ProAir® digihaler®
(albuterol sulfate 117 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 can be helpful 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 PROAIR DIGIHALER

ProAir® Digihaler® (albuterol sulfate) Inhalation Powder is indicated in patients ≥4 years of age for the treatment or prevention of bronchospasm with reversible obstructive airway disease and in patients ≥4 years of age for the prevention of exercise-induced bronchospasm.

IMPORTANT SAFETY INFORMATION FOR PROAIR DIGIHALER

- **Contraindications:** ProAir Digihaler (albuterol sulfate) Inhalation Powder is contraindicated in patients with hypersensitivity to albuterol or patients with a severe hypersensitivity to milk proteins. Rare cases of hypersensitivity reactions, including urticaria, angioedema, and rash have been reported after the use of albuterol sulfate. There have been reports of anaphylactic reactions in patients using inhalation therapies containing lactose
- **Paradoxical Bronchospasm:** ProAir Digihaler can produce paradoxical bronchospasm that may be life-threatening. Discontinue ProAir Digihaler and institute alternative therapy if paradoxical bronchospasm occurs
- **Deterioration of Asthma:** Need for more doses of ProAir Digihaler than usual may be a marker of acute or chronic deterioration of asthma and requires reevaluation of treatment, such as possible need for anti-inflammatory treatment, e.g., corticosteroids
- **Use of Anti-Inflammatory Agents:** ProAir Digihaler alone may not be adequate to control asthma in many patients. Early consideration should be given to adding anti-inflammatory agents, e.g., corticosteroids

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IMPORTANT SAFETY INFORMATION FOR PROAIR DIGIHALER (CONTINUED)

- **Cardiovascular Effects:** ProAir Digihaler, like other beta-adrenergic agonists, can produce clinically significant cardiovascular effects in some patients, as measured by heart rate, blood pressure, and/or symptoms. If such effects occur, the drug may need to be discontinued. ProAir Digihaler, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension
- **Do Not Exceed Recommended Dose:** Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs in patients with asthma
- **Hypersensitivity Reactions including Anaphylaxis:** Immediate hypersensitivity reactions may occur after administration of albuterol sulfate, as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, anaphylaxis, and oropharyngeal edema. Hypersensitivity reactions including anaphylaxis, angioedema, pruritus, and rash have been reported with the use of therapies containing lactose, an inactive ingredient in ProAir Digihaler.
- **Coexisting Conditions:** ProAir Digihaler, like all sympathomimetic amines, should be used with caution in patients with convulsive disorders, hyperthyroidism, or diabetes mellitus; and in patients who are unusually responsive to sympathomimetic amines.
- **Hypokalemia:** As with other beta-agonists, ProAir Digihaler may produce significant hypokalemia in some patients. The decrease is usually transient, not requiring supplementation
- **Most common adverse reactions** (≥1% and >placebo) are back pain, pain, gastroenteritis viral, sinus headache, urinary tract infection, nasopharyngitis, oropharyngeal pain and vomiting
- **Drug Interactions:** Other short-acting sympathomimetic bronchodilators should not be used concomitantly with ProAir Digihaler
    - **Beta-Blockers:** Beta-adrenergic-receptor blocking agents not only block the pulmonary effect of beta-agonists, such as ProAir Digihaler, but may produce severe bronchospasm in asthmatic patients. Therefore, patients with asthma should not normally be treated with beta-blockers
    - **Diuretics:** Caution is advised in the coadministration of beta-agonists with non-potassium sparing diuretics (such as loop or thiazide diuretics). Consider monitoring potassium levels
    - **Digoxin:** Carefully evaluate the serum digoxin levels in patients who are currently receiving digoxin and ProAir Digihaler
    - **Monoamine Oxidase Inhibitors or Tricyclic Antidepressants:** ProAir Digihaler should be administered with extreme caution to patients being treated with these agents, or within 2 weeks of discontinuation of these agents, because the action of albuterol on the cardiovascular system may be potentiated. Consider alternative therapy

Please see the full Prescribing Information for ProAir 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.]