

Frequently Asked Questions About Pellet Implant Therapy

Q: What is Natural Hormone Therapy?

A: Hormone therapy is considered the most effective treatment for symptoms of Menopause and Andropause. In the interest of a straightforward approach to hormone therapy, Natural Hormone Therapy has become widely used. These are hormones that are identical in molecular structure to the hormones made in the human body, which is thought to provide improved absorption. They are made from a plant chemical extracted from yams and soy, and act in the body just like the natural hormones our body naturally produces.

Q: What are pellet implants?

A: The implants are small cylindrical pellets created in a compounding pharmacy that are made in many different formulations and doses customized for the needs of the patient. Pellet therapy is a safe and effective method for delivering needed medications in small doses consistently over time. Pellet therapy can be a convenient choice for achieving balance in natural hormone therapy.

Q: Are pellet implants safe and effective?

A: Hormone replacement therapy by pellet implantation has been used in the United States, Europe and Australia for more than 75 years. Research has shown pellet implantation therapy to be superior to other methods of hormone delivery because it delivers small, physiologic doses of medication consistently over time. Also, unlike oral methods, the pellet delivery system bypasses the liver, which is shown to not negatively impact clotting factors, blood pressure, lipid levels, glucose, or liver function.

Pellet Implants May Improve

- Cardiovascular Health
- Sex Drive
- Headaches
- Bone Density
- Insomnia
- Hot Flashes
- Mood
- Aches and Pains
- Emotional Stability

Q: Could I benefit from pellet implant therapy?

A: Before starting any hormone replacement therapy, patients should work directly with a knowledgeable healthcare practitioner for a combined evaluation of the patient's current hormone levels (through blood or saliva testing) and personal health history profile. Based on existing hormone levels and health history, the practitioner will make a hormone replacement recommendation. Once pellets have been inserted, hormone levels will be reevaluated prior to the insertion of the next round of pellets. After the first year of therapy, the practitioner may suggest testing less frequently based upon patient feedback and prior hormone levels.

Q: How do I get pellet implants?

A: Pellet Implants require a consultation and a prescription from your healthcare practitioner. Once you are evaluated and lab values are reviewed, your practitioner will help you decide the best method for therapy. Pellet implants are usually made by a compounding pharmacy.

Q: How are the pellets implanted?

A: Pellet insertion is an outpatient procedure done in your practitioner's office. A local anesthetic is used to numb the area, usually the hips or buttocks, and the pellets are inserted through a very small incision under the fatty layer of skin. The incision is then closed with sterile-tape strips. You should not be able to feel the implants under the skin. Minimal bruising or no tenderness should be expected. However, any side effects should be discussed with your practitioner. After the pellet procedure, vigorous activity should be avoided for 2-3 days, or as suggested by your health care practitioner.

Q: How long will the pellet implant last?

A: In most patients, pellet implants last between 3-6 months. The dissolution time is based upon how rapidly the patient metabolizes hormones. Patients can experience the effect of the therapy in as little as 2 days, however it can take up to 2 weeks to experience symptom relief. The pellets do not need to be removed, as the body absorbs them completely over time.

Q: How much does pellet therapy cost?

A: The cost for pellet therapy varies based on your individualized plan. The dosage required to achieve balance will be based upon your complete blood count, your healthcare practitioner will determine the type and number of pellets required. The frequency of pellet insertion will depend on how your body metabolizes hormones. In most cases hormone implants will last between 3 and 6 months. In comparison to traditional pharmaceutical prescriptions, the cost of pellet therapy for natural hormone replacement therapy is cost effective.

Q: Is the pellet procedure covered by my insurance?

A: Most insurance companies reimburse for outpatient procedures. Some insurance companies will cover the cost of pellets. The best way to ensure accurate information about your specific insurance coverage is to call the carrier directly and inquire about the procedure. The procedure code (or CPT) is 11980, Subcutaneous Hormone Pellet Implantation; the drug code (or HCPCS) would be J3490 Unclassified drugs [when specified as estrogen or estrogen/testosterone pellets]. Your physician will need to provide applicable diagnosis codes (or ICD-9) based on your evaluation to share with your insurance company.

Q: Are the pellets FDA approved?

A: The pellet implants are not considered a FDA approved drug. However, this does not mean that they are not considered safe. The process to seek FDA approval for a drug is lengthy and very expensive. Because the compounds used to make the pellets are natural, and therefore not patentable, drug companies are not interested in manufacturing them nor going to the expense of having them approved.

Our licensed facilities, in which the pellets are produced, are compliant with USP-797 and ISO-Class 5 clean room regulations, exceeding the standards required for sterilization and quality. The pharmacies employ non-bias testing from independently registered FDA testing labs to promise sterility and potency with each and every pellet batch produced. Ensuring physicians and patients high quality, consistent pellet implant products.

Supporting Information:

Hormonal profiles in postmenopausal women after therapy with subcutaneous implants

Margaret H. Thom, W. P. Collins and J. W. W. Studd, *BJOG: An International Journal of Obstetrics & Gynecology*, Volume 88, Issue 4, pages 426–433, April 1981

Abstract Summary: Plasma hormones were estimated in 24 postmenopausal patients who had been castrated. Each was given a sub-cutaneous implant of either 100 mg or 50 mg of oestradiol, or 50 mg of oestradiol with 100 mg of testosterone, or 200 mg of testosterone. These values compare favorably with those attained after oral estrogen therapy.

Pharmacokinetics and pharmacodynamics of testosterone pellets in man

David J. Handelsman, Ann J. Conway, and Lyn M. Boylan, *The Journal of Clinical Endocrinology & Metabolism*, Volume 71, Issue 1, October 23, 1989

Abstract Summary: We studied the pharmacokinetics and pharmacodynamics of implanted pellets of fused crystalline testosterone. We conclude that fused pellets of crystalline testosterone provide very satisfactory depot androgen replacement exhibiting many desirable features for androgen replacement.

Subcutaneous hormone implants for the control of climacteric symptoms: a prospective study

M. Brincat, J.W.W. Studd, T. O'Dowd, A. Magos, L.D. Cardozo, P.J. Wardle, D. Cooper

The Lancet Volume 323, Issue 8367, 7 January 1984, Pages 16–18

Originally published as Volume 1, Issue 8367

Abstract Summary: The statistically highly significant levels of symptom relief that followed an oestradiol and testosterone implant were contrasted sharply with the lack of any significant relief with placebo. Despite the success of oestradiol and testosterone implants in relieving symptoms of the climacteric, symptoms returned once the treatment was stopped.

Testosterone release rate and duration of action of testosterone pellet implants

S. Kelleher, C. Howe, A. J. Conway and D. J. Handelsman

Clinical Endocrinology, Volume 60, Issue 4, pages 420–428, April 2004

Conclusion Summary: Testosterone pellet implants release testosterone at a steady rate of 1.3 mg/200 mg implant/day (95% CI). The duration of action is about 6 months in an uncomplicated cycle with timing of return shortened by extrusions only in the 3.6% of procedures followed by multiple extrusions.

Bone mineral density outcomes following long-term treatment with subcutaneous testosterone pellet implants in male hypogonadism

Margaret R. Zacharin, Joseph Pua and Shankar Kanumakala

Clinical Endocrinology, Volume 58, Issue 6, pages 691–695, June 2003

Conclusion Summary: Long-acting subcutaneous testosterone pellet implants as replacement therapy in male hypogonadism are safe, acceptable to the patient, result in adequate bone mass accumulation and maintenance of normal bone mineral density.

Supporting Information (Cont'd):

An analysis of testosterone implants for androgen replacement therapy

David J. Handelsman, Mary-Anne Mackey, Chris Howe, Leo Turner and Ann J. Conway, *Clinical Endocrinology*, Volume 47, Issue 3, pages 311–316, September 1997

Conclusion Summary: This study demonstrates the very satisfactory clinical acceptability of testosterone pellet implants for androgen replacement therapy within a single unit with experienced operators.

A comprehensive review of the safety and efficacy of bioidentical hormones for the management of menopause and related health risks

B Hormones - *Altern Med Rev*, 2006, D. Moskowitz