

Appendix A

Includes the following information from the Local Coverage Determination (LCD): NEBULIZERS (L33370)

<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33370&ver=14&SearchType=Advanced&CoverageSelection=Local&ArticleType=SAD%7cEd&PolicyType=Both&s=All&CntrctrType=10&Keyword=nebulizers&KeywordLookup=Doc&KeywordSearchType=Exact&kq=true&bc=IAAAACAAAAAAAA%3d%3d&>

1. Examples of Pulmonary/Lung Diseases Supporting Use of Nebulized FDA-Approved Drugs
2. FDA-Approved Nebulizers/Related Compressors-Accessories
3. FDA-Approved Inhalation Drugs/Related Nebulizers/Related Compressors-Accessories
4. Maximum Milligrams/Month in Dosing of FDA-Approved Inhalation Drugs
5. Usual Maximum Replacement for the FDA-Approved Accessory
6. Compounded/Non-FDA-Approved Inhalation Drugs - Not Covered by Medicare

Diagnosis	Compressor/ Generator	Related Accessories	FDA Approved Inhalation Solution(s)	Comments
Obstructive Pulmonary Disease (J41.0 – J70.9)	E0570	Small Volume Nebulizer A7003, A7004, A7005	albuterol (J7611, J7613) arformoterol (J7605) budesonide (J7626) cromolyn (J7631) formoterol (J7606) ipratropium (J7644) levalbuterol (J7612, J7614) metaproterenol (J7669)	
Cystic Fibrosis (E84.0)	E0570	Small Volume Nebulizer A7003, A7004, A7005	dornase alpha (J7639) tobramycin (J7682) acetylcysteine (J7608)	
Bronchiectasis 2° (A15.0, J47.0, J47.1, J47.9,	E0570	Small Volume Nebulizer A7003, A7004,	tobramycin (J7682)	

DRAFT

Q33.4)		A7005		
HIV, pneumocystosis, or complications of organ transplants (B20 and B59) (T86.00 – T86.99)	E0570	Small Volume Nebulizer A7003, A7004, A7005	pentamidine (J2545)	
Persistent thick or tenacious pulmonary secretions (A22.1, A37.01 – A37.91, A48.1, B25.0, B44.0, B77.81, E84.0, J09.X1 – J09.9X, J10.00 – J10.2, J10.81 – J10.89, J11.00, J11.08, J11.1, J11.2, J11.81 – J11.89, J12.0 – J12.3, J12.81, J12.89, J12.9, J13, J14, J15.0, J15.1, J15.20 – J15.29, J15.3 – J15.9, J16.0, J16.8, J18.0, J18.8, J18.9, J40 – J47.9, J60 – J69.8, J70.0 – J70.9)	E0570	Small Volume Nebulizer A7003, A7004, A7005	acetylcysteine (J7608)	
Thick, tenacious secretions, who has cystic fibrosis, bronchiectasis, a tracheostomy, or a tracheobronchial stent (A15.0, E84.0, J39.8, J47.0, J47.1, J47.9, J98.00, Q33.4, Z43.0, Z93.0)	E0565 E0572 Combination code E0585 (Also covered)	Large Volume Nebulizer A7007, A7017 and Water or Saline A4217, A7018	Acetylcysteine (J7608)	E0575 <i>No proven clinical advantage over a pneumatic compressor and nebulizer</i>
HIV, pneumocystosis, or complications of organ transplants (A15.0, B20 and B59) (E84.0, J39.8, J47.0, J47.1, J47.9, J98.09, Q33.4, T86.00 – T86.40)	E0565 or E0572	Filtered Nebulizer A7006	pentamidine (J2545)	

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Pulmonary Artery Hypertension	E0574	A7014, A7016	treprostinil (J7686)	Covered when all of the following criteria 1-3 listed below are met:
Pulmonary Artery Hypertension	K0730	A7005	Loprost (Q4074)	
<p>1. <i>The beneficiary has a diagnosis of pulmonary artery hypertension (Applicable Diagnosis Codes that Support Medical Necessity:</i></p> <ul style="list-style-type: none"> • <i>I27.0 Primary pulmonary hypertension</i> • <i>I27.2 Other secondary pulmonary hypertension</i> • <i>I27.89 Other specified pulmonary heart diseases); and</i> 				
<p>2. <i>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</i></p>				
<p>3. <i>The beneficiary has primary pulmonary hypertension or pulmonary hypertension which is secondary to one of the following conditions:</i></p> <ul style="list-style-type: none"> • <i>connective tissue disease,</i> • <i>thromboembolic disease of the pulmonary arteries,</i> • <i>human immunodeficiency virus (HIV) infection,</i> • <i>cirrhosis,</i> • <i>diet drugs</i> • <i>anorexigens, or congenital left to right shunts.</i> <p><i>If these conditions are present, the following criteria (a-d) must be met:</i></p> <p><i>a. The pulmonary hypertension has progressed despite maximal medical and/or surgical treatment of the identified condition; and</i></p> <p><i>b. The mean pulmonary artery pressure is > 25 mm Hg at rest or > 30 mm Hg with exertion; and</i></p> <p><i>c. The beneficiary has significant symptoms from the pulmonary hypertension (i.e., severe dyspnea on exertion, and either fatigability, angina, or syncope); and</i></p> <p><i>d. Treatment with oral calcium channel blocking agents has been tried and failed, or has been considered and ruled out.</i></p>				
<p><i>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.</i></p> <p><i>A controlled dose inhalation drug delivery system (K0730) is covered when it is reasonable and necessary to deliver iloprost (Q4074) to beneficiaries with pulmonary hypertension only. (Applicable Diagnosis Codes that Support Medical Necessity:</i></p> <ul style="list-style-type: none"> • <i>I27.0 Primary pulmonary hypertension</i> • <i>I27.2 Other secondary pulmonary hypertension</i> • <i>I27.89 Other specified pulmonary heart diseases) ;).</i> <p><i>Claims for code K0730 for use with other inhalation solutions will be denied as not reasonable and necessary.</i></p>				

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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, A7012, A7013, A7014, A7015, A7017, A7525, E1372
E0570	A7003, A7004, A7005, A7006, A7013, A7015, A7525
E0572	A7006, A7014
E0574	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.

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

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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
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 beneficiaries 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.

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,

DRAFT

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.

Non-Coverage

- Large volume pneumatic nebulizer (E0580) and water or saline used with oxygen equipment
- Prefilled disposable large volume nebulizer (A7008)
- Albuteral, levalbuterol and metaproterenol used at the same time
- Formoterol and arformoterol used at the same time
- Albuterol sulfate (J7611, J7613), levalbuterol and /or inotropium bromide (J7644) billed with J7620