

Local Coverage Determination (LCD) for Nebulizers (L5007)

Contractor Information

Contractor Name

[CGS Administrators, LLC opens in new window](#)

[Back to Top](#)

Contractor Number
18003

Contractor Type
DME MAC

LCD Information

Document Information

LCD ID Number
L5007

LCD Title
Nebulizers

Contractor's Determination Number
NEB

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Alabama
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New Mexico
Oklahoma
Puerto Rico
South Carolina
Tennessee
Texas
Virginia
Virgin Islands
West Virginia

Oversight Region
Region IV

DME Region LCD Covers
Jurisdiction C

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 08/05/2011

Revision Ending Date

CMS National Coverage Policy

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

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 local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, 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 reasonable and necessary.

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

- a. It is reasonable and 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 reasonable and necessary to administer dornase alpha (J7639) to a patient with cystic fibrosis (ICD-9 diagnosis code 277.02); or
- c. It is reasonable and 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 reasonable and necessary to administer pentamidine (J2545) to a patient with HIV (ICD-9 diagnosis code 042), pneumocystosis (ICD-9 diagnosis code 136.3), or complications of organ transplants (ICD-9 diagnosis codes 996.80-996.89); or
- e. It is reasonable and 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 reasonable and 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 reasonable and necessary.

A large volume nebulizer (A7007, A7017), related compressor (E0565 or E0572), and water or saline (A4217 or A7018) are covered when it is reasonable and 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 reasonable and 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).

A small volume ultrasonic nebulizer (E0574) and related accessories are reasonable and necessary to administer treprostinil inhalation solution only. Claims for code E0574 used with other inhalation solutions will be denied as not reasonable and necessary.

Treprostinil inhalation solution (J7686) and iloprost (Q4074) are covered when all of the following criteria 1-3 are met:

1. The patient has a diagnosis of pulmonary artery hypertension (ICD-9 diagnosis codes 416.0 or 416.8); and,

2. 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,
3. 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, anorexigens or congenital left to right shunts. 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 > 25 mm Hg at rest or > 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, code E0574 and the related drug (J7686 for treprostinil) or code K0730 and the related drug (Q4074 for iloprost) will be denied as not reasonable and necessary.

A controlled dose inhalation drug delivery system (K0730) is covered when it is reasonable and necessary to deliver iloprost (Q4074) to patients with pulmonary hypertension (ICD-9 diagnosis codes 416.0 or 416.8) only. Claims for code K0730 for use with other inhalation solutions will be denied as not reasonable and necessary.

A large volume ultrasonic nebulizer (E0575) offers no proven clinical advantage over a pneumatic compressor and nebulizer and will be denied as not reasonable and necessary.

ACCESSORIES:

Accessories are separately payable if the related aerosol compressor and the individual accessories are reasonable and necessary. The following table lists the compressor/generator, which is related to the accessories described. Other compressor/generator/accessory combinations are considered not reasonable and necessary.

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
E0572	A7006, A7014
E0574	A7013, 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 reasonable and necessary.

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

INHALATION DRUGS AND SOLUTIONS:

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

Inhalation Drugs and Solutions	Maximum Milligrams/Month
Acetylcysteine	74 grams/month
Albuterol	465 mg/month (See below for exception)
Albuterol/Ipratropium combination	186 units/month
Arformoterol	930 micrograms/month – 62 units/month
Budesonide	62 units/month
Cromolyn sodium	2480 mg/month – 248 units/month
Dornase alpha	78 mg/month
Formoterol	1240 micrograms/month – 62 units/month
Ipratropium bromide	93 mg/month
Levalbuterol	

	232.5 mg/month – 465 units/month (See below for exception)
Metaproterenol	2800 mg/month – 280 units/month (See below for exception)
Pentamidine	300 mg/month
Treprostinil	31 units/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:

Inhalation Drugs and Solutions	Maximum Milligrams/Month
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 reasonable and necessary.

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 reasonable and 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 reasonable and necessary if used for this purpose. These codes are only reasonable and 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 reasonable and 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 reasonable and 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 reasonable and 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 reasonable and necessary.

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

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products (A4619, A7003-A7017, A7525, all inhalation medications) that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. (CMS' Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a three (3)-month quantity at a time.

[Back to Top](#)

Coding Information

Bill Type Codes:

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

Revenue Codes:

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

CPT/HCPCS Codes

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

HCPCS MODIFIERS:

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

GA - Waiver of liability statement issued as required by payer policy, individual case

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

ACCESSORIES

A4619 FACE TENT
A7003 ADMINISTRATION SET, WITH SMALL VOLUME NONFILTERED PNEUMATIC NEBULIZER, DISPOSABLE
A7004 SMALL VOLUME NONFILTERED PNEUMATIC NEBULIZER, DISPOSABLE
A7005 ADMINISTRATION SET, WITH SMALL VOLUME NONFILTERED PNEUMATIC NEBULIZER, NON-DISPOSABLE
A7006 ADMINISTRATION SET, WITH SMALL VOLUME FILTERED PNEUMATIC NEBULIZER
A7007 LARGE VOLUME NEBULIZER, DISPOSABLE, UNFILLED, USED WITH AEROSOL COMPRESSOR
A7008 LARGE VOLUME NEBULIZER, DISPOSABLE, PREFILLED, USED WITH AEROSOL COMPRESSOR
A7009 RESERVOIR BOTTLE, NON-DISPOSABLE, USED WITH LARGE VOLUME ULTRASONIC NEBULIZER
A7010 CORRUGATED TUBING, DISPOSABLE, USED WITH LARGE VOLUME NEBULIZER, 100 FEET
A7011 CORRUGATED TUBING, NON-DISPOSABLE, USED WITH LARGE VOLUME NEBULIZER, 10 FEET
A7012 WATER COLLECTION DEVICE, USED WITH LARGE VOLUME NEBULIZER
A7013 FILTER, DISPOSABLE, USED WITH AEROSOL COMPRESSOR OR ULTRASONIC GENERATOR
A7014 FILTER, NONDISPOSABLE, USED WITH AEROSOL COMPRESSOR OR ULTRASONIC GENERATOR
A7015 AEROSOL MASK, USED WITH DME NEBULIZER
A7016 DOME AND MOUTHPIECE, USED WITH SMALL VOLUME ULTRASONIC NEBULIZER
A7017 NEBULIZER, DURABLE, GLASS OR AUTOCLAVABLE PLASTIC, BOTTLE TYPE, NOT USED WITH OXYGEN
A7525 TRACHEOSTOMY MASK, EACH
E0580 NEBULIZER, DURABLE, GLASS OR AUTOCLAVABLE PLASTIC, BOTTLE TYPE, FOR USE WITH REGULATOR
OR FLOWMETER
E1372 IMMERSION EXTERNAL HEATER FOR NEBULIZER

INHALATION DRUGS

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

ACETYLCYSTEINE, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED,
ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER GRAM

J7609 ALBUTEROL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT
DOSE, 1 MG

J7610 ALBUTEROL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME,
CONCENTRATED FORM, 1 MG

J7611 ALBUTEROL, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED,
ADMINISTERED THROUGH DME, CONCENTRATED FORM, 1 MG

J7612 LEVALBUTEROL, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED,
ADMINISTERED THROUGH DME, CONCENTRATED FORM, 0.5 MG

J7613 ALBUTEROL, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED,
ADMINISTERED THROUGH DME, UNIT DOSE, 1 MG

J7614 LEVALBUTEROL, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED,
ADMINISTERED THROUGH DME, UNIT DOSE, 0.5 MG

J7615 LEVALBUTEROL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME,
UNIT DOSE, 0.5 MG

J7620 ALBUTEROL, UP TO 2.5 MG AND IPRATROPIUM BROMIDE, UP TO 0.5 MG, FDA-APPROVED FINAL
PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME

J7622 BECLOMETHASONE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME,
UNIT DOSE FORM, PER MILLIGRAM

J7624 BETAMETHASONE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME,
UNIT DOSE FORM, PER MILLIGRAM

J7626 BUDESONIDE, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED,
ADMINISTERED THROUGH DME, UNIT DOSE FORM, UP TO 0.5 MG

J7627 BUDESONIDE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT
DOSE FORM, UP TO 0.5 MG

J7628 BITOLTEROL MESYLATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH
DME, CONCENTRATED FORM, PER MILLIGRAM

J7629 BITOLTEROL MESYLATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH
DME, UNIT DOSE FORM, PER MILLIGRAM

J7631 CROMOLYN SODIUM, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED,
ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 10 MILLIGRAMS

J7632 CROMOLYN SODIUM, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME,
UNIT DOSE FORM, PER 10 MILLIGRAMS

J7634 BUDESONIDE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME,
CONCENTRATED FORM, PER 0.25 MILLIGRAM

J7635 ATROPINE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME,
CONCENTRATED FORM, PER MILLIGRAM

J7636 ATROPINE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT
DOSE FORM, PER MILLIGRAM

J7637 DEXAMETHASONE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME,
CONCENTRATED FORM, PER MILLIGRAM

J7638 DEXAMETHASONE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME,
UNIT DOSE FORM, PER MILLIGRAM

J7639 DORNASE ALFA, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED,
ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM

J7640 FORMOTEROL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT
DOSE FORM, 12 MICROGRAMS

J7641 FLUNISOLIDE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT
DOSE, PER MILLIGRAM

J7642 GLYCOPYRROLATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME,
CONCENTRATED FORM, PER MILLIGRAM

J7643 GLYCOPYRROLATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME,
UNIT DOSE FORM, PER MILLIGRAM

J7644 IPRATROPIUM BROMIDE, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED,
ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM

J7645 IPRATROPIUM BROMIDE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH
DME, UNIT DOSE FORM, PER MILLIGRAM

J7647 ISOETHARINE HCL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME,
CONCENTRATED FORM, PER MILLIGRAM

J7650 ISOETHARINE HCL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME,
UNIT DOSE FORM, PER MILLIGRAM

J7657

ISOPROTERENOL HCL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM

J7660 ISOPROTERENOL HCL, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM

J7667 METAPROTERENOL SULFATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, CONCENTRATED FORM, PER 10 MILLIGRAMS

J7669 METAPROTERENOL SULFATE, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 10 MILLIGRAMS

J7670 METAPROTERENOL SULFATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 10 MILLIGRAMS

J7676 PENTAMIDINE ISETHIONATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 300 MG

J7680 TERBUTALINE SULFATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM

J7681 TERBUTALINE SULFATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM

J7682 TOBRAMYCIN, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, UNIT DOSE FORM, ADMINISTERED THROUGH DME, PER 300 MILLIGRAMS

J7683 TRIAMCINOLONE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM

J7684 TRIAMCINOLONE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM

J7685 TOBRAMYCIN, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER 300 MILLIGRAMS

J7686 TREPROSTINIL, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, 1.74 MG

J7699 NOC DRUGS, INHALATION SOLUTION ADMINISTERED THROUGH DME

Q0513 PHARMACY DISPENSING FEE FOR INHALATION DRUG(S); PER 30 DAYS

Q0514 PHARMACY DISPENSING FEE FOR INHALATION DRUG(S); PER 90 DAYS

Q4074 ILOPROST, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON-COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, UP TO 20 MICROGRAMS

ICD-9 Codes that Support Medical Necessity

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

For HCPCS codes A4619, E0565, E0572:

[011.50 - 011.56 opens in new window](#) TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION - TUBERCULOUS BRONCHIECTASIS TUBERCLE BACILLI NOT FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER METHODS (INOCULATION OF ANIMALS)

042 HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE

136.3 PNEUMOCYSTOSIS

277.02 CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS

494.0 BRONCHIECTASIS WITHOUT ACUTE EXACERBATION

494.1 BRONCHIECTASIS WITH ACUTE EXACERBATION

519.19 OTHER DISEASES OF TRACHEA AND BRONCHUS

748.61 CONGENITAL BRONCHIECTASIS

[996.80 - 996.89 opens in new window](#) COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN

V44.0 TRACHEOSTOMY STATUS

V55.0 ATTENTION TO TRACHEOSTOMY

For HCPCS codes A7015, A7525:

[011.50 - 011.56 opens in new window](#) 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 opens in new window	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 opens in new window	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:

011.50 - 011.56 opens in new window	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 opens in new window	PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY CONDITIONS DUE TO UNSPECIFIED EXTERNAL AGENT
748.61	CONGENITAL BRONCHIECTASIS
786.4	ABNORMAL SPUTUM
996.80 - 996.89 opens in new window	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 opens in new window	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 opens in new window	TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION - TUBERCULOUS BRONCHIECTASIS TUBERCLE BACILLI NOT FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER METHODS (INOCULATION OF ANIMALS)
277.02	CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS
494.0	BRONCHIECTASIS WITHOUT ACUTE EXACERBATION
494.1	BRONCHIECTASIS WITH ACUTE EXACERBATION
519.19	OTHER DISEASES OF TRACHEA AND BRONCHUS
748.61	CONGENITAL BRONCHIECTASIS
V44.0	TRACHEOSTOMY STATUS
V55.0	ATTENTION TO TRACHEOSTOMY

For HCPCS code A4216:

042	HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE
136.3	PNEUMOCYSTOSIS
491.0 - 508.9 opens in new window	SIMPLE CHRONIC BRONCHITIS - RESPIRATORY CONDITIONS DUE TO UNSPECIFIED EXTERNAL AGENT
996.80 - 996.89 opens in new window	COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN

For HCPCS code J7608:

480.0 - 508.9 opens in new window	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 opens in new window](#)

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 opens in new window](#)

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 A7016, E0574, J7686, K0730, Q4074:

416.0 PRIMARY PULMONARY HYPERTENSION

416.8 OTHER CHRONIC PULMONARY HEART DISEASES

For HCPCS code A7005:

[011.50 -](#)

[011.56 opens in new window](#)

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 opens in new window](#) PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY CONDITIONS DUE TO UNSPECIFIED EXTERNAL AGENT

748.61 CONGENITAL BRONCHIECTASIS

786.4 ABNORMAL SPUTUM

[996.80 -](#)

[996.89 opens in new window](#)

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

For HCPCS code A7013, A7014:

[011.50 -](#)

[011.56 opens in new window](#)

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

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[480.0 - 508.9 opens in new window](#) 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 opens in new window](#)

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

V44.0 TRACHEOSTOMY STATUS

V55.0 ATTENTION TO TRACHEOSTOMY

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.

[Back to Top](#)

General Information

Documentations Requirements

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

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

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

Examples of (a) would be: albuterol 0.083% 3 ml; or albuterol 0.5% 20 ml; or cromolyn 20 mg/2 ml. An example of (b) is: albuterol 1.25 mg in 3 ml saline. For compounded inhalation solutions, the order must include the following statement prior to signature by the physician: compounded inhalation solution – not FDA-approved.

Administration instructions must specify the amount of solution and specific frequency of use. As noted in the Program Integrity Manual (Internet-Only Manual, Pub. 100-8), Chapter 5, Section 5.9 "...do not accept 'PRN' or 'as needed' utilization estimates for supply replacement, use, or consumption." For orders that include "PRN" or "as needed", reimbursement will be based on the specified frequency of use on the order only.

REFILLS

A routine refill prescription is not needed. A new prescription is needed when:

- There is a change of supplier
- There is a change in treating physician
- There is a change in the item(s), frequency of use, or amount prescribed

- There is a change in the length of need or a previously established length of need expires
- State law requires a renewal

For items that the patient obtains in person at a retail store, the signed delivery slip or copy of itemized sales receipt is sufficient documentation of a request for refill.

For items that are delivered to the beneficiary, documentation of a request for refill must be either a written document received from the beneficiary or a contemporaneous written record of a phone conversation/contact between the supplier and beneficiary. The refill request must occur and be documented before shipment. A retrospective attestation statement by the supplier or beneficiary is not sufficient. The refill record must include:

- Beneficiary's name or authorized representative if different than the beneficiary
- A description of each item that is being requested
- Date of refill request
- Quantity of each item that the beneficiary still has remaining

This information must be kept on file and be available upon request.

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 E0574, J7686, K0730 and Q4074 only if all of the criteria in the Indications and Limitations of Coverage and/or Medical Necessity section of this policy have been met.

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

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

MISCELLANEOUS

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

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

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

Appendices

Utilization Guidelines Refer to Indications and Limitations of Coverage and/or Medical Necessity

Sources of Information and Basis for Decision
Advisory Committee Meeting Notes

Start Date of Comment Period 03/24/2006

End Date of Comment Period 05/08/2006

Start Date of Notice Period 04/10/2008

Revision History Number 010

Revision History Explanation 08/27/2011 - This policy was updated by the ICD-9 2011-2012 Annual Update.

08/05/2011 - The Jurisdiction C contractor adopted a new business name. This LCD revision only includes the change from CIGNA Government Services to CGS Administrators, LLC. No coverage information was included in this revision and no provider action is needed regarding this revision.

Revision Effective Date: 08/02/2011

INDICATIONS AND LIMITATIONS OF COVERAGE:

Revised: Refills information

DOCUMENTATION SECTION:

Added: Refills documentation information

Deleted: Statement requiring routine prescription every 12 months

Revision Effective Date: 02/04/2011

ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:

Revised: Diagnosis sets containing A7013 and A7014 and created separate diagnosis set for A7013 and A7014

DOCUMENTATION REQUIREMENTS:

Added: Clerical correction to restore prohibition on "prn" or "as needed" orders

Revision Effective Date: 02/04/2011

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added: Coverage for treprostinil inhalation solution (Effective 1/1/2011)

Revised: Coverage of E0574, E0575

Deleted: References to code E0571

HCPCS CODES AND MODIFIERS (Effective 1/1/2011):

Added: J7686

Revised: J7013

Revised: GA modifier

Deleted: E0571

ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:

Added: A7013, A7014, A7016, E0574, J7686 to pulmonary hypertension ICD-9 code

Deleted: Code E0574 from COPD code set

Deleted: Code E0571

11/21/2010 - For the following CPT/HCPCS codes either the short description and/or the long description was changed. Depending on which description is used in this LCD, there may not be any change in how the code displays in the document:

A7013 descriptor was changed in Group 2

09/06/2010 - This policy was updated by the ICD-9 2010-2011 Annual Update.

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

11/15/2009 - CPT/HCPCS code Q4080 was deleted from group 3

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

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:

Added: Code J7606 (formoterol fumarate)

Deleted: Code Q4099 (formoterol fumarate)

11/09/2008 - CPT/HCPCS code Q4099 was deleted from group 3

11/09/2008 - The description for CPT/HCPCS code J7611 was changed in group 3

11/09/2008 - The description for CPT/HCPCS code J7613 was changed in group 3

11/09/2008 - The description for CPT/HCPCS code J7614 was changed in group 3

11/09/2008 - The description for CPT/HCPCS code J7639 was changed in group 3

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

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

INDICATIONS AND LIMITATIONS OF COVERAGE:

Removed: Least costly alternative statement for levalbuterol

Revised: Effective date for implementation of least costly alternative statement for albuterol/ipratropium combination (DuoNeb – J7620)

Removed: Bibliography references to levalbuterol

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

NATIONAL COVERAGE POLICY:

Added: NCD 200.2

INDICATIONS AND LIMITATIONS OF COVERAGE:

Substituted: J7611-J7614 for Q4093, Q4094

Added: Q4099 as a new code for formoterol

Added: Coverage criteria and maximum covered amount for formoterol.

Added: J7604, J7632, and J7676 to the list of compounded drugs that are not covered.

Added: Statement about denial if both formoterol and arformoterol are provided

Added: Least costly alternative statement for levalbuterol.

Added: Least costly alternative statement for unit dose combinations of albuterol and ipratropium.

Revised: Coverage criteria for arformoterol.

Revised: Statements concerning use of rescue medication to include use with formoterol.

HCPCS CODES AND MODIFIERS:

Added: J7604, J7605, J7632, J7676 (effective 1/1/08)

Added: J7611, J7612, J7613, J7614, Q4099 (effective 4/1/08)

Revised: J2545, J7608, J7631, J7639, Q4080 (effective 1/1/08)

Deleted: Q4093, Q4094 (effective 1/1/08)

(Note: Codes J7602 and J7603 were effective 1/1/08 – 3/31/08.)

ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:

Added: J7605, J7611-J7614, Q4099

Removed: Q4093, Q4094

Added: Covered diagnosis codes for formoterol.

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

Added: J7604, J7632, J7676

DOCUMENTATION REQUIREMENTS:

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

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

SOURCES OF INFORMATION/ BASIS FOR DECISION:

Added: Bibliography

LCD ATTACHMENTS:

Response to Comments – April 2008

Revision Effective Date: 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:

Added: Q4093, Q4094

Deleted: J7611, J7612, J7613, J7614

ICD-9 CODES THAT SUPPORT MEDICAL NECESSITY:

Added: Q4093, Q4094

Deleted: J7611, J7612, J7613, J7614

Added: Covered diagnosis codes for arformoterol.

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

Removed: J7699 from the list.

DOCUMENTATION REQUIREMENTS:

Added: Instructions for use of the KX modifier with arformoterol.

Revision Effective Date: 07/01/2007 (March publication)

INDICATIONS AND LIMITATIONS OF COVERAGE:

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

Changed: ICD-9 code 519.1 to 519.19.

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

Added: Utilization guideline for budesonide.

HCPCS CODES AND MODIFIERS:

(HCPCS code changes 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).

Revision Effective Date: 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.

Revision Effective Date: 10/01/2005
HCPCS CODES & 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 & 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

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 Maintenance (annual review with new changes, formatting, etc.)

Related Documents

Article(s)

[A24623 - Nebulizers - Policy Article - Effective - August 2011 opens in new window](#)

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[Back to Top](#)

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