

Triptodur® (triptorelin extended-release suspension) J3490

When requesting Triptodur® (triptorelin extended-release suspension), the individual requiring treatment must be diagnosed with an FDA-approved indication 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(s)

None

Coverage Guidelines

The individual meets **all** of the following criteria for approval:

- The diagnosis of central precocious puberty (CPP) has been confirmed by a pubertal response to a gonadotropin-releasing hormone (GnRH) agonist test or a basal luteinizing hormone (LH) level
- Is 11 years of age or less if female OR 12 years of age or less if male
- For a re-authorization request, an individual is maintaining LH suppression to pre-pubertal levels as documented by a GnRH or GnRH agonist stimulation test, basal LH, or serum concentration of sex steroid levels
- For an initial authorization request, an individual must meet all of the following:
 - ❖ Any central nervous system (CNS) abnormalities have been ruled out
 - ❖ Has advanced bone age that is at least 1 year greater than chronological age
 - ❖ Onset of secondary sexual characteristics was prior to 8 years of age if female OR prior to 9 years of age if male

Approval duration (initial and renewal): 12 months

References

1. Triptodur Prescribing Information. Atlanta, GA. Arbor Pharmaceuticals, LLC. September 2017.
2. Fuqua JS. Treatment and Outcomes of Precocious Puberty: An Update. *J Clin Endocrinol Metab.* 2013;98(6):2198-2207.
3. Kaplowitz P, Bloch C, the Section on Endocrinology . Evaluation and Referral of Children With Signs of Early Puberty. *Pediatrics.* 2016;137(1):e20153732
4. Berberoglu M. Precocious Puberty and Normal Variant Puberty: Definition, etiology, diagnosis and current management. *J Clin Res Ped Endo.* 2009;1(4):164-174.