Implanted Hormone Pellets

Policy Number: 5.02.500  Last Review: 11/2014

Policy
Blue Cross and Blue Shield of Kansas City will provide coverage for Implanted Hormone Pellets when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Testopel® Pellets (testosterone pellets) are considered medically necessary as a second-line testosterone replacement therapy in males with congenital or acquired endogenous androgen absence or deficiency associated with primary or secondary hypogonadism (decreased function of sex organs) after oral and IM testosterone therapies have failed. Testopel® Pellets are also approved for treatment of delayed male puberty.

When Policy Topic is not covered
Compounded hormone replacement therapy pellets for treatment of menopausal symptoms are considered investigational.

Testopel® Pellets are not approved for treatment of menopause symptoms and therefore are considered investigational for this indication.

Considerations
This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Hayes Medical Technology Directory, Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers

Description of Procedure or Service
Hormone replacement therapy (HRT) is used to decrease menopause symptoms, such as hot flashes and vaginal dryness.

In women with an intact uterus, HRT commonly consists of the combination of estrogen and a progestin to prevent endometrial hyperplasia or endometrial cancer. In the absence of a uterus, a progestin is unnecessary. There are many commercially available estrogen, progestin, and combination therapies.

Hormone pellets are a compounded substance where each pellet consists of a hard crystal of estradiol, which gradually releases estrogen into the blood stream.

There are currently no FDA-approved, commercially available formulations of implantable estradiol pellets available in the United States. These compounded formulations of estradiol have been shown to produce unpredictable and fluctuating levels of estrogens in the body.

Commercially prepared therapies are governed by strict guidelines enforced by the Food and Drug Administration. Because custom compounded medications are not governed by such laws, there may
be a lack of appropriate procedures in place at the compounding pharmacy to assure quality control-batch records, or precursor analysis-post manufacture review of potency and consistency.

Testosterone pellets (Testopel® Pellets) are FDA-approved for indications described under “Policy”.

**Rationale**

While implantable estradiol pellets have been suggested as treatment for symptoms of menopause, there are no FDA-approved, commercially available formulations of implantable estradiol pellets available in the United States. These formulations of estradiol have been shown to produce unpredictable and fluctuating serum concentrations of estrogen.

The U.S. Food and Drug Administration's Fertility and Maternal Health Drugs Advisory Committee unanimously agreed to terminate compassionate investigative new drug (IND) programs for estrogen pellets as a last-resort treatment of menopausal disorder. The Committee noted “the risk of bleeding and infection, the lack of information on release rates, difficulty in reversibility of the drug, increased feasibility of over-dosage of the drug, and increased risk of non-compliance with safety measures [such as] the addition of progestin.”

Advocates of hormone implant therapy (HRT) for female menopause report that relief of short-term symptoms and long term prophylaxis against cardiovascular disease and osteoporosis during menopause are significant when HRT is delivered subcutaneously based on avoidance of first-pass metabolism through the liver.

There are several randomized controlled studies and uncontrolled prospective clinical trials evaluating subcutaneous HRT. Subcutaneous HRT therapy was compared with placebo and with oral and transdermal therapy. The studies had relatively few numbers of subjects considering the large number of women that are candidates for HRT. None of the studies were completely blinded. Symptom relief was largely based on subjective and patient reported results. These studies could be subject to bias based on placebo effect. Only 3 studies measured estrogen implant effect on bone density, which provided objective measurement. There have been relatively few studies in which delivery of estrogen replacement therapy using implants was directly compared with other methods of estrogen administration.

HRT for menopause has been the subject of debate. The benefit of HRT therapy as a whole, is not clearly defined. Additional research is needed to determine the optimal dosage and treatment interval.

Testosterone pellets (Testopel® Pellets), on the other hand, are FDA approved and are considered medically necessary as a second-line testosterone replacement therapy in males with congenital or acquired endogenous androgen absence or deficiency associated with primary or secondary hypogonadism (decreased function of sex organs) after oral and IM testosterone therapies have failed. Testopel® Pellets are also approved for treatment of delayed male puberty.

**References:**


8 F-D-C- Reports Inc. Estrogen pellets availability under compassionate INDs should be discontinued as a last resort treatment for menopausal symptoms – FDA advisory committee. The Pink Sheet. 1988 Jan 25;50(4).


Billing Coding/Physician Documentation Information

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

S0189 Testosterone pellet, 75mg
Additional Policy Key Words
N/A

Related Topics
N/A

Policy Implementation/Update Information
11/2002 Origination date
11/2003 Reviewed – No changes made
11/2004 Reviewed – No changes made
11/2005 Reviewed – No changes made

11/2006 Reviewed – No changes made
11/2007 Reviewed – No changes made
11/2008 Reviewed – No changes made
06/2009 Revised – Removed statement “Testosterone pellets require prior authorization through pharmacy services.”
11/2009 Reviewed – No changes made
11/2010 Reviewed – No changes made
11/2011 Reviewed – No changes made
11/2014 Reviewed – no changes made

This Medical Policy is designed for informational purposes only and is not an authorization, an explanation of benefits, or a contract. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there is any exclusion or other benefit limitations applicable to this service or supply. Medical technology is constantly changing and Blue Cross and Blue Shield of Kansas City reserves the right to review and revise medical policy. This information is proprietary and confidential and cannot be shared without the written permission of Blue Cross and Blue Shield of Kansas City.