Subject: **Histrelin acetate subcutaneous implant (Supprelin® LA) ***

Effective Date: **October 25, 2016**

Department: **Utilization Management**

Policy: Histrelin acetate (Supprelin® LA) subcutaneous implant **(CPT-J9226)** is reimbursable under plans administered by QualCare, Inc.

Objective: To assure proper and consistent reimbursement and to delineate criteria that establishes medical necessity.

Procedure: A**.** Central Precocious Puberty **(ICD-10 E22.8):** approvable when the following documentation is present-

1. Clinical documentation of the onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males.

2. A confirmatory stimulation test has been performed (measurement of blood concentrations of total sex steroids, luteinizing hormone (LH) and follicle stimulating hormone (FSH) following stimulation with a GnRH analog).

B. Gender dysphoria (**ICD-10 F64.0**) –for the suppression of puberty in adolescents when ALL of the following criteria are met-

1. Tanner stage 2 of puberty has been attained.

2. Gender dysphoria has emerged or worsened with the onset of puberty.
3. Absence of psychiatric comorbidity that would interfere with diagnosis or treatment.
4. Individual will have psychological and social support during treatment.
5. Demonstrated knowledge and understanding of the expected outcomes of histrelin acetate (Supprelin® LA) treatment.

Dosing- The FDA recommended dose of Supprelin LA for central precocious puberty is one implant every 12 months. Each implant contains 50 mg histrelin acetate. The implant is inserted subcutaneously in the inner aspect of the upper arm and provides continuous release of histrelin (65 mcg/day) for 12 months of hormonal therapy. Supprelin LA should be removed after 12 months of therapy (the implant has been designed to allow for a few additional weeks of histrelin acetate release, in order to allow flexibility of medical appointments). At the time an implant is removed, another implant may be inserted to continue therapy. Discontinuation of Supprelin LA should be considered at the discretion of the physician and at the appropriate time point for the onset of puberty (approximately 11 years for females and 12 years for males).

NOTE: histrelin acetate (Supprelin® LA) in combination with recombinant growth hormone (GH) to prolong the pre-pubertal state is not approvable because this is considered not medically necessary. The use of histrelin acetate (Supprelin® LA) for any other indication is not covered because it is considered experimental, investigational or unproven.

References:

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Drafted By/Date: M. McNeil, MD 10/14/16
Approved By/Date: QM Committee 10/25/16
Reviewed w/o Revision By/Date: M McNeil, MD 06/21/18
Approved By/Date: QM Committee 08/21/18

*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.