Pharmacy Drug Policy & Procedure

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

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 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 (Illinois fully-insured and select Illinois self-funded plans)

2.1 Prior authorization is prohibited per section 356z.60 of the Illinois Insurance code

2.2 The health plan has measures in place to allow for claims to process at $0 cost share without prior authorization being required

2.3 For further questions, please contact the plan

3. Coverage Criteria for Puberty Suppression in Adolescents with Gender Incongruence (all other members)

3.1 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

3.2 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

3.3 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.

3.4 Authorization: 12 months

4. Approval Period

4.1 Approvals will be granted for a period of time ending on the patient's 11^{th} birthday and 12^{th} 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	

HCPCS Codes	
J9226	Histrelin implant (Supprelin LA), 50 mg

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. 215 ILCS 5/356z.60. Coverage for abortifacients, hormonal therapy, and human immunodeficiency virus pre-exposure prophylaxis and post-exposure prophylaxis. 2023

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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.