AirDuo® digihaler®
(fluticasone propionate 113 mcg and salmeterol 14 mcg) Inhalation Powder

ArmonAir® digihaler®
(fluticasone propionate 113 mcg) Inhalation Powder

Your Guide to Preparing an Appeal Letter

If coverage for a particular therapy is denied by the patient's health plan, an Appeal Letter may be needed.

The appeals process is instituted by health plans to review denials of medical necessity rendered for requested therapy.

Appeal Letters should be submitted along with the patient's medical records and can be submitted along with a Letter of Medical Necessity. There are often many levels of appeal, depending on the patient's insurance plan. If you have questions regarding a plan's appeal process or specific requirements for review, be sure to refer to the appeal guideline policies instituted by the plan on how to make the appeal.

The following sample letter may be a helpful tool for you and your office staff to utilize if it becomes necessary to appeal a coverage determination for a patient's plan. The Appeal Letter covers details often required to process a coverage authorization appeal, but may not be all inclusive, including:

- Claim specifics, such as the patient's name, date of denial, claim amount, and group number
- The patient's medical history and course of treatment
- The reason for denial: why the plan was reluctant to provide reimbursement
- Additional scientific/clinical information/data on the use of the medication in a given disease state
- All necessary contact information

This guide and the following sample letter are provided for informational purposes only. They are not intended to support the acquisition of reimbursement or legal advice. When in doubt, you are encouraged to contact third-party payers for specific information on their coverage policies.

Teva recommends confirming the information/documentation that is required to include in an Appeal Letter with individual payers.

INDICATIONS FOR ARMONAIR DIGIHALER AND AIRDUO DIGIHALER

ArmonAir® Digihaler® (fluticasone propionate) inhalation powder is indicated for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older.

Important Limitation of Use: ArmonAir Digihaler is NOT indicated for the relief of acute bronchospasm.

AirDuo® Digihaler® (fluticasone propionate and salmeterol) inhalation powder is indicated for the treatment of asthma in patients aged 12 years and older. AirDuo Digihaler is only for patients uncontrolled on an inhaled corticosteroid (ICS) or whose disease severity clearly warrants an ICS/Long-acting $beta_2$- agonist (LABA).

Important Limitation of Use: AirDuo Digihaler is NOT indicated for the relief of acute bronchospasm.

IMPORTANT SAFETY INFORMATION FOR ARMONAIR DIGIHALER AND AIRDUO DIGIHALER

Contraindications: ArmonAir Digihaler and AirDuo Digihaler are contraindicated in:

- Primary treatment of status asthmaticus or other acute episodes of asthma requiring intensive measures
- Patients with known severe hypersensitivity to milk proteins or any ingredients of ArmonAir Digihaler or AirDuo Digihaler

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IMPORTANT SAFETY INFORMATION FOR ARMONAIR DIGIHALER AND AIRDUO DIGIHALER (CONTINUED)

- **Serious Asthma-Related Events – Hospitalizations, Intubations, Death:** Use of a LABA as monotherapy (without an ICS) for asthma is associated with an increased risk of asthma-related death. Available data from controlled clinical trials also suggest that use of LABA as monotherapy increases the risk of asthma-related hospitalization in pediatric and adolescent patients. These findings are considered a class effect of LABA monotherapy. When LABA are used in fixed-dose combination with ICS (such as AirDuo Digihaler), data from large clinical trials do not show a significant increase in the risk of serious asthma-related events (hospitalizations, intubations, death) compared with ICS alone
- **Deterioration of Disease and Acute Episodes:** AirDuo Digihaler should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of asthma. ArmonAir Digihaler and AirDuo Digihaler are not indicated for the relief of acute bronchospasm. An inhaled, short-acting beta2-agonist, not ArmonAir Digihaler or AirDuo Digihaler, should be used to relieve acute symptoms such as shortness of breath
- **Excessive Use and Use with Other Long acting Beta$_2$-Agonists**: AirDuo Digihaler should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medicines containing LABA, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Patients using AirDuo Digihaler should not use another medicine containing a LABA (e.g., salmeterol, formoterol fumarate, arformoterol tartrate, indacaterol) for any reason
- **Local Effects of ICS:** Oropharyngeal candidiasis has occurred in patients treated with ArmonAir Digihaler or AirDuo Digihaler. Advise patients to rinse the mouth with water without swallowing following inhalation
- **Immunosuppression:** Patients who use corticosteroids, such as found in AirDuo Digihaler and ArmonAir Digihaler are at risk for potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. A more serious or even fatal course of chickenpox or measles may occur in susceptible patients. Use with caution in patients with the above because of the potential for worsening of these infections
- **Transferring Patients from Systemic Corticosteroid Therapy:** Particular care is needed for patients who have been transferred from systemically active corticosteroids to ICS because deaths due to adrenal insufficiency have occurred in patients with asthma during and after transfer from systemic corticosteroids to less systemically available ICS. Taper patients slowly from systemic corticosteroids if transferring to ArmonAir Digihaler or AirDuo Digihaler
- **Hypercorticism and Adrenal Suppression** may occur with high doses of ICS, including fluticasone propionate, or at the recommended dose in susceptible individuals. If such changes occur, discontinue ArmonAir Digihaler or AirDuo Digihaler slowly
- **Drug Interactions with Strong Cytochrome P450 3A4 Inhibitors:** The use of strong cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ritonavir, ketoconazole) with ArmonAir Digihaler or AirDuo Digihaler is not recommended because increased systemic corticosteroid adverse effects may occur; increased cardiovascular adverse effects may also occur with AirDuo Digihaler
- **Paradoxical Bronchospasm and Upper Airway Symptoms:** Paradoxical bronchospasm may occur. If bronchospasm occurs treat immediately with an inhaled, short-acting bronchodilator discontinue AirDuo Digihaler or ArmonAir Digihaler and institute alternative therapy
- **Hypersensitivity Reactions, Including Anaphylaxis:** Immediate hypersensitivity reactions (e.g., urticaria, angioedema, rash, bronchospasm, hypotension), including anaphylaxis, may occur after administration of ArmonAir Digihaler or AirDuo Digihaler. Discontinue ArmonAir Digihaler or AirDuo Digihaler if such reactions occur

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IMPORTANT SAFETY INFORMATION FOR ARMONAIR DIGIHALER AND AIRDUO DIGIHALER (CONTINUED)

- **Cardiovascular and Central Nervous System Effects:** The salmeterol component of AirDuo Digihaler, can be associated with excessive beta-adrenergic stimulation which could present as the following symptoms: seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, palpitation, nausea, dizziness, fatigue, malaise, and insomnia. Use with caution in patients with cardiac arrhythmias, hypertension, coronary insufficiency. Drug may need to be discontinued in certain patients.
- **Reduction in Bone Mineral Density (BMD):**. Decreases in BMD have been observed with long-term administration of products containing ICS. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants, oral corticosteroids) should be monitored and treated with established standards of care when using ArmonAir Digihaler or AirDuo Digihaler
- **Effect on Growth:** ICS may cause a reduction in growth velocity, Patients should be maintained on the lowest dose of inhaled corticosteroid that effectively controls their asthma. Monitor growth of pediatric patients receiving ArmonAir Digihaler and AirDuo Digihaler.
- **Glaucoma and Cataracts:** Long-term use of ICS, including fluticasone propionate, a component of ArmonAir Digihaler and AirDuo Digihaler, may increase the risk for cataracts or glaucoma. Regular eye exams should be considered
- **Eosinophilic Conditions and Churg-Strauss Syndrome:** Systemic eosinophilic conditions, such as Churg- Strauss syndrome, may occur when using ArmonAir Digihaler or AirDuo Digihaler. Be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy
- **Coexisting Conditions:** Use AirDuo Digihaler with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, ketoacidosis, and in patients who are unusually responsive to sympathomimetic amines
- **Hypokalemia and Hyperglycemia:** Beta-adrenergic agonist medicines may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. Decrease in serum potassium are usually transient, not requiring supplementation. Be alert to hypokalemia and hyperglycemia in patients using AirDuo Digihaler
- **Adverse Reactions with ArmonAir Digihaler:** Most common adverse reactions (reported in greater than or equal to 3% of subjects) are: upper respiratory tract infection, nasopharyngitis, oral candidiasis, headache, and cough
- **Adverse Reactions with AirDuo Digihaler:** Most common adverse reactions (reported in greater than or equal to 3% of patients) include nasopharyngitis, oral candidiasis, headache, cough and back pain

Please see the full Prescribing Information for ArmonAir Digihaler and AirDuo Digihaler.

[Physician/Letterhead]

[Date]

[Patient Name]
RE: [Coverage of AirDuo® Digihaler® (fluticasone propionate and salmeterol) Inhalation Powder / Coverage of ArmonAir® Digihaler® (fluticasone propionate) Inhalation Powder]

[Payer Representative]
[Payer Address]
[City, State ZIP Code]
[Payer Fax Number]

[Patient Name]
[Policy Name]
[Group Number]
[Patient DOB]
[Patient Age]
[Patient Sex]

Attention: [Payer Representative], [Claims Department]

Dear Director of Claims,

I am writing to request a review of a denied claim for my patient, [Patient Name]. On [Date of Denial], [Name of Health Plan] denied this claim for treatment with [AirDuo Digihaler / ArmonAir Digihaler] for the following reason(s), [which is/are] listed on the attached Explanation of Benefits (EOB):

[Indicate reason(s) for denial from EOB.]

Below is the medical history and current treatment regimen for [Patient Name]:

Diagnosis

☐ Asthma (J45-J45.998): _____

☐ Other diagnosis with ICD-10 Code: _____

Medication History

- The patient has experienced an inadequate response while being on the following prescribed medication(s):

Medication Name(s)	Dose	Duration

Additional information to consider for this appeal request:

- ☐ Patient has had recent exacerbation(s)
- ☐ Cannot identify reasons why patient is not well controlled and considering escalation of therapy
- ☐ Limited to patient-reported information on inhaler use
- ☐ Interested in objective data on inhaler use to help inform treatment decisions
- ☐ Other: _____
  _____

[NOTE: Physicians should exercise medical judgment and discretion in regard to making an appropriate diagnosis and characterization of an individual patient's medical condition. In addition, physicians are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.]

I am requesting that you reassess this denial. Based on my assessment and in my clinical opinion, [AirDuo® Digihaler® (fluticasone propionate and salmeterol) Inhalation Powder / ArmonAir® Digihaler® (fluticasone propionate) Inhalation Powder] is a necessary therapy for this patient's medical condition, and it is appropriate for treatment.

I trust that the enclosed information, along with my medical recommendations, will establish the medical necessity for payment of this claim. Please contact me at [Office Phone Number] if I can provide you with any additional information to approve this request.

Sincerely,

[Your Signature]

[Enclosures]
[List enclosures as appropriate. Examples of enclosures include excerpt(s) from patient's medical record, Explanation of Benefits (EOB), relevant treatment guidelines, and product Prescribing Information.]