TREATMENT OF CENTRAL PRECOCIOUS PUBERTY
HISTRELIN ACETATE SUBCUTANEOUS IMPLANT (SUPPRELIN LA)

The purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for Supprelin LA subcutaneous implant for the treatment of children with central precocious puberty (CPP). By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

CPP is a condition characterized by secondary sexual characteristics before eight years of age in girls and nine years of age in boys. CPP results from the premature activation of the hypothalamic-pituitary-gonadal (HPG) axis, causing the production of sex steroids such as estrogen and androgen. In most cases, the etiology is idiopathic. Children with CPP show a significantly advanced bone age that can result in diminished adult height attainment.

CLINICAL GUIDELINE

Coverage guidelines for Supprelin LA are made in accordance with the Department of Social Services (DSS) definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an assessment of the individual and his or her clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

Supprelin LA may be considered medically necessary for the treatment of children with a clinical diagnosis of central precocious puberty.

Prior to the initiation of treatment with Supprelin LA:

I. The child should be clinically diagnosed with central precocious puberty (idiopathic or neurogenic), defined as sexual maturation before age eight (8) in girls and age nine (9) in boys; **and**
II. The clinical diagnosis must be confirmed with:
    A. Bone age advanced one year or more beyond chronologic age; **and**
    B. Pubertal response to a GnRH stimulation test; **and**
III. Tumor has been ruled out by CT, MRI or ultrasound; **and**
IV. Baseline laboratory, physical exam and imaging has been performed, including:
    A. Height and weight;
    B. Sex steroid levels;
    C. Adrenal steroid level to exclude congenital adrenal hyperplasia; and
    D. Beta human chorionic gonadotropin to rule out chorionic gonadotropin-secreting tumor; and
    E. Pelvic/adrenal/testicular ultrasound to rule out a steroid-secreting tumor.

Continuation of Supprelin LA may be considered medically necessary beyond the first year of treatment and may be resubmitted for medical necessity review every 12 months.

Discontinuation of therapy should be a decision made between the physician and the individual's caregiver and at the appropriate time point for the onset of puberty (approximately 11 years for females and 12 years for males).

NOTE: EPSDT Special Provision
Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE
Prior authorization of treatment with Supprelin LA is required. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for Supprelin LA:
1. Fully completed Outpatient Prior Authorization Request Form or fully completed authorization request via on-line web portal;
2. Clinical information supporting the medical necessity of the treatment; and
3. Other information as requested.

EFFECTIVE DATE
This Policy is effective for prior authorization requests for Supprelin LA for individuals covered under the HUSKY Health Program beginning December 1, 2014

LIMITATIONS
N/A

CODE:

Code	Description
J9226	Histrelin implant (Supprelin LA), 50mg

DEFINITIONS
1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.

3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
7. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B)recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.
8. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

ADDITIONAL RESOURCES AND REFERENCES:

- Antoniazzi F, Zamboni G. Central precocious puberty: current treatment options. *Pediatr Drugs*. 2004; 6(4):211-231
- CMS, Health Care Procedural Coding System Level II Manual: 2016
- Nakamoto JM, Franklin SL, Geffner ME. Puberty. In: Kappy MS, Allen DB, Geffner ME, eds. *Pediatric Practice Endocrinology*. New York, NY: McGraw Hill; 2010:257-298.
- Supprelin LA [Product Information], Chadds Ford, PA. Endo Pharmaceuticals, Inc.; April 2013. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/022058s011lbl.pdf. Accessed on November 14, 2014.

PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication	December 2014	DSS review. Approved by DSS on November 7, 2014. Approved at the December 15, 2014 Clinical Quality Sub-Committee meeting.
Updated	August 2015	Updated definitions for HUSKY A, B, C and D programs at

		request of DSS.
Updated	March 2016	Updates to language in introductory paragraph pertaining to purpos of policy. Updates to Clinical Guideline section pertaining to definition of Medical Necessity. Updates throughout policy to reflect importance of person-centeredness when reviewing requests for Supprelin. Changes approved at the March 21, 2016 Clinical Quality Subcommittee meeting. Changes approved by DSS on April 25, 2016.
Updated	August 2016	Updates to Clinical Guideline section. Bolded word "and" throughout section. Under III removed word "intracranial" to reflect the importance of investigating for tumors in other body regions. Under IV, added "physical exam, imaging", deleted word "investigations". Added statement "Continuation of Supprelin LA may be considered medically necessary beyond the first year of treatment and may be resubmitted for medical necessity review every 12 months." Approved at the September 19, 2016 Clinical Quality Sub-Committee meeting. Changes approved by DSS on October 10, 2016.