Leuprolide acetate (Fensolvi®, Lupron Depot-PED®, Lupron Depot®)

When requesting a leuprolide acetate product (Fensolvi®, Lupron Depot-PED®, Lupron Depot®) for non-oncology indications, the individual requiring treatment must be diagnosed with the following FDA-approved indications or approved off-label compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Non-oncology Indications

Fensolvi
Fensolvi is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

Lupron Depot-PED
Lupron Depot-PED is indicated in the treatment of children with central precocious puberty (CPP).

Lupron Depot
Lupron Depot is indicated for the management of endometriosis, including pain relief and reduction of endometriotic lesions.

Lupron Depot concomitantly with iron therapy is indicated for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata.

Approved Non-oncology Off-label Compendial Uses

- Gender-dysphoric/gender-incongruent individuals; individuals undergoing gender reassignment
- Abnormal uterine bleeding *(applies to Lupron Depot only)*
- Premenstrual Disorders, including premenstrual syndrome and premenstrual dysphoric disorder *(applies to Lupron Depot only)*

Coverage Guidelines

Fensolvi and Lupron Depot-PED

The individual has one of the following indications for approval:

- Central precocious puberty

  OR

- Gender-dysphoria/gender-incongruence OR is undergoing gender reassignment; AND

- The requested product is prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.

Approval duration: 12 months

Lupron Depot

The individual has one of the following indications for approval:

- Uterine leiomyomata (fibroids)

  OR

- Abnormal uterine bleeding

  OR

- Premenstrual Disorders, including Premenstrual Syndrome and Premenstrual Dysphoric Disorder; AND
    - Is 18 years of age or older; AND
    - Has severe, refractory premenstrual symptoms; AND
    - Has tried one of the following therapies:
        - A selective serotonin reuptake inhibitor (e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline); OR
        - A combined oral contraceptive

  OR

- Endometriosis; AND
    - Has previously tried one of the following: a contraceptive (e.g., combination oral contraceptives, levonorgestrel-releasing intrauterine systems), an oral progesterone, a depo-medroxyprogesterone injection, another gonadotropin-releasing hormone [GnRH] agonist, or GnRH antagonist unless contraindicated

  OR

- Gender-dysphoria/gender-incongruence OR is undergoing gender reassignment; AND
    - The requested product is prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients

Approval duration: 3 months for fibroids; 6 months for abnormal uterine bleeding; 12 months for all others

Dosing Recommendations

Fensolvi

The recommended dose is 45 mg administered by subcutaneous injection once every six months.

LUPRON Depot-PED

The recommended dose is 7.5 mg, 11.25 mg, or 15 mg administered by intramuscular (IM) injection once every month OR 11.25 mg or 30 mg IM once every 3 months OR 45 mg IM once every 6 months.

Lupron Depot

The recommended dose is 3.75 mg administered by intramuscular (IM) injection once every month OR 11.25 mg IM once every 3 months.

References

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2. Lupron Depot® [prescribing information]. North Chicago, IL; AbbVie, Inc.; October 2023.
3. Fensolvi® [prescribing information]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc; November 2022.
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16. Dysmenorrhea and endometriosis in the adolescent. ACOG Committee Opinion. No. 760. December 2018Available at: https://www.acog.org/. Accessed on February 12, 2024.

