LOUDOUN INTERNAL MEDICINE ASSOCIATES

Female Hormone Replacement Insertion Consent

Name: _____ Date of Birth: _____

My physician/practitioner has recommended bioidentical hormone therapy delivered by a pellet inserted under my skin for treatment of symptoms I am experiencing related to low hormone levels. The following information has been explained to me prior to receiving the recommended therapy.

OVERVIEW
Bioidentical hormones are hormones that are biologically identical to that made in my own body. The levels of active estradiol and/or testosterone made by my body have decreased, and therapy using these hormones may have the same or similar effect(s) on my body as my own naturally produced hormones. The pellets are a delivery mechanism for estradiol and/or testosterone, and bioidentical hormone replacement therapy using pellets has been used since the 1930's. There are other formulations of estradiol and testosterone replacement available, and different methods can be used to deliver the therapy. There are no commercially available forms of testosterone that are formulated specifically for use in females. The risks associated with pellet therapy are generally similar to other forms of replacement therapy using bioidentical hormones.

PELLET ACTIVE INGREDIENTS
I understand that (please initial by the appropriate statement):
___ I am receiving pellets today that contain testosterone only.
___ I am receiving pellets today that contain estradiol and testosterone.
___ I am receiving pellets today that contain testosterone and anastrozole.

RISKS/COMPLICATIONS
Risks associated with pellet insertion may include: bleeding from incision site, bruising, fever, infection, pain, swelling, scarring, keloid formation at incision site, vaginal engorgement, pellet extrusion which may occur several weeks or months after insertion, reaction to local anesthetic and/or preservatives, allergy to adhesives from bandage(s), steri strips or other adhesive agents.

Some individuals may experience one or more of the following side effects with testosterone: acne, abnormal bleeding or a change in menstrual cycle (if patient has a uterus), anxiety, breast or nipple tenderness or swelling, insomnia, depression, mood swings, fluid retention, headaches, excess facial hair, hair thinning and/or loss, voice deepening, clitoromegaly, rash, redness, itching, lack of effect hypersexuality (overactive libido) or decreased libido, overproduction of estrogen (called aromatization) or an increase in red blood cell formation or blood count (erythrocytosis). The latter may be diagnosed with a blood test called a complete blood count (CBC). This test should be done at least annually. Erythrocytosis can be reversed simply by donating blood periodically, but further workup or referral may be required if a more worrisome condition is suspected. If you are planning to start or expand your family soon, please talk to your provider about other non-testosterone options. In addition, testosterone may cause some breast cancers to grow more rapidly.

RISKS/COMPLICATIONS OF ESTRADIOL (Only applicable if receiving estradiol in the pellets)
The side-effects of estradiol are similar to those listed above for testosterone. Additionally, there is some risk, even when using bioidentical hormones, that estrogens may cause existing cases of some breast cancers to grow more rapidly. This risk may also apply to some undiagnosed forms of breast cancer.

Using estrogen-alone (without progesterone) may increase the chance of getting cancer of the uterus. Endometrial sampling (biopsy) or surgery may be required if abnormal bleeding occurs.

Please initial if you are postmenopausal, have a uterus, and are getting estradiol.
___ I understand that I have a uterus and am receiving postmenopausal dosing of estradiol. I agree to take progesterone as directed by my health care provider while receiving estradiol.

RISKS/COMPLICATIONS OF ANASTROZOLE (Only applicable if receiving anastrozole in the pellets)
Anastrozole is a type of medication called an aromatase inhibitor. Aromatase inhibitors limit or prevent the conversion of testosterone into estrogen. Aromatase inhibitors can be used for a variety of conditions but are most commonly used in patients with a history of estrogen receptor positive breast cancer.

Anastrozole should not be used in pregnant women and should be used with caution in females with pre-existing ischemic heart disease. Anastrozole in pellets should not be given to premenopausal women nor to women taking oral aromatase inhibitors (anastrozole or letrozole) or selective estrogen receptor modulators (tamoxifen or raloxifene).

The amount of anastrozole used in pellets is very low. The most common side-effects for women taking anastrozole are hot flashes, joint pain, and muscle pain. Because of the low dose in the pellet, these effects are not usually seen with this type of therapy, however.

CONSENT FOR TREATMENT
I agree to immediately report any adverse reactions or problems that may be related to my therapy to my physician or health care provider's office, so that it may be reported to the manufacturer. Potential complications have been explained to me, and I acknowledge that I have received and understand this information, including the possible risks and potential complications and the potential benefits.

I also acknowledge that the nature of bioidentical therapy and other treatments have been explained to me, and I have had all my questions answered. Blood tests may be necessary on several occasions during the 1st year to help w/ dosing, and then annually or biannually at the discretion of the prescribing practitioner.

I understand that my blood tests may reveal that my levels are not optimal which, would mean I may need a higher or lower dose in the future. Furthermore, I have not been promised or guaranteed any specific benefits from the insertion of testosterone pellets.

I accept these risks and benefits, and I consent to the insertion of testosterone pellets under my skin performed by my provider. This consent is ongoing for this and all future insertions in this facility until I am no longer a patient here, but I do understand that I can revoke my consent at any time. I have been informed that I may experience any of the complications to this procedure as described above. I have read or have had this form read to me.

I ACKNOWLEDGE THAT I HAVE RECEIVED A COPY AND UNDERSTAND THE INFORMATION ON THIS FORM

PATIENT:
Print Name: _____

Signature: _____ Date: _____

WITNESS:
Print Name: _____

Signature: _____ Date: _____