

Corporate Medical Policy

Hormone Pellet Implantation for Hormone Replacement Therapy in Women

File Name: hormone_pellet_implantation_for_hormone_replacement_therapy_in_women
Origination: 11/2006
Last CAP Review: 3/2012
Next CAP Review: 3/2013
Last Review: 3/2012

Description of Procedure or Service

Menopause is a normal, natural event that occurs as a woman ages. The ovaries progressively fail to produce estrogen and other hormones. Menopause marks the permanent end of fertility. During the transition from the reproductive years through menopause and beyond, a woman experiences many physical changes. Most of these changes are normal consequences of both menopause and aging. All women experience menopause, but each in a unique way.

Although for many women menopause is asymptomatic and associated with little disruption of normal life and well-being, many women experience symptoms – sometimes severe and disabling – that considerably affect their quality of life. There is a long list of physical changes that women may experience around menopause, which may be related to menopause or aging – or both. Some of these are changes in menstrual periods, hot flashes, sleep disturbances, night sweats, vaginal dryness and decreased sex drive.

Several prescription drugs are available to help relieve menopause-related symptoms. Hormone therapy (HT) is the most effective intervention for management of these quality-of-life issues. HT may be defined as estrogen therapy alone or a combination of estrogen and a progestational agent in women with a uterus. The addition of a progestational agent is to protect the uterus from estrogen stimulation. Endometrial cancer has been shown to be increased with the use of unopposed estrogen.

In addition to falling estrogen levels, the body's production of another hormone – androgen - declines with age possibly contributing to decreased sexual desire. In women, the ovaries and adrenal glands secrete androgen, primarily as testosterone. Testosterone therapy may be indicated for postmenopausal women with symptoms of decreased sexual desire associated with personal distress and who have no other identifiable cause for their sexual concerns.

Over the years a number of research studies presented a complicated picture of the risks and benefits of hormone therapy and its use for prevention of cardiovascular diseases was controversial. This led the National Institutes of Health (NIH) to conduct a large clinical trial of the risks and benefits of hormone therapy. A large randomized clinical trial including more than 16,000 healthy women was conducted. Results from the trial published in 2002 showed that the overall risks of estrogen plus progestin outweigh the benefits. Among the risks observed after 5.6 years of follow-up were increased risks of breast cancer, heart disease, stroke and blood clots. On March 1, 2004, after nearly seven years of follow-up, NIH stopped the estrogen alone arm of the trial, concluding that estrogen alone does not appear to affect (either increase or decrease) heart disease, a key question of the study. In addition, estrogen alone appears to increase the risk of stroke and decrease the risk of hip fracture. No increase in breast cancer risk was

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observed during the study period.

The WHI report resulted in a significant decrease in estrogen and progestin use and a serious reevaluation of menopausal hormone therapy, as well as increased interest in alternative approaches to managing menopausal symptoms including use of "bioidentical" hormones, hormone products available without a prescription and/or other hormone products custom-compounded. Bioidentical hormones made by a compounding pharmacist from a health care provider's prescription are available in various routes of administration, including oral, sublingual, and percutaneous or as implants, injectables, and suppositories.

This policy is specifically related to subcutaneously implanted hormone pellets. The individual pellets are smaller than a grain of rice and are implanted into the subcutaneous tissue, where they provide a slow continuous release of hormone into the bloodstream. The pellets are implanted in the lower abdomen or buttocks. The procedure is done in a physician's office with the use of a local anesthetic and a small incision for insertion. The release of the drug continues over a 3-6 month period.

NOTE: This policy is specifically related to hormone pellet implantation for hormone replacement therapy in females. The use of testosterone pellets for hormone replacement in males is not addressed in this policy.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Hormone pellet implantation is considered investigational for hormone replacement therapy in women. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When hormone pellet implantation for hormone replacement therapy in women is covered

Not applicable.

When hormone pellet implantation for hormone replacement therapy in women is not covered

Subcutaneous hormone pellet implantation of estrogen alone, or estrogen combined with testosterone, or testosterone alone when used as hormone replacement therapy for menopause, is considered investigational.

Policy Guidelines

There are no FDA-approved, commercially available formulations of implantable estradiol pellets

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available in the United States. These formulations of estradiol have been shown to produce unpredictable and fluctuating serum concentrations of estrogen. The FDA 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.”

Estrogen compounded with testosterone for subcutaneous HT is not FDA approved.

Compounded bioidentical hormones are plant-derived hormones that are prepared, mixed, assembled, packaged, or labeled as a drug by a pharmacist and can be custom made for a patient according to a physician’s specifications. Most compounded products have not undergone rigorous clinical testing for safety or efficacy, and issues regarding purity, potency, and quality are a concern. Compounded hormone products have the same safety issues as those associated with hormone therapy agents that are approved by the FDA and may have additional risks intrinsic to compounding. There is no scientific evidence to support claims of increased efficacy or safety for individualized estrogen or progesterone regimens.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 11980, J3490, S0189

Diagnoses that are subject to medical necessity review: V07, V07.4, 627, 627.1, 627.2, 627.3, 627.4, 627.8, 627.9

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

American College of Obstetricians and Gynecologists. ACOG News Release. No Scientific Evidence Supporting Effectiveness or Safety of Compounded Bioidentical Hormone Therapy. Retrieved on October 18, 2006 from: http://www.acog.org/from_home/publications/press_releases/nr10-31-05-1.cfm

American College of Obstetricians and Gynecologists. ACOG Committee Opinion #322, November 2005: Compounded Bioidentical Hormones. Retrieved on October 18, 2006 from: <http://www.fda.gov/ohrms/dockets/dockets/05p0411/05p-0411-c000747-01-vol13.pdf>

North American Menopause Society. Menopause Guidebook: Helping Women Make Informed Healthcare Decisions Around Menopause and Beyond. Retrieved on October 18, 2006 from: <http://www.menopause.org/edumaterials/guidebook/mgtoc.htm>

North American Menopause Society. Bioidentical Hormone Therapy. Retrieved October 18, 2006 from: <http://www.menopause.org/bioidentical.htm>

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American Association of Clinical Endocrinologists (AACE). AACE medical guidelines for clinical practice for management of menopause. *Endocrine Practice* 2006;12 (No.3). Retrieved on October 18 from:
<http://www.aace.com/pub/pdf/guidelines/menopause.pdf>

National Cancer Institute. U.S. National Institutes of Health. "*Menopausal Hormone Use*". Retrieved on October 19, 2006 from:
<http://www.cancer.gov/clinicaltrials/digest-postmenopausal-hormone-use/allpages/print>

Specialty Matched Consultant Advisory Panel review 12/13/2006.

Specialty Matched Consultant Advisory Panel review 12/2008.

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*. 1998:50(4).

American Association of Clinical Endocrinologists (AACE). AACE medical guidelines for clinical practice for management of menopause. *Endocrine Practice* 2011;17 (Suppl 6). November/December 2011. Retrieved on 02/20/12 from:
<https://www.aace.com/sites/default/files/menopause.pdf>

Specialty Matched Consultant Advisory Panel review 3/21/12.

Policy Implementation/Update Information

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| 11/13/06 | Notification of new policy. Subcutaneous hormone pellet implantation of estrogen alone, or estrogen combined with testosterone, or testosterone alone when used as hormone replacement therapy for menopause, is considered investigational. BCBSNC does not cover investigational services. Notification given 11/13/06. Effective date 1/17/07. |
| 1/17/07 | Specialty Matched Consultant Advisory Panel review 12/13/2006. No changes to criteria. Reference source added. (pmo) |
| 1/12/09 | Specialty Matched Consultant Advisory Panel review 12/2008. No changes to criteria. Reference source added. (pmo) |
| 6/22/10 | Policy Number(s) removed. (amw) |
| 10/26/10 | Policy Guidelines updated. Pertinent diagnoses codes added to Billing/Coding section. No change in policy statement. (adn) |
| 1/18/2011 | Specialty Matched Consultant Advisory Panel review 12/16/2010. Policy accepted as written. (adn) |
| 4/17/12 | Reference added. Specialty Matched Consultant Advisory Panel review No change to policy statement 3/21/12. (sk) |

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.