
Medical Policy



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***Current Policy Effective Date: 11/1/26**
(See policy history boxes for previous effective dates)

Title: Implantable Hormone Pellets

Description

Implantable hormone pellet therapy involves the subcutaneous insertion of small pellets containing hormones, most commonly estradiol and/or testosterone. The pellets are typically inserted into the subcutaneous tissue of the hip or buttock through a minor surgical procedure and are designed to provide sustained hormone release over a period of several months. Hormone pellet therapy has been promoted for the treatment of vasomotor symptoms (e.g., hot flashes, night sweats), hypoactive sexual desire, menstrual changes, genitourinary symptoms (e.g., vaginal dryness, pain or discomfort during intercourse, urinary urgency, or recurrent urinary symptoms), sleep and mood disorders (e.g., insomnia, irritability, anxiety, depression), cognitive symptoms (e.g., trouble concentrating forgetfulness, brain fog, difficulty finding words), musculoskeletal symptoms (e.g., joint and muscle aches), physical symptoms (e.g., fatigue, reduced energy, changes in hair or skin, weight redistribution), and other conditions attributed to age-related hormonal decline. Most hormone pellets used in women are compounded preparations and are not approved by the U.S. Food and Drug Administration (FDA). FDA-approved forms of bioidentical hormones are available in other delivery methods (patches, gels, sprays, tablets, and injections).

Note: This policy does not apply to treatments for delayed male puberty, gender dysphoria, and primary or hypogonadotropic hypogonadism.

Medical Policy Statement

Implantable hormone pellet preparations (estrogen alone, testosterone alone, progesterone alone, compounded estrogen, compounded testosterone, and compounded progesterone) for the treatment of menopause-related symptoms, menstrual, genitourinary, sleep, mood, cognitive, musculoskeletal, other physical symptoms, and other conditions attributed to age related hormonal decline are experimental/investigational. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Note: Categorized symptoms are defined as follows: vasomotor symptoms (e.g., hot flashes, night sweats); genitourinary symptoms (e.g., vaginal dryness, pain or discomfort during intercourse, urinary urgency, recurrent urinary symptoms); sleep and mood disorders (e.g., insomnia, irritability, anxiety, depression); cognitive symptoms (e.g., difficulty concentrating, forgetfulness, brain fog, difficulty finding words); musculoskeletal symptoms (e.g., joint and muscle aches); and other physical symptoms (e.g., fatigue, reduced energy, changes in hair or skin, weight redistribution).

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

11980

11981

J1073

J3490

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Background

Hormone Replacement Therapy for Menopause

Menopausal hormone therapy is used to treat symptoms associated with declining endogenous hormone production, including vasomotor, menstrual, genitourinary, sleep, mood, cognitive, musculoskeletal, physical, and sleep disturbance symptoms, and reduced quality of life. FDA-approved hormone therapy products are available in a variety of formulations and routes of administration, including oral tablets, transdermal patches, topical gels, sprays, vaginal preparations, and injectable products. These products have undergone regulatory evaluation for safety, efficacy, manufacturing quality, and dose consistency.

Implantable Hormone Pellet Therapy

Hormone pellets used in women most commonly contain estradiol, testosterone, or combinations of hormones and have been promoted for treatment of menopausal symptoms and sexual dysfunction despite limited evidence regarding safety and effectiveness. Implantable hormone pellet therapy involves the insertion of small pellets containing hormones, most commonly estradiol and/or testosterone, into the subcutaneous tissue through a minor surgical procedure. The pellets are designed to release hormones continuously over several months. Proposed advantages include prolonged hormone delivery and avoidance of daily medication administration. However, once implanted, hormone delivery cannot be readily adjusted or discontinued until hormone stores are depleted or the pellets are surgically removed.

Compounded Hormone Therapy

Compounded hormone therapy refers to hormone preparations that are mixed, combined, or altered by a compounding pharmacy in response to an individual prescription. Compounded products may contain one or multiple hormones and may be prepared in formulations or strengths not commercially available. Compounded hormone products are not reviewed or approved by the U.S. Food and Drug Administration (FDA) for safety, effectiveness, quality, or manufacturing consistency prior to marketing. Due to the lack of FDA oversight, concerns have been raised regarding variability in potency, purity, absorption, and quality control.

Bioidentical Hormones

Bioidentical hormones are hormones that have the same chemical and molecular structure as hormones naturally produced by the human body. Common examples include estradiol, progesterone, and testosterone. The term "bioidentical" refers only to molecular structure and does not indicate whether a product is FDA-approved or compounded. Many FDA-approved hormone therapy products contain bioidentical hormones. Although the term "bioidentical hormone therapy" is often used in marketing materials to describe compounded hormone products), bioidentical hormones are available in both FDA-approved and compounded formulations. It should not be assumed that bioidentical hormones are safer or more effective than conventional FDA-approved hormone therapy.

FDA Concerns

There are currently no FDA-approved implantable estradiol pellet products for the treatment of menopause-related, vasomotor, menstrual, genitourinary, sleep, mood, cognitive, musculoskeletal, other physical symptoms, and other conditions attributed to age related hormonal decline. Most hormone pellets used for symptom management are compounded preparations. Concerns regarding pellet therapy include inconsistent hormone delivery, supraphysiologic hormone exposure, inability to rapidly discontinue treatment, procedural complications related to insertion and removal, and limited evidence regarding long-term safety and effectiveness. The FDA has advised that compounded hormone products have not been demonstrated to be safer or more effective than FDA-approved hormone therapies.

Summary

Implantable hormone pellet therapy involves the subcutaneous placement of pellets containing estrogen, testosterone, progesterone, or combinations of hormones for prolonged hormone

delivery. Most pellet formulations used in the management of menopausal-related symptoms, hypoactive sexual desire, menstrual changes, genitourinary symptoms (e.g., vaginal dryness, pain or discomfort during intercourse, urinary urgency, or recurrent urinary symptoms), sleep and mood disorders (e.g., insomnia, irritability, anxiety, depression), cognitive symptoms (e.g., trouble concentrating, forgetfulness, brain fog, difficulty finding words), musculoskeletal symptoms (e.g., joint and muscle aches), physical symptoms (e.g., fatigue, reduced energy, changes in hair or skin, weight redistribution), and other conditions attributed to age-related hormonal decline are compounded products and are not approved by the FDA. Available evidence regarding implantable hormone pellets is limited by small study populations, methodological weaknesses, heterogeneous outcome measures, and insufficient long-term safety data. Current evidence has not demonstrated improved clinical outcomes compared with FDA-approved hormone therapies administered through established routes such as oral, transdermal, injectable, or vaginal delivery systems. In addition, concerns remain regarding inconsistent hormone delivery, inability to rapidly discontinue therapy, supraphysiologic hormone exposure, local procedural complications, and variability associated with compounded preparations. Major professional societies, including ACOG, The Menopause Society, the Endocrine Society, and the British Menopause Society, recommend FDA-approved hormone therapies over compounded hormone pellet preparations when approved alternatives are available. There is insufficient evidence that this therapy results in an improvement in net health outcomes.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms. The following is a summary of the key literature to date.

Hormone Replacement Therapy for Menopause and other Symptoms

Evidence regarding implantable hormone pellet therapy consists primarily of small prospective studies, observational reports, and older comparative trials. The available literature is limited by small sample sizes, lack of blinding, heterogeneous patient populations, inconsistent outcome measures, and limited long-term follow-up. Most studies evaluate subjective symptom improvement rather than clinically meaningful health outcomes. In addition, many studies predate currently available FDA-approved oral and transdermal hormone therapies, limiting their applicability to current clinical practice.

The primary goal of hormone replacement therapy is the safe and effective management of menopause and other symptoms, including vasomotor, mood and sleep, fatigue, hair loss, and other conditions attributed to age related hormonal decline. Although implantable hormone pellets have been used to deliver estradiol and testosterone, there is insufficient evidence demonstrating superior symptom control, improved quality of life, or improved long-term health outcomes when compared with conventional FDA-approved hormone therapy administered orally or transdermally.

Safety Considerations

Implantable hormone pellets expose patients to continuous hormone delivery for several months following insertion. Unlike oral or transdermal hormone therapy, dosing cannot be readily adjusted or discontinued in response to adverse effects. Reported concerns include supraphysiologic hormone levels, variable absorption, pellet extrusion, local infection, procedural complications, and difficulty removing pellets when treatment discontinuation is necessary. These limitations may increase the risk of both under-treatment and over-treatment.

Compounded Products

Most implantable hormone pellets used for conditions attributed to age related hormonal decline management are compounded formulations. Compounded products are not required to undergo the same FDA review process as commercially marketed hormone therapies. Consequently, there may be variability in potency, purity, quality, and dosing consistency. While compounding may be appropriate in select circumstances when an FDA-approved alternative is not available, evidence is lacking to demonstrate that compounded hormone pellet therapy provides improved clinical outcomes compared with FDA-approved hormone therapy products.

Clinical Practice Guidelines

Multiple professional organizations, including the American College of Obstetricians and Gynecologists (ACOG), The Menopause Society, the Endocrine Society, and the British Menopause Society, recommend the use of FDA-approved hormone therapies when hormone treatment is indicated. These organizations have noted the lack of high-quality evidence supporting compounded hormone therapy and have expressed concerns regarding the safety, dosing consistency, and quality control of compounded hormone pellet preparations. ACOG specifically recommends alternatives to pellet therapy for testosterone delivery because of the limited safety data and inability to remove the pellet once implanted.

No adequately designed randomized controlled trials have demonstrated that implantable hormone pellet therapy provides superior clinical outcomes compared with FDA-approved menopausal hormone therapy delivered through oral, transdermal, injectable, or vaginal routes.

Supplemental Information

The American Association of Clinical Endocrinology

The American Association of Clinical Endocrinology (2011) does not include recommendations supporting the use of implantable pellet therapy for menopausal hormone replacement.

The American College of Obstetricians and Gynecologists

In 2023, the American College of Obstetricians and Gynecologists (ACOG) updated the 2012 clinical consensus and made the following conclusions and recommendations:

- There is a lack of high-quality data on the safety and efficacy of custom-compounded bioidentical hormone therapy for the management of menopausal symptoms. Compounded bioidentical menopausal hormone therapy should not be prescribed routinely when FDA-approved formulations exist.

- There is no FDA-approved testosterone formulation for the management of menopausal symptoms. Clinicians and patients should use a shared decision-making framework when considering the use of compounded testosterone for this indication. Based on the lack of safety data and inability to remove the pellet, ACOG recommends preparations other than pellet therapy for the delivery of testosterone.
- Clinicians should counsel patients that FDA approved menopausal hormone therapies are recommended for the management of menopausal symptoms over compounded bioidentical menopausal hormone therapy. If a patient requests the use of compounded bioidentical menopausal hormone therapy, clinicians should educate them on the lack of FDA approval of these preparations and their potential risks and benefits, including the risks specific to compounding.
- Evidence is lacking to support superiority claims of compounded bioidentical hormones over conventional menopausal hormone therapy.
- Customized compounded hormones pose additional risks. These preparations have variable purity and potency and lack efficacy and safety data.
- Because of variable bioavailability and bioactivity, both underdosage and overdosage are possible.
- Conventional hormone therapy is preferred over compounded hormone therapy given the available data.
- Despite claims to the contrary, evidence is inadequate to support increased efficacy or safety for individualized hormone therapy regimens based on salivary, serum, or urinary testing.

British Menopause Society

The British Menopause Society (2020) released the following recommendation on hormone replacement therapy in menopausal women:

- The potential benefits of bioidentical hormone therapy can be achieved using conventionally licensed products, without having to resort to unregulated compounded varieties from specialist pharmacies.

The Endocrine Society

The Endocrine Society (Santoro [2016]) encourages clinicians to prescribe FDA-approved hormone products according to labeling indications.

Global Consensus - International Menopause Society, The Endocrine Society, The European Menopause and Andropause Society, The International Society for Sexual Medicine, The International Society for the Study of Women's Sexual Health, The North American Menopause Society, The Federacion Latino Americana de Sociedades de Climaterio y Menopausia, The Royal College of Obstetricians and Gynaecologists, The International Society of Endocrinology, The Endocrine Society of Australia, and The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

The Global Consensus (2019) indicates there are insufficient data to make any recommendations regarding the use of testosterone in premenopausal women for treatment of sexual function or any other outcome.

The Menopause Society

The Menopause Society (formerly the North American Menopause Society) notes that nonstandard or untested routes of hormone administration, including subdermal implants and pellets, raise safety concerns. The Society further states that compounded hormone products

lack evidence demonstrating superiority over FDA-approved hormone therapies and may present concerns regarding dosing consistency, purity, and quality control.

The National Institute of Aging

The National Institute of Aging (2021) does not mention subdermal or pellet use as a recommended route for hormone therapy.

Regulatory Status

There are no FDA-approved, commercially available formulations of implantable estradiol pellets for the treatment of vasomotor symptoms (e.g., hot flashes, night sweats), hypoactive sexual desire, menstrual changes, genitourinary symptoms (e.g., vaginal dryness, pain or discomfort during intercourse, urinary urgency, or recurrent urinary symptoms), sleep and mood disorders (e.g., insomnia, irritability, anxiety, depression), cognitive symptoms (e.g., trouble concentrating, forgetfulness, brain fog, difficulty finding words), musculoskeletal symptoms (e.g., joint and muscle aches), physical symptoms (e.g., fatigue, reduced energy, changes in hair or skin, weight redistribution), and other conditions attributed to age-related hormonal decline. The FDA has expressed concerns regarding compounded hormone pellet products because these products have not undergone FDA review for safety, effectiveness, quality, or manufacturing consistency.

Testosterone pellet implants are not FDA-approved for treatment of any of the symptoms listed above.

Many marketed products that are called “bioidentical hormones” are compounded drugs and compounded drugs are not approved by the FDA. The FDA does not have evidence that compounded “bioidentical hormones” are safe and effective, or safer or more effective than the current FDA-approved hormonal therapy.

Government Regulations

National:

No determination found.

Local:

No determination found.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Gender Affirming Services

References

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 9, 2026, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/26	8/18/26		• Joint policy established; • No vendor (slp/lk) • Replacing IMP – Implantable hormone pellets in women

Next Review Date: 3rd Qtr, 2026

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: IMPLANTABLE HORMONE PELLETS

Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.