Preparing a
Letter of Medical Necessity

Xelstrym® (dextroamphetamine) CII transdermal system
4.5mg/9 hours 9mg/9 hours 13.5mg/9 hours 18mg/9 hours

Helpful considerations

Some health insurance plans may require prior authorization and/or other supporting documentation before approving coverage for XELSTRYM. If your patient doesn't meet their individual health plan's full criteria for coverage, a **Letter of Medical Necessity** can help explain why you have prescribed XELSTRYM and why you feel that it is medically necessary. This form can also accompany a prior authorization request or an appeal to help reassess a denial of coverage.

The information below may be used as a guide when writing and submitting a **Letter of Medical Necessity**. Please note that health plan requirements vary, so it's important to refer to the prior authorization or coverage information specific to your patient's individual health plan before submitting.

Tips for drafting a **LETTER OF MEDICAL NECESSITY**

- If your patient's health plan has a coverage policy in place for the product you wish to prescribe, be sure to review the policy ahead of time to determine the criteria that your patient does or does not meet
- Check with the health plan to confirm if the letter should be addressed to a specific person or department
- If there are additional documents that may help support your clinical decision-making and rationale for prescribing XELSTRYM, identify them and set them aside for inclusion. 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)
- Some health plans may have their own request form for supporting medical necessity. Confirm if one exists. If it does not, you can draft the letter on your practice's letterhead
- Specify if XELSTRYM has been prescribed for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD)
- If the prescribed dose differs from the plan's requirements, clarify the requested quantity of the product
- Be clear about your patient's individual circumstances
- Be specific when stating why the insurance plan's recommended agents would not be appropriate therapies for your patient
- Describe your patient's condition with appropriate ICD-10-CM codes
- Once completed, you can submit the letter of medical necessity along with relevant documentation using the method preferred by the health plan (eg, fax, online portal)

FDA: US 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 Medical Necessity

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

The following sample **Letter of Medical Necessity** can be used as a template and may be customized based on your patient's individual medical history and personal information. Unless your patient's health plan has a specific form that they require to document medical necessity, 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

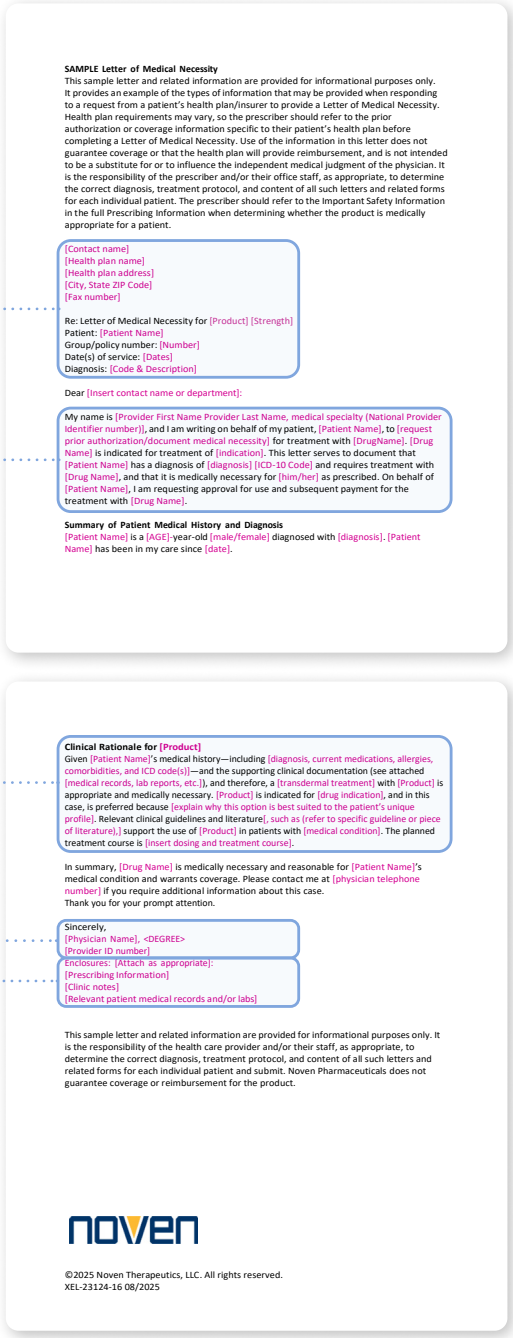
State that you are writing on behalf of your patient to request approval of XELSTRYM

Explain why XELSTRYM is an appropriate treatment for your patient

- Describe your patient's condition and list current and previous therapies (eg, oral/other amphetamine] stimulants, non-stimulants, etc), 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 determined should be included with the letter



SAMPLE Letter of Medical Necessity
This sample letter and related information are provided for informational purposes only. It provides an example of the types of information that may be provided when responding to a request from a patient's health plan/insurer to provide a Letter of Medical Necessity. Health plan requirements may vary, so the prescriber should refer to the prior authorization or coverage information specific to their patient's health plan before completing a Letter of Medical Necessity. Use of the information in this letter does not guarantee coverage or that the health plan will provide reimbursement, and is not intended to be a substitute for or to influence the independent medical judgment of the physician. It is the responsibility of the prescriber and/or their office staff, as appropriate, to determine the correct diagnosis, treatment protocol, and content of all such letters and related forms for each individual patient. The prescriber should refer to the Important Safety Information in the full Prescribing Information when determining whether the product is medically appropriate for a patient.

[Contact name]
[Health plan name]
[Health plan address]
[City, State ZIP Code]
[Fax number]

Re: Letter of Medical Necessity for [Product] [Strength]
Patient: [Patient Name]
Group/policy number: [Number]
Date(s) of service: [Dates]
Diagnosis: [Code & Description]

Dear [Insert contact name or department]:

My name is [Provider First Name Provider Last Name, medical specialty (National Provider Identifier number)], and I am writing on behalf of my patient, [Patient Name], to [request prior authorization/document medical necessity] for treatment with [DrugName]. [Drug Name] is indicated for treatment of [indication]. This letter serves to document that [Patient Name] has a diagnosis of [diagnosis] [ICD-10 Code] and requires treatment with [Drug Name], and that it is medically necessary for [him/her] as prescribed. On behalf of [Patient Name], I am requesting approval for use and subsequent payment for the treatment with [Drug Name].

Summary of Patient Medical History and Diagnosis
[Patient Name] is a [AGE]-year-old [male/female] diagnosed with [diagnosis]. [Patient Name] has been in my care since [date].

Clinical Rationale for [Product]
Given [Patient Name]'s medical history—including [diagnosis, current medications, allergies, comorbidities, and ICD code(s)]—and the supporting clinical documentation (see attached [medical records, lab reports, etc.]), and therefore, a [transdermal treatment] with [Product] is appropriate and medically necessary. [Product] is indicated for [drug indication], and in this case, is preferred because [explain why this option is best suited to the patient's unique profile]. Relevant clinical guidelines and literature[, such as (refer to specific guideline or piece of literature),] support the use of [Product] in patients with [medical condition]. The planned treatment course is [insert dosing and treatment course].

In summary, [Drug Name] is medically necessary and reasonable for [Patient Name]'s medical condition and warrants coverage. Please contact me at [physician telephone number] if you require additional information about this case.
Thank you for your prompt attention.

Sincerely,
[Physician Name], <DEGREE>
[Provider ID number]
Enclosures: [Attach as appropriate]:
[Prescribing Information]
[Clinic notes]
[Relevant patient medical records and/or labs]

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 Medical Necessity** 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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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.

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