

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

DRUG NAME	Lupron Depot and Lupron Depot-PED (leuprolide acetate)
BILLING CODE	J1950, J9217, J9218
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Products) QUANTITY LIMIT— see “ <b>Dosage allowed</b> ” below
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Lupron Depot and Lupron Depot-PED (leuprolide acetate) are **preferred** products and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### CANCER

Any request for **advanced breast cancer** or **advanced prostate cancer** must be submitted through [NantHealth/Eviti](#) portal.

### CENTRAL PRECOCIOUS PUBERTY (CPP) – Lupron Depot – PED only

For **initial** authorization:

1. Member is 2 years old or older; AND
2. Member has early onset of puberty symptoms before the age of 8 for female or 9 for male; AND
3. Member has confirmed diagnosis of central precocious puberty, as evidenced by **both** of the following:
  - a) Pubertal response to a gonadotropin releasing hormone (GnRH) stimulation test OR pubertal levels of basal luteinizing hormones (LH) and estradiol or testosterone hormones;
  - b) Bone age is advanced by at least one year greater than chronological age; AND
4. Medication must be prescribed by or in consultation with an endocrinologist; AND
5. Member’s baseline LH level, sex steroid level (estradiol or testosterone), height, and weight are submitted with chart notes.
6. **Dosage allowed:** Lupron Depot-PED only – 1 intramuscular (IM) injection once a month (7.5mg, 11.25mg, or 15mg) OR 1 injection every 3 months (11.25mg or 30 mg).

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. If member is 11 years or older for females or 12 years or older for males, prescriber must provide a clinical reason for continuing medication beyond the recommended age for resuming puberty; AND
2. Chart notes have been provided showing efficacy of response (e.g., slowed growth rate, slowed bone age advancement, LH and sex steroid hormone levels have been suppressed or reduced from baseline).

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## ENDOMETRIOSIS – Lupron Depot only

For **initial** authorization:

1. Member is premenopausal and 18 years of age or older; AND
2. Member is having painful symptoms (e.g., pelvic pain, dysmenorrhea, etc.) associated with endometriosis (documentation required); AND
3. Medication must be prescribed by or in consultation with a gynecologist; AND
4. Member has tried and failed to control symptoms after trials with **both** of the following, unless not tolerated or contraindicated:
  - a) 30 days of an NSAID;
  - b) 3 months of a hormonal contraceptive; AND
5. Member does **not** have any of the following:
  - a) Pregnancy or plan to become pregnant while taking medication;
  - b) Undiagnosed abnormal uterine bleeding.
6. **Dosage allowed:** Lupron Depot 3.75 mg monthly or 11.25 mg every 3 months.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Member has recurrence of endometriosis symptoms after the first course of treatment; AND
2. Medication must be used concomitantly with norethindrone acetate 5 mg (daily add-back therapy). Retreatment will not be allowed without norethindrone acetate due to risk of bone loss; AND
3. Duration of treatment has not exceeded 12 months.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months. Reauthorization will not be allowed after 12 months of therapy.***

## UTERINE LEIOMYOMAS (FIBROIDS) – Lupron Depot only

For **initial** authorization:

1. Member is premenopausal and 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with a gynecologist; AND
3. Member has anemia associated with heavy menstrual bleeding due to uterine fibroid (hemoglobin lab result required);
4. Member's anemia has not improved after a 30 days of supplemental iron therapy; AND
5. Member will be having a surgery to remove fibroid and the proposed surgery date or timeframe is submitted with chart notes; AND
6. Medication must be used concomitantly with iron, unless not tolerated; AND
7. Member does **not** have any of the following:
  - a) Pregnancy or plan to become pregnant while taking medication;
  - b) Undiagnosed abnormal uterine bleeding.
8. **Dosage allowed:** Lupron Depot 3.75 mg monthly for up to 3 months or Lupron Depot 11.25 (3-month injection) as a single injection. Lupron must be used concomitantly with iron therapy.

***If member meets all the requirements listed above, the medication will be approved for 3 months.***

For **reauthorization**:

The use of Lupron is limited to 3 months of therapy to improve hemoglobin level prior to fibroid surgery. Therefore, reauthorization is not allowed.

**CareSource considers Lupron Depot and Lupron Depot-PED (leuprolide acetate) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:**

- Dysfunctional Uterine Bleeding

DATE	ACTION/DESCRIPTION
10/09/2018	New policy for Lupron created. Age requirement for Central Precocious Puberty and diagnostic evaluation assessment were revised. Coverage for Advanced Breast Cancer is specified for hormone receptor-positive breast cancer. “Proposed date of planned fibroid surgery” criterion was added to diagnosis of Uterine Leiomyomas. Diagnosis of Dysfunctional uterine bleeding was removed. The requirement for increased uterine volume from the female criteria in CPP was removed.
07/28/2020	Carved out Advanced Breast Cancer and Advanced Prostate Cancer to Eviti. For central precocious puberty, updated diagnostic requirements to require both: advanced bone age and GnRH stimulation test or pubertal hormone levels; specified baseline LH hormones; removed ruled out diagnoses; removed list of secondary puberty signs and symptoms (redundancy); added requirement for discontinuation of treatment in reauth; added prescriber requirement. Initial approval duration changed from 12 to 6 months.
10/08/2020	For <u>uterine leiomyomas</u> : Added requirement of anemia associated with heavy bleeding due to fibroids to meet diagnosis. Added a 30-day trial of iron therapy in accordance to drug label. Added that Lupron must be used concomitantly with iron therapy. For <u>endometriosis</u> : Removed requirement of norethindone concurrent use in initial auth. Simplified symptoms. Reduced duration of reauth to 6 months from 12 months. Total duration of approval (initial + retreatment) cannot exceed 12 months per drug labeling. Added that member has to be symptomatic to request reauthorization.

References:

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