

# BIOIDENTICAL HORMONE PELLET THERAPY FOR MEN

Perhaps it is surprising to learn that hormones can be used in both men and women. When you think about it, an important part of a woman's health is her sexuality and the relationship with her intimate partner, so it makes sense for us to include that partner in the discussion and treatment of hormonal health. We chose the Biote Method in Hormone Replacement Therapy.

Both males and females experience a decline in vitality when testosterone levels fall in midlife. For a man, typically hormonal decline begins in his 40's, and by his 50's he may notice symptoms. This naturally occurring decline of testosterone, often referred to as andropause or Low T, is often associated with fatigue, irritability, weight gain, loss of stamina, reduced muscle mass, sleep disturbance, low libido, erectile dysfunction, and generally diminished enjoyment of life. In addition to these symptoms, scientific studies have shown low testosterone levels to be associated with higher risk of cardiovascular disease, abnormal serum lipids, diabetes, low bone mineral density, and prostate cancer. Research has shown that testosterone replacement therapy can relieve the symptoms of testosterone deficiency, as well as reducing inflammation, and being protective to the heart, prostate, bones, and brain [1, 2, 3, 4, 5].

The generally accepted normal range for male testosterone level is 300-1000 ng/dl. There have been numerous medical research studies showing the benefits of maintaining a testosterone level in the uppermost part of the normal range, and it is reasonable for a man to supplement testosterone to relieve symptoms of testosterone deficiency, even though a blood test may show his testosterone level falls at the lower end of the normal range. The use of testosterone for an individual who has a level anywhere in the normal range is considered off-label use. Off-label uses have not been evaluated by the FDA, and claims of benefit are educated opinions based on examination of the numerous medical research studies that are available.

## What is Bioidentical Testosterone Pellet Therapy?

Testosterone, an androgenic hormone produced by the testicles, is the male's primary sex hormone. It plays a key role in the development of male reproductive tissues as well as promoting characteristic male appearance, and being necessary for countless bodily functions, as evidenced by abundant androgen receptors in nearly all tissues of the body. Custom compounded bioidentical testosterone pellets consist of concentrated testosterone, molecularly identical to a man's naturally occurring testosterone. The compounded pellets are obtained from a specialized compounding pharmacy that meets FDA requirements.

Compounded bioidentical hormone pellets are FDA monitored, but not approved in the United States. Hormone pellet therapy has been used in both men and women for decades in Europe and Australia, and this has allowed for the generation of ample scientific data regarding the benefits and safety of this method (see references below). Pellet technology is being used more and more in the US, as men seek a more convenient, more natural way to receive their hormone therapy.

The individual testosterone pellets are slightly larger than of a grain of rice, and are inserted into the subcutaneous fatty tissue of the upper hip or flank, where they provide a slow release of hormone into the bloodstream. The simple procedure takes only a few minutes during an office visit, first with numbing of the skin, then one tiny incision that does not even require a stitch to close. Over a 4-5 month period, the pellets dissolve completely, and must be replaced if therapy is to continue.

The pellet delivery system for men is far superior to other methods of testosterone delivery because of the efficient, gradual, and consistent delivery of the hormone into the circulation. Thus, men are more likely to have symptom relief, and less likely to have side effects with pellet therapy compared to other delivery methods. For example, a significant drawback to intramuscular injection of testosterone (besides the inconvenience of receiving a shot twice a week) is the inconsistent level of serum testosterone with this method, resulting in a roller coaster pattern of hormone excess and deficiency throughout the interval between injections. Testosterone topical gels often do not absorb well enough to provide optimal symptom relief. Additionally, they are associated with odor and risk of transference to a partner, child, or pet. The testosterone patch is often poorly tolerated due to skin irritation and itching, and can also be associated with poor systemic levels.

Note: Do not confuse testosterone pellet therapy discussed here with synthetic androgen used purely to enhance muscle mass or athletic performance. The latter are very potent, have been associated with cardiac and liver damage, are not bioidentical, and are not appropriate for use as hormone supplementation.

## Are There Risks or Side Effects of Testosterone Pellet Therapy for Men?

Testosterone pellet therapy is safe, well tolerated, and convenient, and pellet insertion is a low risk procedure. Procedure related risks include infection, bleeding, bruising, swelling, pain, extrusion of pellets, or scarring.

Scientific understanding of the side effects and risks related to testosterone therapy has evolved over the past two decades, as experience has been gained and medical research has been active. It was once assumed that high levels of testosterone might increase risk

of prostate cancer. This was based on the observation that some advanced prostate cancers slowed with testosterone deprivation therapy. However, further study has shown the mechanism of cancer development to be more complicated than first thought. Many scientific articles have now documented not only that higher testosterone levels are *not* associated with increased prostate cancer risk, but also that lower testosterone levels *are* associated with increased prostate cancer risk. It is now well accepted by experts in the scientific community that testosterone supplementation is safe, and does not increase the risk of prostate cancer [3,8,9].

Another concern has been the question of cardiac risk. There were two studies a few years ago that linked testosterone therapy to stroke and heart attack, and they received so much attention that the FDA announced a new warning about testosterone therapy's potential increase in cardiovascular risk. However, it was later shown that both of these studies were deeply flawed and their reporting was inaccurate. Meanwhile, there are many dozens of studies in the scientific literature showing cardiovascular benefit of testosterone supplementation. Many studies also show an increase of cardiac disease and mortality in men with *low* testosterone levels. Experts agree, and it is now widely accepted that testosterone supplementation is protective of cardiovascular health [3,6,7].

Testosterone therapy is likely to cause shrinkage in testicular size, decreased sperm counts, and infertility. If your plans for fertility change, you will need to stop hormone therapy to allow your sperm count to return to normal, which may take up to a year or more, and there is no guarantee fertility will return. However, it is important also to understand that pellet therapy should not be considered a contraceptive, and it may be possible to maintain some level of fertility while using pellet therapy.

Men using pellet therapy will be monitored with annual measurement of PSA (prostate specific antigen) to detect early signs of prostate cancer, and estradiol levels will be measured at least annually, to be sure levels remain within appropriate range.

## Consultation and Evaluation for Hormone Pellet Therapy

Completion of the Hormone Pellet Therapy Consultation will involve full symptom discussion and evaluation, and a panel of laboratories will be ordered for baseline hormone levels plus other indicated labs. Hormone Pellets may be inserted during the second office visit where lab results will be discussed.

## Fee for Testosterone Pellet Therapy for Men

Generally, health insurance will cover the cost of office visits and laboratory tests for evaluation of hormone related symptoms. However, insurance will not cover compounded bioidentical hormone pellets or the pellet insertion procedure.

The fee for male testosterone pellet therapy (including the procedure and the pellets themselves) is \$750.00. The cost works out to approximately \$4.00 to \$6.00 per day, depending on how often new pellets are needed (typically every 4 to 5 months). When one considers the amount that may be saved in medications for erectile dysfunction, sleep, depression, anxiety, elevated cholesterol, diabetes, and osteoporosis, plus the benefits to quality of life, sexual health, relationships, and job performance, the cost of pellet therapy can be considered quite reasonable.

### References for Testosterone Therapy in Men

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***appears to be a strong beneficial relationship between normal T and CV health that has not yet been widely appreciated.***

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11. Osterberg EC, et al. Risks of testosterone replacement therapy in men. *Indian J Urol*, 2014 Jan-Mar; 30(1): 2–7. ***Discusses risks and summarizes the current literature on safety of TRT.***