BlueCross BlueShield
Federal Employee Program

# LEUPROLIDE
## leuprolide acetate 1mg/0.2mL
## Eligard, Fensolvi, Leuprolide Acetate Depot, Lupron Depot (leuprolide acetate)
## Camcevi (leuprolide mesylate)

## RATIONALE FOR INCLUSION IN PA PROGRAM

### Background

Leuprolide, a GnRH agonist, acts as a potent inhibitor of gonadotropin secretion when given continuously and in therapeutic doses. Human studies indicate that following an initial stimulation of gonadotropins, chronic stimulation with leuprolide results in suppression or "downregulation" of these hormones and consequent suppression of ovarian and testicular steroidogenesis. These effects are reversible on discontinuation of drug therapy (1-7).

### Regulatory Status

FDA-approved indications: (1-8)

- Camcevi is indicated for the treatment of adult patients with advanced prostate cancer.
- Eligard is indicated for the treatment of advanced prostate cancer.
- Fensolvi is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).
- Leuprolide acetate 1mg/0.2mL for subcutaneous injection is indicated:
    - In the palliative treatment of advanced prostatic cancer
- Leuprolide Acetate Depot is indicated:
    - For treatment of advanced prostate cancer
- Lupron Depot is indicated:
    - For the management of endometriosis, including pain relief and reduction of endometriotic lesions.
    - With iron therapy before fibroid surgery to improve anemia from fibroids.
    - For the treatment of advanced prostate cancer.
    - For the treatment of children with central precocious puberty (CPP).

<u>Off-Label Uses</u>: (9-10)

- Breast cancer
- Infertility, with or without assisted reproductive technology (ART)

NCCN recommends the use of Lupron Depot in males and females with breast cancer (8).

BlueCross BlueShield
Federal Employee Program

# LEUPROLIDE
## leuprolide acetate 1mg/0.2mL
## Eligard, Fensolvi, Leuprolide Acetate Depot, Lupron Depot (leuprolide acetate)
## Camcevi (leuprolide mesylate)

Leuprolide may prolong the QT/QTc interval. Providers should consider whether the benefits of leuprolide therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, frequent electrolyte abnormalities, and in patients taking drugs known to prolong the QT interval (1-7).

The safety and effectiveness of leuprolide for CPP in pediatric patients less than 2 years of age have not been established. The safety and effectiveness of leuprolide for advanced prostate cancer in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Lupron Depot for the management of endometriosis and hematologic improvement of women with anemia caused by fibroids have been established in females of reproductive age (1-7).

**Summary**

Leuprolide, a GnRH agonist, acts as a potent inhibitor of gonadotropin secretion when given continuously and in therapeutic doses. Human studies indicate that following an initial stimulation of gonadotropins, chronic stimulation with leuprolide results in suppression or “downregulation” of these hormones and consequent suppression of ovarian and testicular steroidogenesis. These effects are reversible on discontinuation of drug therapy. Leuprolide is used in the treatment of advanced prostate cancer, endometriosis, uterine fibroids, central precocious puberty, breast cancer, or gender dysphoria. The safety and effectiveness of leuprolide for CPP in pediatric patients less than 2 years of age have not been established. The safety and effectiveness of leuprolide for advanced prostate cancer in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Lupron Depot for the management of endometriosis and hematologic improvement of women with anemia caused by fibroids have been established in females of reproductive age (1-7).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of leuprolide while maintaining optimal therapeutic outcomes.

BlueCross BlueShield
Federal Employee Program

# LEUPROLIDE
## leuprolide acetate 1mg/0.2mL
## Eligard, Fensolvi, Leuprolide Acetate Depot, Lupron Depot (leuprolide acetate)
## Camcevi (leuprolide mesylate)

**References**


1. Camcevi [package insert]. Taipei City, Taiwan: Foresee Pharmaceuticals Co., Ltd.; May 2021.
2. Eligard [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; January 2024.
3. Fensolvi [package insert]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc.; November 2023.
4. Leuprolide Acetate Injection [package insert]. Princeton, NJ: Sandoz Inc.; June 2020.
5. Leuprolide Acetate Depot [package insert]. Warren, NJ: Cipla USA, Inc. November 2023.
6. Lupron Depot GYN [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
7. Lupron Depot URO [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
8. Lupron Depot-PED [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
9. NCCN Drugs & Biologics Compendium® Leuprolide Acetate 2024. National Comprehensive Cancer Network, Inc. Accessed on May 6, 2024.
10. Al-Inany HG, Youssef MA, Ayeleke RO, Brown J, Lam WS, Broekmans FJ. Gonadotrophin-releasing hormone antagonists for assisted reproductive technology. Cochrane Database Syst Rev. 2016;4(4):CD001750.