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) is a **preferred** product 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.

ADVANCED BREAST CANCER

For **initial** authorization:

1. Member is pre- OR peri-menopausal women with locally advanced, recurrent, or metastatic hormone receptor-positive breast cancer; AND
2. Member is not currently breast feeding, pregnant, or planning to become pregnant while receiving medication; AND
3. Medication must be prescribed by oncologist, gynecologist or obstetrician.
4. **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. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

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

CENTRAL PRECOCIOUS PUBERTY (CPP)

For **initial** authorization:

1. Pubertal symptoms appeared before the age of 9 in male member or before the age of 8 in female member; AND
2. Member has confirmed diagnostic evaluation, including assessment of **one** of the following:
   a) Bone age advanced one year beyond chronological age;
   b) Pubertal response to a gonadotropin releasing hormone (GnRH) stimulation test; AND
3. Member's baseline gonadal sex steroid hormone levels, adrenal steroid levels, height and weight are submitted with chart notes; AND
4. Other diagnosis are ruled out (e.g., intracranial tumors, congenital adrenal hyperplasia, chronic gonadotropin-secreting tumor, etc.); AND
5. Female member must meet ALL of the following:

a) Breast development Tanner stage 2 or greater;
b) Menstrual bleeding or vaginal discharge;
c) No pregnancy currently;
d) No undiagnosed abnormal vaginal bleeding; OR

6. Male member must meet ALL of the following:
   a) Signs and symptoms as indicated by **one** or more of the following:
      i) Acne;
      ii) Erections;
      iii) Nocturnal emissions;
      iv) Oily skin; AND
   b) Testicular volume 4 mL or greater.
7. **Dosage allowed:** Lupron Depot-PED - Single intramuscular injection. The starting dose 7.5 mg, 11.25 mg, or 15 mg for 1-month administration is based on the child's weight. The doses are either 11.25 mg or 30 mg for 3-month administration.

Note: Discontinuation of leuprolide for central precocious puberty should be considered at age 11 for girls and age 12 for boys.

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

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

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

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 gynecologist or 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.

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ADVANCED PROSTATE CANCER (Palliative Treatment)

For **initial** authorization:

1. Member has signs and symptoms of symptomatic locally advanced, recurrent, or metastatic disease; AND
2. Member has intermediate to high risk of disease recurrence in clinically localized prostate cancer, as indicated by **one** or more of the following:
   a) Intermediate risk of recurrence:
      i) T2a or lower, an aggressive histologic pattern (i.e., Gleason score of 7);
      ii) T2a or lower, and PSA 10 to 20mg/mL (mcg/L);
      iii) T2b or T2c;
   b) High risk of recurrence:
      i) T2c or lower, and aggressive histologic pattern (i.e., Gleason score of 8 to 10);
      ii) T2c or lower, and PSA greater than 20 ng/mL (mcg/L);
      iii) T3a; AND
3. Medication must be prescribed by urologist or oncologist.
4. **Dosage allowed:** Lupron Depot 7.5 mg for 1-month administration, given as a single intramuscular injection every 4 weeks. Lupron Depot 22.5 mg for 3-month administration, given as a single intramuscular injection every 12 weeks. Lupron Depot 30 mg for 4-month administration, given as a single intramuscular injection every 16 weeks. Lupron Depot 45 mg for 6-month administration, given as a single intramuscular injection every 24 weeks.

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

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease or member did not get any worse.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 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.

References:

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