

LCD for Nebulizers (L11499)

Contractor Information

Contractor Name

[NHIC, Corp.](#)

Contractor Number

16003

Contractor Type

DME MAC

LCD Information

LCD ID Number

L11499

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

Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

LCD Information

Oversight Region

Region I

DME Region LCD Covers

Jurisdiction A

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

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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,

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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.

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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

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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.

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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

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

Coding Information

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

Coding Information

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

Coding Information

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

Coding Information

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](#) - TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION - TUBERCULOUS
[011.56](#) 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](#) - COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF
[996.89](#) OTHER SPECIFIED TRANSPLANTED ORGAN

V44.0 TRACHEOSTOMY STATUS

V55.0 ATTENTION TO TRACHEOSTOMY

For HCPCS codes A7013, A7014, A7015, A7525:

[011.50](#) - TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION - TUBERCULOUS
[011.56](#) 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

Coding Information

[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:

Coding Information

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 codes 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 -	COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF

Coding Information

[996.89](#) 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.

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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

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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

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End Date of Comment Period

05/08/2006

Start Date of Notice Period

04/10/2008

Revision History Number

NEB011

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 REQUIREMENTS:

Deleted: KX requirements from J7605 & J7606.

Added: Instructions for use of GA and GZ modifiers.

Revision Effective Date: 1/01/2009

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 CODES AND MODIFIERS:

Added: Code J7606 (formoterol fumarate).

Deleted: Code Q4099 (formoterol fumarate).

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

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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

03/01/2008 - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC CIGNA Government Services (18003) LCD L11517 from DME PSC TrustSolutions (77012) LCD L11517.

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: Codes Q4093 and Q4094 for J7611-J7614.

HCPCS CODES AND MODIFIERS:

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.

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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 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.

Revision Effective Date: 06/01/2007

In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC TrustSolutions (77012) from DMERC Palmetto GBA (00885).

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 appropriately.

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, 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.

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Revision Effective Date: 10/01/2005

HCPCS CODES AND MODIFIERS:

Added: 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 AND MODIFIERS:

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

Deleted: J7618, J7619, J7621, E0590

INDICATIONS AND LIMITATIONS OF MEDICAL NECESSITY:

Tobramycin coverage expanded.

Revision Effective Date: 04/01/2004

HCPCS CODES AND MODIFIERS:

Added: A4217, A7525, J7621

Deleted: A4621, A7019, A7020

INDICATIONS AND LIMITATIONS:

Added: References to new HCPCS codes.

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.

General Information

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 Advisory for a detailed report of the revision.

Reason for Change

Last Reviewed On Date

Related Documents

Article(s)

[A24944 - Nebulizers - Policy Article - Effective January 2010](#)

LCD Attachments

There are no attachments for this LCD

Article for Nebulizers - Policy Article - Effective January 2010 (A24944)

Contractor Information

Contractor Name

[NHIC, Corp.](#)

Contractor Number

16003

Contractor Type

DME MAC

Article Information

Article ID Number

A24944

Article Type

Article

Key Article

Yes

Article Title

Nebulizers - Policy Article - Effective January 2010

Primary Geographic Jurisdiction

Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

DME Region Article Covers

Jurisdiction A

Original Article Effective Date

04/01/2005

Article Information

Article Revision Effective Date

01/01/2010

Article Text

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

A large volume pneumatic nebulizer (E0580) and water or saline (A4217 or A7018) are not separately payable and should not be separately billed when used for patients with rented home oxygen equipment.

If a large volume nebulizer, related compressor/generator, and water or saline are used predominantly to provide room humidification it will be denied as noncovered.

A prefilled disposable large volume nebulizer (A7008) is noncovered under the DME benefit because it is a convenience item. An unfilled nebulizer (A7007, A7017, or E0585) filled with water or saline (A4217 or A7018) by the patient/caregiver is an acceptable alternative.

Kits and concentrates for use in cleaning respiratory equipment will be denied as noncovered.

DISPENSING FEE:

An initial dispensing fee (G0333) is payable to a pharmacy for the initial 30 day supply of covered inhalation drug(s) regardless of the number of drugs dispensed, the number of shipments, or the number of pharmacies used by the beneficiary during that time. This initial 30-day dispensing fee is a once in a lifetime fee and only applies to beneficiaries who are using inhalation drugs for the first time as a Medicare beneficiary on or after 01/01/2006.

Medicare will only pay for one of the following for covered inhalation drugs regardless of the number of drugs dispensed, the number of shipments, or the number of pharmacies used by the beneficiary during that time period-an initial dispensing fee (G0333), a 30 day dispensing fee (Q0513), or a 90 day dispensing fee (Q0514).

If code G0333 is billed for a 30 day supply of covered inhalation drugs and criteria for payment of G0333 are not met but criteria for payment of Q0513 are met, it will be payable based on the allowance for code Q0513.

For a refill prescription, payment of a dispensing fee will be allowed no sooner than 7 days before the end of usage for the current 30 day or 90 day period for which a dispensing fee was previously paid. Medicare will not pay for more than 12 months of dispensing fees per beneficiary per 12 month period.

If the dispensing fee is billed sooner than the interval specified above, it will be denied as not separately payable. For example, if a 90 day fee (Q0514) is billed on 01/30/2006 and is covered and there is a subsequent claim for a 30 day fee (Q0513) on 04/20/2006, the dispensing fee on 04/20/2006 will be denied as not separately payable.

Both a Q0513 and a Q0514 dispensing fee are not covered on the same date of service. If a supplier dispenses a 90 day supply of one drug and a 30 day supply of another drug on the same day, code Q0514 (90 day fee) must be billed.

The dispensing fee must be billed on the same claim as the inhalation drug(s). If it is not, it will be denied as incorrect billing.

A dispensing fee is not separately billable or payable for saline, whether used as a diluent or for humidification therapy.

Article Information

Medicare will not pay for a separate fee for the compounding of inhalation drug(s).

CODING GUIDELINES

EQUIPMENT

In this policy, the actual equipment (i.e., electrical device) will generally be referred to as either a compressor (when nebulization of liquid is achieved by means of air flow) or as a generator (when nebulization of liquid is achieved by means of ultrasonic vibrations). The term nebulizer is generally used for the actual chamber in which the nebulization of liquid occurs and is an accessory to the equipment. The nebulizer is attached to an aerosol compressor or an ultrasonic generator in order to achieve a functioning delivery system for aerosol therapy.

Code E0565 describes an aerosol compressor, which can be set for pressures above 30 psi at a flow of 6-8 L/m and is capable of continuous operation.

A nebulizer with compressor (E0570) is an aerosol compressor, which delivers a fixed, low pressure and is used with a small volume nebulizer. It is only AC powered.

A portable compressor (E0571) is an aerosol compressor, which delivers a fixed, low pressure and is used with a small volume nebulizer. It must have battery or DC power capability and may have an AC power option.

A light duty adjustable pressure compressor (E0572) is a pneumatic aerosol compressor which can be set for pressures above 30 psi at a flow of 6-8 L/m, but is capable only of intermittent operation.

Code E0574 describes an ultrasonic/electronic generator used with a small volume chamber for medication delivery, which is capable only of intermittent operation.

Code E0575 describes a large volume ultrasonic nebulizer system which is used for medication and humidification delivery, and which is capable of continuous operation.

Code K0730 describes a controlled dose inhalation drug delivery system. Aerosol is delivered in pulses during the inspiration. The duration of each pulse is adapted according to the breathing pattern.

ACCESSORIES

Code A7003, A7005, and A7006 include the lid, jar, baffles, tubing, T-piece and mouthpiece. In addition, code A7006 includes a filter.

Code A7004 includes only the lid, jar and baffles.

Code A7012 describes a device to collect water condensation, which is placed in line with the corrugated tubing, used with a large volume nebulizer.

Code E0585 is used when a heavy-duty aerosol compressor (E0565), durable bottle type large volume nebulizer (A7017), and immersion heater (E1372) are provided at the same time. If all three items are not provided initially, the separate codes for the components would be used for billing. Code A7007 or A7017 is billed when an unfilled large volume nebulizer is used with a E0572 compressor or a separately billed E0565 compressor. Code A7007 or A7017 would not be separately billed when an E0585 system was also being billed. Code E0580 (Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flow meter) describes the same piece of equipment as A7017, but should only be billed when this type of nebulizer is used with a beneficiary-owned oxygen system.

Article Information

INHALATION DRUGS

The following instructions apply to claims billed using J codes. When claims are billed in NCPDP format using NDC numbers, different instructions may apply. Refer to the NCPDP Companion Document available through the CMS website.

A compounded inhalation solution is one in which the product that is delivered to the patient is not an FDA-approved preparation. It is produced by a pharmacy that is not an FDA-approved manufacturer and involves the mixing, combining, or altering of ingredients for an individual patient. Even if one of the ingredients is an FDA-approved product (e.g., an injectable form of the drug) that is mixed by the pharmacy with other ingredients, the solution that is dispensed to the patient is considered to be a compounded product.

There are distinct codes for FDA-approved final products and for compounded final products. The appropriate code must be used when a claim is submitted.

Codes J2545 (pentamidine), J7608 (acetylcysteine), J7631 (cromolyn), J7639 (dornase alpha), and Q4074 (iloprost) may only be used for inhalation solutions which are FDA-approved. If compounded versions of these drugs are provided, they must be billed using code J7699.

There are no FDA-approved final products that are described by the following codes: J7633 (budesonide, concentrate), J7648 (isoetharine, concentrate), J7649 (isoetharine, unit dose), J7658 (isoproterenol, concentrate), J7659 (isoproterenol, unit dose), and J7668 (metaproterenol, concentrate). These codes are invalid for claim submission.

Codes J7602 (Albuterol, all formulations including separated isomers, inhalation solution, FDA-approved final product, non-compounded, administered through DME, concentrated form, per 1 mg (albuterol) or per 0.5 mg (levalbuterol)) and J7603 (Albuterol, all formulations including separated isomers, inhalation solution, FDA-approved final product, non-compounded, administered through DME, unit dose, per 1 mg (albuterol) or per 0.5 mg (levalbuterol)) were effective for claims with dates of service from 01/01/2008 – 3/31/2008. They are invalid for claim submission for dates of service on or after 04/01/2008.

Unit dose form of an inhalation drug or a combination of drugs is one in which the medication is dispensed to a patient (1) in a bottle/vial/ampule which contains the dose usually used for a single inhalation treatment, and (2) in a concentration which is dilute enough that it may be administered to a patient without adding any separate diluent.

Concentrated form of a drug used for inhalation is one in which the drug is dispensed to a patient in a concentration which requires that a separate diluent (usually saline) be added to the nebulizer when the drug is administered to a patient.

The coding of a unit dose form or a concentrated form of an inhalation drug is determined by the formulation of the drug as it is dispensed to the patient. For example, if a pharmacist takes a concentrated form of a single inhalation drug (e.g., 0.5% albuterol) and dilutes it to a ready-to-use concentration (e.g., 0.083% albuterol), which is then dispensed to the patient in a single-dose bottles/vials/ampules, the inhalation solution is billed as the unit dose form not the concentrated form.

When there is a single drug in a unit dose container, the KO modifier is added to the unit dose form code. (Exception: The KO modifier is not used with code J2545 or Q4074.)

Except for code J7620, when two or more drugs are combined and dispensed to the patient in the same unit dose container, each of the drugs is billed using its unit dose form code. The KP modifier is added to only one of the unit dose form codes and the KQ modifier is added to the other unit dose code(s).

Article Information

Whenever a unit dose form code is billed, it must have a KO, KP or KQ modifier. (Exception: The KO, KP and KQ modifiers should not be used with code J7620.) If a unit dose code does not have one of these modifiers, it will be denied as an invalid code. The KO, KP, and KQ modifiers are not used with the concentrated form codes.

The only FDA-approved unit dose preparation containing more than one drug is J7620, the combination of albuterol and ipratropium. Therefore, if the following FDA-approved unit dose codes are billed with a KP or KQ modifier, they will be rejected as invalid for claim submission: J2545, J7608, J7613, J7614, J7626, J7631, J7639, J7644, J7669, J7682, and Q4074.

The billing unit of service for inhalation drug codes varies. Suppliers must be sure that they use the correct billing unit of the code when calculating the number of units of service to enter on the claim. The following is guidance on a few codes where errors are commonly seen:

- Code J7620 is used for an FDA-approved combination of albuterol and ipratropium, which contains 3.0 mg of albuterol sulfate (which is 2.5 mg of albuterol base) and 0.5 mg of ipratropium bromide in each unit dose vial. For these products, 1 unit of service of J7620 equals 1 unit dose vial.

- For code J7626 and J7627 (budesonide, unit dose) bill one unit of service for each vial dispensed, regardless of whether a 0.25 mg vial or a 0.5 mg vial is dispensed.

The concentration of the drug in the dispensed solution can be converted to mg or gm as follows: A solution with a labeled concentration of 1% has ten (10) mg of drug in each milliliter (ml) of solution. Therefore, a 0.083% albuterol solution has 0.83 mg of albuterol in each ml of solution. Since albuterol 0.083% solution typically comes in a 3 ml vial/ampule, each vial/ampule contains 2.5mg of albuterol (3X.83 equals 2.5). If a pharmacist provides 120 ampules of 0.83% albuterol solution each containing 3 ml, the billed units of service would be 300 (2.5 X 120) units of code J7613 (for albuterol, 1 mg equals 1 unit).

When a compounded unit dose preparation is billed, the diluent must not be billed separately.

A4218 is used for metered dose sterile saline products that are used to dilute the concentrated form of inhalation drugs.

When a drug is provided in a concentration which is dilute enough that it may be administered to the patient without adding any separate diluent and is dispensed in a multidose container, use J7699.

Code J7699 is also used for an inhalation drug which does not have a valid specific code. Claims for drugs that are incorrectly coded J7699 instead of the appropriate code will be denied for invalid coding.

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

Coding Information

Other Information

Other Comments

3/1/2008- In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) Article A24944 from DME PSC TriCenturion (77011) Article

Other Information

A24944.

Revision History Explanation

Revision Effective Date: 01/01/2010

CODING GUIDELINES:

Replaced: Q4080 with Q4074 in the Inhalation Drug Requirements.

Deleted: J7649 and J7659 from the Inhalation Drug Requirements.

Revision Effective Date: 01/01/2009

CODING GUIDELINES:

Deleted: References to trademarked name DuoNeb.

Revised: Changed SADMERC to PDAC.

Revision Effective Date: 07/01/2008

CODING GUIDELINES:

Added: Effective dates of codes J7602 and J7603.

Deleted: Coding guidelines that are no longer needed due to HCPCS code changes.

Substituted: J7613 or J7614 for Q4094. (J7613 and J7614 were effective 4/1/08.)

Deleted: Billing instructions for Brovana.

03/01/2008 - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) Article A24944 from DME PSC TriCenturion (77011) Article A24944.

Revision Effective Date: 07/01/2007

CODING GUIDELINES:

Added: Billing instructions for Brovana (arformoterol).

Added: Statement that J7611-J7614 are invalid and that Q4093 or Q4094 should be used.

06/01/2007 - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

Revision Effective Date: 01/01/2007

CODING GUIDELINES:

Added: Definition of a compounded inhalation solution.

Added: Instructions for use of codes J7525 (pentamidine), J7608 (acetylcysteine), J7631 (cromolyn), J7639 (dornase alpha), and Q4080 (iloprost).

Listed: Codes J7633, J7648, J7649, J7658, J7659, and J7668 as invalid for claim submission.

Revised: Billing instructions for KO, KP, and KQ modifiers.

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this article was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

Revision Effective Date: 01/01/2006

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

Deleted: A7007 from statement that this code would be denied as a convenience item.

Replaced: Deleted G0371 and G0374 with new dispensing fee HCPCS codes Q0513 and Q0514.

Revised: Guidelines for dispensing fees.

CODING GUIDELINES:

Added: A7007 as equipment that would not be used with oxygen.

Deleted: J7616 and replaced with new HCPCS code J7620.

Added: A4118 to replace J7699 for metered dose dispenser of sterile saline or water.

Revision Effective Date: 10/01/2005

CODING GUIDELINES:

Other Information

Added: Definition of K0730.

Deleted: KP/KQ modifier instructions for albuterol/ipratropium and albuterol/cromolyn.

Revised: Instructions regarding dispensing fee.

Revision Effective Date 04/01/2005

LMRP converted to LCD and Policy Article

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

Added: Coverage statements relating to dispensing fees and compounding fees.

CODING GUIDELINES:

Added: Statement about claims filed in NCPDP format.

Updated: HCPCS codes.

Added: Guidelines for dispensing fee for 30 and 90 days.

Related Documents

LCD(s)

[L11499 - Nebulizers](#)