Drafting a **Letter of Appeal**

Xelstrym® (dextroamphetamine) CII transdermal system
1.5mg/9 hours 9mg/9 hours 13.5mg/9 hours 18mg/9 hours

Important considerations

When a patient's health plan denies coverage for XELSTRYM, it's important to know that an appeal process may be available. Whether the health plan has denied a prior authorization (PA) request, denied payment, or claimed that XELSTRYM was not medically necessary, submitting a **Letter of Appeal** allows you to:

- Further explain your clinical rationale for prescribing XELSTRYM
- Provide supporting documentation to address the reasons for the denial
- Request approval

The following information may be considered by your office staff as you draft and submit a **Letter of Appeal**. Because there may be varying levels of appeals, it is recommended that you check with your patient's health plan to confirm the time frame and specific process involved.

Tips for drafting a **LETTER OF APPEAL**

- ✓ Confirm the specific appeals process for your patient's health plan, as varying processes may exist
- ✓ Unless otherwise stated in the denial communication, confirm with the health plan if the letter should be addressed to a specific person or department
- ✓ Check if the health plan has its own request form for appeals. If not, draft the letter on your practice's letterhead
- ✓ Confirm the health plan's time frame for the submission of an appeal
- ✓ Review the reasons for denial and identify additional documents that can correct or update discrepancies, or that can help support your clinical rationale for prescribing XELSTRYM. These may include:
  - Relevant patient medical records
  - XELSTRYM Prescribing Information
  - XELSTRYM FDA approval letter(s) (available on the FDA website)
  - Peer-reviewed literature (eg, transdermal safety and efficacy studies)
  - Letter of Medical Necessity
- ✓ When directly addressing the reasons for denial, be sure to use exact language from the health plan's denial letter and include why you believe the decision should be reconsidered
- ✓ Be clear about your patient's individual circumstances and include any specific and relevant medical information that supports the use of XELSTRYM for your patient in accordance with the health plan's criteria
- ✓ Specify if XESLTRYM has been prescribed for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD)
- ✓ State why the insurance plan's recommended agents are not appropriate treatments for your patient
- ✓ Describe your patient's condition with appropriate ICD-10-CM codes
- ✓ Submit the letter and documentation using the method preferred by the health plan (eg, fax, online portal)

FDA: Food and Drug Administration; ICD-10-CM: International Classification of Diseases, Tenth Revision, Clinical Modification.

INDICATION AND LIMITATIONS OF USE

XELSTRYM (dextroamphetamine) transdermal system, CII is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adult and pediatric patients 6 years and older. The use of XELSTRYM is not recommended in pediatric patients younger than 6 years of age because they had higher plasma exposure and a higher incidence of adverse reactions (e.g., weight loss) than patients 6 years and older at the same dosage.

IMPORTANT SAFETY INFORMATION

WARNING: ABUSE, MISUSE, AND ADDICTION

XELSTRYM has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including XELSTRYM, can result in overdose and death, and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Before prescribing XELSTRYM, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout XELSTRYM treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction.

Please click here for full Prescribing Information, including BOXED WARNING.

Sample
Letter of Appeal

Xelstrym® (dextroamphetamine) II transdermal system
1.5mg/9 hours 9mg/9 hours 13.5mg/9 hours 18mg/9 hours

The information below may be helpful when drafting a **Letter of Appeal**

The following sample **Letter of Appeal** can be used as a template and can be customized based on your patient's individual information. Unless your patient's health plan has a specific form that they require for **Letters of Appeal**, it is recommended that this letter be drafted on your practice's letterhead.

Include additional details to help identify your patient, such as health plan policy and group numbers, diagnosis, claim number, and submission and denial dates

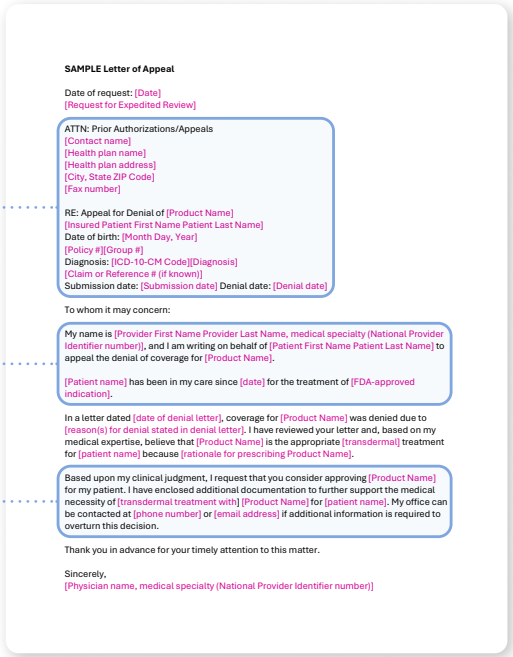
State that you are writing on behalf of your patient to appeal the denial of coverage for XELSTRYM

Explain why XESLTRYM is an appropriate treatment for your patient

- Describe your patient's condition and list current and previous therapies (eg, oral stimulants or non-stimulants), including dose, frequency, dates of use, reasons for discontinuation, and contraindications, if any

Provide your contact information in case the health plan needs more information to reassess coverage

List any additional documents that you have included with the letter



SAMPLE Letter of Appeal

Date of request: [Date]
[Request for Expedited Review]

ATTN: Prior Authorizations/Appeals
[Contact name]
[Health plan name]
[Health plan address]
[City, State ZIP Code]
[Fax number]

RE: Appeal for Denial of [Product Name]
[Insured Patient First Name Patient Last Name]
Date of birth: [Month Day, Year]
[Policy #][Group #]
Diagnosis: [ICD-10-CM Code][Diagnosis]
[Claim or Reference # (if known)]
Submission date: [Submission date] Denial date: [Denial date]

To whom it may concern:

My name is [Provider First Name Provider Last Name, medical specialty (National Provider Identifier number)], and I am writing on behalf of [Patient First Name Patient Last Name] to appeal the denial of coverage for [Product Name].

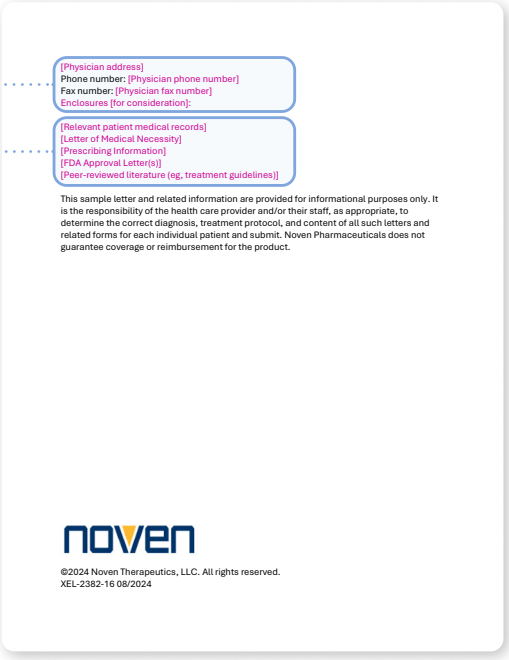
[Patient name] has been in my care since [date] for the treatment of [FDA-approved indication].

In a letter dated [date of denial letter], coverage for [Product Name] was denied due to [reason(s) for denial stated in denial letter]. I have reviewed your letter and, based on my medical expertise, believe that [Product Name] is the appropriate [transdermal] treatment for [patient name] because [rationale for prescribing Product Name].

Based upon my clinical judgment, I request that you consider approving [Product Name] for my patient. I have enclosed additional documentation to further support the medical necessity of [transdermal treatment with] [Product Name] for [patient name]. My office can be contacted at [phone number] or [email address] if additional information is required to overturn this decision.

Thank you in advance for your timely attention to this matter.

Sincerely,
[Physician name, medical specialty (National Provider Identifier number)]



[Physician address]
Phone number: [Physician phone number]
Fax number: [Physician fax number]
Enclosures [for consideration]:

[Relevant patient medical records]
[Letter of Medical Necessity]
[Prescribing Information]
[FDA Approval Letter(s)]
[Peer-reviewed literature (eg, treatment guidelines)]

This sample letter and related information are provided for informational purposes only. It is the responsibility of the health care provider and/or their staff, as appropriate, to determine the correct diagnosis, treatment protocol, and content of all such letters and related forms for each individual patient and submit. Noven Pharmaceuticals does not guarantee coverage or reimbursement for the product.

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A sample **Letter of Appeal** is available for **download here**

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

- Known hypersensitivity to amphetamine products or other components in XELSTRYM. Anaphylactic reactions, Stevens-Johnson Syndrome, angioedema, and urticaria have been observed.
- Use with monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including linezolid or intravenous methylene blue) due to increased risk of hypertensive crisis.

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Xelstrym®
(dextroamphetamine) CII
transdermal system
1.5mg/9 hours 9mg/9 hours 13.5mg/9 hours 18mg/9 hours

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Risks to Patients with Serious Cardiac Disease: Avoid XELSTRYM use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac diseases. Sudden death has been reported in patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulants at the recommended ADHD dosage.

Increased Blood Pressure and Heart Rate: CNS stimulants cause an increase in blood pressure (mean increase about 2 to 4 mm Hg) and heart rate (mean increase about 3 to 6 bpm). Monitor all patients for potential tachycardia and hypertension.

Psychiatric Adverse Reactions: *Exacerbation of Pre-existing Psychosis*: May exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder. *Induction of a Manic Episode in Patients with Bipolar Disorder*: May induce a mixed/manic episode in patients. Prior to initiating XELSTRYM treatment, screen for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms, or a family history of suicide, bipolar disorder, and depression). *New Psychotic or Manic Symptoms*: At recommended doses, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients with no prior history of psychotic illness or mania. Discontinue XELSTRYM if symptoms occur.

Long-Term Suppression of Growth in Pediatric Patients: XELSTRYM is not approved for use and is not recommended in pediatric patients below 6 years of age. CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Closely monitor growth (weight and height). Treatment may need to be interrupted in pediatric patients not growing or gaining weight as expected. XELSTRYM is not approved for use in pediatric patients below 6 years of age.

Peripheral Vasculopathy, including Raynaud's Phenomenon: Stimulants, including XELSTRYM, are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; very rare sequelae include digital ulceration and/or soft tissue breakdown. Careful observation for digital changes is necessary during treatment with stimulants. Further evaluation including rheumatology referral, may be appropriate for certain patients.

Serotonin Syndrome: Risk is increased when XELSTRYM is co-administered with serotonergic agents (e.g., SSRIs, SNRIs, triptans), and with CYP2D6 inhibitors. If it occurs, discontinue XELSTRYM and initiate supportive treatment.

Contact Sensitization: Use of XELSTRYM may lead to contact sensitization. Discontinue XELSTRYM if contact sensitization is suspected.

Application Site Reactions: During wear time or immediately after removal of XELSTRYM, local skin reactions such as pain, pruritus, burning sensation, erythema, discomfort, edema, and/or swelling were reported. Select a different application site each day to minimize skin reactions.

External Heat: Avoid exposing XELSTRYM to direct external heat sources during wear because both the rate and extent of absorption are increased.

Motor and Verbal Tics, and Worsening of Tourette's Syndrome: Before initiating XELSTRYM, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor XELSTRYM-treated patients for the emergence or worsening of tics or Tourette's syndrome, and discontinue treatment if clinically appropriate. CNS stimulants, including methylphenidate, have been associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported.

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥2% and greater than the rate for placebo) in pediatric patients 6 to 17 years treated with XELSTRYM were: decreased appetite, headache, insomnia, tic, abdominal pain, vomiting, nausea, irritability, increased blood pressure, and increased heart rate.

Most common adverse reactions (incidence of ≥5% and a rate at least twice placebo) in adults treated with lisdexamfetamine were: decreased appetite, insomnia, dry mouth, diarrhea, nausea, and anxiety.

USE IN SPECIFIC POPULATIONS

Pregnancy and Lactation: XELSTRYM may cause fetal harm. Breastfeeding is not recommended during XELSTRYM treatment.

Pediatric Use: The safety and effectiveness of XELSTRYM have not been established in pediatric patients below the age of 6 years.

Please click here for full Prescribing Information, including BOXED WARNING.

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