**Letter of Medical Necessity Template**

**FOR PATIENTS WITH CHRONIC RHINOSINUSITIS WITHOUT NASAL POLYPS**

**XHANCE® (fluticasone propionate) nasal spray (93 mcg)**

The template below is intended to provide a starting point for writing a letter of medical necessity for XHANCE® (fluticasone propionate) nasal spray (93 mcg) for patients with chronic rhinosinusitis without nasal polyps. You are responsible for ensuring the accuracy and adequacy of the information provided. This sample letter provides insight into what plans may consider relevant information regarding your patient’s treatment. Please note that submitting the information below to the health plan does not guarantee they will provide coverage for the prescribed medication, and some plans may require different or additional information. This example is not meant as a substitute for a prescriber’s independent medical decision-making.

**Instructions for completing the LETTER OF MEDICAL NECESSITY:**

1. Open a new document (e.g., Microsoft Word) with your facility’s letterhead. Select/highlight the template below, beginning with the “Date of Request” on page 3 and all the way through to the end of the document. “Copy” the highlighted template to “paste” it into your letterhead.

**PLEASE DO NOT INCLUDE THESE INSTRUCTIONAL PAGES WITH YOUR SUBMISSION.**

1. Customize the Letter of Medical Necessity for your patient. Update all YELLOW HIGHLIGHTED FIELDS with appropriate patient information, including medical diagnosis and history. It is important to provide the most complete and specific information for your patient to assist with the review process.
2. The information below can be used for reference while completing the XHANCE-specific information within the letter. You may choose to include several or all these references as enclosures with your submission package.

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| **QUICK**  **TIPS** | * Include specific ICD-10 diagnosis codes where appropriate. * Clearly state the rationale for the recommended therapy and why it is appropriate for your patient. * Do not forget to delete any instructional or unnecessary patient-related information before submitting. |

**INDICATIONS**

XHANCE is a corticosteroid indicated for the treatment of chronic rhinosinusitis with or without nasal polyps in adults.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS:**

Hypersensitivity to any ingredient in XHANCE.

**WARNINGS AND PRECAUTIONS:**

* **Local nasal adverse reactions**, including epistaxis, erosion, ulceration, septal perforation, *Candida albicans* infection, and impaired wound healing, can occur. Monitor patients periodically for signs of possible changes on the nasal mucosa. Avoid use in patients with recent nasal ulcerations, nasal surgery, or nasal trauma until healing has occurred.
* **Glaucoma and cataracts** may occur with long-term use. Consider referral to an ophthalmologist in patients who develop ocular symptoms or use XHANCE long-term.
* **Hypersensitivity reactions** (e.g., anaphylaxis, angioedema, urticaria, contact dermatitis, rash, hypotension, and bronchospasm) have been reported after administration of fluticasone propionate. Discontinue XHANCE if such reactions occur.

**IMPORTANT SAFETY INFORMATION CONTINUED**

**WARNINGS AND PRECAUTIONS CONTINUED**

* **Immunosuppression and infections** can occur, including potential increased susceptibility to or worsening of infections (e.g., existing tuberculosis; fungal, bacterial, viral, or parasitic infection; ocular herpes simplex). Use with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients.
* **Hypercorticism and adrenal suppression** may occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue XHANCE slowly.
* **Assess for decrease in bone mineral density** initially and periodically thereafter.

**ADVERSE REACTIONS:**

* **Chronic rhinosinusitis without nasal polyps**: The most common adverse reactions (incidence ≥ 3%) are epistaxis, headache, and nasopharyngitis.
* **Chronic rhinosinusitis with nasal polyps**: The most common adverse reactions (incidence ≥ 3%) are epistaxis, nasal septal ulceration, nasopharyngitis, nasal mucosal erythema, nasal mucosal ulcerations, nasal congestion, acute sinusitis, nasal septal erythema, headache, and pharyngitis.

**DRUG INTERACTIONS:**

Strong cytochrome P450 3A4 inhibitors (e.g., ritonavir, ketoconazole): Use not recommended. May increase risk of systemic corticosteroid effects.

**USE IN SPECIFIC POPULATIONS:**

Hepatic impairment. Monitor patients for signs of increased drug exposure.

**Please see full Prescribing Information.**

Link to: https://www.xhance.com/files/XHANCE\_Full\_Prescribing\_Information.pdf

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**Date of Request:**  *[Date]*

**ATTN:**

*[Contact name]*

*[Health plan name]*

*[Health plan address]*

*[City, State ZIP Code]*

*[Fax number]*

**RE: LETTER OF MEDICAL NECESSITY FOR XHANCE® *(fluticasone propionate)* nasal spray 93 mcg**

**Patient Name:** *[Insured Patient First Name Patient Last Name]*

**Patient Date of Birth:**  *[Month, Day, Year]*

**Patient Insurance Information:** [*Policy #] & [Group #]*

**Patient Diagnosis:** *[ICD-10-CM Code] [Diagnosis]*

* *J32 Chronic sinusitis*
  + *J32.0 Chronic maxillary sinusitis*
  + *J32.1 Chronic frontal sinusitis*
  + *J32.2 Chronic ethmoidal sinusitis*
  + *J32.3 Chronic sphenoidal sinusitis*
  + *J32.4 Chronic pansinusitis*
  + *J32.8 Other chronic sinusitis*
  + *J32.9 Chronic sinusitis, unspecified*

**To whom it may concern with** *[INSURANCE COMPANY or REPRESENTATIVE NAME]*:

My name is *[Provider Name], [Medical Specialty] [National Provider Identifier number (NPI)]*, and I am writing on behalf of *[Patient Name]* to request approval to treat *[Patient Name]* with XHANCE. [*Patient Name]’s* plan does not cover XHANCE at this time, however, it is my professional opinion that it is medically necessary for [him/her]. *[Patient Name]* has been in my care since *[month, day, year]*, for the management of their chronic sinusitis without nasal polyps.

**XHANCE is the only FDA-approved medication for chronic rhinosinusitis without nasal polyps, and the only nasal steroid to demonstrate consistent and significant clinical benefit in the chronic sinusitis without nasal polyp population**. There are no other products on your formulary that are FDA-approved to treat chronic sinusitis without nasal polyps.

Based on my clinical judgment, I believe that XHANCE is specifically medically necessary for *[Patient Name]* because they continue to experience chronic sinusitis symptoms of nasal congestion, facial pain/pressure, and/or rhinorrhea despite use of standard delivery corticosteroid nasal sprays. *[Patient Name]* has previously received the following treatment(s) for chronic sinusitis: [*indicate which prior therapies the patient has received, including all chronic sinusitis-related medications, and outline any specific reasons for any discontinuation or non-compliance*]. *[Insert any additional rationale for prescribing* XHANCE].

For these reasons, I believe that treatment with XHANCE is medically necessary and will provide essential clinical benefit in [*Patient Name*]’s current course of care. Please promptly review the enclosed information to authorize treatment of XHANCEfor *[Patient Name]*.

My office can be contacted at *[phone number]* or *[email address]* if additional information is required to approve this request. Thank you in advance for your timely attention to this matter.

**Sincerely,**

*[Provider Name], [Medical Specialty]*

*[National Provider Identifier number (NPI)]*

*[Physician address]*

*[Physician phone number]*

*[Physician fax number]*

***ENCLOSURES TO SUPPORT THE MEDICAL NECESSITY REQUEST OF XHANCE:***

*[Relevant patient medical records]*

Please see full Prescribing Information.

Link to: https://www.xhance.com/files/XHANCE\_Full\_Prescribing\_Information.pdf