ProAir® digihaler®
(albuterol sulfate 117 mcg)
Inhalation Powder

Your Guide to Preparing a Letter of Medical Necessity

A Letter of Medical Necessity is used when the insurance company may deny a request to pay for a medication. It provides necessary information for the insurance company to consider when reviewing a request for coverage (eg, diagnosis, treatment history). It can be helpful to patients when the medication is:

- Subject to step therapy or prior authorization
- Not available in the plan's formulary
- Requiring supplemental information to be provided to the plan, to ensure patient access to therapy

The letter should contain the information needed to support the proposition that the requested medication is necessary to meet the medical needs of your patient.

The following sample letter may be a helpful tool for you and your office staff to utilize when a Letter of Medical Necessity is needed. The content of the letter should include:

- The patient's diagnosis, condition, and medical history
- Information about your patient's previous therapies and his/her response to those therapies
- A summary of your opinion about the patient's prognosis without treatment and documentation that supports your position
- 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 a Letter of Medical Necessity 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

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IMPORTANT SAFETY INFORMATION FOR PROAIR DIGIHALER (CONTINUED)

- **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
- **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 ProAir® Digihaler® (albuterol sulfate) 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: [Medical/Pharmacy Director], [Department]

Dear [Medical/Pharmacy Director],

I am writing to document the medical necessity of ProAir Digihaler, which I have prescribed for my patient, [Patient Name], [Policy Number].

ProAir Digihaler is a prescription medicine used for the treatment or prevention of bronchospasm with reversible obstructive airway disease and prevention of exercise-induced bronchospasm. The full Prescribing Information for ProAir Digihaler can be found at www.digihalerhcp.com.

[Patient Name]'s medical history and course of treatment are as follows:

Date of Birth

[MM/DD/YYYY]

Diagnosis

- ☐ Asthma
- ☐ COPD
- ☐ Exercise-induced bronchospasm
- ☐ Other diagnosis with ICD-10 Code: [Diagnosis and ICD-10 Code]

Medication History

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

Medication Name(s)	Dose	Duration

Additional information pertinent to this request:

- ☐ Patient has reported excessive use of their short-acting beta$_2$-agonist (SABA) inhaler
- ☐ Patient is refilling their SABA inhaler prescription frequently
- ☐ Limited to patient-reported information on inhaler use
- ☐ Interested in objective data on inhaler use to help inform treatment decisions
- ☐ Other:_____
  _____

In my clinical opinion, ProAir Digihaler is necessary and reasonable for [Patient Name]'s medical condition. Please contact me at [Office Phone Number] if any additional information is required to ensure the prompt approval of this course of treatment.

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.]