rehabilitation technology) service requested. c. Uses body structure and function and/or activity components of the International Classification of Functioning model to provide justification for recipient ~~member~~ specific needs for each requested line item. d. Includes a signed statement from the qualified health care professional who is writing the evaluation indicating that they do not have a financial relationship with the CRT supplier requesting the durable medical equipment. 4.A complete CRT professional evaluation that meets the following criteria: a. Is performed by a qualified CRT professional. b. Includes a copy of the certification as defined in § DHS 101.03 (28m). c. Indicates the qualified CRT professional performing the CRT evaluation was present at the recipient's CRT clinical evaluation or indicates that documentation of coordination has been submitted with the CRT clinical evaluation performed by the qualified health care professional. 5.Assessments that are completed in-person, signed and dated, and include details of the following areas: a. Current equipment the recipient ~~member~~ may be using (such as the equipment's make, model, and age). b. Projected life expectancy of the current and proposed CRT item. c. Recipient's home or setting for accessibility using the Durable Medical Equipment Home Accessibility Report, F-02891 (08/2022).	approved by the FDA as a Humanitarian Device Exemption (HDE) under the Safe Medical Device Act of 1990 and as defined by the FDA. That is, a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year.

		d. Transportation method, including the make and model of vehicle, if applicable. e. Cost-effectiveness of the requested service compared to a similar service and the reason the comparable service would not meet the recipient's needs, if applicable. f. Other specific models ruled out and why they would not meet medical needs. 6. Signed and dated statement asserting that the qualified CRT professional will provide appropriate training to the recipient and will maintain adequate documentation of the training provided. 7. The recipient's current age, height, and weight, as well as the source and date of the height and weight record. 8. Clinical documentation of the recipient's functional status that includes the following: a. Ambulation status, including what ambulation aids are used (if any). b. Transfer performance. c. Head and trunk stability. d. Sitting and standing balance. e. Sitting and standing endurance. 9. Clinical documentation of the recipient's diagnosis(es) and/or all other medical conditions, including complications of the following: a. Airway b. Skin integrity c. Circulation d. Behavior, if applicable 10. Description of the recipient's current equipment and the reason the existing equipment no longer meets the recipient's medical needs, including adaptations or modifications to commercially available items. 11. Manufacturer product information/ order form, including the make, model, size, height and weight user limits, and growth capacity of the positioning seat.	

		12. A cost or MSRP Invoice if there is no rate established by the DHCFP.	
Wheelchairs *(pertains to all wheelchair types – manual and power)*	1. In addition to the MAE General Qualification section, a wheelchair may be covered if the recipient's mobility limitation cannot be sufficiently resolved by the use of an appropriately fitted cane(s), crutches or a walker; and 2. The recipient meets the specific qualifications listed further in this section for the type of wheelchair being requested. The recipient must have a medical need for, and the requested item must be suitable for use in the home and other locations the recipient is likely to encounter in their normal life activities, in accordance with 42 CFR	All from MAE General Qualification section; and 1. Mobility Assessment form found on the QIO-like vendor's website (refer to detailed requirements in Form Instructions at: https://www.medicaid.nv.gov/providers/forms/forms.aspx and in MSM Chapter 1300. 2. An MSRP Invoice if there is no rate established by the DHCFP.	1. Medicaid allows only one wheelchair at a time. Backup chairs are denied as a duplicate benefit. For all Medicare/Medicaid dual eligible recipients, Medicaid is payer of last resort. Therefore, any MAE that qualifies as an Advanced Determination of Medicare Coverage (ADMC) item must be submitted to Medicare prior to requesting approval by Medicaid. After the ADMC decision is received from Medicare, provider/supplier must submit a copy of the ADMC written

Policy: MOBILITY ASSISTIVE EQUIPMENT (MAE)			
EQUIPMENT OR ITEM	**QUALIFICATIONS**	**FORMS AND DOCUMENTATION REQUIREMENTS**	**MISCELLANEOUS POLICY STATEMENTS**
(continued) **Power Mobility Devices (PMDs)** *(pertains to all POVs and PWCs below)*	1. The recipient meets the additional qualifications for the specific device requested, as indicated further in this section.	2. Mobility Assessment form found on the QIO-like vendor's website (refer to detailed requirements in Form Instructions at: https://www.medicaid.nv.gov/providers/forms/forms.aspx and in MSM Chapter 1300 Prior Authorization section. 3. Additional supporting documentation may include the Medicare-required Face-to-Face evaluation/examination.	recipient's home can accommodate the requested equipment, which may be obtained from or documented by the DME provider/supplier. 3. Prescribing physician/practitioners may bill an additional fee using HCPCS code G0372 on the claim for the office visit (CPT 99211) during which the Medicare-required Face-to-Face examination was completed.
Power Operated Vehicle (POV)	1. The recipient is able to: a. safely transfer to and from the POV; b. operate the tiller steering system; and c. maintain postural stability and position while operating the POV for normal life; 2. The recipient's mental capabilities (e.g., cognition and judgment) and physical capabilities (e.g., vision and hearing) are sufficient for safe mobility using a POV in the home; 3. The recipient's home provides adequate access between rooms, maneuvering space and surfaces for use of the POV that is requested/provided; 4. Use of a POV will significantly improve the recipient's ability to participate in MRADLs; 5. The recipient will use it on a regular basis; 6. The recipient or their caregiver has not expressed an unwillingness to use the POV that is provided in the home; 7. If unable to operate the POV independently, the recipient has a caretaker available, willing and able to assist in the operation of the POV;		

Policy: MOBILITY ASSISTIVE EQUIPMENT (MAE)			
EQUIPMENT OR ITEM	**QUALIFICATIONS**	**FORMS AND DOCUMENTATION REQUIREMENTS**	**MISCELLANEOUS POLICY STATEMENTS**
Wheelchair Options, Accessories, and Seating Systems	1. Options and accessories for wheelchairs may be covered if: a. The recipient meets the wheelchair qualifications as indicated previously, and has either a manual or power wheelchair; b. The device is an appropriate option/accessory for the type of chair the individual has; c. The option/accessory itself is medically necessary, as determined through the Mobility Assessment, form found on the QIO-like vendor's website; d. When the option/accessory is not a required component of the mobility device at the time of initial dispensing; e. The option/accessory is not covered under an existing warranty; and f. As indicated for each specific item listed further in this section. 2. All wheelchair seating system items in this category may be covered if: a. The recipient meets the wheelchair qualifications as indicated above, and has either a manual or power wheelchair; b. The item is appropriate for the type of chair the individual has; c. The item itself is medically necessary, as determined through the Mobility Assessment, form found on the QIO-like vendor's website; d. When the item is not a required component of the mobility device at the time of initial dispensing;	For all items under this heading: all from General Information section above; and 1. Mobility Assessment form found on the QIO-like vendor's website (refer to detailed requirements in Form Instructions at: https://www.medicaid.nv.gov/providers/forms/forms.aspx and MSM Chapter 1300 - Prior Authorization section. 2. An MSRP Invoice if there is no rate established by the DHCFP.	See also General Information and Coverage and Limitations that may include items desired for reasons other than medical necessity: 1. Any DMEPOS or services within other DHCFP programs that meet the same medical purpose may be duplicative. 2.An option/accessory that is primarily to allow the recipient to perform leisure or recreational activities. 3. Electronic interface used to control lights or other electrical devices. 4. Power seat elevation feature and power standing feature. 5. Power wheelchair features may include, but not limited to: stair climbing (A9270), electronic balance (A9270), ability to balance on two wheels (A9270), remote operation (A9270), an attendant control (E2331) provided in addition to a patient-operated drive control system are considered duplicative and contradictory as one option indicates recipient's ability to operate safely and the other indicates it is not safe for the recipient to operate.

Power Tilt and/or Recline Seating Systems: (E1002- E1010,E1012) Power Seating System (tilt only, recline only, or combination tilt and recline – with or without power elevating leg rests)	1. May be covered if the recipient meets the criteria for a power wheelchair and the outcome of the Mobility Assessment, form found on the QIO-like vendor's website has determined the specific feature to be medically necessary; and a. The recipient is at high risk for development of a pressure ulcer and is unable to perform a functional weight shift; b. The recipient utilizes intermittent catheterization for bladder management and is unable to independently transfer from the wheelchair to bed; or 2. The power seating system is needed to manage increased tone or spasticity Power Elevating Leg rests: (E1010) may be considered medically necessary if: a. The recipient has significant lower extremity edema that requires having an elevating leg rest; or b. The recipient meets the criteria for and has a reclining back on the wheelchair. AND the following is noted: a. The patient is unable to use upper extremities to elevate leg rests independently, and b. The recipient is left alone for periods of two or more hours during the day or does not have someone readily available to assist with needed positioning such as in a work or school setting. Center Mount Power Elevating leg rest/Platform: (E1012) may be considered medically necessary if criteria for E1010 are met AND at least one of the following: a. The recipient has a musculoskeletal condition such as contracture or the presence of a cast or brace which prevents 90 degree flexion at the knee.		

	b. The recipient's feet are too close together to use individual foot plates (this might be because they have insufficient hip range (not enough abduction). OR c. The recipient -is a bariatric recipient, and they are wider at the knees than at the hips, and their legs are too wide to fit in between the hinge points of the standard power elevated leg rest. ~~ELR~~.		

Policy: MOBILITY ASSISTIVE EQUIPMENT (MAE)			
EQUIPMENT OR ITEM	**QUALIFICATIONS**	**FORMS AND DOCUMENTATION REQUIREMENTS**	**MISCELLANEOUS POLICY STATEMENTS**
Safety Belt / Pelvic Strap (E0978)	1. May be covered if the recipient has weak upper body muscles, upper body instability or muscle spasticity which requires use of this item for proper positioning.		
Seating Systems (wheelchair):	As listed for Wheelchair Options, Accessories and Seating Systems.	For all items under this heading: all from MAE General Information; and 1. Mobility Assessment, form found on the QIO-like vendor's website (refer to detailed requirements in Form Instructions at: https://www.medicaid.nv.gov/providers/forms/forms.aspx and MSM Chapter 1300 - Prior Authorization section.	All from MAE General Information; and 1. All seating and positioning devices/ material and included components must meet the requirements of CMS and as set forth in the DME MAC Local Coverage Determination (LCD) – L15670 (or more current) and related Policy Articles at the time of dispensing. 2. Coverage and Limitations/Non-Covered are typically not medically necessary but

			may be reviewed under special criteria, see Appendix A: a. Powered seat cushion (E2610) (effectiveness has not been established). b. A seat or back cushion provided for a transport chair (these are for short-term sitting). c. A prefabricated seat cushion, a prefabricated positioning back cushion or a brand name custom fabricated seat or back cushion which has not received a written coding verification from the DME Pricing, Data Analysis and Coding (PDAC) contractor.

Policy: ORTHOTIC AND PROSTHETIC DEVICES

EQUIPMENT OR ITEM	QUALIFICATIONS	FORMS AND DOCUMENTATION REQUIREMENTS	MISCELLANEOUS POLICY STATEMENTS
Orthotics and/or Prosthetics **Adjustments, Repairs and Component Replacements**	1. Replacement of a prosthesis, prosthetic component or orthosis is covered if the treating physician orders a replacement device or part because of any of the following: a. A change in the physiological condition of the recipient; b. Irreparable wear of the device or a part of the device, without evidence of recipient negligence; or c. The condition of the device or part of the device requires repairs and the cost of such repairs would be more than 60% of the cost of a replacement device or of the part being replaced.	1. Physician's/Practitioner's Order/Prescription. 2. Prior authorization, when indicated.	1. Adjustments, routine periodic servicing (testing, cleaning and checking) to a prosthesis needed for wear or by a change in the recipient's condition are covered under the initial physician's order for the prosthesis for the life of the prosthetic. 2. Maintenance recommended by the manufacturer that must be performed by the prosthetist is a covered repair. 3. Repairs are covered when necessary to make the prosthesis functional. The cost of the repairs must not exceed the cost for a replacement.
Orthopedic Shoe-Related Services (inserts, arch supports, footwear, lifts, wedges, heels, and related services) – HCPCS "L" codes	1. Devices are covered for individuals under age 21 years when determined to be medically necessary through EPSDT screening and recommendations. 2. A surgical boot/shoe or Plastazote sandal may be covered for individuals of any age when ordered and determined to be medically necessary.	1. Physician's order. 2. Prior authorization is required when "L" code product rate is $250.00 or more per unit.	1. Refer to Diabetic Services section and HCPCS "A" codes in Fee Schedule for diabetic shoe insert coverage information.
Cranial Remolding Orthotic Devices ~~HCPCS S1040~~ Cranial remolding orthosis, pediatric, ridged, with soft interface material, custom fabricated, **includes fitting and adjustment(s)** HCPCS S1040	**EPSDT ONLY:** Medically necessary for either of the following 2 diagnosis: 1.Craniosynostosis following surgical correction, or 2.Treatment of cranial asymmetry in infants 3-18 months of age with severe non-synostotic cranial positional asymmetry (plagiocephaly or brachycephaly). **ALL of the following criteria must be present in infants with non-synostotic positional cranial asymmetry:** 1.Infant is 18 months of age or younger.	1. Physician's/Practitioner's Order/Prescription 2. Prior authorization. 3.Indication within prior authorization documents referencing EPSDT. 4. If applicable, therapy notes reflecting repositioning and stretching therapy. 5. Anthropometric measurements.	To meet criteria for a cranial remolding orthotic device, Cranial vault anthropometric measurements must show **at least one** of the following: 1.Asymmetry discrepancy of 10mm or more in one of the following anthropometric measurements: a. Cranial vault, or b. Skull base, or c. Orbit tragal depth. **OR** 2. A cephalic index (CI), head with times 100 divided by head length, of two or

	2.Severe asymmetry is present with or without torticollis. 3.For children less than 6 months of age, there must be documentation clearly noted in the medical records that medical personnel have instructed caregivers in appropriate positional therapies and that those therapies have been administered for at least two months without improvement, or there must be documentation of a comorbid diagnosis or delay in diagnosis that prevents the completion of a trial of conservative therapy.		more standard deviations above or below the mean for age and gender. Table located from www.aetna.com Cephalic Index Gender Age - 2 SD - 1SD Mean + 1SD + 2SD Male 16 days–6 months 63.7 68.7 73.7 78.7 83.7 6–12 months 64.8 71.4 78.0 84.6 91.2 Female 16 days–6 months 63.9 68.6 73.3 78.0 82.7 6–12 months 69.5 74.0 78.5 83.0 87.5

Policy: RESPIRATORY SERVICES

EQUIPMENT OR ITEM	QUALIFICATIONS	FORMS AND DOCUMENTATION REQUIREMENTS	MISCELLANEOUS POLICY STATEMENTS
Apnea Monitor	1. One-year qualification for at least one of: a. Prematurity (gestational age must be listed on CMS 1500); b. Substantially small for gestational age; c. HX of maternal alcohol abuse; d. HX of maternal narcotics abuse; and/or e. HX of maternal hallucinogenic agent abuse. 2. Six-month qualification for at least one of: a. Gastro-esophageal reflux; b. Abnormal pneumogram indicating desaturating apnea; c. Periodic respirations; d. Significant bradycardia or tachycardia of unknown or specified origin; e. Congenital heart defect; f. Bronchopulmonary dysplasia or newborn respiratory distress; g. Respiratory distress; h. Family history of SIDS (siblings only); i. Respiratory Syncytial Virus (RSV); j. Apparent Life-Threatening Episode (ALTE) with subsequent visits to physician or emergency room; k. Laryngotracheal malacia; l. Tracheal stenosis; and/or m. Swallowing abnormality.	1. Prescription and/or MD signed Prior Authorization Form. 2. Medical documentation supporting qualifying factors.	1. Program limit to one year for diagnoses including prematurity and maternal substance abuse. 2. Other diagnoses limited to six months. 3. An Apnea Monitor is a non-reimbursable service in conjunction with a pressure ventilator, with pressure control pressure support and flow triggering features.
Bi-Level Positive Airway Pressure (BiPAP) Device **BiPAP "S" (E0470) (without back u)** **BiPAP "ST" (E0471) (with back up)**	1. For an E0470 or E0471 Respiratory Assist Device (RAD) to be covered, the treating physician must fully document in the recipient's medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.		**Exception:** To discharge from a hospital setting for the initial rental period a sleep study is not required.

Policy: RESPIRATORY SERVICE~~S~~

EQUIPMENT OR ITEM	QUALIFICATIONS	FORMS AND DOCUMENTATION REQUIREMENTS	MISCELLANEOUS POLICY STATEMENTS
(continued) **Bi-Level Positive Airway Pressure (BiPAP) Device** **BiPAP 'S' (E0470) (without back up)** **BiPAP 'ST' (E0471) (with back up rate)**	2. For an E0470 or E0471 Respiratory Assist Device (RAD) to be covered, the treating physician must fully document in the recipient's medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc. A RAD (E0470, E0471) used to administer Noninvasive Positive Pressure Respiratory Assistance (NPPRA) therapy is covered for those recipients with clinical disorder groups characterized as (Group I) restrictive thoracic disorders (e.g., progressive neuromuscular diseases or severe thoracic cage abnormalities), (Group II) severe chronic obstructive pulmonary disease (COPD), (Group III) central sleep apnea (CSA), or (Group IV) obstructive sleep apnea (OSA) (E0470 only) and who also meet the following criteria: <u>Group I: Restrictive Thoracic Disorders:</u> a. There is documentation in the recipient's medical record of a progressive neuromuscular disease (e.g., amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (e.g., post-thoracoplasty for TB); and b. An arterial blood gas PaCO2, done while awake and breathing the recipient's usual FIO2 is > 45 mm Hg; or c. Sleep oximetry demonstrates oxygen saturation < 88% for at least five continuous minutes, done while breathing the recipient's usual FIO2; or	1. Prescription and/or MD signed Prior Authorization/CMN Form. 2. Sleep Study (Diagnostic and Titrated sleep studies). 3. Medical documentation supporting qualifying factors. 4. Refer to specific documentation requirements specified in the Qualifications section for each scenario. 5. ~~MSRPs Invoice is required when no rate is established by the DHCFP.~~	1. The initial rental will be for three months. 2. Further approval requires: a. A letter of compliance from the recipient; or b. A completed form found on the QIO-like vendor's website; or c. Follow up notes from physician documenting compliance with the BiPAP; or d. A readout/printout from the BiPAP supplier documenting regular usage of the BiPAP. 3. BiPAP replacement requires proof of compliance or medical necessity. **<u>Note</u>**: The BiPAP will be rented until the purchase price is reached; this includes the initial three-month rental period.

Policy: RESPIRATORY SERVICES

EQUIPMENT OR ITEM	QUALIFICATIONS	FORMS AND DOCUMENTATION REQUIREMENTS	MISCELLANEOUS POLICY STATEMENTS
(continued) **Bi-Level Positive Airway Pressure (BiPAP) Device** **BiPAP 'S' (E0470) (without back up)** **BiPAP 'ST' (E0471)** ***(with back up rate)***	d. For a progressive neuromuscular disease (**only**), maximal inspiratory pressure is < 60 cm H20 or forced vital capacity is < 50% predicted; and e. Chronic Obstructive Pulmonary Disease (COPD) does not contribute significantly to the recipient's pulmonary limitation. 3. If all previously described criteria are met, either an E0470 or E0471 device (based upon the judgment of the treating physician) will be covered for recipients within this group of conditions for the first three months of NPPRA therapy (see continued coverage after the initial three months). If all of the previously described criteria are not met, then E0470 or E0471 and related accessories will be denied as not medically necessary. <u>Group II: Severe COPD</u>: a. An arterial blood gas $PaCO_2$ done while awake and breathing the recipient's usual FIO_2 is <u>≥</u> 52 mm Hg; and b. Sleep oximetry demonstrates oxygen saturation <u>≤</u> 88% for at least five continuous minutes, done while breathing oxygen at 2 LPM or the recipient's usual FIO_2 (whichever is higher); ~~c. An arterial blood gas $PaCO_2$, done while awake and breathing the recipient's usual FIO_2, is <u>≥</u> 52 mm Hg; and~~ ~~d.~~c. Prior to initiating therapy, OSA (and treatment with CPAP) has been considered and ruled out.		

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EQUIPMENT OR ITEM	QUALIFICATIONS	FORMS AND DOCUMENTATION REQUIREMENTS	MISCELLANEOUS POLICY STATEMENTS
(continued) **Bi-Level Positive Airway Pressure (BiPAP) Device** **BiPAP 'S' (E0470)** ***(without back up)*** **BiPAP 'ST' (E0471)** ***(with back up rate)***	4. If all of the previously described criteria for recipients with COPD are met, an E0470 device will be covered for the first three months of NPPRA therapy (see Continued Coverage). An E0471 device will not be covered for a recipient with COPD during the first two months, because therapy with a E0470 device with proper adjustments of the device's settings and recipient accommodation to its use will usually result in sufficient improvement without the need of a back-up ~~rate~~. (See further in this section for coverage of an E0471 device for COPD after two month's use of an E0470 device). 5. If all of the previously described criteria are not met, E0470 and related accessories will be denied as not medically necessary. If E0471 is billed, even if the criteria for an E0470 device are met, since the E0471 is in a different payment category than E0470 and a least costly medically appropriate alternative payment cannot be made, it will be denied as not medically necessary. Group III: – Obesity hypoventilation syndrome (also known as Pickwickian Syndrome) 1. BMI greater than 30; and one of the below three, a. An initial arterial blood gas PaCO2, done while awake and breathing the recipient's prescribed FIO2, is greater than or equal to 45 mm Hg, or b. Asleep PaCO2 increase of at least 10mmHg from baseline awake value and at least50 mmHg for at least 10 min sleep time, or c. Asleep PCO2 55 mmHg or more for at least 10 minutes.		

	Group IV~~II~~: Central Sleep Apnea (e.g., apnea not due to airway obstruction): Prior to initiating therapy, a complete polysomnogram must be performed documenting the following: a. The diagnosis of central sleep apnea (CSA); b. The exclusion of obstructive sleep apnea (OSA) as the predominant cause of sleep-associated hypoventilation; c. The ruling out of CPAP as effective		

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EQUIPMENT OR ITEM	**QUALIFICATIONS**	**FORMS AND DOCUMENTATION REQUIREMENTS**	**MISCELLANEOUS POLICY STATEMENTS**
(continued) **Bi-Level Positive Airway Pressure (BiPAP) Device** **BiPAP 'S' (E0470)** ***(without back up)*** **BiPAP 'ST' (E0471)** ***(with back up rate)***	therapy if OSA is a component of the sleep-associated hypoventilation; and d. Oxygen saturation <u>≤</u> 88% for at least five continuous minutes, done while breathing the recipient's usual FIO_2; and e. Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the recipient's usual FIO_2. 6. If all previously described criteria are met, either an E0470 or E0471 device (based upon the judgment of the treating physician) will be covered for recipients with documented CSA conditions for the first three months of NPPRA therapy (see Continued Coverage). If all of the previously described criteria are not met, then E0470 or E0471 and related accessories will be denied as not medically necessary. <u>Group ~~I~~V: Obstructive Sleep Apnea (OSA)</u>: Criteria (a) and (b) are both met: a. A complete polysomnogram has established the diagnosis of obstructive sleep apnea according to the following criteria: 1. The apnea-hypopnea index (AHI) is <u>≥</u> 15 events per hour; <u>or</u> 2. The AHI is from five to 14 events per hour with documented symptoms of: a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; <u>or</u> b. Hypertension, ischemic heart		

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EQUIPMENT OR ITEM	**QUALIFICATIONS**	**FORMS AND DOCUMENTATION REQUIREMENTS**	**MISCELLANEOUS POLICY STATEMENTS**
(continued) **Bi-Level Positive Airway Pressure (BiPAP) Device** **BiPAP 'S' (E0470)** ***(without back up)*** **BiPAP 'ST' (E0471)** ***(with back up rate)***	disease or history of stroke; and c. A single level device E0601, Continuous Positive Airway Pressure (CPAP) device has been tried and proven ineffective. 7. If the previously described criteria is met, an E0470 device will be covered for the first three months of NPPRA therapy (see Continued Coverage). If E0470 is billed and these criteria are not met but the coverage criteria in the DMEMAC LCD and/or Policy Articles for Continuous Positive Airway Pressure System (CPAP) are met, payment will be based on the allowance for the least costly medically appropriate alternative, E0601. 8. An E0471 device is not medically necessary if the primary diagnosis is OSA. If E0471 is billed, since the E0471 is in a different payment category than E0470 and E0601 and a least costly medically appropriate alternative payment cannot be made, it will be denied as not medically necessary. Continued Coverage for E0470 And E0471 Devices Beyond First Three Months of Therapy: 1. Recipients covered for the first three months for an E0470 or E0471 device must be re-evaluated to establish the medical necessity of continued coverage beyond the first three months. While the recipient may certainly need to be evaluated at earlier intervals after this therapy is initiated, the re-evaluation upon		

	which will base a decision to continue coverage beyond this time must occur no sooner than the 31st day~~61~~		

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EQUIPMENT OR ITEM	QUALIFICATIONS	FORMS AND DOCUMENTATION REQUIREMENTS	MISCELLANEOUS POLICY STATEMENTS
(continued) **Bi-Level Positive Airway Pressure (BiPAP) Device** **BiPAP 'S' (E0470)** ***(without back up)*** **BiPAP 'ST' (E0471)** ***(with back up rate)***	days after initiating therapy by the treating physician. Medicaid will not continue coverage for the fourth and succeeding months of NPPRA therapy until this re-evaluation has been completed. 2. There must be documentation in the recipient's medical record about the progress of relevant symptoms and recipient usage of the device up to that time. Failure of the recipient to be consistently using the E0470 or E0471 device for an average of 4 hours per 24-hour period for 70% of nights during a consecutive 30-day period (ie: 21 out of 30 nights). ~~f~~ by the time of the re-evaluation (on or after the 31st day, but no later than 91 days after initiation of therapy) would represent non-compliant utilization for the intended purposes and expectations of benefit of this therapy. This would constitute reason to deny continued coverage as not medically necessary. 3. The following items of documentation must be obtained by the supplier of the device for continuation of coverage beyond three months: a signed and dated statement completed by the treating physician no sooner than 31 ~~61~~ days after initiating use of the device, declaring that the recipient is compliantly using the device- ~~(~~an average of ~~4four~~ hours per 24-hour period~~)~~ for 70% of nights during a consecutive 30-day period (ie: 21 out of 30 nights). and that the recipient is benefiting from its use. A "Usage Evaluation" form FH-1A, found on the QIO-like vendor's website is available for use at: https://www.medicaid.nv.gov/, select "Provider" then "Forms." It is not mandatory that this form be used as long as the above		

	information is provided by the treating physician.		

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EQUIPMENT OR ITEM	**QUALIFICATIONS**	**FORMS AND DOCUMENTATION REQUIREMENTS**	**MISCELLANEOUS POLICY STATEMENTS**
(continued) **Bi-Level Positive Airway Pressure (BiPAP) Device** **BiPAP 'S' (E0470)** ***(without back up)*** **BiPAP 'ST' (E0471)** ***(with back up rate)***	4. If the above criteria are not met, continued coverage of an E0470 or E0471 device and related accessories will be denied as not medically necessary. 5. For Group II (COPD) recipients who qualified for an E0470 device, if at a time no sooner than the 31st ~~61~~ days after initial issue and compliant use of an E0470 device, the treating physician believes the recipient requires an E0471 device, the E0471 device will be covered if the following criteria are met: a. an arterial blood gas $PaCO_2$, repeated no sooner than 31 ~~61~~ days after initiation of compliant use of the E0470, done while awake and breathing the recipient's usual FIO_2, still remains $\geq$ 52 mm Hg; b. a sleep oximetry, repeated no sooner than 31~~61~~ days after initiation of compliant use of an E0470 device, and while breathing with the E0470 device, demonstrates oxygen saturation < 88% for at least five continuous minutes, done while breathing oxygen at 2 LPM or the recipient's usual FIO_2 (whichever is higher); and c. a signed and dated statement from the treating physician, completed no sooner than 31~~61~~ days after initiation of the E0470 device, declaring that the recipient has been compliantly using the E0470 device 4 hours per 24 hour period for 70% of nights during a consecutive 30-day period (ie:21 out of 30		

	nights). ~~(an average of four hours per 24 hour period)~~ but that the recipient is NOT benefiting from its use. 6. If the above criteria for an E0471 are not met, since the E0471 is in a different payment category than E0470 and a least costly		

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EQUIPMENT OR ITEM	**QUALIFICATIONS**	**FORMS AND DOCUMENTATION REQUIREMENTS**	**MISCELLANEOUS POLICY STATEMENTS**
(continued) **Bi-Level Positive Airway Pressure (BiPAP) Device** **BiPAP 'S' (E0470)** ***(without back up)*** **BiPAP 'ST' (E0471)** ***(with back up rate)***	medically appropriate alternative payment cannot be made, it will be denied as not medically necessary.		
Continuous Positive Airway Pressure Device **CPAP (E0601)**	1. A single level continuous positive airway pressure (CPAP) device (E0601) is covered if the recipient has a diagnosis of obstructive sleep apnea (OSA) documented by complete polysomnogram and meets either of the following criteria (a or b): a. The AHI is ≥ 15 events per hour; or b. The AHI is from five to 14 events per hour with documented symptoms of: 1. Excessive daytime sleepiness, impaired cognition, mood disorders or insomnia; or 2. Hypertension, ischemic heart disease, or history of stroke. **Note**: The AHI must be calculated based on a minimum of two hours of recorded sleep and must be calculated using actual recorded hours of sleep (e.g., the AHI may not be an extrapolated or a projected calculation).	1. Prescription and/or MD signed Prior Authorization/CMN For 2. Sleep Study (Diagnostic and Titrated sleep studies). 3.Medical documentation supporting qualifying factors. 4. MSRP Invoice is required when no rate is established by the DHCFP. 5. Refer to specific documentation requirements specified in the Qualifications section for each scenario. **Exception:** To discharge from a hospital setting for the initial rental period a sleep study is not required.	1. The initial rental will be for three months. 2. Further approval requires: a. letter of compliance from the recipient; or b. a completed form found on the QIO-like vendor's website; or c. follow up notes from physician documenting compliance with the CPAP; or d. a readout/printout from the CPAP supplier documenting regular usage of the CPAP. 3. CPAP replacement requires proof of compliance or medical necessity. **Note**: The CPAP will be rented until the purchase price is reached; this includes the initial three-month rental period.

	2. Continued coverage of an E0601 device beyond the first three months of therapy requires that, no sooner than the 31st day but no later than 91 days after initiating therapy, the supplier ascertain from either the recipient or the treating physician that the recipient is continuing to use		

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EQUIPMENT OR ITEM	**QUALIFICATIONS**	**FORMS AND DOCUMENTATION REQUIREMENTS**	**MISCELLANEOUS POLICY STATEMENTS**
(continued) **Continuous Positive Airway Pressure Device** **CPAP (E0601)**	the CPAP device. Continued use is defined as an average of 4 hours per 24-hour period or 70% of nights during a consecutive 30-day period (ie:21 out of 30 nights). average of four hours per 24-hour period. A "Usage Evaluation" form FH-1A, found on the QIO-like vendor's website is available for use at: https://www.medicaid.nv.gov/, select "Provider" then "Forms." It is not mandatory that this form be used as long as the previously listed is provided by the treating physician. The supplier cannot provide answers to any of the information, as it must be obtained from the recipient, caregiver, spouse or attending physician. Information should include: a. Number of hours a day the machine is used. b. Number of months using machine. c. Will the recipient continue to use the machine in the future? Identify who has answered the information (cannot be the supplier).		

EQUIPMENT OR ITEM	QUALIFICATIONS	FORMS AND DOCUMENTATION REQUIREMENTS	MISCELLANEOUS POLICY STATEMENTS
Non-invasive ventilator (NIV)(E0466)	1. For a Non-invasive ventilator (NIV) (E0466) to be covered: a. The treating physician must fully document in the recipient's medical record all rationale for NIV. b. Recipient must have demonstrated failure of bilevel positive airway pressure (BPAP) to improve hypercapnia and/or oxygen saturation level. (this B-PAP trial must be provided along with all supportive clinical documents). **Note:** PaCO2 levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize PaCO2 levels alone is not considered a therapeutic failure of Bi-PAP). AVAPS mode is available on Bi-level PAP devices coded E0471. A non-invasive ventilator(E0466) is not considered medically necessary when the sole purpose of the home ventilator is to function as a respiratory assistance device (RAD) including continuous positive airway pressure (CPAP), auto-titrating PAP (APAP), bilevel positive airway pressure (BPAP, BiPAP, AVAPS) or adaptive servo-ventilation (ASV). NV Medicaid considers NIV to be medically necessary for the following indications when criteria are met: 1. Restrictive Thoracic Disorders 2. Severe COPD, and 3. Obesity hypoventilation syndrome (also known as the Pickwickian Syndrome) **NOTE**: Overlap syndromes (presence of more than one condition, such as COPD and sleep apnea), and pediatric respiratory failure cases require secondary medical review by a physician.		1.The initial rental will be for 3 months 2.Continued use of noninvasive home ventilators after the initial three-month certification period is considered medically necessary when all the following are met: a. Medical records document improvement in relevant signs or symptoms due to use of the device; and b. The device is used for at least an average of 4 hours per 24-hour period or 70% of nights out of a consecutive 30-day period (ie: 21 nights out of 30 nights) based on a download of compliance from the device; and c. None of the following contraindications: 1. FIO2 requirement > 0.40; 2. PEEP > 10 cm H2O; 3. Need for continuous invasive monitoring. **Note:** The NIV will be rented until the purchase price is reached; this includes the initial 3-month rental period.

	Criteria for Restrictive Thoracic disorders (all 4 of the below criteria must be met): **1.** Documentation of a neuromuscular disease (ex. amyotrophic lateral sclerosis, muscular dystrophy, progressive neuromuscular disorder with respiratory muscle weakness) or a severe thoracic cage abnormality (ex. post-thoracoplasty for tuberculosis or severe kyphoscoliosis) and both of the following (a. and b.): a. One of the following: i. An arterial blood gas partial pressure of carbon dioxide (PaCO2) was measured while awake and breathing room air or on prescribed oxygen with a measurement of: PaCO2 ≥ 45 mm Hg; or ii. Sleep Oximetry demonstrates O2 saturation ≤88% for at least 5 mins while breathing **prescribed** O2; and b. If neuromuscular disease is present, maximal inspiratory pressure is < -60 cm H20, or forced vital capacity is < 50% predicted; and **2.** Respiratory failure has failed to improve with an adequate trial of bilevel positive airway pressure (Bi-PAP), as evidenced by one of the following: a. Intolerance to Bi-PAP, or b. Worsening dyspnea, hemodynamic instability, or unresponsive hypoxemia; or c. Signs of respiratory failure, including tachypnea (respiratory rate >24/min) and respiratory acidosis (e.g., pH<7.35) **(Note:** PaCO2 levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize PaCO2 levels alone is not considered a therapeutic failure of Bi-PAP),		

	3. Chronic obstructive pulmonary disease (COPD) does not contribute significantly to the pulmonary limitation; and 4. None of the following contraindications: a. FIO2 requirement > 0.40; b. Positive-end expiratory pressure (PEEP) > 10 cm H2O; c. Need for continuous invasive monitoring in adult patients. **Criteria for Severe COPD (all 4 of the below criteria must be met):** 1. An arterial blood gas PaCO2 measurement was done while awake *and* breathing at baseline and prescribed FIO2, which is greater than or equal to 52 mm Hg; and 2. Prior to initiating therapy, sleep apnea and treatment with a continuous positive airway pressure device (CPAP) has been considered and ruled out. **(Note**: Formal sleep testing is not required if the medical record demonstrates that sleep apnea (Obstructive Sleep Apnea (OSA), CSA and/or Comp SA) is not the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation; and 3.Respiratory failure has failed to improve with an adequate trial of Bi-PAP(trial must be included in the clinical provided), as evidenced by *one* of the following: **(Note**: PaCO2 levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize PaCO2 levels alone is not considered a therapeutic failure of Bi-PAP); a. Intolerance to Bi-PAP, or b. Worsening dyspnea, hemodynamic instability, or unresponsive hypoxemia; **or**		

	c. Signs of respiratory failure: include tachypnea (respiratory rate >24/min) and respiratory acidosis (e.g., pH <7.35), and **4.** None of the following contraindications: a. FIO2 requirement > 0.40; b. PEEP > 10 cm H2O; c. Need for continuous invasive monitoring. **Criteria for obesity hypoventilation syndrome (all 4 of the below criteria must be met):** 1. BMI greater than 30; and 2. An initial arterial blood gas PaCO2, done while awake and breathing the recipient's prescribed FIO2, is greater than or equal to 45 mm Hg; and 3. Respiratory failure has failed to improve with an adequate trial of Bi-PAP(trial must be included in the clinical provided), as evidenced by *one* of the following**:** **(Note:** PaCO2 levels may not normalize even with adequate response to Bi-PAP therapy. Failure to normalize PaCO2 levels alone is not considered a therapeutic failure of Bi-PAP); a. Intolerance to Bi-PAP, or b. Worsening dyspnea, hemodynamic instability, or unresponsive hypoxemia; **or** c. Signs of respiratory failure: include tachypnea (respiratory rate >24/min) and respiratory acidosis (e.g., pH<7.35), and 4. None of the following contraindications: a. FIO2 requirement > 0.40; b. PEEP > 10 cm H2O; c. Need for continuous invasive monitoring.		