

**LCD for Nebulizers - Draft (DL11499)**

**Draft**

**Please note: This is a Draft policy.**

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**Contractor Information**

**Draft Draft**  
**Draft**

**Contractor Name**

[TriCenturion](#)

**Contractor Number**

77011

**Contractor Type**

DME PSC

**DME MAC this DME PSC is affiliated with**

AdminaStar Federal, Inc., Tricenturion

**LCD Information**

**Draft Draft**



**LCD ID Number**

DL11499

**LCD Title**

Nebulizers - Draft

**Contractor's Determination Number**

NEB20060324

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**CMS National Coverage Policy**

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

**Primary Geographic Jurisdiction**

Connecticut  
District of Columbia  
Delaware  
Illinois  
Indiana  
Massachusetts  
Maryland  
Maine  
Michigan  
Minnesota  
New Hampshire  
New Jersey  
New York - Entire State  
Ohio  
Pennsylvania

Rhode Island  
Virginia  
Vermont  
Wisconsin  
West Virginia

**Oversight Region**

Central Office

**DME Region LCD Covers**

Jurisdiction A/B

**Projected Determination Effective Date**

**Original Determination Ending Date**

**Revision Effective Date**

**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 to the DMERC. 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) and related compressor (E0570, E0571) are covered when:

- a) It is medically necessary to administer albuterol, budesonide, cromolyn, ipratropium, isoetharine, isoproterenol, levalbuterol, or metaproterenol 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 to a patient with cystic fibrosis (ICD-9 diagnosis code 277.02) or

c) It is medically necessary to administer tobramycin 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 to patients with HIV (ICD-9 diagnosis code 042), pneumocystosis (ICD-9 diagnosis code 136.3), and complications of organ transplants (ICD-9 diagnosis codes 996.80-996.89), or

e) It is medically necessary to administer acetylcysteine for persistent thick or tenacious pulmonary secretions (ICD-9 diagnosis codes 480.0-508.9, 786.4).

Use of inhalation drugs, other than those listed above or iloprost (see below) will be denied as not medically necessary.

If none of the drugs used with a nebulizer are covered, the nebulizer and its 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), a tracheobronchial stent (ICD-9 diagnosis code 519.1). 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) and 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 model, when a small volume ultrasonic nebulizer (E0574) is ordered, it will be reimbursed at the least costly alternative of 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 alternate 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 this compressor is provided without accompanying documentation, which justifies its medical necessity, and the coverage criteria for code E0570 are met, payment will be based on the allowance for the least costly medically acceptable alternative, E0570.

A controlled dose inhalation drug delivery system K0730 is covered when it is medically necessary to deliver the iloprost (Q4080) to patients with pulmonary artery hypertension (ICD-9 diagnosis codes: 416.0 or 416.8) who meet the

following criteria.

Iloprost (Q4080) 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 (Q4080) 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)**

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 must be supported by documentation on the patient's medical record which must be available to the DMERC upon request.

Accessory **(Usual maximum replacement)**

A4619 **(One/month)**  
A7003 **(Two/month)**  
A7004 **(Two/month (in addition to A7003))**  
A7005 **(One/6 months)**  
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)**

#### INHALATION DRUGS AND SOLUTIONS:

The following table represents the maximum milligrams/month of inhalation drugs that would be reasonably billed for each nebulizer drug.

Acetylcysteine: **(up to 74 grams/month)**  
Albuterol: **(up to 465 mg/month)**  
Budesonide: **(up to 31 mg/month (62 units/month))**  
Cromolyn sodium: **(up to 2480 mg/month (248 units/month))**  
Dornase alpha: **(up to 78 mg/month)**  
Ipratropium bromide: **(up to 93 mg/month)**  
Isoetharine: **(up to 930 mg/month)**  
Isoproterenol: **(up to 450 mg/month)**  
Levalbuterol: **(up to 232.5 mg/month (465 units/month))**  
Metaproterenol: **(up to 2800 mg/month (280 units/month))**  
Pentamidine: **(up to 300 mg/month)**  
Sterile saline or water, 10ml/unit (A4216, A4218): **(up to 56 units/month)**  
Distilled water, sterile water, or sterile saline in large volume nebulizer: **(up to 18 liters/month)**

Claims for more than these amounts of drugs will be denied as not medically necessary unless there is documentation in the patient's medical record which

justifies a larger amount in the individual case. This information must be available to the DMERC upon request.

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.

When a "concentrated form" of an inhalation drug is dispensed, 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 (A7017 or E0585).

Albuterol, isoetharine, isoproterenol, levalbuterol, and metaproterenol are all bronchodilators with beta-adrenergic stimulatory effect. It would rarely be medically necessary for a patient to be using 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 unless there is documentation in the patient's medical record supporting the medical necessity.

The medical necessity for levalbuterol compared to albuterol has not been established. Therefore, when codes J7612 or J7614 are billed, if coverage criteria are met, payment will be based on the allowance for the least costly medically appropriate alternative - J7611 or J7613 respectively.

The medical necessity for administering albuterol and ipratropium in a non-compounded combined unit dose preparation (J7620) has not been established. Therefore, when one unit of service of code J7620 is billed, if coverage criteria are met, payment will be based on the allowance for the least costly medically appropriate alternative - 2.5 units of J7613KO and 0.5 units of J7644KO.

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 bill the DMERC for nebulizer drugs. Physicians may bill the DMERC 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

### **Coverage Topic**

Durable Medical Equipment

Prescription Drugs

### 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**

**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 - Specified required documentation on file**

#### 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

A4218	STERILE SALINE OR WATER, METERED DOSE DISPENSER, 10 ML
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), 10 ML
A4217	STERILE WATER/SALINE, 500 ML

- A4218 STERILE SALINE OR WATER, METERED DOSE DISPENSER, 10 ML
- A7018 WATER, DISTILLED, USED WITH LARGE VOLUME NEBULIZER, 1000 ML
- G0333 PHARMACY DISPENSING FEE FOR INHALATION DRUG(S); INITIAL 30-DAY SUPPLY AS A BENEFICIARY
- J2545 PENTAMIDINE ISETHIONATE, INHALATION SOLUTION, PER 300 MG, ADMINISTERED THROUGH A DME
- J7608 ACETYLCYSTEINE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER GRAM
- J7611 ALBUTEROL, INHALATION SOLUTION, ADMINISTERED THROUGH DME, CONCENTRATED FORM, 1 MG
- J7612 LEVALBUTEROL, INHALATION SOLUTION, ADMINISTERED THROUGH DME, CONCENTRATED FORM, 0.5 MG
- J7613 ALBUTEROL, INHALATION SOLUTION, ADMINISTERED THROUGH DME, UNIT DOSE, 1 MG
- J7614 LEVALBUTEROL, INHALATION SOLUTION, ADMINISTERED THROUGH DME, UNIT DOSE, 0.5 MG
- J7620 ALBUTEROL, UP TO 2.5 MG AND IPRATROPIUM BROMIDE, UP TO 0.5 MG, NON-COMPOUNDED INHALATION SOLUTION, ADMINISTERED THROUGH DME
- J7622 BECLOMETHASONE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7624 BETAMETHASONE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7626 BUDESONIDE INHALATION SOLUTION, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, UP TO 0.5 MG
- J7628 BITOLTEROL MESYLATE, INHALATION SOLUTION ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
- J7629 BITOLTEROL MESYLATE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7631 CROMOLYN SODIUM, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 10 MILLIGRAMS
- J7633 BUDESONIDE, INHALATION SOLUTION ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER 0.25 MILLIGRAM
- J7635 ATROPINE, INHALATION SOLUTION ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
- J7636 ATROPINE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
- J7637 DEXAMETHASONE, INHALATION SOLUTION ADMINISTERED

	THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
J7638	DEXAMETHASONE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
J7639	DORNASE ALPHA, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
J7640	FORMOTEROL, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, 12 MICROGRAMS
J7641	FLUNISOLIDE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE, PER MILLIGRAM
J7642	GLYCOPYRROLATE, INHALATION SOLUTION ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
J7643	GLYCOPYRROLATE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
J7644	IPRATROPIUM BROMIDE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
J7648	ISOETHARINE HCL, INHALATION SOLUTION ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
J7649	ISOETHARINE HCL, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
J7658	ISOPROTERENOL HCL, INHALATION SOLUTION ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
J7659	ISOPROTERENOL HCL, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
J7668	METAPROTERENOL SULFATE, INHALATION SOLUTION ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER 10 MILLIGRAMS
J7669	METAPROTERENOL SULFATE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 10 MILLIGRAMS
J7680	TERBUTALINE SULFATE, INHALATION SOLUTION ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
J7681	TERBUTALINE SULFATE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM
J7682	TOBRAMYCIN, UNIT DOSE FORM, 300 MG, INHALATION SOLUTION, ADMINISTERED THROUGH DME
J7683	TRIAMCINOLONE, INHALATION SOLUTION ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM
J7684	TRIAMCINOLONE, INHALATION SOLUTION ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM

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

Q4080 ILOPROST, INHALATION SOLUTION, ADMINISTERED THROUGH DME, 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 -  
[011.56](#) 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

519.1 OTHER DISEASES OF TRACHEA AND BRONCHUS NOT ELSEWHERE CLASSIFIED

748.61 CONGENITAL BRONCHIECTASIS

[996.80](#) - COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN -  
[996.89](#) COMPLICATIONS OF 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 -  
[011.56](#) 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](#) - PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY CONDITIONS  
[508.9](#) DUE TO UNSPECIFIED EXTERNAL AGENT

519.1 OTHER DISEASES OF TRACHEA AND BRONCHUS NOT ELSEWHERE  
CLASSIFIED

748.61 CONGENITAL BRONCHIECTASIS

786.4 ABNORMAL SPUTUM

[996.80](#) - COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN -  
[996.89](#) COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN

V44.0 TRACHEOSTOMY STATUS

V55.0 ATTENTION TO TRACHEOSTOMY

**For HCPCS codes A7003, A7004, A7005, E0570, E0571, E0574:**

[011.50](#) - TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION -  
[011.56](#) 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](#) - PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY CONDITIONS  
[508.9](#) DUE TO UNSPECIFIED EXTERNAL AGENT

748.61 CONGENITAL BRONCHIECTASIS

786.4 ABNORMAL SPUTUM

[996.80](#) - COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN -  
[996.89](#) COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN

**For HCPCS codes A7006, J2545:**

042 HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE

136.3 PNEUMOCYSTOSIS

[996.80](#) - COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN -  
[996.89](#) COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN

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

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

519.1 OTHER DISEASES OF TRACHEA AND BRONCHUS NOT ELSEWHERE CLASSIFIED

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](#) - SIMPLE CHRONIC BRONCHITIS - RESPIRATORY CONDITIONS  
[508.9](#) DUE TO UNSPECIFIED EXTERNAL AGENT

[996.80](#) - COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN -  
[996.89](#) COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN

**For HCPCS codes J7608:**

[480.0](#) - PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY CONDITIONS  
[508.9](#) DUE TO UNSPECIFIED EXTERNAL AGENT

786.4 ABNORMAL SPUTUM

**For HCPCS codes J7611, J7612, J7613, J7614, J7620, J7626, J7627, J7631, J7633, J7644, J7648, J7649, J7658, J7659, J7668, J7669, J7683, J7684:**

[491.0](#) - SIMPLE CHRONIC BRONCHITIS - RESPIRATORY CONDITIONS  
[508.9](#) DUE TO UNSPECIFIED EXTERNAL AGENT

**For HCPCS code J7639:**

277.02 CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS

**For HCPCS code J7682:**

[011.50](#) - TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION -  
[011.56](#) 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, Q4080:**

416.0 PRIMARY PULMONARY HYPERTENSION

416.8 OTHER CHRONIC PULMONARY HEART DISEASES

**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, J7622, J7624, J7628, J7629, J7635, J7636, J7637, J7638, J7640, J7641, J7642, J7643, J7680 and J7681, 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, A7016, E0575, J7622, J7624, J7628, J7629, J7635, J7636, J7637, J7638, J7640, J7641, J7642, J7643, J7680, and J7681, 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" (42 U.S.C. section 13951(e)). 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 to the DMERC 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 to the DMERC upon request. Items billed to the DMERC 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. Examples of (b) would be: albuterol 1.25 mg in 3 ml saline; or albuterol 2.5 mg and cromolyn 20 mg in 3 ml saline. 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.

If all the coverage criteria described in the Indications and Limitations of Coverage section have been met for K0730 and/or Q4080 a KX modifier must be added to the code(s).

Situations which the medical record must specifically address include:

1) When billing for quantities of supplies greater than those described in the policy as the usual maximum amounts, there must be clear documentation in the patient's medical records corroborating the medical necessity of the current usage.

2) If more than one beta-adrenergic or more than one anticholinergic inhalation drug is billed during the same month there must be clear documentation in the patient's medical records corroborating the medical necessity of this current use.

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, 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**

#### Levalbuterol

Ahrens R, Weinberger M. "Levalbuterol and racemic albuterol: Are there therapeutic differences?" *The Journal of Allergy and Clinical Immunology*; November 2001, Volume 108:681-684.

Asmus M, Hendeles L, Weinberger M, Ahrens R, Bisgaard H, Lötval J, O'Byrne P, Cockroft D. "Levalbuterol has not Been Established to Have Therapeutic Advantage over Racemic Albuterol". *The Journal of Allergy and Clinical Immunology*; August 2002, part 1, Volume 110, Number 2.

Carl J, Myers T, Kirchner H, Kerckmar C. "Comparison of Racemic Albuterol and

Levalbuterol for Treatment of Acute Asthma". *The Journal of Pediatrics*; December 2003, 143:731-736.

Chowdhury B. "Comparative efficacy of levalbuterol and racemic albuterol in the treatment of asthma". *The Journal of Allergy and Clinical Immunology*; August 2002, part 1, Volume 110, No. 2.

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Datta D, Vitale A, Lahiri B, ZuWallack R. "An Evaluation of Nebulized Levalbuterol in Stable COPD". *Chest*; September 2003; 124, 3:844-849.

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Emerman C, Nowak R, Claus R, Roach J, Baumgartner RA, Hanrahan JP. "Clinical Response to Levalbuterol (LEV) vs Racemic Albuterol (RAC) in Acute Asthma: Impact of (S)-Albuterol Levels". *American Journal of Respiratory Critical Care Med* 2004; 169:A310.

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Hendeles L, Hartzema A. "Levalbuterol Is Not More Cost-Effective Than Albuterol for COPD". *Chest* September 2003; 124, 3:1176-1178.

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Nelson H, Bensch G, Pleskow W, Disantostefano R, DeGraw S, Phil M, Reasner D, Rollins T, Rubin P. "Improved Bronchodilation with Levalbuterol Compared with Racemic Albuterol in Patients with Asthma". *The Journal of Allergy and Clinical Immunology* December 1998:943-952.

Nowak R, Emerman C, Claus R, Schaefer K, McVicar W, Hanrahan JP, Baumgartner RA. "Levalbuterol (LEV) vs Racemic Albuterol (RAC) in Acute Severe Asthma: A Prospective Trial". *American Journal of Respiratory Critical Care Medicine* 2004; 169:A310.

Nowak R, Emerman C, Schaefer K, Disantostefano R, Vaickus L, Roach J. "Levalbuterol Compared With Racemic Albuterol in the Treatment of Acute Asthma: Results of a Pilot Study". *American Journal of Emergency Medicine* January 2004; Vol. 22, No. 1:29-36.

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Scott V, Frazee L. "Retrospective Comparison of Nebulized Levalbuterol and Albuterol for Adverse Events in Patients With Acute Airflow Obstruction". *American Journal of Therapeutics* 2003; 10:341-347.

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Weinberger M. "Is There Any Advantage to Using Levalbuterol in the Treatment of Asthma?" *Clinical Pulmonary Medicine* May 2004; Vol. 11, No. 3:129-134.

#### **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**

#### **Revision History Number**

### **Revision History Explanation**

Revision Effective Date : To be determined

#### **INDICATIONS AND LIMITATIONS OF COVERAGE:**

Eliminated coverage for atropine, beclomethasone, betamethasone, bitolterol, dexamethasone, flunisolide, glycopyrrolate, terbutaline, and triamcinolone.

Added statement that levalbuterol will be paid comparable to albuterol.

Added statement that non-compounded combinations of albuterol and ipratropium will be paid comparable to separate unit dose vials.

#### **HCPCS Codes:**

Added J7640

#### **ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:**

Removed J7622, J7624, J7628, J7629, J7635, J7636, J7637, J7638, J7640, J7641, J7642, J7643, J7680, and J7681.

#### **ICD-9 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY:**

Added J7622, J7624, J7628, J7629, J7635, J7636, J7637, J7638, J7640, J7641, J7642, J7643, J7680, and J7681.

#### **SOURCES OF INFORMATION:**

Added bibliography for levalbuterol.

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.

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  
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

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.

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

#### **Last Reviewed On Date**

#### **Related Documents**

This LCD has no Related Documents.

#### **LCD Attachments**

There are no attachments for this LCD

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