ArmonAir® digihaler®
(fluticasone propionate 113 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 often 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 ARMONAIR 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.

IMPORTANT SAFETY INFORMATION FOR ARMONAIR DIGIHALER

- **Contraindications:** ArmonAir Digihaler is contraindicated in:
  - primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required
  - patients with known severe hypersensitivity to milk proteins or known hypersensitivity to fluticasone propionate or any of the excipients
- **Local Effects of Inhaled Corticosteroids (ICS):** Oropharyngeal candidiasis has occurred in patients treated with ArmonAir Digihaler. Advise patients to rinse the mouth with water without swallowing following inhalation.
- **Acute Asthma Episodes:** ArmonAir Digihaler is not indicated for the relief of acute bronchospasm. An inhaled, short-acting beta$_2$-agonist, not ArmonAir Digihaler, should be used to relieve acute symptoms such as shortness of breath

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IMPORTANT SAFETY INFORMATION FOR ARMONAIR DIGIHALER (CONTINUED)

- **Immunosuppression:** Patients on corticosteroids 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
- **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 slowly
- **Hypersensitivity Reactions, Including Anaphylaxis:** Immediate hypersensitivity reactions (e.g., urticaria, angioedema, rash, bronchospasm, hypotension), including anaphylaxis, may occur after administration of ArmonAir Digihaler. Discontinue ArmonAir Digihaler if such reactions occur
- **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
- **Effect on Growth:** ICS, including ArmonAir Digihaler, may cause a reduction in growth in pediatric patients. Patients should be maintained on the lowest dose of inhaled corticosteroid that effectively controls their asthma. Monitor growth of pediatric patients
- **Glaucoma and Cataracts:** Long-term use of ICS, including fluticasone propionate, may increase the risk of cataracts, intraocular pressure and glaucoma. Regular eye exams should be considered
- **Paradoxical Bronchospasm:** Paradoxical bronchospasm may occur. If bronchospasm occurs treat immediately with an inhaled, short-acting bronchodilator, discontinue ArmonAir Digihaler and institute alternative therapy
- **Drug Interactions with Strong Cytochrome P450 3A4 Inhibitors:** The use of strong cytochrome P450 3A4 (CYP3A4) inhibitors (e.g., ritonavir, ketoconazole) with ArmonAir Digihaler is not recommended because increased systemic corticosteroid adverse effects may occur
- **Eosinophilic Conditions and Churg-Strauss Syndrome:** Systemic eosinophilic conditions, vasculitis consistent with Churg-Strauss syndrome, may occur. These events usually, but not always, have been associated with the reduction and/or withdrawal of oral corticosteroids following the introduction of fluticasone propionate. Be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy
- **Adverse Reactions:** Most common adverse reactions (reported in ≥3% of subjects) are: nasopharyngitis, upper respiratory tract, oral candidiasis, headache, and cough

Please see the full Prescribing Information for ArmonAir Digihaler.

[Physician/Letterhead]

[Date]

[Patient Name]
RE: 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: [Medical/Pharmacy Director], [Department]

Dear [Medical/Pharmacy Director],

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

ArmonAir Digihaler is a prescription medicine used for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older. The full Prescribing Information for ArmonAir 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, ArmonAir 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.]