



(fluticasone propionate
113 mcg and salmeterol
14 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 editable template 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 often includes:

- 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 need for this 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 AIRDUO DIGIHALER

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 beta₂-agonist (LABA).

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

IMPORTANT SAFETY INFORMATION FOR AIRDUO DIGIHALER

- **Contraindications:** AirDuo Digihaler is contraindicated in:
 - o Primary treatment of status asthmaticus or other acute episodes of asthma requiring intensive measures
 - o Patients with known severe hypersensitivity to milk proteins or any ingredients of AirDuo Digihaler.
- **Serious Asthma-Related Events – Hospitalizations, Intubations, Death:** Use of LABA as monotherapy (without 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, 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



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IMPORTANT SAFETY INFORMATION FOR AIRDUO DIGIHALER (CONTINUED)

- **Deterioration of Disease and Acute Episodes:** AirDuo Digihaler should not be initiated in patients during rapidly deteriorating or potentially life-threatening episodes of asthma. AirDuo Digihaler is not indicated for the relief of acute bronchospasm. An inhaled, short acting beta₂-agonist, not AirDuo Digihaler, should be used to relieve acute symptoms such as shortness of breath
- **Avoid Excessive Use and Avoid Use with Other Long acting Beta₂-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
- **Oropharyngeal Candidiasis** has occurred in patients treated with AirDuo Digihaler. Advise patients to rinse the mouth with water without swallowing following inhalation
- **Immunosuppression and Risks of Infections:** Patients who use corticosteroids, such as found in AirDuo 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 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 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 AirDuo Digihaler is not recommended because increased systemic corticosteroid and increased cardiovascular adverse effects may occur
- **Paradoxical Bronchospasm and Upper Airway Symptoms:** Paradoxical bronchospasm may occur. If bronchospasm occurs treat immediately with an inhaled short-acting bronchodilator, discontinue AirDuo 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 AirDuo Digihaler. Discontinue AirDuo Digihaler if such reactions occur
- **Cardiovascular and Central Nervous System Effects:** The salmeterol component of AirDuo Digihaler, can be associated with excessive betaadrenergic 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 AirDuo Digihaler



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IMPORTANT SAFETY INFORMATION FOR AIRDUO DIGIHALER (CONTINUED)

- **Effect on Growth:** ICS, as well as poorly controlled asthma, may cause a reduction in growth velocity, and the long-term effect on final adult height is unknown. Patients should be maintained on the lowest dose of inhaled corticosteroid that effectively controls their asthma. Monitor growth of pediatric patients receiving AirDuo Digihaler
- **Glaucoma and Cataracts:** Long-term use of ICS, including fluticasone propionate, a component of 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 AirDuo Digihaler. Be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy
- **Coexisting Conditions:** Use 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 patient using AirDuo Digihaler
- **Adverse Reactions:** Most common adverse reactions (greater than or equal to 3%) include nasopharyngitis, oral candidiasis, headache, cough and back pain

Please see the [full Prescribing Information](#) for AirDuo Digihaler.

[Physician/Letterhead]

[Date]

[Patient Name]

RE: Coverage of AirDuo® Digihaler® (fluticasone propionate and salmeterol) 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 AirDuo Digihaler, which I have prescribed for my patient, [Patient Name], [Policy Number].

AirDuo Digihaler is a prescription medicine used for the treatment of asthma in patients aged 12 years and older. The full Prescribing Information for AirDuo 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

☐ 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 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: _____

In my clinical opinion, AirDuo 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.]