Updated: 04/2025
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Request for Prior Authorization for Leuprolide Acetate Products
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Leuprolide acetate products require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Leuprolide Acetate Prior Authorization Criteria:

Leuprolide acetate products include Lupron, Lupron Depot, Lupron Depot Ped, Fensolvi, Camcevi, Eligard and Viadur. New leuprolide acetate products will require the same documentation.

* Note: please reference the Highmark Health Options Gender Transition Services (MP-033-MD-DE) policy for all gender dysphoria requests.

For all requests for leuprolide acetate products all of the following criteria must be met:

- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
- 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 prostatic 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
  - Chart documentation of an adequate work-up that includes the clinical rationale for the diagnosis
- 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:
  - A three (3) month trial of an oral contraceptive or progestins
  - NSAIDs
- Prescribed by or in consultation with a gynecologist or reproductive endocrinologist
- **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 (one additional treatment course; maximum of 2 courses)

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

- If member has anemia, must have tried and failed a one month trial of iron therapy
- Must be used preoperatively to shrink fibroid(s) to allow a less invasive surgical approach
- History of trial (based on a three month trial) and failure, contraindication, or intolerance to one of the following:
  - Estrogen-progestin contraceptives
  - Progestins
- **Initial Duration of Approval:** 3 months (one treatment course)
- **Reauthorization criteria:**
  - Documentation of the reason for delay in surgery
  - Maximum of 2 total courses of treatment
- **Reauthorization Duration of Approval:** 3 months (one additional treatment course; maximum of 2 courses total)

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

- Current age ≤ 11 years of age for female, ≤ 12 years of age for male
- Must meet all of the following diagnostic criteria:
  - Baseline LH and FSH measurements in the pubertal range
  - A pubertal response to a GnRH stimulation test performed by a pediatric endocrinologist
  - 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 CNS lesions
  - If a male, beta human chorionic gonadotropin level to rule out a chorionic gonadotropin secreting tumor
- Baseline evaluation including height, weight, sex steroid levels, and adrenal steroid level
- Onset of secondary sexual characteristics occurred < 8 years of age in a female child or < 9 years of age in a male child
- Prescribed by or in consultation with a pediatric endocrinologist
- **Initial Duration of Approval:** 12 months
- **Reauthorization Criteria:**

  - Documentation of a physical exam within the past year with evaluation of growth and pubertal development

  - Current age ≤ 11 years of age for female or ≤ 12 years of age for male
- **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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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LEUPROLIDE ACETATE PRODUCTS
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 Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon-Fri 8:00am to 7:00pm

PROVIDER INFORMATION

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

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No		

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 adequate workup that includes clinical rationale for the diagnosis)*
- What has been tried (list below with dates)? ☐ NSAIDs ☐ Contraceptives, progestins, or danazol

☐ 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
- Has the member had a trial and failure, contraindication or intolerance to one of the following: estrogen-progestin contraceptives or progestins? ☐ 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

☐ Other: _____, ICD-10: _____

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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 Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6253 Mon-Fri 8:00am to 7:00pm

MEMBER INFORMATION

Member Name:	DOB:	
Health Options ID:	Member weight:	Height:

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

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date