Lupron Depot®
(leuprolide acetate for depot suspension)



NAVIGATING THE PRIOR AUTHORIZATION (PA) PROCESS FOR LUPRON DEPOT®

Learn How You Can Help Your Patients With Uterine Fibroids Access Their Medication Without Delay

INDICATION

Uterine Leiomyomata (Fibroids)

LUPRON DEPOT® (leuprolide acetate for depot suspension) 3.75 mg or 11.25 mg used concomitantly with iron therapy is indicated for the preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary.

Consider a one-month trial period on iron alone, as some women will respond to iron alone. LUPRON DEPOT 3.75 mg or 11.25 mg may be added if the response to iron alone is considered inadequate.

Limitations of Use:

LUPRON DEPOT 3.75 mg or 11.25 mg is not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- LUPRON DEPOT 3.75 mg or 11.25 mg is contraindicated in patients who are hypersensitive to gonadotropin-releasing hormone (GnRH), GnRH agonist analogs including leuprolide acetate, or any of the excipients in LUPRON DEPOT; in patients with undiagnosed abnormal uterine bleeding; and in pregnancy.

WARNINGS AND PRECAUTIONS

Loss of Bone Mineral Density

- LUPRON DEPOT 3.75 mg or 11.25 mg induces a hypoestrogenic state that results in loss of bone mineral density (BMD), some of which may not be reversible after stopping treatment. In women with major risk factors for decreased BMD, such as chronic alcohol use (>3 units per day), tobacco use, strong family history of osteoporosis, or chronic use of drugs that can decrease BMD, such as anticonvulsants or corticosteroids, use of LUPRON DEPOT may pose an additional risk. Carefully weigh the risks and benefits of LUPRON DEPOT use in these populations.
- The duration of LUPRON DEPOT 3.75 mg or 11.25 mg treatment is limited by the risk of loss of BMD.

Please see additional Important Safety Information for LUPRON DEPOT® throughout.
Please see full Prescribing Information at www.luprongyn.com/prescribing-information

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WHEN PRESCRIBING LUPRON DEPOT® FOR YOUR PATIENT, DETERMINE WHETHER THE PAYER REQUIRES A PA

Overview of the PA Process and where to find plan-specific forms

Insurance plans often require a PA for certain medications to confirm their medical necessity and to manage healthcare costs effectively. Generally, healthcare providers must fill out a form and submit to the patient's medical or pharmacy insurance benefit plan.

Completing PA Forms: Healthcare providers must fill out a form detailing the necessity of the medication for the patient's condition. This form is then submitted to the patient's medical or pharmacy insurance benefit plan for review

- Providers should verify with each insurer if specific PA forms are needed

You may obtain the PA form through one of the following:

- Health plan's website
- Third-party vendors (see below for more)
- Lupron Support PLUS™ 1-855-LUPRON-P (1-855-587-7667)
- Pharmacy

Third-Party Vendors: Some third-party vendors provide online portals to help streamline the PA process, with the goal of:

- Assisting with patient access to appropriate treatments and products
- Improvement in time-to-therapy and decreased prescription abandonment

LUPRON DEPOT® partners with CoverMyMeds®—to learn more, call 1-866-452-5017 or visit covermymeds.com

Approval: After submission, the medical or pharmacy insurance benefit plan reviews the PA request. The insurance plan must approve the medication before it can be dispensed.

Documentation: Healthcare providers must document claim approval or denial outcome, including date and reference number to the patient's chart.

PA Approval Timeline: PA approval may vary. Please follow up directly with the patient's health plan (payer/insurance provider) if your office has not received a PA approval or denial determination in a timely manner.

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HELP REDUCE PA DELAYS AND DENIALS

From coverage limits to documentation gaps, small issues can lead to delays or denials

Most Common Reasons for PA Denial May Include:

- The patient hasn't stepped through the required medications
- Questions about necessity
- Administrative errors
- Incomplete documentation
  - Missing or outdated lab results (LH/FSH, steroids)
  - Bone age x-ray report not attached
  - GnRH stimulation test not documented with actual values
  - Age at onset not clearly stated in chart notes
- LUPRON DEPOT® is not covered by the patient's medical or pharmacy benefit formulary
- Unspecified ICD-10 codes
- For PA renewals, missing documentation of clinical improvement

Helpful Tips for a Streamlined PA Process:

- Check Specific Payer Requirements: PA criteria can differ for each health plan
  - Always verify the patient's insurance requirements beforehand

- Complete Documentation Is Key. Ensure these areas are clearly documented:
  - Patient Name
  - Insurance ID/member ID, group number
  - Medicaid/Medicare ID (if applicable)
  - Accurate diagnosis with correct ICD-10 code
  - Medical benefit/pharmacy benefit J-code
  - Place of service (office, clinic, or home infusion)
  - Disease severity
  - Individual clinical considerations that support starting and continuing treatment
  - Patient's age and duration since diagnosis
  - Current and previous therapies—hormonal treatments, other relevant medications, therapies contraindicated or previously tried—include drug name, duration on therapy, and outcomes
  - Prescribed dosing and duration
  - Results from any clinical testing

If you have any questions about payer requirements, documentation, or follow-up steps, contact your Sales Representative for support that can help keep the prior authorization process moving smoothly.



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KEY REQUIREMENTS FOR PRIOR AUTHORIZATION

Patients will likely need to meet authorization criteria, which may vary slightly with each plan. Below are the general PA requirements.*

	Treatment of Patients With: Uterine Fibroids
Diagnostic Criteria	**Documentation** of a confirmed uterine fibroids diagnosis, which may include: • Imaging, ultrasound, MRI, or gynecologic evaluation supporting the diagnosis • Documentation of disease severity and related symptoms • If used preoperatively, documentation of the planned surgery and treatment goal
Medication-Specific Requirements	• **Prescriber requirements** may vary by plan • **Step therapy:** Some plans may require a trial of or documented intolerance to preferred therapies before approval • **Prior treatment history** should be documented, including use of hormonal contraceptives, progestins, NSAIDs, or other relevant therapies, along with outcomes • If anemia is **part of the rationale**, hemoglobin/hematocrit or iron studies may be needed
Continuation of Therapy	• Documentation that treatment **remains medically necessary** • Evidence of **continued benefit**, such as improved anemia, reduced fibroid-related symptoms, or continued preoperative support • **Continued alignment** with plan criteria for duration and dosing

*Not a complete list. This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. The information presented here does not guarantee payment or coverage. Providers are encouraged to contact third-party payers for specific information about their coverage policies.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Embryo-Fetal Toxicity

- Based on animal reproduction studies and the drug's mechanism of action, LUPRON DEPOT 3.75 mg or 11.25 mg may cause fetal harm if administered to a pregnant woman and is contraindicated in pregnant women. Exclude pregnancy prior to initiating treatment with LUPRON DEPOT 3.75 mg or 11.25 mg, if clinically indicated. Discontinue LUPRON DEPOT 3.75 mg or 11.25 mg if the woman becomes pregnant during treatment and inform the woman of potential risk to the fetus. Advise women to notify their healthcare provider if they believe they may be pregnant.
- When used at the recommended dose and dosing interval, LUPRON DEPOT 11.25 mg usually inhibits ovulation and stops menstruation. Contraception, however, is not ensured by taking LUPRON DEPOT 11.25 mg. If contraception is indicated, advise women to use non-hormonal methods of contraception while on treatment with LUPRON DEPOT 3.75 mg or 11.25 mg.

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KEY REQUIREMENTS FOR RENEWAL AUTHORIZATION

To support renewal authorization, confirm that the patient continues to meet the plan's coverage criteria and that documentation is available to show ongoing benefit from treatment.

Patient status and treatment response

- The patient is **still currently receiving** LUPRON DEPOT® through a paid pharmacy or medical benefit
- The patient **continues** to have a documented diagnosis of uterine fibroids
- If treatment is being used **preoperatively**, documentation supports that the patient is still preparing for surgery or continuing to benefit from preoperative therapy
- The patient has shown **ongoing clinical benefit**, such as reduced fibroid-related symptoms and/or improved anemia
- The patient has not experienced **treatment failure**, loss of response, or intolerable adverse effects
- If applicable, documentation supports **continued improvement** in hemoglobin/hematocrit or other anemia-related measures

Prescribing and supporting documentation

- The medication is being prescribed by, or in consultation with, an **appropriate specialist or physician** experienced in this area
- **Supporting clinical documentation**, imaging, labs, or notes are available to confirm the above

Helpful tip...
Consider including a Letter of Medical Necessity (LMN) when appropriate. It may help support the patient-specific rationale for medical necessity and continuity of care.

For support during both authorization and renewal requests, your Sales Representative can help guide you through payer requirements, documentation needs, and follow-up steps.



IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Severe Cutaneous Adverse Reactions

- Severe cutaneous adverse reactions (SCARs) have been reported in patients receiving GnRH agonists, including LUPRON DEPOT. These reactions include Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP), including cases with visceral involvement and/or requiring skin grafts.

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GET THE CODES RIGHT TO SUPPORT A SMOOTHER PA PROCESS

Using the right codes can support timely review and accurate claims submission

Using the correct diagnosis and billing codes can reduce delays and support more complete prior authorization and claims submission.

Diagnosis code

For uterine fibroids, the relevant ICD-10 codes are:

- **D25.0** — Submucous leiomyoma of uterus
- **D25.1** — Intramural leiomyoma of uterus
- **D25.2** — Subserosal leiomyoma of uterus
- **D25.9** — Leiomyoma of uterus, unspecified

Billing and administration codes

For claims, you may also need the following codes for the medication and its administration:

- **HCPCS J1950** — Injection, leuprolide acetate for depot suspension, per 3.75 mg
- **HCPCS J9217** — Leuprolide acetate for depot suspension, 7.5 mg
- **HCPCS 96402** — Chemotherapy administration, subcutaneous or intramuscular, non-hormonal anti-neoplastic

Helpful tip...
Always confirm the exact ICD-10 and billing requirements with the patient's health plan before submitting. Requirements may vary by insurer.

For help with confirming payer-specific coding and billing requirements, contact your Sales Representative.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Severe Cutaneous Adverse Reactions (continued)

- Monitor patients for the signs and symptoms of SCARs, such as fever, flu-like symptoms, mucosal lesions, progressive skin rash, or lymphadenopathy. Advise patients of the signs and symptoms of SCARs.
- If a SCAR is suspected, discontinue LUPRON DEPOT 3.75 mg or 11.25 mg. Consult with a healthcare provider with expertise in the diagnosis and management of SCARs. If a diagnosis of SCAR is confirmed, permanently discontinue LUPRON DEPOT 3.75 mg or 11.25 mg.

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STAY ON TRACK FROM START TO FINISH

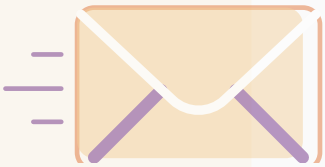
A simple process can help support smoother prior authorizations and renewals

Prepare



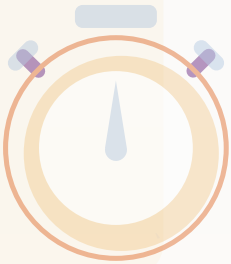
- **Obtain** the prior authorization form from the patient's medical or pharmacy benefit health plan website, pharmacy, or third-party vendor
- **Complete** the form with the required clinical and medication information
- **Verify** that all information is accurate and supported by the chart

Send



- **Submit** the completed form to the patient's health plan for review
- **Photocopy** the patient's pharmacy or medical benefit plan care card (front and back)
- **Follow up** with the payer if a decision has not been received in a timely manner
- **Review** submission status based on the payer's process and submission method

Track



- **Follow up** with the health plan to verify that all documentation was received
  - Log every phone call you make
  - Write down the person's name with whom you speak, the date and time, what was said, and the call reference number they provide
- **Contact** your local Sales Representative for help reviewing the outcome and next steps
- **Notify** the patient's pharmacy once the prior authorization is approved
- **Document** the prior authorization expiration date so renewal can be managed on time

Helpful tip...
Have the correct contact information ready so you can quickly reach the appropriate personnel at the health plan.

If you need help streamlining your PA process, contact your Sales Representative.



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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Hypersensitivity Reactions

- Hypersensitivity reactions, including anaphylaxis, have been reported with LUPRON DEPOT use. LUPRON DEPOT 3.75 mg and 11.25 mg are contraindicated in women with a history of hypersensitivity to gonadotropin-releasing hormone (GnRH) or GnRH agonist analogs.
- In clinical trials of LUPRON DEPOT 3.75 mg and 11.25 mg, adverse events of asthma were reported in women with pre-existing histories of asthma, sinusitis, and environmental or drug allergies. Symptoms consistent with an anaphylactoid or asthmatic process have been reported postmarketing.

Initial Flare of Symptoms

- Following the first dose of LUPRON DEPOT 3.75 mg or 11.25 mg, sex steroids temporarily rise above baseline because of the physiologic effect of the drug. Therefore, an increase in symptoms may be observed during the initial days of therapy, but these should dissipate with continued therapy.

Convulsions

- There have been postmarketing reports of convulsions in women on GnRH agonists, including leuprolide acetate. These included women with and without concurrent medications and comorbid conditions.

Clinical Depression

- Depression may occur or worsen during treatment with GnRH agonists, including LUPRON DEPOT 3.75 mg or 11.25 mg. Carefully observe women for depression, especially those with a history of depression, and consider whether the risks of continuing LUPRON DEPOT 3.75 mg or 11.25 mg outweigh the benefits. Women with new or worsening depression should be referred to a mental health professional, as appropriate.

ADVERSE REACTIONS

- Most common adverse reactions (>10%) in clinical trials were hot flashes/sweats, headache/migraine, vaginitis, depression/emotional lability, general pain, weight gain/loss, nausea/vomiting, decreased libido, and dizziness.

These are not all the possible side effects of LUPRON DEPOT 3.75 mg or 11.25 mg.

- Safety and effectiveness of LUPRON DEPOT 3.75 mg or 11.25 mg for the preoperative hematologic improvement of women with anemia caused by fibroids have been established in females of reproductive age. Efficacy is expected to be the same for postpubertal adolescents under the age of 18 as for users 18 years and older. The safety and effectiveness of LUPRON DEPOT 3.75 mg or 11.25 mg for this indication have not been established in premenarcheal pediatric patients.
- LUPRON DEPOT 3.75 mg or 11.25 mg is not indicated in postmenopausal women and has not been studied in this population.

Please click here for full Prescribing Information, or visit www.luprongyn.com/prescribing-information

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