

Triptodur® (triptorelin extended-release suspension)

When requesting Triptodur® (triptorelin extended-release suspension), the individual requiring treatment must be diagnosed with the following FDA-approved indication or an approved off-label compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Triptodur 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
- Triptodur 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

The recommended dose of Triptodur is 22.5 mg administered as a single intramuscular injection once every 24 weeks.

References

1. Triptodur™ [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; November 2023.
2. 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.
3. 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.
4. Eugster EA. Treatment of central precocious puberty. *J Endo Soc*. 2019;3:965-972.
5. 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.
6. World Professional Association for Transgender Health (WPATH). Standards of care for the health of transgender and gender diverse people (version 8). Available at: <https://www.wpath.org/publications/soc>. Accessed on November 6, 2023.
7. Rosenthal SM. Approach to the patient: transgender youth: endocrine considerations. *J Clin Endocrine Metab*. 2014;99:4379-4389.
8. Spack NP. Management of transgenderism. *JAMA*. 2013;309:478-484.