

LCD for Nebulizers (L11488)**Contractor Information****Contractor Name**

Noridian Administrative Services

Contractor Number

19003

Contractor Type

DME MAC

LCD Information**LCD ID Number**

L11488

LCD Title

Nebulizers

Contractor's Determination Number

NEB

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CMS National Coverage Policy

CMS Manual System, Pub. 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Section 200.2, 280.1

Primary Geographic Jurisdiction

Alaska

American Samoa

Arizona

California - Entire State

Guam

Hawaii

Iowa
Idaho
Kansas
Missouri - Entire State
Montana
North Dakota
Nebraska
Nevada
Oregon
South Dakota
Utah
Washington
Wyoming
Northern Mariana Islands

Oversight Region

Region X

DME Region LCD Covers

Jurisdiction D

Original Determination Effective Date

For services performed on or after 04/01/1997

Original Determination Ending Date**Revision Effective Date**

For services performed on or after 01/01/2010

Revision Ending Date**Indications and Limitations of Coverage and/or Medical Necessity**

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. For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of

coverage and/or medical necessity.

For an item to be covered by Medicare, a written signed and dated order must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.

A small volume nebulizer (A7003, A7004, A7005), related compressor (E0570, E0571), and FDA-approved inhalation solutions of the drugs listed below are covered when:

- a. It is medically necessary to administer albuterol (J7611, J7613), arformoterol (J7605), budesonide (J7626), cromolyn (J7631), formoterol (J7606), ipratropium (J7644), levalbuterol (J7612, J7614), or metaproterenol (J7669) for the management of obstructive pulmonary disease (ICD-9 diagnosis codes 491.0-508.9); **or**
- b. It is medically necessary to administer dornase alpha (J7639) to a patient with cystic fibrosis (ICD-9 diagnosis code 277.02); **or**
- c. It is medically necessary to administer tobramycin (J7682) to a patient with cystic fibrosis or bronchiectasis (ICD-9 diagnosis code 277.02, 494.0, 494.1, 748.61, 011.50-011.56); **or**
- d. It is medically necessary to administer pentamidine (J2545) to a patient with HIV (ICD-9 diagnosis code 042), pneumocystosis (ICD-9 diagnosis code 136.3), or complications of organ transplants (ICD-9 diagnosis codes 996.80-996.89); **or**
- e. It is medically necessary to administer acetylcysteine (J7608) for persistent thick or tenacious pulmonary secretions (ICD-9 diagnosis codes 480.0-508.9, 786.4).

Compounded inhalation solutions (J7604, J7607, J7609, J7610, J7615, J7622, J7624, J7627, J7628, J7629, J7632, J7634, J7635, J7636, J7637, J7638, J7640, J7641, J7642, J7643, J7645, J7647, J7650, J7657, J7660, J7667, J7670, J7676, J7680, J7681, J7683, J7684, J7685, and compounded solutions billed with J7699) will be denied as not medically necessary.

If none of the drugs used with a nebulizer are covered, the compressor, the nebulizer, and other related accessories/supplies will be denied as not medically necessary.

A large volume nebulizer (A7007, A7017), related compressor (E0565 or E0572), and water or saline (A4217 or A7018) are covered when it is medically necessary to deliver humidity to a patient with thick, tenacious secretions, who has cystic fibrosis (ICD-9 diagnosis code 277.02), bronchiectasis (ICD-9 diagnosis code 494.0, 494.1, 011.50-011.56 or 748.61), a tracheostomy (ICD-9 diagnosis code V44.0 or V55.0), or a tracheobronchial stent (ICD-9 diagnosis code 519.19). Combination code E0585 will be covered for the same indications.

An E0565 or E0572 compressor and filtered nebulizer (A7006) are also covered when it is medically necessary to administer pentamidine to patients with HIV (ICD-9 diagnosis code 042), pneumocystosis (ICD-9 diagnosis code 136.3) or complications of organ transplants (ICD-9 diagnosis codes 996.80-996.89).

Because there is no proven medical benefit to nebulizing particles to diameters smaller than achievable with a pneumatic compressor, when a small volume ultrasonic nebulizer (E0574) is ordered to administer a covered inhalation solution, payment will be based on the allowance for the least costly medically appropriate alternative, a pneumatic compressor (E0570).

Similarly, a large volume ultrasonic nebulizer (E0575) offers no proven clinical advantage over a pneumatic compressor. However, since code E0575 is in a different payment category than pneumatic compressors, payment for a least costly alternative cannot be made. Therefore, when an E0575 nebulizer is provided, it will be denied as not medically necessary as will any related accessories and supplies.

A battery-powered compressor (E0571) is rarely medically necessary. If an E0571 compressor is provided and the coverage criteria for code E0570 are met, payment will be based on the allowance for the least costly medically appropriate alternative, E0570.

A controlled dose inhalation drug delivery system (K0730) is covered when it is medically necessary to deliver the iloprost (Q4074) to patients with pulmonary artery hypertension (ICD-9 diagnosis codes 416.0 or 416.8) who meet the following criteria.

Iloprost (Q4074) is covered when both criteria 1 and 2 are met:

1. The pulmonary hypertension is not secondary to pulmonary venous hypertension (e.g., left sided atrial or ventricular disease, left sided valvular heart disease, etc) or disorders of the respiratory system (e.g., chronic obstructive pulmonary disease, interstitial lung disease, obstructive sleep apnea or other sleep disordered breathing, alveolar hypoventilation disorders, etc.), **and**
2. The patient has primary pulmonary hypertension or pulmonary hypertension which is secondary to one of the following conditions: connective tissue disease, thromboembolic disease of the pulmonary arteries, human immunodeficiency virus (HIV) infection, cirrhosis, diet drugs, congenital left to right shunts, etc. If these conditions are present, the following criteria (a-d) must be met:
 - a. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; **and**
 - b. The mean pulmonary artery pressure is greater than 25 mm Hg at rest or greater than 30 mm Hg with exertion; **and**
 - c. The patient has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); **and**
 - d. Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out.

If the above criteria are not met the controlled dose inhalation drug delivery system (K0730) and the iloprost (Q4074) will be denied as not medically necessary.

If K0730 is used to administer any other covered nebulizer drug other than iloprost and the coverage criteria for E0570 are met, payment will be based on the allowance for the least costly medically appropriate alternative, E0570.

ACCESSORIES:

Accessories are separately payable if the related aerosol compressor and the individual accessories are medically necessary. The following table lists the compressor/generator, which is related to the accessories described. Other compressor/generator/accessory combinations are considered medically unnecessary.

Compressor/Generator	Related Accessories
E0565	A4619, A7006, A7007, A7010, A7011, A7012, A7013, A7014, A7015, A7017, A7525, E1372
E0570	A7003, A7004, A7005, A7006, A7013, A7015, A7525
E0571	A7003, A7004, A7005, A7006, A7013, A7015, A7525
E0572	A7006, A7014
E0574	A7014, A7016
E0585	A4619, A7006, A7010, A7011, A7012, A7013, A7014, A7015, A7525
K0730	A7005

This array of accessories represents all possible combinations but it may not be appropriate to bill any or all of them for one device.

The following table lists the usual maximum frequency of replacement for accessories. Claims for more than the usual maximum replacement amount will be denied as not medically necessary.

Accessory	Usual maximum replacement
A4619	One/month
A7003	Two/month
A7004	Two/month (in addition to A7003)
A7005	One/6 months
A7005	One/3 months only with K0730
A7006	One/month
A7007	Two/month
A7010	One unit (100 ft.)/2 months
A7011	One/year
A7012	Two/month
A7013	Two/month
A7014	One/3 months
A7015	One/month
A7016	Two/year
A7017	One/3 years
A7525	One/month
E1372	One/3 years

The supplier must monitor the amount of supplies and accessories a patient is actually using and assure that the patient has nearly exhausted the supply on hand prior to dispensing any additional items. CMS' Program Integrity Manual (Internet-Only Manual, CMS Pub. 100-8, Chapter 4, Section 4.26.1) requires, "Contact with the beneficiary or designee regarding refills should take place no sooner than approximately 7 days prior to the delivery/shipping date. For subsequent deliveries of refills, the supplier should deliver the DMEPOS product no sooner than approximately 5 days prior to the end of usage for the current product."

INHALATION DRUGS AND SOLUTIONS:

The following table represents the maximum milligrams/month of inhalation drugs that are medically necessary for each nebulizer drug.

Inhalation Drugs and Solutions	Maximum Milligrams/Month
Acetylcysteine	74 grams/month
Albuterol	465 mg/month (See below for exception)
Albuterol/Ipratropium combination	186 units/month
Arformoterol	930 micrograms/month - 62 units/month
Budesonide	62 units/month
Cromolyn sodium	2480 mg/month - 248 units/month
Dornase alpha	78 mg/month
Formoterol	1240 micrograms/month - 62 units/month
Ipratropium bromide	93 mg/month
Levalbuterol	232.5 mg/month - 465 units/month (See below for exception)
Metaproterenol	2800 mg/month - 280 units/month (See below for exception)
Pentamidine	300 mg/month
Sterile saline or water, 10ml/unit (A4216, A4218)	56 units/month
Distilled water, sterile water, or sterile saline in large volume nebulizer	18 liters/month

When albuterol, levalbuterol, or metaproterenol are prescribed as rescue/supplemental medication for patients who are taking formoterol or arformoterol, the maximum milligrams/month that are reasonably billed are:

Albuterol	78 mg/month
Albuterol/Ipratropium combination	31 units/month

Levalbuterol	39 mg/month (78 units/month)
Metaproterenol	470 mg/month (47 units/month)

Claims for more than these amounts of drugs will be denied as not medically necessary.

The pharmacist is responsible for assessing how much inhalation solution a patient is actually using. Considering this information, the pharmacist is responsible for assuring that the patient has used almost all of his/her supply on hand prior to dispensing a new supply. As referenced in the Program Integrity Manual (Internet-Only Manual, CMS Pub. 100-8, Chapter 4.26.1) "Contact with the beneficiary or designee regarding refills should take place no sooner than approximately 7 days prior to the delivery/shipping date. For subsequent deliveries of refills, the supplier should deliver the DMEPOS product no sooner than approximately 5 days prior to the end of usage for the current product."

When a "concentrated form" of an inhalation drug is covered, separate saline solution (A4216 or A4218 [metered dose]) used to dilute it will be separately reimbursed. Saline dispensed for the dilution of concentrated nebulizer drugs must be billed on the same claim as the drug(s) being diluted. If the unit dose form of the drug is dispensed, separate saline solution (A4216 or A4218 [metered dose]), will be denied as not medically necessary. Water or saline in 500 or 1000 ml quantities (A4217 or A7018) are not appropriate for use by patients to dilute inhalation drugs and will therefore be denied as not medically necessary if used for this purpose. These codes are only medically necessary when used in a large volume nebulizer (A7007, A7017 or E0585).

Albuterol, levalbuterol and metaproterenol are all short-acting bronchodilators with beta-adrenergic stimulatory effect. It is not medically necessary for a patient to use more than one of these at a time. The use of more than one of these drugs at the same time will be denied as not medically necessary.

Albuterol, levalbuterol, or metaproterenol is covered if it is used as a rescue/supplemental medication in addition to the long-acting beta-adrenergic agonist drug, formoterol or arformoterol.

Formoterol and arformoterol are long-acting bronchodilators with beta-adrenergic stimulatory effect. It is not medically necessary for a patient to use more than one of these at a time. The use of more than one of these drugs at the same time will be denied as not medically necessary.

Code J7620 describes the FDA-approved unit dose combination of albuterol base 2.5 mg and ipratropium bromide 0.5 mg in unit dose vials. The medical necessity for administering additional albuterol sulfate (J7611, J7613), levalbuterol (J7612, J7614) and/or ipratropium bromide (J7644) has not been established. Claims for J7611-J7614 and J7644 billed in addition to J7620 will be denied as not medically necessary.

Charges for the drugs, diluent, and dispensing fees may only be billed by the entity that actually dispenses the drug to the Medicare beneficiary and that entity must be permitted under all applicable federal, state, and local laws and regulations to dispense drugs. Only entities licensed in the state where they are physically located may submit a claim for nebulizer drugs. Physicians may submit a claim for drugs if all of the following conditions are met: the physician is 1) enrolled as a DMEPOS supplier with the National Supplier Clearinghouse, and 2) dispensing the drug(s) to the Medicare beneficiary, and 3) authorized by the State to dispense drugs as part of

the physician's license. Claims submitted by entities not licensed to dispense drugs will be denied for lack of medical necessity.

Coding Information

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 policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

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 policy 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 policy should be assumed to apply equally to all Revenue Codes.

CPT/HCPCS Codes

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

EY - No physician or other licensed health care provider order for this item or service.

GA - Waiver of liability statement on file

GZ - Item or service expected to be denied as not reasonable and necessary

KO - Single drug unit dose formulation.

KP - First drug of a multiple drug unit dose formulation.

KQ - Second or subsequent drug of a multiple drug unit dose formulation.

KX - Requirements specified in the medical policy have been met

HCPCS CODES:

EQUIPMENT

E0565

COMPRESSOR, AIR POWER SOURCE FOR EQUIPMENT WHICH IS NOT SELF- CONTAINED OR CYLINDER DRIVEN

E0570 NEBULIZER, WITH COMPRESSOR
E0571 AEROSOL COMPRESSOR, BATTERY POWERED, FOR USE WITH SMALL VOLUME NEBULIZER
E0572 AEROSOL COMPRESSOR, ADJUSTABLE PRESSURE, LIGHT DUTY FOR INTERMITTENT USE
E0574 ULTRASONIC/ELECTRONIC AEROSOL GENERATOR WITH SMALL VOLUME NEBULIZER
E0575 NEBULIZER, ULTRASONIC, LARGE VOLUME
E0585 NEBULIZER, WITH COMPRESSOR AND HEATER
K0730 CONTROLLED DOSE INHALATION DRUG DELIVERY SYSTEM

ACCESSORIES

A4619 FACE TENT
A7003 ADMINISTRATION SET, WITH SMALL VOLUME NONFILTERED PNEUMATIC NEBULIZER, DISPOSABLE
A7004 SMALL VOLUME NONFILTERED PNEUMATIC NEBULIZER, DISPOSABLE
A7005 ADMINISTRATION SET, WITH SMALL VOLUME NONFILTERED PNEUMATIC NEBULIZER, NON-DISPOSABLE
A7006 ADMINISTRATION SET, WITH SMALL VOLUME FILTERED PNEUMATIC NEBULIZER
A7007 LARGE VOLUME NEBULIZER, DISPOSABLE, UNFILLED, USED WITH AEROSOL COMPRESSOR
A7008 LARGE VOLUME NEBULIZER, DISPOSABLE, PREFILLED, USED WITH AEROSOL COMPRESSOR
A7009 RESERVOIR BOTTLE, NON-DISPOSABLE, USED WITH LARGE VOLUME ULTRASONIC NEBULIZER
A7010 CORRUGATED TUBING, DISPOSABLE, USED WITH LARGE VOLUME NEBULIZER, 100 FEET
A7011 CORRUGATED TUBING, NON-DISPOSABLE, USED WITH LARGE VOLUME NEBULIZER, 10 FEET
A7012 WATER COLLECTION DEVICE, USED WITH LARGE VOLUME NEBULIZER
A7013 FILTER, DISPOSABLE, USED WITH AEROSOL COMPRESSOR
A7014 FILTER, NONDISPOSABLE, USED WITH AEROSOL COMPRESSOR OR ULTRASONIC GENERATOR
A7015 AEROSOL MASK, USED WITH DME NEBULIZER
A7016 DOME AND MOUTHPIECE, USED WITH SMALL VOLUME

ULTRASONIC NEBULIZER

- A7017 NEBULIZER, DURABLE, GLASS OR AUTOCLAVABLE PLASTIC, BOTTLE TYPE, NOT USED WITH OXYGEN
- A7525 TRACHEOSTOMY MASK, EACH
- E0580 NEBULIZER, DURABLE, GLASS OR AUTOCLAVABLE PLASTIC, BOTTLE TYPE, FOR USE WITH REGULATOR OR FLOWMETER
- E1372 IMMERSION EXTERNAL HEATER FOR NEBULIZER

INHALATION DRUGS

- A4216 STERILE WATER, SALINE AND/OR DEXTROSE, DILUENT/FLUSH, 10 ML
- A4217 STERILE WATER/SALINE, 500 ML
- A4218 STERILE SALINE OR WATER, METERED DOSE DISPENSER, 10 ML
- G0333 PHARMACY DISPENSING FEE FOR INHALATION DRUG(S); INITIAL 30-DAY SUPPLY AS A BENEFICIARY
- J2545 PENTAMIDINE ISETHIONATE, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 300 MG
- J7604 ACETYLCYSTEINE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER GRAM
- J7605 ARFORMOTEROL, INHALATION SOLUTION, FDA APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, 15 MICROGRAMS
- J7606 FORMOTEROL FUMARATE, INHALATION SOLUTION, FDA APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, 20 MICROGRAMS
- J7607 LEVALBUTEROL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED FORM, 0.5 MG
- J7608 ACETYLCYSTEINE, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER GRAM
- J7609 ALBUTEROL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE, 1 MG

- J7610 ALBUTEROL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED FORM, 1 MG
- J7611 ALBUTEROL, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, CONCENTRATED FORM, 1 MG
- J7612 LEVALBUTEROL, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, CONCENTRATED FORM, 0.5 MG
- J7613 ALBUTEROL, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE, 1 MG
- J7614 LEVALBUTEROL, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE, 0.5 MG
- J7615 LEVALBUTEROL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE, 0.5 MG
- J7620 ALBUTEROL, UP TO 2.5 MG AND IPRATROPIUM BROMIDE, UP TO 0.5 MG, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME
- J7622 BECLOMETHASONE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7624 BETAMETHASONE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7626 BUDESONIDE, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, UP TO 0.5 MG
- J7627 BUDESONIDE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, UP TO 0.5 MG
- J7628 BITOLTEROL MESYLATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
- J7629 BITOLTEROL MESYLATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7631 CROMOLYN SODIUM, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 10 MILLIGRAMS

- J7632 CROMOLYN SODIUM, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 10 MILLIGRAMS
- J7634 BUDESONIDE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER 0.25 MILLIGRAM
- J7635 ATROPINE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
- J7636 ATROPINE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7637 DEXAMETHASONE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
- J7638 DEXAMETHASONE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7639 DORNASE ALFA, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7640 FORMOTEROL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, 12 MICROGRAMS
- J7641 FLUNISOLIDE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE, PER MILLIGRAM
- J7642 GLYCOPYRROLATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
- J7643 GLYCOPYRROLATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7644 IPRATROPIUM BROMIDE, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7645 IPRATROPIUM BROMIDE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7647 ISOETHARINE HCL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED

- FORM, PER MILLIGRAM
- J7650 ISOETHARINE HCL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7657 ISOPROTERENOL HCL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
- J7660 ISOPROTERENOL HCL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7667 METAPROTERENOL SULFATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, CONCENTRATED FORM, PER 10 MILLIGRAMS
- J7669 METAPROTERENOL SULFATE, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 10 MILLIGRAMS
- J7670 METAPROTERENOL SULFATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 10 MILLIGRAMS
- J7676 PENTAMIDINE ISETHIONATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 300 MG
- J7680 TERBUTALINE SULFATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
- J7681 TERBUTALINE SULFATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7682 TOBRAMYCIN, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, UNIT DOSE FORM, ADMINISTERED THROUGH DME, PER 300 MILLIGRAMS
- J7683 TRIAMCINOLONE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
- J7684 TRIAMCINOLONE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7685 TOBRAMYCIN, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 300 MILLIGRAMS

J7699	NOC DRUGS, INHALATION SOLUTION ADMINISTERED THROUGH DME
Q0513	PHARMACY DISPENSING FEE FOR INHALATION DRUG(S); PER 30 DAYS
Q0514	PHARMACY DISPENSING FEE FOR INHALATION DRUG(S); PER 90 DAYS
Q4074	ILOPROST, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, UP TO 20 MICROGRAMS

ICD-9 Codes that Support Medical Necessity

The presence of an ICD-9 code listed in this section is not sufficient by itself to assure coverage. Refer to the section on "Indications and Limitations of Coverage and/or Medical Necessity" for other coverage criteria and payment information.

For HCPCS codes A4619, E0565, E0572:

011.50 - 011.56	TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION - TUBERCULOUS BRONCHIECTASIS TUBERCLE BACILLI NOT FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER METHODS (INOCULATION OF ANIMALS)
042	HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
136.3	PNEUMOCYSTOSIS
277.02	CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS
494.0	BRONCHIECTASIS WITHOUT ACUTE EXACERBATION
494.1	BRONCHIECTASIS WITH ACUTE EXACERBATION
519.19	OTHER DISEASES OF TRACHEA AND BRONCHUS
748.61	CONGENITAL BRONCHIECTASIS
996.80 - 996.89	COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN
V44.0	TRACHEOSTOMY STATUS
V55.0	ATTENTION TO TRACHEOSTOMY

For HCPCS codes A7013, A7014, A7015, A7525:

011.50 - 011.56 TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION
- TUBERCULOUS BRONCHIECTASIS TUBERCLE BACILLI NOT
FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL
EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER
METHODS (INOCULATION OF ANIMALS)

042 HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE

136.3 PNEUMOCYSTOSIS

277.02 CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS

480.0 - 508.9 PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY
CONDITIONS DUE TO UNSPECIFIED EXTERNAL AGENT

519.19 OTHER DISEASES OF TRACHEA AND BRONCHUS

748.61 CONGENITAL BRONCHIECTASIS

786.4 ABNORMAL SPUTUM

996.80 - 996.89 COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN -
COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED
ORGAN

V44.0 TRACHEOSTOMY STATUS

V55.0 ATTENTION TO TRACHEOSTOMY

For HCPCS codes A7003, A7004, E0570, E0571, E0574:

011.50 - 011.56 TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION
- TUBERCULOUS BRONCHIECTASIS TUBERCLE BACILLI NOT
FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL
EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER
METHODS (INOCULATION OF ANIMALS)

042 HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE

136.3 PNEUMOCYSTOSIS

277.02 CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS

480.0 - 508.9 PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY
CONDITIONS DUE TO UNSPECIFIED EXTERNAL AGENT

748.61 CONGENITAL BRONCHIECTASIS

786.4 ABNORMAL SPUTUM

996.80 - 996.89 COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN -
COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED
ORGAN

For HCPCS codes A7006, J2545:

042 HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE

136.3 PNEUMOCYSTOSIS

996.80 - 996.89 COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN -
COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED
ORGAN

For HCPCS codes A4217, A7007, A7010, A7011, A7012, A7017, A7018, E0585, E1372:

011.50 - 011.56 TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION
- TUBERCULOUS BRONCHIECTASIS TUBERCLE BACILLI NOT
FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL
EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER
METHODS (INOCULATION OF ANIMALS)

277.02 CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS

494.0 BRONCHIECTASIS WITHOUT ACUTE EXACERBATION

494.1 BRONCHIECTASIS WITH ACUTE EXACERBATION

519.19 OTHER DISEASES OF TRACHEA AND BRONCHUS

748.61 CONGENITAL BRONCHIECTASIS

V44.0 TRACHEOSTOMY STATUS

V55.0 ATTENTION TO TRACHEOSTOMY

For HCPCS code A4216:

042 HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE

136.3 PNEUMOCYSTOSIS

491.0 - 508.9 SIMPLE CHRONIC BRONCHITIS - RESPIRATORY CONDITIONS
DUE TO UNSPECIFIED EXTERNAL AGENT

996.80 - 996.89 COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN -
COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED
ORGAN

For HCPCS code J7608:

480.0 - 508.9 PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY
CONDITIONS DUE TO UNSPECIFIED EXTERNAL AGENT

786.4 ABNORMAL SPUTUM

For HCPCS codes J7605, J7606, J7611, J7612, J7613, J7614, J7620, J7626, J7631, J7644, J7669:

491.0 - 508.9 SIMPLE CHRONIC BRONCHITIS - RESPIRATORY CONDITIONS
DUE TO UNSPECIFIED EXTERNAL AGENT

For HCPCS code J7639:

277.02 CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS

For HCPCS code J7682:

011.50 - 011.56 TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION

- TUBERCULOUS BRONCHIECTASIS TUBERCLE BACILLI NOT FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER METHODS (INOCULATION OF ANIMALS)

277.02 CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS
 494.0 BRONCHIECTASIS WITHOUT ACUTE EXACERBATION
 494.1 BRONCHIECTASIS WITH ACUTE EXACERBATION
 748.61 CONGENITAL BRONCHIECTASIS

For HCPCS codes K0730, Q4074:

416.0 PRIMARY PULMONARY HYPERTENSION
 416.8 OTHER CHRONIC PULMONARY HEART DISEASES

For HCPCS code A7005:

011.50 - 011.56 TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION
 - TUBERCULOUS BRONCHIECTASIS TUBERCLE BACILLI NOT FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER METHODS (INOCULATION OF ANIMALS)
 042 HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
 136.3 PNEUMOCYSTOSIS
 277.02 CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS
 416.0 PRIMARY PULMONARY HYPERTENSION
 416.8 OTHER CHRONIC PULMONARY HEART DISEASES
 480.0 - 508.9 PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY CONDITIONS DUE TO UNSPECIFIED EXTERNAL AGENT
 748.61 CONGENITAL BRONCHIECTASIS
 786.4 ABNORMAL SPUTUM
 996.80 - 996.89 COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN

Diagnoses that Support Medical Necessity

Refer to the previous section for the specific HCPCS code indicated. For all other HCPCS codes listed in the policy refer to the section on "Indications and Limitations of Coverage and/or Medical Necessity" for other criteria and payment information.

ICD-9 Codes that DO NOT Support Medical Necessity

For the specific HCPCS codes indicated above, all ICD-9 codes that are not specified in the previous section.

For HCPCS codes A7009, E0575, J7604, J7607, J7609, J7610, J7615, J7622, J7624, J7627, J7628, J7629, J7632, J7634, J7635, J7636, J7637, J7638, J7640, J7641, J7642, J7643, J7645, J7647, J7650, J7657, J7660, J7667, J7670, J7676, J7680, J7681, J7683, J7684, and J7685, all ICD-9 codes.

For all other HCPCS codes, ICD-9 codes are not specified.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

For the specific HCPCS codes indicated above, all diagnoses that are not specified in the previous section.

For HCPCS codes A7009, E0575, J7604, J7607, J7609, J7610, J7615, J7622, J7624, J7627, J7628, J7629, J7632, J7634, J7635, J7636, J7637, J7638, J7640, J7641, J7642, J7643, J7645, J7647, J7650, J7657, J7660, J7667, J7670, J7676, J7680, J7681, J7683, J7684, and J7685, all diagnoses.

For all other HCPCS codes, diagnoses are not specified.

General Information

Documentation Requirements

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

The order for any drug must clearly specify the type of solution to be dispensed to the patient and the administration instructions for that solution. The type of solution is described by a combination of: (a) the name of the drug and the concentration of the drug in the dispensed solution and the volume of solution in each container, or (b) the name of the drug and the number of milligrams/grams of drug in the dispensed solution and the volume of solution in that

container.

Examples of (a) would be: albuterol 0.083% 3 ml; or albuterol 0.5% 20 ml; or cromolyn 20 mg/2 ml. An example of (b) is: albuterol 1.25 mg in 3 ml saline. For compounded inhalation solutions, the order must include the following statement prior to signature by the physician: compounded inhalation solution - not FDA-approved. Administration instructions must specify the amount of solution and frequency of use. Examples would be: 3 ml qid and prn - max 6 doses/24 hr.; or one ampule q 4 hr prn; or 0.5 ml diluted with saline to 3.0 ml tid and prn. A new order is required if there is a change in the type of solution dispensed or the administration instructions. For all inhalation drugs, a new order is required at least every 12 months even if the prescription has not changed.

An ICD-9 code describing the condition which necessitates nebulizer therapy must be included on each claim for equipment, accessories and/or drugs.

KX, GA, AND GZ MODIFIERS:

Suppliers must add a KX modifier to codes for K0730 and Q4074 only if all of the criteria in the Indications and Limitations of Coverage and/or Medical Necessity section of this policy have been met.

If all of the criteria in the Indications and Limitations of Coverage and/or Medical Necessity section have not been met, the GA or GZ modifier must be added to the code. When there is an expectation of a medical necessity denial, suppliers must enter GA on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or GZ if they have not obtained a valid ABN.

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

Miscellaneous

When code E1399 is billed for miscellaneous equipment or accessories, the claim must be accompanied by a clear description of the item including the manufacturer and the model name/number if applicable.

When Not Otherwise Classified (NOC) drug code J7699 is billed for miscellaneous inhalation drugs, the claim must be accompanied by the detailed order information described above and a clear statement of the number of ampules/bottles of solution dispensed.

Refer to the Supplier Manual for more information on documentation requirements.

Appendices

Utilization Guidelines

Refer to Indications and Limitations of Coverage and/or Medical Necessity.

Sources of Information and Basis for Decision**Advisory Committee Meeting Notes****Start Date of Comment Period**

03/24/2006

End Date of Comment Period

05/08/2006

Start Date of Notice Period

04/10/2008

Revision History Number

NEB0011

Revision History Explanation**Revision Effective Date: 01/01/2010****INDICATIONS AND LIMITATIONS OF COVERAGE:**

Replaced: Q4080 with Q4074 in the Iloprost coverage indications

HCPCS CODES AND MODIFIERS:

Replaced: Q4080 with Q4074

ICD-9 CODES:

Replaced: Q4080 with Q4074 in the ICD-9 requirements

DOCUMENTATION REQUIREMENTS:

Replaced: Q4080 with Q4074 in the KX, GA and GZ modifiers requirements

Revision Effective Date: 12/01/2009**INDICATIONS AND LIMITATIONS OF COVERAGE:**

Added: Language from Program Integrity Manual on timing of refills and shipping of supplies/medications

Revised: Coverage criteria for long-acting bronchodilators

HCPCS CODES AND MODIFIERS:

Added: GA and GZ modifiers

Revised: KX modifier descriptor

ICD-9 CODES:

Revised: ICD-9 codes that support medical necessity for J7605, J7606

DOCUMENTATION:

Deleted: KX requirements from J7605 & J7606
 Added: Instructions for use of GA and GZ modifiers

08/08/2009 - This policy was updated by the ICD-9 2009-2010 Annual Update.

Revision Effective Date: 01/01/2009

INDICATIONS AND LIMITATIONS OF COVERAGE:

Deleted: Least costly alternative statement for albuterol/ipratropium combination (J7620) scheduled to become effective November 1, 2008
 Revised: Statement about denial of coverage when more than one beta-adrenergic agent is provided
 Added: Maximum amount for albuterol/ipratropium combination
 Added: Delivery timeframe for shipping of refills
 HCPCS:
 Added: Code J7606 (formoterol fumarate)
 Deleted: Code Q4099 (formoterol fumarate)

08/10/2008 - This policy was updated by the ICD-9 2008-2009 Annual Update.

Revision Effective Date: 07/01/2008 unless otherwise noted (June 2008 Publication)

INDICATIONS AND LIMITATIONS OF COVERAGE:

Removed: Least costly alternative statement for levalbuterol
 Revised: Effective date for implementation of least costly alternative statement for albuterol/ipratropium combination (DuoNeb - J7620)
 Removed: Bibliography references to levalbuterol

Revision Effective Date: 07/01/2008 (April 2008 Publication)

NATIONAL COVERAGE POLICY:

Added: NCD 200.2

INDICATIONS AND LIMITATIONS OF COVERAGE:

Substituted: J7611-J7614 for Q4093, Q4094
 Added: Q4099 as a new code for formoterol
 Added: Coverage criteria and maximum covered amount for formoterol.
 Added: J7604, J7632, and J7676 to the list of compounded drugs that are not covered.
 Added: Statement about denial if both formoterol and arformoterol are provided
 Added: Least costly alternative statement for levalbuterol.
 Added: Least costly alternative statement for unit dose combinations of albuterol and ipratropium.
 Revised: Coverage criteria for arformoterol.
 Revised: Statements concerning use of rescue medication to include use with formoterol.
 HCPCS CODES AND MODIFIERS:
 Added: J7604, J7605, J7632, J7676 (effective 1/1/08)
 Added: J7611, J7612, J7613, J7614, Q4099 (effective 4/1/08)
 Revised: J2545, J7608, J7631, J7639, Q4080 (effective 1/1/08)
 Deleted: Q4093, Q4094 (effective 1/1/08)
 (Note: Codes J7602 and J7603 were effective 1/1/08 - 3/31/08.)
 ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:
 Added: J7605, J7611-J7614, Q4099
 Removed: Q4093, Q4094
 Added: Covered diagnosis codes for formoterol.

ICD-9 CODES/ DIAGNOSES THAT DO NOT SUPPORT MEDICAL NECESSITY:

Added: J7604, J7632, J7676

DOCUMENTATION REQUIREMENTS:

Added: Instructions for use of the KX modifier with Perforomist (formoterol).

Revised: Instructions for use of the KX modifier with Brovana (arformoterol).

SOURCES OF INFORMATION/ BASIS FOR DECISION:

Added: Bibliography

LCD ATTACHMENTS:

Response to Comments - April 2008

Revision effective 3/1/2008

In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC Noridian Administrative Services (19003) LCD L11488 from DME PSC Electronic Data Systems Corp. (77006) LCD L11488.

Revision Effective Date: 07/01/2007 (June publication)**INDICATIONS AND LIMITATIONS OF COVERAGE:**

Added coverage criteria and maximum covered amount for arformoterol.

Revised statement about J7699 to say that it will be denied when it is used to bill for a compounded inhalation solution.

Added coverage statement and maximum covered amount for albuterol, levalbuterol, and metaproterenol when used in addition to arformoterol.

Substituted code Q4093 and Q4094 for J7611-J7614.

HCPCS CODES:

Added: Q4093, Q4094

Deleted: J7611, J7612, J7613, J7614

ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:

Added: Q4093, Q4094

Deleted: J7611, J7612, J7613, J7614

Added covered diagnosis codes for arformoterol.

ICD-9 CODES/DIAGNOSES THAT DO NOT SUPPORT MEDICAL NECESSITY:

Removed J7699 from the list.

DOCUMENTATION REQUIREMENTS:

Added instructions for use of the KX modifier with arformoterol.

Revision Effective Date: 07/01/2007 (March publication)**INDICATIONS AND LIMITATIONS OF COVERAGE:**

Eliminated coverage for atropine, beclomethasone, betamethasone, bitolterol, dexamethasone, flunisolide, glycopyrrolate, isoetharine, terbutaline, triamcinolone, and all other compounded inhalation solutions.

Changed ICD-9 code 519.1 to 519.19.

Deleted the statement concerning providing information on a claim about the need for a portable compressor.

Added utilization guideline for budesonide.

HCPCS CODES AND MODIFIERS:

(HCPCS code changes that were effective 01/01/2007.)

Added: J7607, J7609, J7610, J7615, J7634, J7640, J7645, J7647, J7650, J7657, J7660, J7667, J7670, J7685

Revised: J7611, J7612, J7613, J7614, J7620, J7622, J7624, J7626, J7627, J7628, J7629, J7635, J7636, J7637, J7638, J7640, J7641, J7642, J7643, J7644, J7669, J7680, J7681, J7682, J7683,

J7684, Q4080

Removed: J7633, J7648, J7649, J7658, J7659, J7668

ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:

Changed ICD-9 code 519.1 to 519.19.

Added: 416.0 and 416.8 to covered codes for A7005.

Removed: J7622, J7624, J7627, J7628, J7629, J7633, J7635, J7636, J7637, J7638, J7640, J7641, J7642, J7643, J7648, J7649, J7658, J7659, J7668, J7680, J7681, J7683, J7684

ICD-9 CODES AND DIAGNOSES THAT DO NOT SUPPORT MEDICAL NECESSITY:

Added: J7607, J7609, J7610, J7615, J7622, J7624, J7627, J7628, J7629, J7634, J7635, J7636, J7637, J7638, J7640, J7641, J7642, J7643, J7645, J7647, J7650, J7657, J7660, J7667, J7670, J7680, J7681, J7683, J7684, J7685, J7699

DOCUMENTATION REQUIREMENTS:

Added a requirement for a specific statement on orders for compounded inhalation solutions.

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC Electronic Data Systems Corp. (77006) from DMERC CIGNA Government Services (05655).

Revision Effective Date: 01/01/2006

INDICATIONS AND LIMITATIONS OF COVERAGE AND MEDICAL NECESSITY:

Inserted new HCPCS Codes A4216, A4218 and deleted codes J7051 and J7699 where appropriate.

Added coverage statement for code A7007.

Added A7007 to the related code table for E0565.

Added A7007 to usual maximum amount.

Added usual maximum amount for A4216 and A4218.

HCPCS CODES & MODIFIERS:

Added: HCPCS codes A4218, G0333, J7620, J7627, Q0513 and Q0514.

Verbiage revision to description of HCPCS codes A4216, J7626.

Deleted: HCPCS codes J7051, J7616, G0371 and G0374.

ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:

Added J7620 and J7627 to the list of codes requiring ICD-9 code 491.0-508.9; deleted J7616.

Added: A7007 to the 5th paragraph of HCPCS codes requiring specific ICD-9 codes.

Added A4216 and deleted A7051 from the 6th paragraph of HCPCS codes requiring specific ICD-9 codes.

DOCUMENTATION REQUIREMENTS:

Revised E1399 and J7699 documentation requirements.

Revision Effective Date: 10/01/2005

HCPCS CODES & MODIFIERS:

Added codes: K0730 and Q4080 and KX modifier.

INDICATIONS AND LIMITATIONS OF COVERAGE AND/OR MEDICAL NECESSITY:

Added criterion for K0730 and Q4080.

ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:

Added diagnoses codes 416.0, 416.8, necessary for codes K0730 and Q4080.

DOCUMENTATION REQUIREMENTS:

Added KX modifier requirement for K0730 and Q4080.

Revision Effective Date: 04/01/2005

LMRP converted to LCD and Policy Article.

HCPCS CODES & MODIFIERS:

Added Codes: J7611, J7612, J7613, J7614, J7616, G0371, G0374

Deleted Codes: J7618, J7619, J7621, E0590

INDICATIONS AND LIMITATIONS OF MEDICAL NECESSITY:

Tobramycin coverage expanded.

Revision Effective Date: 04/01/2004**INDICATIONS AND LIMITATIONS OF COVERAGE:**

Added references to new HCPCS codes.

HCPCS CODES AND MODIFIERS:

Added: A4217, A7525, J7621

Deleted: A4621, A7019, A7020

CODING GUIDELINES:

Added references to new HCPCS codes.

Clarified use of J7699.

Added billing guidelines for J7621.

Removed billing guidelines for A4323.

Added correct coding guidelines for compounded albuterol and ipratropium.

Added instructions for billing metered dose sterile saline products.

Revision Effective Date: 04/01/2003**HCPCS CODES AND MODIFIERS:**

Added: EY modifier, J7633

Revised: E0574, J7626

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added standard language concerning coverage of items without an order.

Added standard language concerning the medical necessity for use of a greater quantity and combinations of usually contraindicated drugs requirement.

Removed language about physician documenting having considered use of an MDI prior to prescribing a nebulizer.

Added pneumocystosis and complications of organ transplants as coverage criteria for E0565 or E0572 compressor used with filtered nebulizer (A7006).

Removed specific coverage criteria for dornase alpha, other than its being used for treatment of cystic fibrosis.

Removed grandfathering language for aerosol compressors and small and large volume ultrasonic generators.

CODING GUIDELINES:

Added: Instructions on how to bill J7626 0.5mg as one unit of service.

Added definitions of equipment and inhalations drugs to this section of policy.

DOCUMENTATION REQUIREMENTS:

Added: Standard language concerning use of EY modifier for items without an order; standard language regarding excess quantity utilization.

Listed specific codes in which extra documentation should be attached to claim via hardcopy or narrative field.

The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.

04/01/2002 - Expansion of coverage for large volume nebulizers with saline or water for use with tracheobronchial stents (519.1). Expansion of

indications for use of pentamidine with added ICD-9 codes. Expansion of indications for use of mucolytics with added ICD-9 codes. New HCPCS E codes replace K codes. New HCPCS codes for inhaled corticosteroids. Revision of HCPCS code for albuterol to include levalbuterol and its proper billing unit.

04/01/2000 - Several K codes crosswalked to A codes or J codes. Added "reasonable and necessary" language in Coverage and Payment Rules section. Revised all references of previous K codes.

06/01/1997 - Removed E0575 information in Documentation section. K0171 removed from covered codes for small volume nebulizer in Coverage and Payment Rules section. K0171 is not medically necessary for the administration of medications other than pentamidine.

03/01/1997 - Refer to article entitled "Nebulizer Policy Update" in the March 1997 DMERC Dialogue for a detailed report of the revision.

01

Reason for Change

Last Reviewed On Date

01/28/2010

Related Documents

Article(s)

[A24942 - Nebulizers - Policy Article - Effective January 2010](#)

LCD Attachments

[Response to Comments - June 2008 Revision](#) (PDF - 28,888 bytes)

All Versions

Updated on 01/31/2010 with effective dates 01/01/2010 - N/A

Updated on 01/31/2010 with effective dates 01/01/2010 - N/A

Updated on 10/04/2009 with effective dates 12/01/2009 - 12/31/2009

Updated on 11/30/2008 with effective dates 01/01/2009 - 11/30/2009

Updated on 08/22/2008 with effective dates 07/01/2008 - 12/31/2008

Updated on 06/23/2008 with effective dates 07/01/2008 - N/A

Updated on 04/03/2008 with effective dates 07/01/2008 - N/A