



Stefanie A. Schultis, M.D.
110 Lakeview Drive Ste 100 Covington, LA 70433
985-898-1940 www.stefanieaschultismd.com

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Bio-Identical Hormone Replacement Pellet Therapy (BHRPT) For Women

The body's natural function beautifully orchestrates a delicate balance and release of hormones throughout our body. Hormones are the chemical messengers which keep our bodies in rhythm.

Hormones contribute to our well-being, our mental clarity and focus, our sexual desire and many other functions needed for a happy and healthy life. As men and women age, this delicate balance of hormones with the body is no longer in "sync".

A few of the physical symptoms of hormone deficiency may include:

- Fatigue
- Weight Gain
- Insomnia/Restless Sleep
- Hot Flashes
- Mood Swings
- Night Sweats Decreased Sex Drive
- Hormone Related Migraine

Is BHRPT Safe?

Bio-Identical Hormones are all natural plant based products and have been in use in the United States since 1938. Derived from yams and a small amount of soy, these hormones have the same molecular structure as the hormones produced within our own bodies. Numerous studies worldwide documents the benefits and safety of Bio-Identical Hormones.

These studies also report a lower incidence of side effects when compared to other prescription drugs. BHRPT should not be confused with "synthetic" hormones typically found in many creams, gels and injectables used for hormone replacement.

How Does BHRPT Work?

When your body no longer produces the proper levels and ratios of hormones needed, Bio-Identical Hormone Pellets replace the hormones your body is lacking. It's critical to deliver the right amount of hormones to the body at the right time. The pellets placed under the skin provide a constant low dose of the hormones for your body to use as needed. BHRPT is proven to be the most effective delivery system for both absorption and availability of the specific hormones your body requires. Unlike creams, gels and injectables, BHRPT provides a consistent dose of hormones your body desires over a longer duration.

What Are The Benefits of BHRPT?

After initial pellet treatment, your hormones can be restored to their optimal balance. The results for both men and women can include:

- Increased Energy Level
- Enhanced Sexual Libido
- Improved Mental Clarity
- Reduced Body Fat
- Decreased Depression/Anxiety
- Healthy Sense of Well Being

Data supports that hormone pellets effectively treat symptoms in both men and women. Pellet therapy is a precision method of delivering the hormones your body needs to achieve a balanced state. They are inserted under the skin where they release a steady stream of hormones 24/7. Once inserted, pellets consistently release small, physiologic doses of hormones providing optimal therapy with potentially low adverse effects.

What Are Pellets?

Pellets or implants are made up of bio-identical hormones (i.e., testosterone, estrogen or both) that are the exact formula your body produces and are derived from plants that are pressed or fused into very small solid cylinders. These pellets are larger than a grain of rice and smaller than a "TicTac".

In the United States, the majority of pellets are made by compounding pharmacists and delivered in sterile vials. Bio-Identical Hormone Pellets should not be confused with "synthetic" hormones which are typically found in many creams, gels and injectables used for hormone replacement.

Why Pellets?

Pellets deliver consistent, healthy levels of hormones for 3-4 months in women and 5-6 months in men. They avoid the fluctuations of hormone levels (roller coaster effect) seen with other methods of delivery. This is important for optimal health and disease prevention. There is less risk of blood clots with transdermal estrogen than with oral forms.

In studies, when compared to conventional hormone replacement therapy, **pellets have been shown to be superior for relief of menopausal symptoms, maintenance of bone density, restoration of sleep patterns, and improvement in sex drive, libido, sexual response and performance.**

Testosterone delivered by a pellet implant has been used to **treat migraine and menstrual headaches, vaginal dryness, incontinence, urinary urgency and frequency.** In both men and women, **testosterone has been shown to increase energy, relieve depression, increase sense of well-being, relieve anxiety and improve memory and concentration.** Testosterone pellet therapy **increases lean body mass, muscle strength, bone density and decreases fat mass. Men and women need adequate levels of testosterone for optimal and physical health and for the prevention of chronic illnesses like Alzheimer's and Parkinson's disease,** which are associated with low testosterone levels.

Even patients who have failed other types of hormone therapy have **a very high success rate with pellets. There is no other method of hormone delivery that is as convenient for the patient as the implants.** Implants have been used in both men and women since the late 1930s. There is significant data that supports the use of testosterone implants in both men and women.

Is There A Role For Testosterone Pellets In Pre-Menstrual Women?

Testosterone pellets may be used in pre-menopausal women (those who have not stopped menstruating). Testosterone has been shown to relieve migraine or menstrual headaches, help with symptoms of PMS (premenstrual syndrome), relieve anxiety and depression, increase energy, help with sleep and improve sex drive and libido. **If a pre-menopausal woman has a testosterone pellet inserted, birth control is a must.** There is a theoretical risk of "masculinizing" a female fetus (giving male traits to a female fetus).

Can A Patient Be Allergic To The Pellets?

Very rarely, a patient will develop a local zone of redness (3-8cm) with itching at the insertion site. There is minimal tenderness and minimal risk of infection. Pellets are made of hormones, stearic acid and cholesterol. If needed, 25-50 mg of Benadryl works well for the itching.

What Side Effects Can You Expect?

One of the greatest benefits of pellets is they cause minimal side effects, which can vary by person. The most common side effects you can experience include slight bruising, minor bleeding, infection, or extrusion of the pellet. However, complications beyond these are extremely rare.

How Long Until A Patient Feels Better After Pellets Are Inserted?

Some patients begin to "feel better" within 24-48 hours while others may take 10-14 days to notice a difference. Diet and lifestyle (exercise), along with hormone balance are critical for optimal health. Stress is a major contributor to hormone imbalance and illness. Side effects and adverse drug events from prescription medications may interfere with the beneficial effects of the hormone pellets.

How Long Do Pellets Last?

The pellets usually last between 3-4 months in women and 5-6 months in men. The pellets do not need to be removed. They completely dissolve on their own. And, **remember, not all pellets are created equal!**

Do Patients Need Progesterone When They Use Pellets?

Women who are treated with testosterone implants alone (no estrogen therapy) do not require progesterone therapy.

However, **if estradiol or other estrogen therapy is prescribed to women with a uterus, progesterone is required.** The main indication for progesterone is to prevent the proliferation (stimulation) of the uterine lining caused by estrogen. Progesterone therapy is NOT required if estrogen therapy is not prescribed. However, there may be other health benefits from progesterone. It may be used in addition to testosterone to help women who have difficulty with sleep, hot flashes, tension or anxiety. Testosterone and progesterone have beneficial effects on the brain and nervous system.

How Are Hormones Monitored During Therapy?

Hormone levels may be drawn and evaluated before therapy is started. This may include an FSH, estradiol and testosterone for women. Men need a PSA (prostate specific antigen), sensitive estradiol, testosterone (free and total), liver profile and a complete blood count prior to starting therapy.

Women are advised to continue their monthly self-breast exam and obtain a mammogram and/or pap smear as advised by their gynecologist or primary care physician.

How Much Do Pellets Cost?

The cost of insertion of pellets is \$365 for women. Pellets need to be inserted 2 to 4 times a year depending on how rapidly a patient metabolizes hormones. When compared to the cost of drugs to treat the individual symptoms of hormone decline, pellets are very cost effective.

Will Insurance Cover The Procedure?

Insurance companies **DO NOT** cover the cost of pellets. Payment is required prior to ordering the pellets. **Prevention is much more cost effective than disease.**

For more information, contact our office:

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Consent for Hormone Pellet Insertion for Women

1. I, _____ authorize Dr. Stefanie A. Schultis or a designated medical professional to perform the following procedure: **STERILE PLACEMENT OF HORMONE PELLETS UNDER THE SKIN.**
2. I understand the reason for the procedure is hormone replacement therapy using Estradiol alone, Testosterone alone, or both. I understand there are other methods to receive hormones including but not limited to creams, gels, patches, orals and injectables.
3. **RISKS:** Risks that may be associated with this procedure include bleeding and/or infection. A local reaction at the insertion site may occur, (i.e., itching swelling, redness, scarring or keloid formation). It has been explained to me that hormone therapy is controversial and effective. I understand:
 - a. Some believe estrogen may increase my risk of breast cancer.
 - b. Estrogen may increase my risk of endometrial cancer. I understand if I have a uterus, I **MUST** take progesterone as prescribed.
 - c. If I have an undiagnosed breast, uterine cancer or liver tumor, it may present itself and increase in growth after insertion of hormone therapy.
 - d. There might be a very low risk of stroke or deep venous thrombosis (blood clots in legs) with hormone therapy, but, this is thought to be significantly lower with bio-identical hormones and with transdermal methods like pellets.
 - e. Hormone therapy does not preclude me from developing other medical conditions like heart disease, diabetes, cancers of any kind or any other medical condition that I may or may not have gotten whether I ever used hormone pellet therapy or not.
 - f. I must inform my healthcare provider of any significant changes in my or my family's medical condition while continuing with hormone therapy.
4. There is a rare risk of reaction to medications used as local anesthetic. To the best of my knowledge, I am not allergic to lidocaine, betadine, iodine or ethyl chloride.
5. I understand that no guarantee or assurance has been made as to the results of the procedure and that it may not cure any condition I may have.
6. If I received estrogen implants and I have a uterus, I understand I must take progesterone as directed by my healthcare provider so that estrogen pellets do not increase my risk of endometrial cancer.
7. I have had within the past 12 months a breast exam and pelvic exam and agree to do this annually.
8. **PATIENT'S CONSENT:** I have read and fully understand this consent form and understand I should not sign this form if all items, including my answers, have not been explained or answered to my satisfaction or if I do not understand any of the terms or words contained in this consent form.

Patient Name (Print) Date _____

Patient Signature Date _____

9. **PROVIDERS DECLARATION:** I have explained the contents of this document and have answered the patient's questions, and to the best of my knowledge, the patient has been adequately informed and consented.

Provider's Signature Date _____

Witness Date _____



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Hormone Pellet Insertion Consent For Women

A significant hormonal transition will occur in the first four weeks after the insertion of hormone pellets. Therefore, certain changes might develop that can be bothersome.

- ❖ **Pain/Inflammation at Pellet site is expected;** Extrusion of pellets may occur; overt infection is uncommon but can occur.
- ❖ **Fluid Retention:** Testosterone stimulates the muscle to grow and retain water which may result in a weight change of two to five pounds. This happens frequently with the first insertion, and especially during hot, humid weather. Swelling of the hands and feet may occur. It may be treated by drinking lots of water, reducing your salt intake, taking cider vinegar capsules daily (found at most health food stores), or by taking a mild diuretic, which the office can prescribe.
- ❖ **Breast Tenderness and Nipple Sensitivity:** These may develop with the first pellet insertion of estrogen. The increase in estrogen sends more blood to the breast tissue. Increased blood supply is a good thing, as it nourishes the tissue. To combat the tenderness, an excellent treatment is a capsule of Oil of Evening Primrose 2-3 times a day. You may need to take them for 2-3 weeks.
- ❖ **Uterine Spotting or Bleeding:** If you have a uterus, this may occur in the first few months after an insertion with estrogen, especially if your progesterone is not taken properly (missing doses). Notify the office if this persists after 3 months or is excessive. Bleeding is not necessarily an indication of a significant uterine problem. More than likely, the uterus may be releasing tissue that needs to be eliminated. This tissue may have already been present in your uterus prior to getting pellets and is being released in response to the increase in hormones. Patients on progesterone methods only ½ the month have a regular withdrawal flow. Make sure you understand your progesterone and do not stop it until discussed with the office.
- ❖ **Mood Swings and Irritability:** These occur if you were quite deficient in hormones. They may resolve when enough hormones are in your system.
- ❖ **Facial Breakout:** Acne may develop if the body is very deficient in testosterone. This usually lasts only a short period of time and can often be handled with a good face cleansing routine, astringents and toner. If these solutions do not help, please call our office.
- ❖ **Hair Loss:** This is rare and usually only occurs in patients who convert testosterone to DHT. Dosage adjustment generally reduces or eliminates the problem. Medibles™ Hair Repair Formula may help with the loss of hair (available online) or a supplement called "Hair, Skin and Nails".
- ❖ **Hair Growth:** Testosterone may stimulate some growth of hair on your chin, chest, nipples, and/or lower abdomen. This tends to be hereditary. You may also have to shave your legs and arms more often. Dosage adjustments generally reduce or eliminate this problem. DHT may also contribute to this, so Medibles™ Hair Repair may help.
- ❖ **New Medical Conditions:** New medical conditions may be diagnosed while undergoing Pellet Therapy (i.e., cancers, blood clots). If diagnosed with conditions that may be affected (possibly worsened) by hormone therapy while undergoing hormone therapy (breast or uterine cancer, deep venous thrombosis, cardiac or other diseases) **it is not possible to remove the hormone pellets**, but, they will wear off in 3-4 months (most of the time) from the last insertion.

I have read and understand the above.

Patient Name (print) Date _____

Patient Signature Date _____

Physician/Nurse Practitioner Signature Date _____

Date _____