Nebulizers and Related Drugs

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan 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. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. 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.

Suppliers are to follow The Health Plan requirements for precertification as applicable.

Nebulizers do not require precertification unless requesting over the allowable limits for Medicare, Medicaid, Commercial plans. Per ACA 6407 guidelines requires a physician face-to-face.

Reimbursement of rental or purchase will be based on acute versus chronic diagnoses per the information below. This includes Mountain Health Trust and D-SNP plans.

Reimbursement and/or coverage of some codes may be subject to specific contract information.

National Coverage Determination Policy	CMS Publication 100-3 Medicare National Coverage Determinations Manual, Chapter 1, Section 200.2, 280.1
Local Coverage Determination Policy	J- B/C
Effective Date	For services performed on or after: 10/31/13
Review/Revisions Effective Date	01/19, 10/18, 06/05/2018, 06/01/16, 12/2015, 10/31/13
The Health Plan	Will follow Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy or contractual agreement

DESCRIPTION

There are several devices used to reduce liquid medication to fine cloudlike particles useful in delivering inhaled medication to deeper parts of the respiratory tract. The medical indications range from asthma

and chronic bronchitis to more severe respiratory conditions such as cystic fibrosis or pulmonary hypertension.

For purposes of this policy, the actual equipment (i.e. electrical device) will be referred to as either a compressor (when nebulization of liquid is achieved by means of air flow) or 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 the liquid occurs and is an accessory to the base equipment.

The nebulizer is attached to an aerosol compressor or an ultrasonic generator in order to achieve a functioning delivery system for the aerosol therapy.

COVERAGE GUIDELINES

Small Volume Nebulizer (A7003, A7004, and A7005), related compressor (E0570) and FDA approved inhalation drugs are considered medically necessary and are covered for the following:

a. **Obstructive pulmonary disease**, used to administer: albuterol, afromoterol, budesonide, cromolyn, formoterol, ipratropium, levalbuterol or metaproterenol (Short acting beta-adrenergic agonist inhalation solutions), or
b. **Cystic fibrosis,** used to administer dornase alpha, or
c. **Bronchiectasis** or **Cystic fibrosis** used to administer tobramycin, or
d. **HIV** patients, **pneumocystosis** ,or complications of an **organ transplant** used to administer pentamidine, or
e. Persistent, **thick or tenacious pulmonary secretions,** used to administer acetylcysteine.

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

Large Volume Nebulizer (A7007 and A7017) related compressor (E0565, E0572) and water or saline solutions (A4217 or A7018) are covered when medically necessary to deliver humidity to a patient with thick, tenacious secretions, who has cystic fibrosis, bronchiectasis, a tracheostomy or a tracheobronchial stent.

An E0565 or E0572 compressor and filtered nebulizer A7006 are also covered when it is medically necessary to administer pentamidine to patients with HIV, pneumocystosis, or complications of organ transplant.

NOTE: The combination code **E0585** (nebulizer with compressor and heater) will be covered for the same indications as a large volume nebulizer (A7007 and A7017).

Small Volume Ultrasonic/Electronic Nebulizer (E0574) is covered to administer treprostinil inhalation solution only. It will be denied when used with other inhalation solutions.

NOTE: Effective 04/01/2011, Medicare has stated that the only products that may be billed using E0574 are those for which a written coding verification has been made by the PDAC and are listed in the product classification matrix. Products that were listed on the DMECS prior were end dated 12/31/10.

https://www.dmepdac.com/dmecsapp/

dmepdac.com/review/apps_check.html

NOTE: Whether or not a nebulizer is reimbursed as a purchased or rental item will be based on diagnosis codes. Chronic diagnoses will be reimbursed as a purchase and temporary, acute diagnosis, for example: pneumonia, will be reimbursed as a rental.

INHALATION SOLUTION COVERAGE GUIDELINES

Treprostinil Inhalation Solution Yyvaso® (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; 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.

Controlled Dose Inhalation Drug Delivery System (K0730) is covered to deliver iloprost (Q4074) to patients with pulmonary hypertension only.

COVERAGE GUIDELINES FOR ACCESSORIES

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

Compressor/Generator	Related Accessories
E0565	A4619, A7006, A7007, A7010, 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	A7013, A7014, A7016
E0585	A4619, A7006, A7010, 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. Requests for more than the usual maximum replacement amount without clinical support from the medical record will be denied.

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
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

NOTE: 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 the supply on hand, prior to dispensing a new supply. Likewise, the patient should always have a supply on hand equal to the medical indications for their condition.

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 & 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 per month – 62 units per month is allowed twice per day for total of 30 mcg/day (2 units/day), each unit =15mcg.
Cromolyn Sodium	2480 mg / month – 248 units / month
Dornase Alpha	78 mg / month
Formoterol	1240 micrograms per month – 62 units per month
Ipratropium Bromide	93 mg / month
Levalbuterol	232.5 mg / month – 465 units / month (see below for exception)
Metaproterenol	2800 mg / month – 280 units per month (see below for exception)
Pentamidine	300 mg / month
Sterile saline or water, 10ml/unit (A4216, A4218)	56 units / month
Budesonide	62 units per month
Distilled water, sterile water, or sterile saline in large volume nebulizer	18 liters / month
Treprostinil	31 units/month

If providers have questions concerning the allowable limits on medication, they should contact The Health Plan Pharmacy Department.

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:

Drug	Maximum Milligrams/Month
Albuterol	78 mg / month
Albuterol / Ipratroprium 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 require precertification and may be denied as not meeting reasonable and necessary guidelines.

NONCOVERAGE STATEMENT

Only one type of nebulizer will be coved at any one time, the type of nebulizer, which best suits the patient's needs based on the above coverage criteria.

A large volume ultrasonic nebulizer **(E0575)** offers no proven clinical advantage over a pneumatic compressor. Therefore, when an E0575 nebulizer is provided, it will be denied along with any related accessories and supplies.

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

If the drugs used for any covered nebulizers are not from the list of covered drugs, the nebulizers and accessories will not be covered.

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

Aztreonam lysine is an inhalation solution that is indicated for patients with cystic fibrosis with chronic pseudomonas aeruginosa infection. Because it has been determined that the nebulizer that is FDA-approved for administration of aztreonam lysine is not sufficiently durable to meet the statutory requirements for coverage under the DME benefit, claims for that nebulizer, aztreonam lysine inhalation solution, and related accessories will be denied as not covered. Aztreonam lysine is FDA-approved for administration only with the **Altera® (Pari) nebulizer**. It has been determined that the **Altera nebulizer is not sufficiently durable to meet the statutory requirements for coverage under the DME benefit.** This item must be coded and billed using HCPCS code **A9270**, noncovered item or service. **Aztreonam Lysine (Cayston®) Inhalation Solution – Coding and Coverage (A50218)**

Disposable equipment or equipment where the major component required is disposable is **noncovered**, as they do not meet the definition of durable medical equipment. Providers are to code **A9270**.

The use of nebulizers to administer morphine or other opioids is considered experimental and investigational for the relief of cancer-related dyspnea, or dyspnea in persons with COPD because the effectiveness of this approach has not been established.

The use of nebulizers to administer corticosteroids for the treatment of nasal polyps, including the pre- and post-polypectomy periods, experimental and investigational because of insufficient evidence supporting use over other established forms of nasal corticosteroid administration (e.g., nasal spray, metered-dose nasal inhaler).

The use of nebulizers to administer lidocaine for the treatment of chronic cough as it is considered experimental and investigational based on peer review of available literature.

The **TOBI PODHALER ™** A disposable hand held medication dispenser used for the inhalation of tobramycin. It includes both the device and tobramycin capsules (J7682). It is not considered a nebulizer or other DME item and must not be billed as such. It must be billed using A9270.

REPAIR, REPLACEMENT AND REASONABLE USEFUL LIFETIME

Replacements and repairs require precertification. See **Replacement and Repair** policy.

Repairs are not separately payable during rental period.

Replacements are not covered due to neglect or misuse.

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 ISSUED AS REQUIRED BY PAYOR POLICY, INDIVIDUAL CASE
GZ	ITEM OR SERVICE EXPECTED TO BE DENIED AS NOT REASONABLE AND NECESSARY
JW	DRUG AMOUNT DISCARDED/NOT ADMINISTERED TO ANY PATIENT
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
	NOTE: WHENEVER A UNIT DOSE DRUG IS BILLED, IT MUST HAVE EITHER A KO, KP OR KQ MODIFIER (THESE MODIFIERS SHOULD NOT BE USED W/J7620)
	NOTE: MEDICARE HAS SPECIFIC GUIDELINES FOR THE APPROPRIATE AND REQUIRED USE OF THIS MODIFIER. THESE ARE LISTED AT THE END OF THIS POLICY. THEY MAY OR MAY NOT APPLY WHEN COORDINATING BENEFITS FOR MEMBERS WHO HAVE MEDICARE AS PRIMARY

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

HCPCS CODES
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
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

HCPCS INHALATION CODES

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
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, 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, NONCOMPOUNDED, ADMINISTERED THROUGH DME, 1.74 MG
J7699	NOC DRUGS, INHALATION SOLUTION ADMINISTERED THROUGH DME
Q0513	PHARMACY DISPENSING FEE FOR INHALATION DRUG(S); PER 30 DAY
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-10 CODES THAT SUPPORT MEDICAL NECESSITY

The presence of an ICD-10 code listed in this section is not sufficient by itself to assure coverage, nor does it indicate reimbursement type (rental or purchase). They must have a covered respiratory diagnosis. Refer to coverage guidelines and documentation requirements for further information.

Examples of covered chronic diagnoses: Pseudomonas, HIV, Pneumocystosis, Cystic fibrosis, Primary pulmonary hypertension, Other chronic pulmonary hypertension, chronic obstructive pulmonary disease, asthma, tracheostomy complications, bronchiectasis, complications of a transplant.

Short term diagnosis such as pneumonia will be reviewed on a case by case basis ad may not be covered.

Also, please be careful to request appropriate device for the specific diagnosis. For example Codes A4619, E0565, and E0572 are not covered for the diagnosis of asthma.

For a complete list, please refer to the following website for the covered ICD 10 codes: https://www.cms.gov/medicare-coverage-database/details/lcd details.aspx?LCDId=33370&ContrID=140

DOCUMENTATION REQUIREMENTS

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes 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 with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
    a. Member's name
    b. Date
    c. Description of item. The medical record must contain the information that supports the request for each item and must be submitted with the precertification, if the item requires precertification, or with the claim, if no precertification was required
    d. Order must include diagnosis code
    e. Physician signature with date. Date stamps are not appropriate
    f. Quantity of items required and duration. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used

    The supplier is to contact The Health Plan in this instance to update referral

2. There must be documentation in the supplier's records to support the medical necessity of that type of device. This information but must be available upon request usually with precertification per The Health Plan policy.

3. Proof of delivery to be kept on file by the provider of the item.

    Note: If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, and home health records.

    Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

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

Examples of (a) would be: albuterol 0.083% 3 ml; or albuterol 0.5% 20 ml; or cromolyn 20 mg/2 ml. An example of (b) is: albuterol 1.25 mg in 3 ml saline. For compounded inhalation solutions, the order must include the following statement prior to signature by the physician: compounded inhalation solution – not FDA-approved. Administration instructions must specify the amount of solution and frequency of use. "PRN" and "as needed" are not acceptable usage estimates for supply replacement. Reimbursement will be based on the specified frequency indicated in order.

New prescription required when:

1. Change in supplier
2. Change in ordering physician
3. Change in prescription
4. When required by state law

Providers are to have all the necessary orders and information on file prior to dispensing medication. An ICD-9 code describing the condition which necessitates nebulizer therapy must be included on each claim for equipment, accessories, and/or drugs.

NEBULIZER PROVIDED WHILE MEMBER IN A PART A FACILITY

Nebulizers provided while member is receiving treatment in a Part A inpatient level of care is the responsibility of that facility per most The Health Plan contracts as it is considered respiratory care.

EQUIPMENT RETAINED FROM A PRIOR PAYOR:

The Health Plan will not pay in excess of the contracted purchase price for any item in this policy. If the provider is seeking payment from The Health Plan, the item must be precerted and The Health Plan will pay the remaining rental months up to purchase price- if member meets guidelines above.

DISPENSING SUPPLIES

The Health Plan is following Medicare guidelines for supplies provided on reoccurring basis.

Suppliers are not to automatically dispense supplies according to allowable limits. Suppliers are required to reorder supplies based on actual usage of each member. There must be a specific request for the supplies from the member or caregiver prior to dispensing the supplies. Supplies should not be shipped/delivered sooner than 10 days prior to end of usage. *Please refer to CMS Program Integrity Manual for more information.* (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

The DME supplier is responsible to monitor utilization of rented and covered frequently purchase supplies for member owned equipment that they would be requesting reimbursement from The Health Plan.

Utilization above the current allowable quantities will not be reimbursed unless corroborated by medical record of the medical necessity of the quantity of supplies being used.

BILLING GUIDELINES

HCPCS codes E0565, E0570, E0572, E0585, A4619, A7003, A7004, A7005, A7006, A7007, A7012, A7013, A7014, A7015, A7017, A7525, and E1372 are included in the rental rate of Home ventilator E0467 and separate payment will not be made.

The Health Plan is following the following Medicare billing guidelines across all lines of business where it does not conflict with the member's benefit plan. The Health Plan will only cover one nebulizer within the reasonable useful lifetime limits.

When code **E1399** is going to be billed for miscellaneous equipment or accessories, it requires precertification with description of item, manufacturer's invoice, and the reason another specific HCPCS code is not applicable.

The **Optineb® ir (Nebu-tec)** is a nebulizer used to administer treprostinil inhalation should be billed with code E0574 (ultrasonic nebulizer). Because E0574 is in the capped rental category, in order for it to be paid it must be billed as a rental (RR modifier). **If the Optineb® ir nebulizer is billed as a purchase (NU modifier), it will be denied and the drugs and accessories will also be denied.** The submitted charge for code E0574 should just reflect the charges for the nebulizer - not the drug or accessories.

If two ultrasonic nebulizers are provided and the submitted charges reflect two nebulizers, you must bill two units of service on the claim line for E0574RR. **The Health Plan will only pay for one nebulizer. Please refer to PDAC for those devices approved for coding as E0574.**

Accessories used in conjunction with the ultrasonic nebulizer should be billed on separate claim lines. The dome and mouthpiece should be billed with code A7016. Other accessories should be billed with code A9999. When code A9999 is used, the claim must clearly describe the type and quantity of accessories provided.

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 were 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 an 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.

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 a compounded product. Please contact The Health Plan Pharmacy Department or The Heath Plan pharmacy benefits manager for questions concerning compound drugs.

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.

HCPCS code **J7999** (COMPOUNDED DRUG, NOT OTHERWISE CLASSIFIED) does not apply to compounded nebulizer drugs. Use the specific compounded drug HCPCS code listed in the HCPCS CODES.

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 medically necessary when used in a large volume nebulizer (A7007, A7017, or E0585).

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. 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 reasonable and necessary

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 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.**

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 for review.

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

Refer to Medicare's Supplier Manual for more information on documentation requirements.

- Please refer to The Health Plan's Pharmacy Department if you have any questions regarding compounded drugs.
- Approved drugs used with a nebulizer are covered under the member's medical benefit, but the drugs must be obtained through The Health Plan's pharmacy benefit manager. Questions regarding covered/approved drugs used with a covered nebulizer should be addressed to the Pharmacy Department.

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

There is not a separate fee for the compounding of inhalation drug(s).

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 coverage guidelines, documentation requirements, and billing guidelines are met.

If all of the criteria are not 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.

ADVANCED BENEFICIARY NOTICE

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

NOTE: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health

Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare's PDAC contractor for review of authorizations. Please refer to PDAC website for the appropriate product classification list. dmepdac.com/

MEDICARE DEFINITIONS AND DESCRIPTION

DISPENSING FEE: Refers to Medicare plan types and members where The Health Plan may be secondary to Medicare. For other plan types, please check specific contract or plan documents for coverage. It is also dependent on specific provider contract language.

If code is allowed, the dispensing fee is only payable to the provider that actually dispenses the drug.

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.

Code **G0333** is only allowed once per lifetime as the initial 30-day dispensing fee. **Subsequent 30-day dispensing fees** are coded Q0513.

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).

For a refill prescription, payment of a dispensing fee will be allowed no sooner than seven 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 1.30.06 and is covered and there is a subsequent claim for a 30-day fee (Q0513) on 4.20.06, the dispensing fee on 4.20.06 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.

Pneumatic compressor nebulizers use air flow to nebulize a liquid.

Ultrasonic or electronic nebulizers use a vibrating mechanism.

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 AC, DC–powered, or both.

A **portable compressor** (E0571) is an aerosol compressor, which delivers a fixed, low pressure and used with a small volume nebulizer. It is no longer valid for submission as of 2.1.11.

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. **Aerosolization** of the inhalation solution occurs in a nebulization chamber by means of a vibrating mechanism such as a vibrating disk, pizo-electric device or vibrating mesh. As previously stated please refer to PDAC to verify that product requested now meets guidelines to be billed as code E0574.

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 A7016 describes the dome and mouthpiece containing the aerosolization mechanism for an ultrasonic /electronic nebulizer system.

AMA CPT/ADA CDT COPYRIGHT STATEMENT

INTERNET LINKS AND SOURCES

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