Supprelin LA (histrelin acetate implant)

**Line(s) of Business:**
HMO; PPO; QUEST Integration

**Original Effective Date:**
10/01/2015

**Current Effective Date:**
01/01/2017

**POLICY**

A. **INDICATIONS**

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

**FDA-Approved Indications**

Supprelin LA is a gonadotropin releasing hormone (GnRH) agonist indicated for the treatment of children with central precocious puberty.

**Compendial Uses**

- Puberty suppression therapy for gender dysphoria

B. **REQUIRED DOCUMENTATION**

- Central Precocious Puberty:
  - Diagnosis confirmed by a pubertal response to a GnRH agonist test or a third generation basal LH assay
  - Documentation that supports the need to delay puberty for the continuation of treatment

C. **CRITERIA FOR APPROVAL**

1. **Central precocious puberty**

   Authorization for use up to 12 years of age may be granted for female members when the following criteria are met:
   - Member has a diagnosis of central precocious puberty confirmed by a GnRH test or third-generation basal LH assay
   - Member has advanced bone age (bone age at least 1 year greater than chronological age)
   - Intracranial tumor has been excluded with diagnostic imaging of the brain
   - Onset of secondary sexual characteristics occurred at age < 8 years

   Authorization for use up to 13 years of age may be granted for male members when the following criteria are met
   - Member has a diagnosis of central precocious puberty confirmed by a GnRH test or third-generation basal LH assay
b. Member has advanced bone age (bone age at least 1 year greater than chronological age)
c. Intracranial tumor has been excluded with diagnostic imaging of the brain
d. Onset of secondary sexual characteristics occurred at age < 9 years

2. Puberty suppression therapy for gender dysphoria
Puberty suppression therapy is covered for 12 months when all of the following criteria are met:
   a. The patient has been diagnosed with persistent, well-documented gender dysphoria as defined by the current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria (see Appendix A) and gender identity disorder as defined by the current International Classification of Diseases (ICD) criteria by a qualified mental health professional (see Appendix B);
   b. The patient has exhibited the first physical changes of puberty, indicated by a minimum Tanner stage of 2 or 3;
   c. The patient has completed at least three months of successful continuous full time real-life experience in their gender identity across a wide span of life experiences and events (e.g., holidays, vacations, season-specific school and/or work experience, family events);
   d. Clinical records document that the patient assents to treatment and the parent/guardian has made a fully informed decision and consents to treatment;
   e. The patient’s comorbid medical and mental health conditions (if present) are reasonably well-controlled; and
   f. Puberty suppression therapy will be administered in a safe, appropriate, medically supervised manner.

D. CONTINUATION OF THERAPY
   1. Central precocious puberty
      • No previous authorization/precertification:
         o All members (including members currently receiving treatment without prior authorization) must meet criteria for initial approval in section C.
      • Reauthorization beyond 12 years of age in females or 13 years of age in males:
         o Authorization of a 12 month extension may be granted for members (until the age of 18 years old) when there is a continued need to delay puberty (such as extreme short stature) and appropriate documentation is provided.

   2. Puberty suppression therapy for gender dysphoria
      • No previous authorization/precertification:
         o All members (including members currently receiving treatment without prior authorization) must meet criteria for initial approval in section C.
      • Reauthorization:
         o Authorization of 12 months may be granted when there is a continued need to delay puberty (until the age of 18 years old) and appropriate documentation is provided.

E. DOSAGE AND ADMINISTRATION
   Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. ADMINISTRATIVE GUIDELINES
Precertification is required. Please refer to the [HMSA medical policy web site](http://www.hmsa.com) for the fax form.

G. **IMPORTANT REMINDER**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

H. **APPENDICES**

Appendix A: Diagnostic Statistical Manual of Mental Disorders (DSM-5) Criteria for Gender Dysphoria

(A) Adults and Adolescents

A. A marked incongruence between one’s experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by two or more of the following:

1. A marked incongruence between one’s experienced/expressed gender and primary and/or secondary sex characteristics (or, in young adolescents, the anticipated secondary sex characteristics).

2. A strong desire to be rid of one’s primary and/or secondary sex characteristics because of a marked incongruence with one’s experienced/expressed gender (or, in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).

3. A strong desire for the primary and/or secondary sex characteristics of the other gender.

4. A strong desire to be of the other gender (or some alternative gender different from one’s assigned gender).

5. A strong desire to be treated as the other gender (or some alternative gender different from one’s assigned gender).

6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one’s assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

(Children)
A. A marked incongruence between one’s experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by six or more of the following (one of which must be criterion A.1.):
   1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender, different from one’s assigned gender).
   2. In boys (assigned gender), a strong preference for cross dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to wearing of typical feminine clothing.
   3. A strong preference for cross-gender roles in make-believe play or fantasy play.
   4. A strong preference for toys, games, or activities stereotypically used or engaged in by the other gender.
   5. A strong preference for playmates of the other gender.
   6. In boys (assigned gender), a strong rejection of typically masculine toys, games and activities and a strong avoidance of rough and tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games and activities.
   7. A strong dislike of one’s sexual anatomy.
   8. A strong dislike for the primary and/or secondary sex characteristics that match one’s experienced gender.

B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.

Appendix B: Characteristics of a Qualified Mental Health Professional
A. A master’s degree or its equivalent in a clinical behavioral science field. This degree, or a more advanced one, should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent for that country;
B. Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Diseases for diagnostic purposes;
C. Ability to recognize and diagnose coexisting mental health concerns and to distinguish these from gender dysphoria;
D. Documented supervised training and competence in psychotherapy or counseling;
E. Knowledgeable about gender-nonconforming identities and expressions, and the assessment and treatment of gender dysphoria;
F. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

I. REFERENCES

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<td>10/01/2015</td>
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