

Pharmacy Drug Policy & Procedure

Policy Name:	Triptodur (triptorelin)	Policy #:	2618P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Triptodur.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Triptodur under the specialty medical benefit when the following criteria have been met.

Criteria

1. Coverage criteria for Central Precocious Puberty (CPP)

- Onset of symptoms of puberty (breast and genital development, development of pubic hair) occurred before 8 years of age in females and before 9 years of age in males
- 1.2 Blood tests show pubertal response to a test with a GnRH agonist (such as leuprolide)
 - Luteinizing hormone (LH) and follicle-stimulating hormone (FSH) are measured by blood test
 - LH above 3.3 to 5IU/mL suggest CPP
 - LH:FSH ratio greater than 0.66 is typically seen with CPP
- 1.3 Bone age is 2 standard deviations (SD) beyond chronological age
- 1.4 MRI is used to rule out brain or steroid-secreting tumors
- 1.5 Documented lab testing for adrenal steroid levels to rule out congenital adrenal hyperplasia and adrenal tumors:
 - Early morning 17-OHP concentration between 82ng/dl and 200ng/dl should indicate non-classical congenital adrenal hyperplasia (CAH) and ACTH stimulation testing should be performed, OR
 - Concentrations 200ng/dl indicate a high sensitivity and specificity for non-classical CAH and ACTH testing may still be performed

2. Approval Times

- 2.1 Diagnostic purposes: One-time approval
- 2.2 Initial: 12 months
- 2.3 Renewal: 12 months if a female and chronological age < 11, or < 12 for males, or prescriber submits a statement of medical necessity which indicates the member requires continued therapy to prevent the onset of puberty and this request is approved by a Medical Director

CPT Codes		
HCPCS Codes		
J3316	Injection, triptorelin, extended-release, 3.75 mg	

References

- 1. Triptodur (triptorelin) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals LLC; December 2022.
- 2. Kaplowitz P, Bloch C, the SECTION ON ENDOCRINOLOGY. Evaluation and Referral of Children With Signs of Early Puberty. Pediatrics. 2016;137(1):e20153732.
- 3. Klein K, Yang J, Aisenberg J, et al. Efficacy and safety of triptorelin 6-month formulation in patients with central precocious puberty. J Pediatr Endocrinol Metab 2016; 29:1241.
- 4. Eugster E. Treatment of Central Precocious Puberty. Journal of the Endocrine Society. 2019: 3(5): 965-972.
- 5. Kletter GB, Klein KO, Wong YY, et al. A pediatrician's guide to central precocious puberty. Clin Pediatr. 2015;54:414-424.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.