

Policy Name:	Supprelin LA (histrelin acetate)	Policy #:	1922P
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Purpose of the Policy

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

Statement of the Policy

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

Criteria

1. Coverage Criteria for Central Precocious Puberty (CPP)

- 1.1 Onset of pubertal symptoms (such as breast development, breast growth, etc) occurred before 8 years of age in females and before 9 years of age in males
- 1.2 Documented pubertal response with a GnRH agonist, such as leuprolide
 - Luteinizing hormone (LH) and follicle-stimulating hormone (FSH) are measured by blood test
 - Upper limit for LH is 3.3 to 5 mIU/ml suggest CPP
 - LH:FSH ratio greater than 0.66 suggest CPP
- 1.3 Bone age is 2 standard deviations (SD) beyond chronological age
- 1.4 Documented imaging tests to rule out brain tumor or steroid secreting tumor
- 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. Coverage Criteria for Puberty Suppression in Adolescents with Gender Incongruence

- 2.1 A health care provider with experience prescribing or delivering gender-affirming treatment has confirmed all of the following
 - The adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender incongruence (whether suppressed or expressed),
 - Gender incongruence worsened with the onset of puberty,
 - Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment,
 - The adolescent has sufficient mental capacity to give informed consent to this (reversible) treatment
- 2.2 The adolescent meets all of the following
 - Has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,
 - Has given informed consent
 - For members less than 18 years old, informed consent must be provided by the member's legal

guardian unless state or federal legislation allows for the treatment without the informed consent of a legal guardian

2.3 A pediatric endocrinologist (hormone doctor) or other clinician experienced in pubertal assessment indicates the following:

- Agrees with the indication for GnRH agonist treatment,
- Has confirmed that puberty has started in the adolescent (Tanner stage G2/B2),
- Has confirmed that there are no medical contraindications to GnRH agonist treatment.

2.4 Authorization: 12 months

2.5 **For Washington members, effective January 1, 2022:**

- A health carrier may not deny or limit coverage for gender affirming treatment when that treatment is prescribed to an individual because of, related to, or consistent with a person's gender expression or identity, as defined in RCW 49.60.040, is medically necessary, and is prescribed in accordance with accepted standards of care.
- A health carrier may not apply categorical cosmetic or blanket exclusions to gender affirming treatment. When prescribed as medically necessary gender affirming treatment, a health carrier may not exclude as cosmetic services facial feminization surgeries and other facial gender affirming treatment, such as tracheal shaves, hair electrolysis, and other care such as mastectomies, breast reductions, breast implants, or any combination of gender affirming procedures, including revisions to prior treatment.*
- Health carriers may not issue an adverse benefit determination denying or limiting access to gender affirming services, unless a health care provider with experience prescribing or delivering gender-affirming treatment has reviewed and confirmed the appropriateness of the adverse benefit determination.

3. Approval Period

3.1 Approvals will be granted for a period of time ending on the patient's 11th birthday and 12th birthday for females and males, respectively. Approvals will be for a period of 12 months if it is indicated that initiation or continuation of therapy after the previously listed ages. These requests will require a statement of medical necessity which indicates the member requires therapy to prevent the onset of puberty and each request must be reviewed and approved by a Medical Director.

CPT Codes

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HCPCS Codes

J9226	Histrelin implant (Supprelin LA), 50 mg
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References

1. Supprelin LA [package insert]. Chadds Ford, PA: Endo Pharmaceuticals Solutions Inc.; April 2022.
2. Nield LS, Cakan N, Kamat D. A practical approach to precocious puberty. Clin Pediatr. 2007;46(4):299–306.
3. Eugster E. Treatment of Central Precocious Puberty. Journal of the Endocrine Society. 2019; 3(5): 965-972.
4. Kletter GB, Klein KO, Wong YY, et al. A pediatrician's guide to central precocious puberty. Clin Pediatr. 2015;54:414-424.
5. Coleman E, Radix AE, Bouman WP, et al. The World Professional Association for Transgender Health

(WPATH), Standards of Care for the Health of Transgender and Gender Diverse People, Version 8, International Journal of Transgender Health. 2022 23:sup1, S1-S259.

6. SECOND SUBSTITUTE SENATE BILL 5313 Washington 67th Legislature 2021 Regular Session, Revised Code of Washington (RCW) 49.60.040

Created Date: 07/15/10

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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.