MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

February 25, 2020

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: CODY L. PHINNEY, DEPUTY ADMINISTRATOR

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1300 – DME DISPOSABLE SUPPLIES AND SUPPLEMENTS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 1300 – DME Disposable Supplies and Supplements are being proposed to update the invoice verbiage for consistency throughout, referenced provider type (PT 33) billing guideline, removed the Insulin Pump policy and made reference along with Continuous Glucose Monitors that they will now be under the pharmacy benefit, removed the rental option verbiage for Osteogenesis Stimulators to allow straight purchase and removed facility based polysomnogram verbiage which opens up to allow home based sleep studies.

Throughout the chapter, grammar, punctuation and capitalization changes were made, duplications removed, acronyms used and standardized, and language reworded for clarity. Renumbering and re-arranging of sections was necessary.

Entities Financially Affected: DME (PT 33) and Pharmacy (PT 28).

Financial Impact on Local Government: Unknown at this time.

These changes are effective February 26, 2020.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
OL 12/18/19 MSM Chapter 1300 – DME Disposable Supplies and Supplements	MTL 07/18 MSM Chapter 1300 – DME Disposable Supplies and Supplements

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
1303.2(A)(2)	**Detailed Product Description**	Removed “of cost” for the type of invoice.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
1303.4(C)	**Provider Responsibility**	Added verbiage to direct providers to the (PT 33) DMEPOS specific billing guide.
Appendix B, pages 16 and 17	**Diabetic Services**	Removed section on External Ambulatory Infusion Pump, Insulin E0784. Added verbiage referring Insulin systems and Continuous Glucose Monitors are now under the pharmacy program.
Appendix B, page 48	**Osteogenesis Stimulator Devices, Qualifications and Misc. policy Statements**	Changed six months to three or more months for non-spinal. Removed the rental requirement verbiage for both to match Medicare and allow access to care.
Appendix B, pages 56, 57, 61	**Respiratory Services, BiPAP and CPAP, Qualifications**	Removed facility based, attended verbiage and added complete.

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;

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, 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) within 30 - 60 days prior to the start 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 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 by the DHCFP (except when Medicare is primary and Medicaid co-payment will be requested, and Medicare requires a written order for that item prior to delivery). Refer online to the DME MAC Jurisdiction D Supplier Manual, Chapter 3 – Documentation Requirements, for a current listing of those items at: https://med/noridianmedicare.com/web/jddme/education/supplier-manual

2. The verbal dispensing order must include:

a. A description of the item;

b. The recipient's name;

c. The physician's name;

d. The start date and length of need of the order; and

e. Additional information sufficient to allow appropriate dispensing of the item.

3. Suppliers must maintain written documentation of the verbal order and, if the verbal order is used for dispensing the item, the supplier must obtain a detailed written order prior to billing the DHCFP.

c. Written Orders:

1. Written orders are acceptable for all transactions involving DMEPOS and must be obtained prior to submitting a prior authorization for any DMEPOS items. Written orders may take the form of a photocopy, facsimile image, electronically maintained, or original "pen-and-ink" document.

2. All written orders must, at a minimum:

   a. Clearly specify the start date of the order;

   b. Include the length of need;

   c. Be sufficiently detailed, including all options or additional features that are needed to meet the recipient's needs. The description must be either a narrative description (e.g., lightweight wheelchair base) or a brand name/model number; and

   d. Be signed and dated by the treating physician/practitioner. Signature includes computer signature and pen and ink, no signature stamps allowed.

3. Certain items require additional elements in the written orders, as follows:

   a. If the written order is for supplies that will be provided on a periodic basis, the written order must include appropriate information on the quantity used, frequency of change and duration of need. (For example, an order for surgical dressings might specify one 4x4-hydrocolloid dressing that is changed one to two times per week for one month or until the ulcer heals).

   b. If the written order is for an item such as, but not limited to, enteral formula, oxygen, etc., the order must specify the name of the product, concentration (if applicable), dosage, frequency and route of administration and duration of infusion (if applicable).

   c. Custom-fabricated items must be clearly indicated on the written order that has been signed and dated by the prescribing physician/practitioner.

4. There are additional specifications for orders for certain items, such as, but not limited to, Power Mobility Devices (PMDs). Refer to Appendix B for details.

5. The detailed description of the item(s) may be completed by an employee of the ordering physician/practitioner; however, the

prescriber must review the detailed description and personally indicate agreement by signing and dating the order.

6. Medical necessity information (such as the most current appropriate diagnosis code(s) (ICD), narrative description of the recipient's condition, abilities and limitations) is not in itself considered to be part of the order although it may be put on the same document as the order.

d. New Orders Are Required When:

1. There is a change in the order of a specific DMEPOS item;

2. There is a change in the resident's condition that warrants a change in the order, a change in the treating physician/practitioner or DMEPOS supplier;

3. An item is replaced for any reason; or

4. 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 ~~of cost~~ 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. 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. 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

purchased, such as disposable supplies and custom-made items which can only be used by that recipient. These will be considered for purchase when, in addition to all other requirements and qualifications for a specific item/device:

1. the anticipated length of need (per physician's order) is long term (more than six months); and

2. the provider will be supplying a new device/item to the recipient; or

3. the item is only available for purchase.

2. Purchase Rental Equipment Option:

a. Nevada Medicaid identifies specific products for purchase when an item was new at the time it was dispensed to a recipient for rental purposes, and prior to billing the third month of rental, if it is determined the item will be needed indefinitely, the DHCFP may purchase the item for the recipient for ongoing use. The DHCFP does not purchase used equipment from the provider's inventory of rental items used for re-issuance to same or multiple persons over time (rental fleets, etc.).

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 prior 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 the request must include the physician's order and 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.

2. Review Consideration:

   a. In addition to the specifications mentioned previously for reviewing the prior authorization, products 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 needs.

   b. The recipient must have a medical need for and the requested item must be suitable for use for locations in which normal life activities take place. Consideration will also be based on the recipient's additional use of the item for the conditions in each of the environments the recipient is likely to encounter in their daily routines, such as, but not limited to: attending school, work and shopping. This information must be included in the supportive documentation submitted with the prior authorization.

   c. For durable medical equipment, prosthetics, orthotics and disposable medical supplies and appliances where coverage and limitation policies have not been established within this Chapter or its Appendices, the DHCFP may defer to DME MAC Jurisdiction D, Local Coverage Determination (LCD) and policy articles for coverage and limitation criteria. These can be accessed at: https://med.noridianmedicare.com/web/jddme. The item must meet the definition of durable medical equipment, prosthetic, orthotic or disposable medical supply and must be necessary to meet the medical needs of the recipient, and must be part of the prescribing physician's/practitioner's Plan of Care (POC).

   d. The DHCFP has the option of requesting an Independent Medical Evaluation (IME) to determine the recipient's limitations and abilities to support medical necessity.

3. Prior Authorization Requirements for Third Party Liability (TPL) and Medicare Crossovers:

   a. Refer to MSM Chapter 100, for more information on TPL, and Medicare Crossovers and the requirements for securing prior authorizations.

4. Prior Authorization Emergency Situations:

   a. In an emergency situation, when an order is received by the supplier after the QIO-like vendor working hours or over weekends or State holidays, dispensing of a 72-hour supply of those DMEPOS items that require prior authorization will be allowed only when:

1. A delay of 24 hours of treatment could result in very severe pain, loss of life or limb, loss of eyesight or hearing, injury to self or bodily harm to others; and

2. The treating physician/practitioner indicates the most current appropriate diagnosis code(s)/ICD code on the prescription that supports the use of the emergency policy.

b. The provider/supplier must submit the prior authorization the next business day with all required supportive documentation. The documentation must include proof of the date and time the order was received by the supplier and documentation to support both 1303.4(a)(1) and (2).

5. DMEPOS Specific Prior Authorization Forms:

All forms must be completed and submitted by a current Medicaid provider. Forms used must be the most current version.

a. Specific DME prior authorization forms are found on the QIO-like vendor's website: https://www.medicaid.nv.gov/providers/forms/forms.aspx. All DMEPOS items that require prior authorization must be requested on these forms and submitted electronically, by fax or by mail to the QIO-like vendor for approval.

b. Usage Evaluation – For Continuing Use of Bi-Level and Continuous Positive Airway Pressure (BIPAP and CPAP) Devices use the form, FA-1A found on the QIO-like vendor's website. This form may be completed and submitted for continuing usage of BIPAP or CPAP devices.

c. Mobility Assessment for Mobility Devices, Wheelchair Accessories and Seating Systems, form FA-1B found on the QIO-like vendor's website. This form must be submitted for all mobility devices, wheelchair accessories and seating systems. The Clinical Assessment must be completed and signed by the treating physician.

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 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.

2. Refer to the Nevada Medicaid Provider Type 33 – DME Fee Schedule posted at: http://dhcfp.nv.gov/Resources/Rates/FeeSchedules/ for covered services. The Fee Schedule identifies covered services/items (listed in alpha-numeric order according to HCPCS code), and rates. Codes are updated yearly. Codes not included in the fee schedule after the yearly update are considered non-covered.

C. PROVIDER RESPONSIBILITY

1. The requesting DME provider (supplier) and the prescribing physician/practitioner must work collaboratively to accurately and timely complete and submit prior authorization requests, including all supportive documentation in order to ensure the item(s) being requested is/are the most appropriate to meet the recipient's medical needs. This must be done prior to dispensing any DMEPOS item requiring a prior authorization. Refer to the prior authorization section of the general Billing Manual for all providers and PT 33 Billing Guidelines at:

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; 3.1. 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.a. Signed narrative from the physician documenting the recipient's compliance.	1. External ambulatory infusion pump recipients with Gestational Diabetes whom 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

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.~~1. ~~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 ~~M~~modification A5500 – A5507, A5512 – A5513 2. Diabetic equipment and supplies, such as Glucometers, Test strips, Lancet Device~~,~~ ~~and~~ Lancets, Insulin syringes for self-injection, External Ambulatory Infusion Pump, Insulin systems and Continuous Glucose Monitors are not covered under the DHCFP's DME program. These ~~supplies~~ 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: OSTEOGENESIS STIMULATOR DEVICES

EQUIPMENT OR ITEM	QUALIFICATIONS	FORMS AND DOCUMENTATION REQUIREMENTS	MISCELLANEOUS POLICY STATEMENTS
Osteogenesis Stimulator ***(Non-spinal Noninvasive Electrical)***	Device may be covered if: 1. Non-union of a long bone fracture after ~~six~~ three or more months have elapsed without healing of the fracture; 2. Failed fusion of a joint, other than in the spine, where a minimum of nine months has elapsed since the last surgery; or 3. Congenital pseudarthrosis	1. Prescription and/or MD signed Prior Authorization Form. 2. Medical documentation supporting qualifying factors.	~~1. Rental for 20 week intervals, additional authorization will be considered with medical justification.~~ ~~2.~~1. Electric Implantable Osteogenic Stimulators are included in the surgical service thus are non-covered under this chapter.
Osteogenesis Stimulator ***(Spinal Noninvasive Electrical)***	Device may be covered if: 1. Failed spinal fusion where a minimum of nine months has elapsed since the last surgery; 2. Following a multilevel spinal fusion surgery involving three or more vertebrae; or 3. Following spinal fusion surgery where there is a history of a previously failed spinal fusion.	1. Prescription and/or MD signed Prior Authorization Form. 2. Medical documentation supporting qualifying factors.	~~1. Rental for 20 week intervals, additional authorization will be considered with medical justification.~~ ~~2.~~1. Electric Implantable Osteogenic Stimulators are included in the surgical service thus are non-covered under this chapter.

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)** **Bi~~Pi~~AP "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.		

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)**	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. Prior to initiating therapy, OSA (and treatment with CPAP) has been considered and ruled out.		

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)***	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. <u>Group III: Central Sleep Apnea (e.g., apnea not due to airway obstruction)</u>: Prior to initiating therapy, a complete ~~facility-based, attended~~ 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		

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)***	therapy if OSA is a component of the sleep-associated hypoventilation; and d. Oxygen saturation ≤ 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. Group IV: Obstructive Sleep Apnea (OSA): Criteria (a) and (b) are both met: a. A complete ~~facility based, attended~~ polysomnogram has established the diagnosis of obstructive sleep apnea according to the following criteria: 1. The apnea-hypopnea index (AHI) is ≥ 15 events per hour; or 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; or 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 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 four hours per 24-hour period 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 61 days after initiating use of the device, declaring that the recipient is compliantly using the device (an average of four hours per 24-hour period) 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	QUALIFICATION	**FORMS AND DOCUMENTATION** REQUIREMENT	**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 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 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 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 61 days after initiation of the E0470 device, declaring that the recipient has been compliantly using the E0470 device (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 ~~an attended, facility based~~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). 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	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. 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.	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.