

Fensolvi® (leuprolide acetate)

When requesting Fensolvi® (leuprolide acetate), the individual requiring treatment must be diagnosed with either the FDA-approved indication or approved compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-Approved Indication

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

Approved Off-label Compendial Use

Gender-dysphoric/gender-incongruent individuals; individuals undergoing gender reassignment

Coverage Guidelines

The individual meets one of the following for approval:

- Has a diagnosis of central precocious puberty

OR

- Is gender-dysphoric/gender-incongruent OR is undergoing gender reassignment and
- Fensolvi is prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients

Approval duration: 12 months

Recommended Dosing

- Approve up to one injection (45mg) given subcutaneously once every 6 months

References

1. Lupron Depot-Ped® [prescribing information]. North Chicago, IL; AbbVie, Inc.; May 2017.
2. Triptodur™ [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2018.
3. Fensolvi® [prescribing information]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc; May 2020
4. Carel JC, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009;123(4):e752-62.
5. Krishna KB, Fuqua JS, Rogol AD, et al. Use of gonadotropin-releasing hormone analogs in children: update by an international consortium. *Horm Res Paediatr*. 2019;91:357-372.
6. Eugster EA. Treatment of central precocious puberty. *J Endo Soc*. 2019;3:965-972.

7. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guidelines. *J Clin Endocrinol Metab*. 2017;102:3869-3903.
8. World Professional Association for Transgender Health (WPATH). Standards of Care for the health of transsexual, transgender, and gender non-conforming people (version 7). Available at: https://s3.amazonaws.com/amo_hub_content/Association140/files/Standards%20of%20Care%20V7%20-%202011%20WPATH%20%282%29%281%29.pdf. Accessed on September 13, 2019.
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10. Spack NP. Management of transgenderism. *JAMA*. 2013;309:478-484.