Updated: 03/2019
PARP Approved: 04/2019

Prior Authorization Criteria

Lupron, Lupron Depot, Lupron Depot-Ped (leuprolide acetate)

All requests for Lupron, Lupron Depot, Lupron Depot-Ped (leuprolide acetate) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Lupron, Lupron Depot, Lupron Depot-Ped (leuprolide acetate) all of the following criteria must be met:

- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

Coverage may be provided with a diagnosis of **advanced prostate cancer** for palliative treatment

- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Documentation of continued benefit from therapy
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **endometriosis** and the following criteria is met:

- Must meet one of the following diagnostic criteria:
  - Confirmed by laparoscopy
  - Must complete an evaluation to exclude other causes of pelvic pain, such as irritable bowel syndrome (IBS), interstitial cystitis, fibromyalgia, and musculoskeletal disorders (e.g. trigger point pain and pelvic floor dysfunction), abnormalities of the urinary, gastrointestinal, neurologic and musculoskeletal systems, as well as manifestations of psychological or psychiatric disorders
- Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to BOTH of the following:
  - Estrogen-progestin contraceptives, progestins, or danazol
  - NSAIDs
- **Initial Duration of Approval:** 6 months (1 treatment course)
- **Reauthorization criteria**
  - Documentation of the reason for retreatment
  - Maximum of 2 total courses of treatment (12 months)
- **Reauthorization Duration of Approval:** 6 months

Coverage may be provided with a diagnosis of **uterine leiomyomata (fibroids)** and the following criteria is met:

- Must be used preoperatively to shrink fibroid(s) to allow a less invasive surgical approach
- If member has anemia, must have tried and failed a one month trial of iron therapy
- **Initial Duration of Approval:** 3 months (1 treatment course)
- **Reauthorization criteria**

  - Documentation of the reason for delay in surgery
  - Maximum of 2 total courses of treatment (6 months)
- **Reauthorization Duration of Approval:** 3 months (1 treatment course)

Coverage may be provided with a diagnosis of **central precocious puberty** (CPP) and the following criteria is met:

- Current age ≤ 11 for females or ≤ 12 for males
- Must meet all of the following diagnostic criteria:
  - Baseline LH and FSH in pubertal range
  - A pubertal response to a GnRH stimulation test
  - Advanced bone age (≥2 standard deviations above the gender/age related mean or bone age at least 1 year greater than chronological age)
  - Neuro-imaging (CT or MRI) to rule out intracranial tumor
  - Adrenal steroid levels to exclude congenital adrenal hyperplasia
  - If a male, human chorionic gonadotropin level to rule out a chorionic gonadotropin secreting tumor
- Onset of secondary sexual characteristics occurred < 8 years of age in a female or < 9 years of age in a male
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Current age ≤ 11 years old for females or ≤ 12 years old for males
  - Documentation of a physical exam in the past year with evaluation of growth and pubertal development
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **gender dysphoria** to suppress puberty in an adolescent and the following criteria is met:

- The adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed)
- Co-existing psychological, medical, or social problems that could interfere with treatment (e.g. that may compromise treatment adherence) have been addressed, such that the adolescent's situation and function are stable enough to start treatment
- The adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parent or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process. When parental consent cannot be obtained, exceptions will be reviewed on a case by case basis and in conjunction with the prescriber.
- Documentation of laboratory testing to monitor the safety of continuous hormone therapy
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria:**
  - Documentation indicating stability or improvement in gender dysphoria
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or

peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

Gateway Health

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LUPRON, LUPRON DEPOT, LUPRON DEPOT-PED (leuprolide acetate)
PRIOR AUTHORIZATION FORM – PAGE 1 of 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health[SM] Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____
Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:

☐ Advanced prostate cancer, ICD-10: _____
☐ Endometriosis, ICD-10: _____
- Has the diagnosis been confirmed by laparoscopy? ☐ Yes ☐ No *(must provide chart documentation of an evaluation to exclude other diagnoses)*
- What has been tried? ☐ NSAIDs *(listed below)* ☐ Contraceptives, progestins, or danazol *(listed below)*

☐ Uterine leiomyomata (fibroids), ICD-10: _____
- Does the member have anemia? ☐ Yes ☐ No
  - If yes, has a month of iron therapy been tried? ☐ Yes ☐ No
- Is this being used as a preoperative adjuvant to surgery? ☐ Yes ☐ No

☐ Central precocious puberty (CPP), ICD-10: _____
- What age was the onset of secondary sexual characteristics? _____
- Is baseline LH and FSH in pubertal range? ☐ Yes ☐ No
- Was there a pubertal response to a GnRH stimulation test? ☐ Yes ☐ No
- Does the member have advanced bone age? ☐ Yes ☐ No
- Has neuro-imaging been done? ☐ Yes ☐ No
- Have adrenal steroid levels been checked? ☐ Yes ☐ No
- If male, has human chorionic gonadotropin level been checked? ☐ Yes ☐ No

☐ Gender Dysphoria, ICD-10: _____
- Is this being used to suppress puberty in an adolescent? ☐ Yes ☐ No
- Has the adolescent demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed)? ☐ Yes ☐ No
- Have co-existing psychological, medical, or social problems that could interfere with treatment been addressed such that the adolescent's situation and function are stable enough to start treatment? ☐ Yes ☐ No
- Has the adolescent, parent, or other caretaker/guardian given informed consent? ☐ Yes ☐ No
- Has baseline lab monitoring been done? ☐ Yes ☐ No

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LUPRON, LUPRON DEPOT, LUPRON DEPOT-PED (leuprolide acetate)
PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Prostate cancer: Does the member continue to benefit from therapy? ☐ Yes ☐ No

Endometriosis: Provide the reason for retreatment: _____
_____

Uterine leiomyomata (fibroids): Provide the reason for delay in surgery:
_____

Central precocious puberty (CPP): Did member have a physical exam in the past year with evaluation of growth and pubertal development? ☐ Yes ☐ No

Gender dysphoria: Has the member experienced stability or improvement as a result of treatment? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date