

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 an FDA-approved indication or approved off-label compendial use 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 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*)

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

- Endometriosis

AND

- Has previously tried one of the following: a contraceptive, 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 45mg 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 IM once every 3 months.

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References

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11. Spack NP. Management of transgenderism. *JAMA*. 2013;309:478-484.
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