CareSource

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 Product) QUANTITY LIMIT— see "**Dosage allowed**" below
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

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-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.

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ENDOMETRIOSIS

For **initial** authorization:

1. Member is a female of 18 years of age or older; AND
2. Member is not currently breast feeding, pregnant, or planning to become pregnant while receiving medication; AND
3. Medication must be prescribed by a gynecologist or an obstetrician; AND
4. Medication must be prescribed with daily norethindrone acetate 5 mg (Leuprolide Depot alone is not recommended for retreatment. If norethindrone acetate is contraindicated, then retreatment is not recommended); AND
5. Endometriosis symptoms, as indicated by **one** or more of the following:
   a) Dysmenorrhea;
   b) Dyspareunia;
   c) Pelvic pain; AND
6. Member has failed control of symptoms with ALL of the following:
   a) NSAIDs;
   b) Any contraceptives.
7. **Dosage allowed:** Lupron Depot 3.75 mg for 1-month or 11.25 mg for 3-month administration.

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

For **reauthorization**:

1. Leuprolide Depot alone is not recommended for retreatment. If norethindrone acetate is contraindicated, then retreatment is not recommended.

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

UTERINE LEIOMYOMAS (FIBROIDS)

For **initial** authorization:

1. Member is a female of 18 years of age or older; AND
2. Member is not currently breast feeding, pregnant, or planning to become pregnant while receiving medication; AND
3. Medication must be prescribed by gynecologist or obstetrician; AND
4. Proposed date of planned fibroid surgery submitted with chart notes; AND
5. Leiomyoma symptoms, as indicated by **one** or more of the following:
   a) Abnormal uterine bleeding;
   b) Bulk-related symptoms (e.g., pelvic pain or pressure, dyspareunia, urinary symptoms);
   c) Iron deficiency anemia;
   d) Other causes of symptoms or bleeding ruled out (e.g., by endometrial biopsy).
6. **Dosage allowed:** Lupron Depot 3.75 mg for 1-month and 11.25 mg for 3-month administration with iron therapy are prescription medications used before fibroid surgery to improve anemia due to vaginal bleeding from fibroids.

Note: Treatment beyond total of 3 months is considered unproven, therefore second reauthorization would not be allowed.

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

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.

References:

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