Tips for composing a **Letter of Medical Necessity**

fensolvi® (leuprolide acetate) for injectable suspension

When submitting a prior authorization (PA) request to a patient's health insurance plan, including a Letter of Medical Necessity can help explain the clinical decision-making behind your choice of a specific therapy.

AVOID DENIALS

When you submit the PA request to the payer, familiarize yourself with the plan's specific guidelines such as obtaining any referrals.

MEET ALL DEADLINES

Be sure to keep track of, and meet all deadlines for submitting the PA form and other required documents. Once you have received the PA, check with the payer to determine the length of the authorization, as this can vary.

BE DETAILED AND THOROUGH

Recommended information for a Letter of Medical Necessity includes:

1. The patient's information:
   - Full name
   - Date of birth
   - Insurance ID number
   - Insurance group number
   - Case ID number (if available)
2. The patient's diagnosis and the indication for the Tolmar medicine being prescribed.
3. The severity of the patient's condition.
4. If applicable, including a brief summary of the patient's previous treatments, the duration of each and the rationale for discontinuation. Including coding information for prior treatments/services may help the health insurance plan conduct their research in a timely manner.
5. The clinical rationale for treatment, including trial data supporting the FDA approval, administration and dosing information.
6. A summary of your recommendation.
7. Additional enclosures, including:
   - Prescribing information
   - Clinical notes/medical records
   - Diagnostic test results
   - Scans for showing progressive disease
   - Pathology reports
   - Relevant peer-reviewed articles

Remember to keep complete records, including a copy of the materials that you send and a log of telephone calls made to the patient's health insurance plan.

Sample Letter of Medical Necessity

Below is a template you can use to draft your Letter of Medical Necessity.

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Physician Letterhead

Current Date
[Insurance Company Contact]
[Insurance Company Name]
[Insurance Company Address]
[Insurance Company City, State, ZIP]
Re: Letter of Medical Necessity for FENSOLVI®

Patient: [Patient's First and Last Name]
Subscriber ID #: [Insurance Subscriber ID]
Subscriber Group #: [Insurance Group ID]
Case ID Number: [if available]
Date of Birth: [Patient's Date of Birth]

To Whom It May Concern:

I am writing on behalf of my patient, [patient first and last name] to document the medical necessity and support for the coverage of FENSOLVI® (leuprolide acetate) for injectable suspension for the treatment of central precocious puberty (CPP).

This letter provides my reasons for requesting the use of FENSOLVI® for [Patient's First and Last Name]. I have also included a brief description of the patient's medical history, including prior therapies, and their current condition and diagnosis and a statement summarizing my treatment rationale.

Patient's Clinical History and Diagnosis:
[Patient first and last name] was diagnosed with CPP on [date]. [He/She] has been in my care since [date]. [Include a brief summary of rationale for treatment with Fensolvi. This may include the ICD-10-CM code, the severity of the patient's condition, and any prior treatments, including the duration of those treatments. You may also include any other factors (e.g., underlying health issues, age) that have affected your treatment selection.]

Treatment Rationale and Plan:
FENSOLVI® received FDA approval on May 4, 2020 for the treatment of CPP. FENSOLVI® is administered by subcutaneous injection once every 6 months, and provides a wide range of injection site options. FENSOLVI® has been selected over other available GnRHa treatments because of its clinical data and unique product characteristics. [Include your specific treatment plan and clinical practice guidelines that support the use of FENSOLVI®. You may consider mentioning experts in the field who also support the treatment or other relevant experience that supports the use of FENSOLVI®. You may also choose to include your professional opinion about the anticipated outcomes and the potential to reach the anticipated outcome, as well as the patient's likely prognosis or disease progression without treatment with FENSOLVI®.]

Summary:
Based on the above information [and attached documentation], FENSOLVI® is medically appropriate and necessary to manage CPP in [patient first and last name]. Please contact my office by calling [Practice Phone Number] for any additional information you may require to ensure the prompt approval of FENSOLVI®.

Sincerely,
(Physicians name signature)
(Physicians name)
[Provider Identification Number]
[Name of Practice]
[Phone Number]

RELEVANT ICD-10 CODES	E30.1 (precocious puberty) E22.8 (other hyperfunction of pituitary gland)

Please see Important Safety Information on page 3

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Important Safety Information for Fensolvi®

fensolvi® (leuprolide acetate) for injectable suspension

INDICATION

FENSOLVI® (leuprolide acetate) for injectable suspension is a gonadotropin releasing hormone (GnRH) agonist used to treat patients 2 years of age and older with central precocious puberty (CPP). CPP may be diagnosed when signs of sexual maturity begin to develop in girls under the age of 8 or in boys under the age of 9.

IMPORTANT SAFETY INFORMATION

FENSOLVI is contraindicated in individuals with hypersensitivity to any drug that is in the same class as FENSOLVI, in individuals who are allergic to any of the ingredients in FENSOLVI, or in individuals who are pregnant. FENSOLVI may cause fetal harm when administered to a pregnant patient.

During the first few weeks of treatment, increases in gonadotropins and sex steroids above baseline may result in an increase in signs and symptoms of puberty including vaginal bleeding in girls.

Psychiatric events have been reported in patients taking GnRH agonists. Events include emotional lability, such as crying, irritability, impatience, anger, and aggression. Patients should be monitored for development or worsening of psychiatric symptoms.

Convulsions have been observed in patients treated with GnRH agonists with or without a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and in patients on concomitant medications that have been associated with convulsions such as bupropion and SSRIs.

Pseudotumor Cerebri (Idiopathic Intracranial Hypertension) has been reported in pediatric patients treated with GnRH agonists. Patients should be monitored for headache, papilledema and blurred vision.

The most common adverse events seen with FENSOLVI were: injection site pain, nasopharyngitis, pyrexia, headache, cough, abdominal pain, injection site erythema, nausea, constipation, vomiting, upper respiratory tract infection, bronchospasm, productive cough and hot flush.

Please click for full Prescribing Information or visit fensolvi.com/hcp

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