SmartHealth Ascension

Leuprolide Acetate (for depot suspension) 3.75mg, 7.5mg

(Lupron Depot®) (Lupron Depot-Ped®) J1950 (3.75mg); J9217 (7.5mg)

Covered with prior authorization

Leuprolide Acetate (Lupron Depot®) (Lupron Depot-Ped®) may be authorized when the following criteria are met:

- **Individual is using for the treatment of salivary gland tumors**; **AND**
  - Individual has androgen receptor positive recurrent disease with distant metastases; **AND**
  - Individual has a current Easter Cooperative Oncology Group (ECOG) performance status of 0-3.

OR

- **Individual is using for the treatment of prostate cancer and any of the following are met:**
  - Used as androgen deprivation therapy as a single agent or in combination with an antiandrogen; **OR**
  - Used for clinically localized disease with intermediate (T2b to T2c cancer, Gleason score of 7/Gleason grade group 2-3, or prostate specific antigen (PSA) value of 10-20 ng/mL) or higher risk of recurrence as neoadjuvant therapy with radiation therapy or cryosurgery; **OR**
  - Used for progressive castration-naïve disease; **OR**
  - Used for castration-recurrent disease; **OR**
  - Other advanced, recurrent, or metastatic diseases.

OR

- **Individual is using for the treatment of ovarian cancer (including fallopian tube cancer and primary peritoneal cancer) and the following are met:**
  - Hormonal therapy for clinical relapse in individuals with stage II-IV granulosa cell tumors; **OR**
  - Hormonal therapy for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer as a single agent for persistent disease or recurrence.

OR

- **Individual is using for the treatment of men and pre- or peri-menopausal women with hormone receptor positive breast cancer.**

OR

- **Individual is using in the preservation of fertility in pre-menopausal women; AND**
  - Individual currently has a cancer diagnosis; **AND**
  - Individual meets one of the following:
    - Individual will receive chemotherapy for cancer with a curative intent; **OR**
    - Individual will receive radiation therapy for cancer with a curative intent.

OR

- **Individual has a diagnosis of central precocious puberty (CPP)** (defined as the beginning of secondary sexual characteristics before age 8 in girls and 9 in boys); **AND**
- Individual is 14 years of age or younger; **AND**
- Documentation is provided that the diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin hormone (GnRH) agonist test of a pubertal level of a third generation luteinizing hormone (LH) assay; **AND**
- The diagnosis has been confirmed by assessment of bone age versus chronological age.

OR

- **Individual has a diagnosis of chronic pelvic pain** (defined as ”pain symptoms perceived to originate from pelvic organs or structures typically lasting more than six months…with symptoms suggestive of lower urinary tract, sexual, bowel, pelvic floor, myofascial, or gynecological dysfunction”.)

OR

- **Individual is using to induce amenorrhea** (such as, but not limited to, menstruating women diagnosed with severe thrombocytopenia or aplastic anemia.)

OR

- **Individual is using for initial treatment or retreatment of endometriosis.**

OR

- **Individual is using for preoperative treatment as adjunct to surgical treatment of uterine fibroids (leiomyoma uteri), such as, but not limited to, reducing the size of fibroids to allow for a vaginal procedure.**

OR

- **Individual is using prior to surgical treatment (myomectomy or hysterectomy) in those with a diagnosis of confirmed anemia**.

OR

- **Individual is using for endometrial thinning prior to endometrial ablation for dysfunctional uterine bleeding.**

Exclusion criteria:
Requests may not be approved for the following:

- Pre-menopausal women diagnosed with non-invasive ductal carcinoma in situ (DCIS) of the breast.
- Peripheral precocious puberty.
- Benign or non-progressive precocious puberty.
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization approval

- Chronic Pelvic Pain: up to 3 months
- Endometriosis:Initial Treatment: up to 6 months
- Other indications: up to 12 months

Reauthorization approval

- Chronic Pelvic Pain: up to 3 months
- Endometriosis Retreatment: A single course may be approved for 6 months. Total duration of therapy should not exceed 12 months.
- Other indications: up to 12 months

Reauthorization Criteria
Leuprolide Acetate is considered medically necessary for continued use when initial criteria are met **AND** the patient has experienced clinical benefit to therapy **AND** has not experienced an unacceptable toxicity.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Leuprolide Acetate (Lupron Depot®) is a gonadotropin-releasing hormone (GnRH) agonist indicated for:

Endometriosis

- Management of endometriosis, including pain relief and reduction of endometriotic lesions.
- In combination with a norethindrone acetate for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms.

Uterine Leiomyomata (Fibroids)

- 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.**

Treatment of advanced prostatic cancer.

Leuprolide Acetate (Lupron Depot®) (Lupron Depot-Ped®) is a gonadotropin releasing hormone (GnRH) agonist indicated for the treatment of pediatric patients with central precocious puberty.

Quantity Limitations:
Leuprolide Acetate (Lupron Depot®) (Lupron Depot-Ped®):

- Prostate cancer: up to total of 90mg per 12 months
- Central precocious puberty: 15mg every month (180mg every 12 months)
- All other indications: 11.25mg every 3 months (22.5mg every 6 months)

References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. Lupron Depo®, Lupron Depot-Ped® [Prescribing Information]. North Chicago, IL 60064: AbbVie; 2022.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022
4. NCCN Clinical Practice Guidelines in Oncology™.National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.
5. Elgindy EA, El-Haieg DO, Khorshid OM, et al. Gonadotropin suppression to prevent chemotherapy-induced ovarian damage: a randomized controlled trial. Obstet Gynecol. 2013; 121(1):78-86.
6. Kaplowitz P, Bloch C, the SECTION ON ENDOCRINOLOGY. Evaluation and Referral of Children With Signs of Early Puberty. Pediatrics. 2016;137(1):e20153732
7. Chronic Pelvic Pain: ACOG Practice Bulletin, Number 218. Obstet Gynecol. 2020;135(3):e98-e109. doi:10.1097/AOG.0000000000003716.
8. Lethaby A, Vollenhoven B, Sowter M. Pre-operative GnRH analogue therapy before hysterectomy or myomectomy for uterine fibroids. Cochrane Database Syst Rev. 2001; (2):CD000547.

Criteria History/ Revision Information:

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.