Status
Active

Medical and Behavioral Health Policy
Section: Medicine
Policy Number: II-159
Effective Date: 07/21/2014

SUBCUTANEOUS HORMONE PELLETS

Description:

Hormone therapy can be delivered by several routes of administration: oral, transdermal, vaginal, injection, or subcutaneous implantation of pellets. When implanted in pellet form, the pellet is placed in the lower abdomen or buttocks. The procedure is performed in the physician's office with the use of a local anesthetic and a small incision for insertion. Release of the drug continues over a 3-6 month time period.

The testosterone pellet, Testopel™, has received approval from the U.S. Food and Drug Administration (FDA) as replacement therapy for the following conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired) - testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testes syndrome or orchidectomy;
- Hypogonadotrophic hypogonadism or secondary hypogonadism (congenital or acquired) - idiopathic or gonadotropic LHRH deficiency, or pituitary-hypothalamic injury from tumors, trauma or radiation.

The FDA approval also states:
If the above conditions occur prior to puberty, androgen replacement therapy will be needed during the adolescent years for development of secondary sexual characteristics. Prolonged androgen treatment will be required to maintain sexual characteristics in these and other males who develop testosterone deficiency after puberty.

- Androgens may be used cautiously to stimulate puberty in carefully selected males with clearly delayed puberty. These patients usually have a familial pattern of delayed puberty that is not secondary to a pathological disorder; puberty is expected to occur spontaneously at a relatively late date. Brief treatment with conservative doses may occasionally be justified in these patients if they do not respond to psychological support. The potential adverse effect on bone maturation should be discussed with the

patient and parents prior to androgen administration. An X-ray of the hand and wrist to determine bone age should be taken every 6 months to assess the effect of treatment on epiphyseal centers.

Adverse cardiovascular events (e.g., elevated blood pressure, myocardial infraction, stroke) have been reported in men receiving testosterone replacement therapy. This association has been reported in recent studies and is currently under review by the FDA.

Implantation of pellets containing estrogen or estrogen combined with testosterone has also been proposed as treatment for symptoms associated with a decrease in naturally occurring hormones, such as female menopause. To date, no formulations of either of these types of pellets have received FDA approval. In addition, the use of these pellets has been shown to produce unpredictable and fluctuating serum concentrations of estrogens.

NOTE: This policy does not address the use of implanted progesterone products.

Definitions:

Androgen: A male hormone that stimulates development and maintenance of male characteristics. Testosterone is the major androgen in the body.

Policy:

I. Subcutaneous Administration of Testosterone

A. Use of the subcutaneous testosterone pellet Testopel™ may be considered **MEDICALLY NECESSARY** as replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone when the following criteria are met:
   1. Diagnosis of **ONE** of the following:
      a. Primary hypogonadism (congenital or acquired), **OR**
      b. Secondary hypogonadism (congenital or acquired), **OR**
      c. Delayed puberty

      AND
   2. Oral, topical, and/or intramuscular testosterone replacement therapy have been tried and found to be ineffective or not tolerated.

B. Use of the subcutaneous testosterone pellet Testopel™ is considered **NOT MEDICALLY NECESSARY** for the treatment of male infertility, due to its adverse effect on sperm production and fertility.

C. Use of the subcutaneous testosterone pellet Testopel™ is considered **INVESTIGATIVE** for treatment of all other indications including, but not limited to symptoms associated with female menopause, due to lack of FDA approval of any other indications

D. The subcutaneous administration of formulations of testosterone other than Testopel™ is considered **INVESTIGATIVE** due to lack of FDA approval of any other products.

II. Subcutaneous Administration of Estrogen or Estrogen Combined with Testosterone

Subcutaneous hormone pellets containing estrogen alone OR estrogen combined with testosterone (including bioidentical hormone formulations) are considered **INVESTIGATIVE** for all indications including, but not limited to, symptoms associated with female menopause because there are no FDA-approved formulations of these products.

Coverage:

Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding:

The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT:

11980 Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin)

HCPCS:

J3490 Unclassified drugs

S0189 Testosterone pellet, 75 mg

Policy History:

Developed May 9, 2012

Most recent history:
Reviewed May 8, 2013
Revised May 14, 2014

Cross Reference: Saliva Hormone Tests, VI-08