

Policy Number: M-0033

Nebulized Medications

Payment will not be made for any use of these drugs outside of the criteria without prior authorization. The member may not be billed unless the member explicitly agrees in writing to be responsible for the charges in accordance with the contract/provider manual. Prior authorization will only be given if the provider demonstrates the intended use meets Medicare coverage guidelines.

Coding Information:

HCPCS Codes

Inhalation Drugs

| innalation Drugs | | |
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| 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- | |
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Page | 1



| | 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 |
| 37022 | 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 |
| | BITOLTEROL MESYLATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED |
| J7628 | THROUGH DME, CONCENTRATED FORM, PER MILLIGRAM |
| J7629 | BITOLTEROL MESYLATE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED |
| 37029 | THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM |
| J7631 | CROMOLYN SODIUM, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON- |
| 37031 | 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 |
| | DEXAMETHASONE, INHALATION SOLUTION, COMPOUNDED PRODUCT, ADMINISTERED |
| J7638 | THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM |
| 17620 | DORNASE ALFA, INHALATION SOLUTION, FDA-APPROVED FINAL PRODUCT, NON- |
| J7639 | COMPOUNDED, ADMINISTERED THROUGH DME, UNIT DOSE FORM, PER MILLIGRAM |

Page | 2



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| 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 |
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Page | 3



| | 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 |
| 102072 | 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

For HCPCS codes A4619, E0565, E0572:

| | TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION - TUBERCULOUS |
|----------|--|
| 011.50 - | BRONCHIECTASIS TUBERCLE BACILLI NOT FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL |
| 011.56 | EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER METHODS (INOCULATION OF |
| | ANIMALS) |
| 042 | HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE |
| 136.3 | PNEUMOCYSTOSIS |
| 277.02 | CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS |
| 494.0 | BRONCHIECTASIS WITHOUT ACUTE EXACERBATION |
| 494.1 | BRONCHIECTASIS WITH ACUTE EXACERBATION |
| 519.19 | OTHER DISEASES OF TRACHEA AND BRONCHUS |
| 748.61 | CONGENITAL BRONCHIECTASIS |
| 996.80 - | COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER |
| 996.89 | SPECIFIED TRANSPLANTED ORGAN |

Page | 4



| V44.0 | TRACHEOSTOMY STATUS |
|-------|---------------------------|
| V55.0 | ATTENTION TO TRACHEOSTOMY |

For HCPCS codes A7015, A7525:

| | TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION - TUBERCULOUS |
|----------|--|
| 011.50 - | BRONCHIECTASIS TUBERCLE BACILLI NOT FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL |
| 011.56 | EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER METHODS (INOCULATION OF |
| | ANIMALS) |
| 042 | HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE |
| 136.3 | PNEUMOCYSTOSIS |
| 277.02 | CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS |
| 480.0 - | PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY CONDITIONS DUE TO UNSPECIFIED |
| 508.9 | EXTERNAL AGENT |
| 519.19 | OTHER DISEASES OF TRACHEA AND BRONCHUS |
| 748.61 | CONGENITAL BRONCHIECTASIS |
| 786.4 | ABNORMAL SPUTUM |
| 996.80 - | COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER |
| 996.89 | SPECIFIED TRANSPLANTED ORGAN |
| V44.0 | TRACHEOSTOMY STATUS |
| V55.0 | ATTENTION TO TRACHEOSTOMY |
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For HCPCS codes A7003, A7004, E0570:

| | TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION - TUBERCULOUS |
|----------|--|
| 011.50 - | BRONCHIECTASIS TUBERCLE BACILLI NOT FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL |
| 011.56 | EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER METHODS (INOCULATION OF |
| | ANIMALS) |
| 042 | HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE |
| 136.3 | PNEUMOCYSTOSIS |
| 277.02 | CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS |
| 480.0 - | PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY CONDITIONS DUE TO UNSPECIFIED |
| 508.9 | EXTERNAL AGENT |
| 748.61 | CONGENITAL BRONCHIECTASIS |
| 786.4 | ABNORMAL SPUTUM |
| 996.80 - | COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER |
| 996.89 | SPECIFIED TRANSPLANTED ORGAN |
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For HCPCS codes A7006, J2545:

| 042 | HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE |
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| 136.3 | PNEUMOCYSTOSIS |
| 996.80 - | COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER |
| 996.89 | SPECIFIED TRANSPLANTED ORGAN |

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

| 011.50 - | TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION - TUBERCULOUS | |
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Page | 6



| 011.56 | 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 |
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| 136.3 | PNEUMOCYSTOSIS |
| 491.0 - 508.9 | SIMPLE CHRONIC BRONCHITIS - RESPIRATORY CONDITIONS DUE TO UNSPECIFIED EXTERNAL AGENT |
| 996.80 - 996.89 | COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER SPECIFIED TRANSPLANTED ORGAN |

For HCPCS code J7608:

| 480.0 - | PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY CONDITIONS DUE TO UNSPECIFIED | |
|---------|---|--|
| 508.9 | EXTERNAL AGENT | |
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Page | 7



| 786.4 | ABNORMAL SPUTUM |
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For HCPCS codes J7605, J7606, J7611, J7612, J7613, J7614 J7620, J7626, J7631, J7644, J7669:

| 491.0 - | SIMPLE CHRONIC BRONCHITIS - RESPIRATORY CONDITIONS DUE TO UNSPECIFIED EXTERNAL |
|---------|--|
| 508.9 | AGENT |
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For HCPCS code J7639:

| 277.02 | CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS |
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For HCPCS code J7682:

| BERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION - TUBERCULOUS | |
|--|--|
| BRONCHIECTASIS TUBERCLE BACILLI NOT FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL | |
| 66 EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER METHODS (INOCULATION OF | |
| ANIMALS) | |
| CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS | |
| BRONCHIECTASIS WITHOUT ACUTE EXACERBATION | |
| BRONCHIECTASIS WITH ACUTE EXACERBATION | |
| CONGENITAL BRONCHIECTASIS | |
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For HCPCS codes A7016, E0574, J7686, K0730, Q4074:

| 416.0 | PRIMARY PULMONARY HYPERTENSION | |
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Page | 8



| 416.8 | OTHER CHRONIC PULMONARY HEART DISEASES | |
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For HCPCS code A7005:

| TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION - TUBERCULOUS | |
|--|--|
| BRONCHIECTASIS TUBERCLE BACILLI NOT FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL | |
| EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER METHODS (INOCULATION OF | |
| ANIMALS) | |
| HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE | |
| PNEUMOCYSTOSIS | |
| CYSTIC FIBROSIS WITH PULMONARY MANIFESTATIONS | |
| PRIMARY PULMONARY HYPERTENSION | |
| OTHER CHRONIC PULMONARY HEART DISEASES | |
| PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY CONDITIONS DUE TO UNSPECIFIED | |
| EXTERNAL AGENT | |
| CONGENITAL BRONCHIECTASIS | |
| ABNORMAL SPUTUM | |
| COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER | |
| SPECIFIED TRANSPLANTED ORGAN | |
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For HCPCS code A7013, A7014:

| 0 | 011.50 - TUBERCULOUS BRONCHIECTASIS UNSPECIFIED EXAMINATION - TUBERCULOUS | |
|--|---|--|
| 011.56 BRONCHIECTASIS TUBERCLE BACILLI NOT | | BRONCHIECTASIS TUBERCLE BACILLI NOT FOUND BY BACTERIOLOGICAL OR HISTOLOGICAL |
| | | EXAMINATION BUT TUBERCULOSIS CONFIRMED BY OTHER METHODS (INOCULATION OF |

Page | 9



| | 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 - | PNEUMONIA DUE TO ADENOVIRUS - RESPIRATORY CONDITIONS DUE TO UNSPECIFIED | |
| 508.9 | EXTERNAL AGENT | |
| 519.19 | OTHER DISEASES OF TRACHEA AND BRONCHUS | |
| 748.61 | CONGENITAL BRONCHIECTASIS | |
| 786.4 | ABNORMAL SPUTUM | |
| 996.80 - | - COMPLICATIONS OF UNSPECIFIED TRANSPLANTED ORGAN - COMPLICATIONS OF OTHER | |
| 996.89 | SPECIFIED TRANSPLANTED ORGAN | |
| V44.0 | TRACHEOSTOMY STATUS | |
| V55.0 | ATTENTION TO TRACHEOSTOMY | |
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Indications and Limitations:

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.

Page | 10



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),

Page | 11



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,

Page | 12



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.

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 |

Page | 13



| | 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/Ipratroprium combination | 31 units/month |
| Levalbuterol | 39 mg/month – 78 units/month |
| Metaproterenol | 470 mg/month – 47 units/month |

Background:

The liquid medications used in nebulizer treatments are known as nebulizer medications. They are used to treat conditions such as asthma and other respiratory diseases. Nebulizer is a device that turns liquid medication into a mist for inhalation, the liquid is turned to a mist using pressurized or compressed air and the liquid medications that are used in this device are called nebulizer medications. Nebulizer treatments are mostly used on children as they find it difficult to use the inhalers. This treatment option aids in allowing the medication to reach the airways and the patient feels immediate relief during and after the treatment that usually lasts for 5 to 10 minutes. Depending on the kind of medication and the sometimes the severity of the breathing condition or complication of the patient, the medication is advised to be inhaled more than 2 to 3 times a day. Nebulizers can be classified into a couple of categories depending

Page | 14



on what sort of treatment is the patient seeking, the medications varies if the patient is looking for a quick-relief medication and again it is different when they are looking for a preventive long-term medication which prevents the asthma attacks from occurring frequently.

Albuterol

Albuterol is a bronchodilator that eases the breathing process of the patient by relaxing the muscles in the airway and by increasing airflow to the lungs. This nebulizer medication is used to treat bronchospasm with a reversible obstructive airway disease such as asthma and bronchitis.

Levalbuterol

This medication is a bronchodilator again that improves breathing by relaxing strained muscles in the airway and is used for conditions like asthma, emphysema and bronchitis. As a general rule before taking any nebulizer medication, inform and discuss any existing condition with the doctor. For those with an existing health condition, the dosage would be adjusted accordingly. Xoponex is a common brand name associated with levalbuterol.

Budesonide Inhalation

It is an anti-inflammatory medication or a steroid that can only prevent asthma attacks and is not useful in treating an asthma attack that has already begun. If you are allergic to any medication or if you have conditions such as osteoporosis, liver disease, tuberculosis, herpes simplex eye infection or any bacterial, viral or fungal infection should be informed to the doctor. A common brand for this medication is Pulmicort Flexhaler and Pulmicort Respules.

Ipratropium Inhalation

This nebulizer medication is used on people with bronchitis or Chronic Obstructive Pulmonary Disease (COPD) to prevent bronchospasm. Those with bladder obstruction or enlarged prostate should inform the doctor to get the right dosage. Consuming large dosage could lead to further complications. Atrovent is a known brand name for this medication.



Definitions:

HCPCS Code—Healthcare Common Procedure Coding System - A system of letter and number codes assigned to procedures, medications, supplies and equipment used for pricing and billing.

ICD-9 Code—International Classification of Disease, 9th edition. A standardized classification of disease, injuries, and causes of death, by etiology and anatomic localization and codified into a 6-digit number, which allows clinicians, statisticians, politicians, health planners and others to speak a common language, both US and internationally.

References:

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