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. Pubertal response to a GnRH stimulation test; and
   B. Bone age advanced one year or more beyond chronologic age; 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. Diagnostic imaging of the brain to rule out intracranial tumor;
   D. Adrenal steroid level to exclude congenital adrenal hyperplasia;
   E. Beta human chorionic gonadotropin to rule out chorionic gonadotropin-secreting tumor; and
   F. Pelvic/adrenal/testicular ultrasound to rule out a steroid-secreting tumor.

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the Benefit and Authorization Grids summaries on www.ct.gov/husky by clicking on “For Providers” followed by “Benefit Grids”. For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.
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

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<th>Code</th>
<th>Description</th>
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<tr>
<td>J9226</td>
<td>Histrelin implant (Supprelin LA), 50mg</td>
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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

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ADDITIONAL RESOURCES AND REFERENCES:

• CMS, Health Care Procedural Coding System Level II Manual: 2017

PUBLICATION HISTORY

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<thead>
<tr>
<th>Status</th>
<th>Date</th>
<th>Action Taken</th>
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<tbody>
<tr>
<td>Updated</td>
<td>August 2015</td>
<td>Updated definitions for HUSKY A, B, C and D programs at request of DSS.</td>
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<tr>
<td>Updated</td>
<td>March 2016</td>
<td>Updates to language in introductory paragraph pertaining to purpose 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.</td>
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<tr>
<td>Updated</td>
<td>August 2016</td>
<td>Updates to Clinical Guideline section. Bolded word &quot;and&quot; throughout section. Under III removed word &quot;intracranial&quot; to reflect the importance of investigating for tumors in other body regions. Under IV, added “physical exam, imaging”, deleted word &quot;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.</td>
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<tr>
<td>Updated</td>
<td>September 2017</td>
<td>Update to Clinical Guideline section. Added need for diagnostic imaging of the brain to rule out intracranial tumor prior to initiation of treatment with Supprelin LA as indicated in Supprelin LA product information. Update to reflect current year’s HCPCS manual in Additional Resources and References section. Updates approved by the Medical Policy Review Committee on September 27, 2017. Updates approved by the Clinical Quality Subcommittee meeting on December 18, 2017. Updates approved by DSS on January 2, 2018.</td>
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