CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Ohio Medicaid

DRUG NAME	Lupron Depot and Lupron Depot-PED (leuprolide acetate)
BENEFIT TYPE	Medical
STATUS	Prior Authorization Required

Lupron Depot and Lupron Depot-PED, initially approved by the FDA in 1985, are gonadotropin-releasing hormone (GnRH) agonists. Lupron Depot is indicated for the management of endometriosis, including pain relief and reduction of endometriotic lesions and concomitant use with iron therapy for preoperative hematologic improvement of women with anemia caused by fibroids for whom three months of hormonal suppression is deemed necessary. Lupron Depot-PED is indicated for the treatment of pediatric patients with central precocious puberty.

Lupron Depot and Lupron Depot-PED (leuprolide acetate) will be considered for coverage when the following criteria are met:

Central Precocious Puberty (CPP) (Lupron Depot–Ped Only)

For **initial** authorization:

1. Member is 1 year old or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has early onset of puberty symptoms before the age of 8 years for females or 9 years for males; AND
4. Member has a 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 hormone (LH);
    b. Advanced bone age for chronological age; AND
5. Member's baseline LH level, sex steroid level (estradiol or testosterone) weight and height are submitted with chart notes.
6. **Dosage allowed/Quantity limit:**
    a. Inject 11.25 mg or 30 mg intramuscularly once every three months; OR
    b. Inject 45 mg intramuscularly once every six months; OR
    c. Inject intramuscularly once monthly (see table below).

Body Weight	Recommended Monthly Dosage
Less than or equal to 25 kg	7.5 mg
Greater than 25 kg up to 37.5 kg	11.25 mg
Greater than 37.5 kg	15 mg

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided showing improvement in signs and symptoms of CPP (e.g., slowed growth rate, slowed bone age advancement, LH and sex steroid hormone levels have been suppressed or reduced from baseline); AND
2. 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

If all the above requirements are met, the medication will be approved for an additional 12 months.

Endometriosis and Uterine Leiomyomas (Fibroids)

Criteria found on the Ohio Department of Medicaid's Unified Preferred Drug List.

Advanced Breast Cancer or Advanced Prostate Cancer

Any request for cancer must be submitted through NantHealth/Eviti portal.

CareSource considers Lupron Depot and Lupron Depot-PED (leuprolide acetate) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
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.
03/11/2024	Transferred to new template; updated references. CPP: lowered age limit from 2 years of age to 1 year of age; removed requirement of estradiol/testosterone level from LH testing; simplified bone age requirement from 1 year or greater to advanced. 11/19/24 Approved by ODM

References:

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