

Frequently Asked Questions About Hormone Pellet Therapy

Pellet Insertion: Every 3-6 months for women and every 5-6 months for men

These appointments are meant to address minor adjustments in dosage or side effects but if you have complicated medical problems or are having an unusual side effect you will be asked to schedule an appointment with Dr. Frazzetta and blood work will be ordered as indicated.

Will my periods be the same?

Possibly but as the hormones become more in the range of pre-menopause, periods may recur if you are newly menopausal. If they appear after a year of menopause, we may order an ultrasound to make sure the lining of your uterus looks normal.

Are there any side effects and/or complications?

Unlike other forms of hormone therapy, there are fewer side effects than traditional therapy. There will be minor tenderness and or bruising after pellet insertion for 1-2 weeks. This is more common with males due to number of pellets required. Infection and expulsion of pellet are rare.

How long will it take for the pellets to get into my system and work?

24-72 hours. Optimal effects occur about 3 weeks after insertion.

I get horrible headaches-will pellets help me?

Very likely! There has been great success, especially with women who have menstrual migraines, and new migraines that appear after age 35.

Do I need to take other medication?

If you still have a uterus, you will need to be on micronized oral progesterone taken at bedtime as well and possibly if you don't have a uterus.

Why do I need estrogen?

Estrogen has been shown to protect against heart attack, stroke, osteoporosis and Alzheimer's. It also keeps us looking young and healthy!

Why do I need testosterone?

Testosterone is the most abundant sex steroid hormone in women and men. Estrogen is made from testosterone. We need this hormone to keep our thought process's quick and our libido healthy. It improves our bone density, muscle mass, collagen, strength, and prevents some types of depression. It is also the source of our energy and solid sleep.

Will I grow unwanted hair from testosterone?

There is less chance of excess hair growth with natural testosterone than with synthetic hormones. Facial hair will grow with testosterone pellets but usually not worse than when you were in your twenties. This is often managed with tweezing, bleaching, waxing, shaving, or laser hair removal. In general, any areas with hair may be stimulated to grow. Sometimes in a positive way; sometimes in a negative way but usually very manageable. Men or women who are genetically prone to male pattern hair loss may experience hair loss however, there are medications that may help balance this.

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I have no libido-what will this do for that, if anything?

Good hormone balance will typically greatly improve your libido especially with the addition of testosterone in pellet form. It is also important to continually strive to improve your relationship. Dr. Frazzetta may recommend some additional information for you.

6 Week Follow-Up Visit:

This visit is to go over your lab work and physical results. It is a shorter visit, usually 20 minutes. At this appointment, Dr. Frazzetta will recommend when your next pellet should be scheduled and what the dose should be if you choose to continue. Any side effects will be managed at this time.

Yearly care: preventive test and lab

At Montrose Wellness Center we ask that you get the recommended preventive test by your GYN or primary care provider, and that you report back to us with the results; ie any blood work or screening tests. We will not manage the results of these tests but require that you get them to ensure the safety of our treatment.

We may order yearly blood work to see if your treatment is progressing well. You may opt out of these tests if you have them drawn by another doctor or if you are happy with your dosage and have not had any unusual changes in your health. To review the results of these tests we request a follow-up consultation at a separate visit from your pellet insertion if there are any concerns.

Don't fix it if it's not broken!

Once we have you on an effective regiment, and you are feeling well, blood work and consultation visits are not required unless you want them. This is to save you money and to use our time appropriately. So, if you are feeling great, you won't need to schedule an appointment.

Consultations with Dr. Frazzetta:

If you require complicated management, this must be done by Dr. Frazzetta in the office. All questions and consultations must be done with a scheduled appointment within the office.

What do I need for my first appointment? Before we can schedule your first appointment, we will ask that you have a hormone blood panel drawn. This can be done at Dr. Frazzetta's office, your PCP, or hospital laboratory. We also request that you fill out all the appropriate paperwork provided by our office before your first appointment. We do not accept electronic submissions of paperwork. We will request that we receive up to date records of mammogram, DXA (bone density) and PSA (for men).

How much of this is covered by my insurance? Most insurances will not cover the cost of the blood work or it will go towards a deductible. Insurance will not cover pellet procedures. We require payment at time of service. The costs will vary. Forms are available upon request that you can submit to your insurance company if you believe it will be covered by your insurance however, this is the patient's responsibility.

Pellet Insertion After Care

After first night: OK to remove tape, ice pack, and white gauze dressing. It is OK to shower after 24 hours. Leave bandage on for the first shower then remove wet bandage and replace with a new bandage; change daily. It is ok to remove Steri-strips, if they have not fallen off after 7 days.

From day of insertion to day 7:

- NO hot tubs.
- NO hot baths.
- Site may remain tender for 1-2 weeks
- May have slight redness around incision site. This is normal. If redness does not start to resolve as the days of healing progress;
 - Apply a warm heating pad or similar, twice a day, for 10-15 minutes or as needed. You may use a warm washcloth as well.
- Infection is very rare. However, if redness and swelling increases after 72 hours you may have a minor skin infection. Contact the office for further evaluation.

Women ONLY:

- Continue any previous treatments of Estradiol and Testosterone for about **3 days** post procedure then stop.
- If you are currently taking Progesterone this **should be** continued.
- **NO** strenuous exercise or working the gluts for **4 days** post-pellet insertion (NO biking, spinning, elliptical, squats, lunges, etc). It is OK to walk, treadmill flat, upper body and/or abs.

Men ONLY:

- Continue any previous treatments of Testosterone for **3-5 days** post procedure then stop.
- **NO** strenuous exercise or working the gluts for **7 days** post-pellet insertion (NO biking, spinning, elliptical, squats, lunges, etc). It is OK to walk, treadmill flat, upper body and/or abs.

Local Reaction to the Pellet Implant

Very rarely, a patient will develop a local zone of **redness** (3-8cm) and/or **itching** at the site of the hormone implant weeks after the insertion. There is typically minimal or no tenderness and no other signs of infection. This is likely a local inflammatory response and may be a risk factor for extrusion, ie; the pellet working its way out through the incision or through the overlying skin.

Recommendations:

- Apply a **warm heating pad** or similar, twice a day, for 10-15 minutes or as needed. You may use a warm washcloth as well.
- Oral OTC allergy medications daily: Claritin (generic: loratadine), Zyrtec (generic: cetirizine), Allegra (generic: fexofenadine)
- In general, implants are not removed. If there are any questions of infection, please call the office to schedule an evaluation. **(970) 252-9644.**

Females: Informed Consent for Insertion of Subcutaneous Pellet Implants

Testosterone (T) and estrogen (E) pellets have been used for hormone therapy in women since 1940. There is no FDA-approved T therapy for low testosterone in women. Oral Methyl T (synthetic) was approved by the FDA and previously used to treat breast cancer. T and other pellets may be compounded and used off-label in women. Pellets are placed under the skin of the lower abdomen or upper gluteal area as an outpatient office procedure under local anesthesia. Pellets completely dissolve and are not removed.

Possible risks of pellet therapy may include:

- Expulsion of pellet.
- Bleeding, bruising, scarring, infection and pain at the insertion site.
- Lack of effect (from lack of absorption) or need for dosage adjustment.
- Breast tenderness, swelling and itching around nipples especially in the first three weeks.
- Increase in hair growth on the face, groin, legs and arms; similar to pre-menopausal patterns.
- Possible hair loss. Scalp hair thinning occurs with age and hormone decline. However, some studies have shown an association between high testosterone levels and hair loss.
- Water retention (estrogen only).
- Increased growth of estrogen dependent tumors (endometrial cancer, breast cancer). Recent studies have suggested T pellet therapy may lower the risk for breast cancer.
- Birth defects in babies exposed to testosterone during their gestation.
- Blood clots/phlebitis.
- Change in voice (reversible).
- Clitoral enlargement (reversible).
- Acne.

Possible benefits of pellet therapy may include:

- Increased libido, energy and sense of well-being.
- Increase in muscle mass and decrease in subcutaneous fat (cellulite).
- Increase in bone density.
- Decreased frequency and severity of hormonal migraine headaches.
- Decrease in mood swings, anxiety & irritability.
- Decreased central obesity.
- Improved dry eyes.
- Improvement in arthritis and fibromyalgia.
- Improvement in insulin resistance and diabetes parameters.

Pellets deliver hormones for three to five months on average in females. T stimulates the bone marrow to produce red blood cells, which may elevate the red blood cell count (hematocrit). Serum (blood) T levels on pellet therapy are much higher than the “normal” range for females. Symptoms may return when serum levels approach twice the upper normal range for young females. Both T’s effects and side effects are typically dose dependent.

Estrogen may be given along with testosterone as a vaginal cream, topical patch, implant or gel. Estrogen can stimulate the uterus lining and cause bleeding. **Oral** estrogens may increase the risk of blood clots or stroke. **Oral** androgens and other androgen formulations may adversely affect the liver, blood clots or lipid profile. Progesterone may be prescribed as an oral capsule. If you have a uterus or experience vaginal bleeding, you may be asked to get a pelvic ultrasound. Please notify Dr. Frazzetta prior to the procedure if you have a history of breast disease, abnormal uterine bleeding, fibroids, endometriosis, or have required a D&C or endometrial ablation in the past. It is recommended that you have an annual exam by your gynecologist or primary care provider.

Females: Informed Consent for Insertion of Subcutaneous Pellet Implants

T is the major substrate or “building block” for estrogen. Symptoms of excess estrogen include fluid retention, bloating, anxiety, irritability, breast pain or weight gain. Estrogen may stimulate a breast cancer. An estrogen blocker (aromatase inhibitor/ anastrozole) may be combined with T in the compounded implant. This is also off-

label use. Finasteride or spironolactone, which blocks the conversion of T to DHT, may also be used off-label in oral form to help manage hair issues.

- It is recommended that you have a normal breast exam and mammogram prior to therapy. It is your responsibility to notify Dr. Frazzetta about any breast changes or lumps prior to pellet insertion.
- You must notify Dr/ Frazzetta of any allergies or bleeding problems prior to the procedure including anti- coagulant (i.e. Coumadin, Plavix), ibuprofen, naproxen, or aspirin therapy.
- If applicable, you must notify your oncologist prior to having the T or T + anastrozole pellets placed.
- Implants or pellets are not removed.
- If you are **premenopausal**, you **must** use birth control. Theoretically, testosterone could masculinize a female fetus. Aromatase inhibitors are contraindicated in pregnancy: the possible adverse effects on a fetus are unknown. Please notify the office if you become pregnant.

I have read and understand the above information. My signature below certifies I have read the above and acknowledge I have been encouraged to ask any questions regarding testosterone and estrogen pellets. My questions have been answered to my satisfaction. I understand the procedure, benefits, risks, side effects and alternatives to the implantation of hormone pellets.

I understand that testosterone, estrogen, and testosterone-anastrozole pellets are not FDA approved in women. I understand that higher than normal physiologic levels of hormone may be reached to create the necessary hormonal balance. By beginning treatment, I accept all the risks of therapy stated herein and future risks that might be reported. I consent to the insertion of hormone pellets. I have been informed that I may experience one or more of the complications listed above. These side effects are similar to those related to traditional estrogen replacement. The surgical risks are the same as for any minor medical procedure.

I agree to allow Gayle Frazzetta, MD to implant the pellets. I understand that Dr. Frazzetta will not be assuming my healthcare or gynecologic care, unless previously arranged. It is the patient’s responsibility to continue to have regular follow up appointments with their primary care physician and/or gynecologist. My data may be used (anonymously) in a study or for research and may be included in publications. I am aware that Dr. Frazzetta does not accept health insurance for the insertion of pellets. For any hormone therapy that is not covered by health insurance, payment is due at the time of service. Forms are available upon request for self-submission to insurance. All questions and concerns have been addressed. **This consent is ongoing for this and all future pellet insertions.**

Patient Name: _____ Patient Signature: _____ Date: _____