Local Coverage Article:
Respiratory Assist Devices - Policy Article (A52517)

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Rhode Island Vermont
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

Article Information

General Information

Article ID
A52517

Original ICD-9 Article ID
A23659
A47231
A23902
A23974

Article Title
Respiratory Assist Devices - Policy Article

Article Type
Article

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Original Effective Date
10/01/2015

Revision Effective Date
xx/xx/xxxx

Revision Ending Date
N/A

Retirement Date
N/A

Article Guidance

Article Text:

NON-MEDICAL NECESSITY COVERAGE & PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”).

Respiratory assist devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary’s equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Accessories are separately reimbursable when used with E0470, E0471.

No aspect of a home sleep test, including but not limited to delivery and/or pickup of the device, may be performed by a DME supplier. This prohibition does not extend to the results of

studies conducted by hospitals certified to do such tests or to tests conducted in facility-based sleep laboratories.

Services of a respiratory therapist are non-covered under the DME benefit.

A liner used in conjunction with a PAP mask is considered comfort/convenience item. There is no additional payment for liners used with a PAP mask. These products should be coded A9270 (Noncovered item or service) in accordance with the Medicare Benefit Policy Manual (CMS Pub. 100-02) Chapter 15, Section 110.1.

Claims for A9279 (MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, ANY TYPE, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED) are denied as statutorily non-covered (No Medicare benefit).

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO Final Rule 1713 (84 Fed. Reg Vol 217)

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provide a list of the specified codes, which is periodically updated. The link will be located here once it is available.

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD, it will be eligible for coverage.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

REPLACEMENT OF ACCESSORIES FOR MEDICARE-PAID, BENEFICIARY-OWNED EQUIPMENT:

For claims for replacement accessories (e.g., interfaces, tubing, filters, humidifier chambers), if Medicare paid for the base RAD initially (i.e., for 13 months of continuous use), the medical necessity for the beneficiary-owned base RAD is assumed to have been established. Therefore, to make a payment determination, there must only be documentation that the base DME item continues to meet medical need; and (2) The replacement of specific accessories or furnishing of new accessories remain medically necessary and are essential for the effective use of the base DME.

Documentation of continued medical need for the base item must come from the treating practitioner's records. The supplier's documentation records must support the need to replace the accessory to maintain the equipment's functionality and meet the beneficiary's medical need.

This guidance does not apply RADs when Medicare did not originally provide payment for the base item. In cases where Medicare did not originally pay for the DME item, all coverage, coding and documentation requirements in effect for the date of service (DOS) on the claim under review must be met (see Coverage Indications, Limitations, and/or Medical Necessity section of the related LCD).

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS.

MODIFIERS

KX MODIFIER:

Proper use of modifiers is discussed below. Specific modifiers must be used and differ depending on whether or not the requirements outlined in the documentation section have been met.

Where permitted, KX must be added to codes E0470 and E0471 and codes for accessories used with E0470 and E0471. The KX modifier must not be used until the required documentation has actually been obtained and entered into the supplier's files.

On claims for the first through third months, suppliers must add a KX modifier if all of the criteria in the Coverage Indications, Limitations, and/or Medical Necessity section of the related LCD have been met. If the requirements for the KX modifier are not met, the KX modifier must not be used.

On the fourth month's claim (and any month thereafter), the supplier must add a KX modifier if all the "Initial Coverage" criteria in the Coverage Indications, Limitations, and/or Medical Necessity section of the related LCD have been met and the treating practitioner's signed and dated statement described in the Coverage Indications, Limitations, and/or Medical Necessity above, has been obtained for the supplier's files.

If the completed and signed treating practitioner statement is not in the supplier's files in time for submission of the fourth or succeeding months' claims, the supplier may still submit the claims, but a KX modifier must not be added. However, if the supplier chooses to hold claims for the fourth and succeeding months until the completed and signed forms are obtained, those claims may then be submitted with the KX modifier, so long as their answers indicate continued compliant use of and benefit from the therapy, according to the Coverage Indications, Limitations, and/or Medical Necessity section.

GA AND GZ MODIFIERS

In all of the situations above describing use of the KX modifier, if all of the coverage criteria have not been met, the GA or GZ modifier must be added to a claim line for the RAD equipment (E0470 or E0471) and accessories. When there is an expectation of a medical necessity denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Claim lines billed without a GA, GZ or KX modifier will be rejected as missing information.

CODING GUIDELINES

A respiratory assist device (RAD) without backup rate (E0470) delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface (such as a nasal, oral, or facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs. A respiratory cycle is defined as an inspiration, followed by an expiration.

A respiratory assist device (RAD) with backup rate (E0471) delivers adjustable, variable levels (within a single respiratory cycle) of positive air pressure by way of tubing and a noninvasive interface (such as a nasal or oral facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs. In addition, it has a timed backup feature to deliver this air pressure whenever sufficient spontaneous inspiratory efforts fail to occur.

Code A4604 describes tubing used with a heated humidifier and has a heated wire running the length of the tubing. It is designed for use with a positive airway pressure device and a non-invasive interface - i.e., nasal or face mask, nasal cannula, or oral interface.

Code A7032 is used for a replacement nasal mask interface that goes around the nose, but not into the nostrils. The unit of service for this code is "each".

Code A7033 is used for a replacement nasal cannula-type interface. This interface extends a short distance into the nostrils. The unit of service for this code is "pair". For some products, there are two physically separate cushions or "pillows" – one for each nostril. Two cushions/ pillows equal one unit of service of A7033. For other products, the interface is a single piece

with two protrusions that extend into the nostrils. One of these interfaces equals one unit of service of A7033.

Code A7027 (Combination oral/nasal mask, used with continuous positive airway pressure device, each) is a two-piece system with separate elements for oral and nasal use.

A liner is a soft, flexible material, which is placed between the patient's skin and the PAP mask interface. Liners used with a PAP mask are made of cloth, silicone or other materials. Liners are not interfaces for use with a PAP mask. Consequently, liners should not be billed as replacement features of a PAP mask such as A7031 (Face mask interface, replacement for full face mask, each) or A7032 (Cushion for use on nasal mask interface, replacement only, each). Liners billed as replacement features of a PAP mask should be coded A9270 (Non-covered item or service).

Monitoring devices (integrated or modular) are capable of tracking data generated by a RAD device, which can be subsequently downloaded for further analysis by a healthcare provider, DME supplier, or beneficiary. Such technologies include, but are not limited to:

- Smart cards and readers
- USB/Thumb drive accessories
- Wired telephonic transmission modules
- Wireless modems

Code A9279 (MONITORING FEATURE/DEVICE, STAND-ALONE OR INTEGRATED, ANY TYPE, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED) describes any type of monitoring technology. Code A9279 is all-inclusive and is to be used whether the monitoring technology is incorporated as part of a base item, supplied as an add-on module or is a stand-alone item.

Use of multiple instances of A9279 to bill separately for individual monitoring features is incorrect coding.

There is no Medicare benefit or payment to DMEPOS suppliers for remote monitoring services. Suppliers must not bill A9279 for remote monitoring services.

Claims billed for monitoring technologies using other NOC codes such as E1399 [DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS] will be denied as incorrect coding.

Code E0467 (HOME VENTILATOR, MULTI-FUNCTION RESPIRATORY DEVICE, ALSO PERFORMS ANY OR ALL OF THE ADDITIONAL FUNCTIONS OF OXYGEN CONCENTRATION, DRUG NEBULIZATION, ASPIRATION, AND COUGH STIMULATION, INCLUDES ALL ACCESSORIES, COMPONENTS AND SUPPLIES FOR ALL FUNCTIONS) describes a ventilator that integrates the function of multiple types of equipment into a single device. Code E0467 combines the function of a ventilator with those of any combination or all of the following:

- Oxygen equipment
- Nebulizer and compressor
- Aspirator (suction device)
- Cough stimulator (multiple products)
- Positive airway pressure devices (PAP and RAD)
- Custom fabricated oral appliances

The following HCPCS codes for individual items are included in the functionality of code E0467:

- HCPCS codes E0470, E0471, E0472, E0561, E0562, A4604, A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, A7046

<u>For E0467 claims with dates of service before April 3, 2020:</u>

Claims for any of the HCPCS codes listed above that are submitted on the same claim or that overlap any date(s) of service for E0467 is considered to be unbundling.

In addition, any claim for repair (HCPCS code K0739 for labor and any HCPCS code for replacement items) of beneficiary-owned equipment identified by HCPCS codes listed above is considered as unbundling if the date(s) of service for the repair overlaps any date(s) of service for code E0467.

Claims for code E0467 with a date(s) of service that overlaps date(s) of service for any of the following scenarios are considered as a claim for same or similar equipment when the beneficiary:

- Is currently in a rental month for any of the items listed above
- Owns any of the equipment listed above that has not reached the end of its reasonable useful lifetime.

<u>For E0467 claims with dates of service on or after April 3, 2020:</u>

Any claim for repair (HCPCS code K0739 for labor and any HCPCS code for replacement items) of beneficiary-owned equipment identified by HCPCS codes listed above is considered as unbundling if the date(s) of service for the repair overlaps any date(s) of service for code E0467.

Claims for code E0467 with a date(s) of service that overlaps date(s) of service in a rental month for any of the items listed above are considered as a claim for same or similar equipment.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

<u>Coding Information</u>

CPT/HCPCS Codes
N/A

ICD-10 Codes that Support Medical Necessity
N/A

ICD-10 Codes that DO NOT Support Medical Necessity
N/A

Additional ICD-10 Information

N/A

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation
xx/xx/xxxx	R12	**Revision Effective Date: xx/xx/xxxx** NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Added: Language regarding no aspect of a home sleep test may be performed by a DME supplier Revised: Language regarding a liner used in conjunction with a PAP

Revision History Date	Revision History Number	Revision History Explanation
		mask are noncovered Added: Language regarding monitoring devices are statutorily non-covered. Previously under Coding Guidelines POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Revised: Coverage, coding and documentation requirements reference from "see below" to "see Coverage Indications, Limitations, and/or Medical Necessity section of the related LCD" MODIFIERS: Removed: Reference to "Group I – IV" from KX modifier section as groups are no longer referenced in the Coverage Indications, Limitations, and/or Medical Necessity section of the related LCD Revised: Typographical errors to add commas after "Limitations" when referencing "Coverage Indications, Limitations, and/or Medical Necessity" Added: Language to reject claim lines billed without GA, GZ or KX previously noted in the LCD CODING GUIDELINES: Revised: Language related to HCPCS code A9279 and monitoring devices and services *xx/xx/xxxx: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination*
04/03/2020	R11	**Revision Effective Date: 04/03/2020** CODING GUIDELINES: Revised: Guidance for billing HCPCS code E0467 based on DOS *07/16/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.*
01/01/2020	R10	**Revision Effective Date: 01/01/2020** NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Removed: REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO 42 CFR 410.38(g) section REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217): Added: Section and related information based on Final Rule 1713 MODIFIERS: Revised: "physician" to "practitioner"

Revision History Date	Revision History Number	Revision History Explanation
01/01/2019	R9	ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Revised: Section header “ICD-10 Codes that are Covered” updated to “ICD-10 Codes that Support Medical Necessity” ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY: Revised: Section header “ICD-10 Codes that are Not Covered” updated to “ICD-10 Codes that DO NOT Support Medical Necessity” *02/27/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.* **Revision Effective Date: 01/01/2019** CODING GUIDELINES: Revised: E0467 Coding Guidelines to include custom fabricated oral appliances *04/04/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.* **Revision Effective Date: 01/01/2019** CODING GUIDELINES: Added: E0467 Coding Guidelines *03/07/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.* **Revision Effective Date: 01/01/2017** NON-MEDICAL NECESSITY COVERAGE & PAYMENT RULES: Added: Direction for REPLACEMENT OF ACCESSORIES FOR MEDICARE-PAID, BENEFICIARY-OWNED EQUIPMENT
01/01/2017	R7	*06/14/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.* **Revision Effective Date: 01/01/2017** NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES Added: 42 CFR 410.38(g) language, previously in POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section.
01/01/2017	R6	

Revision History Date	Revision History Number	Revision History Explanation
		04/05/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is no a local coverage determination.
01/01/2017	R5	Revision Effective Date: 01/01/2017 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: 42 CFR 410.38(g) and Modifiers requirements RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements Language Article
07/01/2016	R4	Effective July 1, 2016 oversight for DME MAC Articles is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the Articles.
11/05/2015	R3	Revision Effective Date: 11/05/2015 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Revised: Standard Documentation language to remove start date verbiage from Prescription Requirements
10/01/2015	R2	Revision Effective Date: 12/01/2014 (May 2015 Publication) NON-MEDICAL NECESSITY COVERAGE & PAYMENT RULES: Added: Non-coverage statement for liners used in conjunction with a PAP mask Removed: "When required by state law" from ACA new prescription requirements CODING GUIDELINES: Added: Coding guidelines for liners used with PAP mask based on DME MAC article posted on February 13, 2014 Added: Coding guidelines for Monitoring Technology based on DME MAC article posted on November 15, 2013
10/01/2015	R1	**Revision Effective Date: 10/01/2015** NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Added: ACA 6407 prescriber requirements

Associated Documents

Related Local Coverage Document(s)

Article(s)

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

LCD(s)

L33800 - Respiratory Assist Devices

Related National Coverage Document(s)

N/A

Statutory Requirements URL(s)

N/A

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

N/A

Other URL(s)

N/A