



## **Triptodur® (triptorelin extended-release suspension)**

When requesting Triptodur® (triptorelin extended-release suspension), the individual requiring treatment must be diagnosed with an 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; October 2018.
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 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](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 10, 2020.
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.