



Consent for Testosterone Therapy in Men

You have been diagnosed with or have an increased risk of having a hormone deficiency and your provider has recommended treatment with bio-identical hormone replacement therapy (BHRT). Some of the bio-identical hormone preparations that may be prescribed for you may or may not be regulated and/or specifically approved by the FDA or by the Pharmacy Compounding Law. The use of this therapy as it relates to your diagnosis, while common in Age Management, wellness and other non-traditional medical practices, may be considered controversial in the traditional medical community.

You have the right, as a patient, to be informed about your condition and the recommended conventional, integrative, complementary, alternative, non-conventional or non-standard procedures to be used so that you make an informed decision whether or not to undergo the treatments after knowing the potential risks and benefits involved. This disclosure is not meant to scare or alarm you it is simply an effort to make you better informed so you may have the information needed to give or withhold your consent to the recommended treatment.

Alternatives may be the use of specific nutritional supplements and other hormonal therapies such as HCG or Clomiphene. Alternative therapies as such may lessen or eliminate the potential risks of testosterone therapy, but these alternatives may or may not be as effective in the treatment of your condition. Of course, not taking the therapy is an alternative that will eliminate any risk of complications or side effects.

I understand that this prescription for Testosterone is indicated for the treatment of Androgen Deficiency, sometimes called Andropause or Hypogonadism, for Testosterone Deficiency, based upon medical history, physical findings and laboratory tests or for the symptoms of Testosterone deficiency alone.

Testosterone products are FDA-approved only for use in men who lack or have low testosterone levels in conjunction with an associated medical condition. Examples of these conditions include failure of the testicles to produce testosterone because of reasons such as genetic problems or chemotherapy. Other examples include problems with brain structures-the hypothalamus and pituitary, that control the production of testosterone by the testicles. None of the FDA-approved testosterone products are approved for use in men with low testosterone levels who lack an associated medical condition.

Thus, in many cases, especially where a person may have symptoms of low Testosterone but still have "normal" levels of Testosterone, the prescription of Testosterone might be considered an "Off Label" use.



The FDA has issued the following warnings concerning the prescription of Testosterone:

- There is a possible increased cardiovascular risk, heart attack, stroke or cardiovascular death associated with testosterone use.
- There is a possible increased risk of blood clots in the veins, also known as venous thromboembolism (VTE), deep vein thrombosis (DVT) and pulmonary embolism (PE).
- In addition, the following side effects or adverse reaction have been commonly thought to be associated with the use of Testosterone products
 - Worsening of Benign Prostate Hyperplasia
 - Risk of the development of Prostate Cancer
 - Thickening of the blood with potential to cause blood clots
 - Cardiovascular risk, heart attacks, sudden cardiac death, stroke and other Major Adverse Cardiac Events
 - Negative effect on sperm formation and fertility
 - Adverse effects on the liver
 - Edema, ankle swelling
 - Shrinking of the testicles
 - Gynecomastia, enlargement of the breasts
 - Sleep Apnea
 - Adverse effects on lipid profile
 - Elevated calcium levels

The FDA has issued the following warnings regarding Testosterone and its possible transference:

Testosterone, especially in the topical application form may result in transference that may manifest in virilization (development of adult male characteristics) in women, children, house pets, and other acquaintances.

In particular, the use of topical Testosterone should be done with care and the testosterone should be placed in areas that limit exposure to others. Proper administration techniques should be used and proper handwashing carried out immediately after the application of the topical agent.

I have been advised by the treating health care provider that bio-identical testosterone therapy has substantial medical literature in support of the improvement of men's health and longevity. It is the opinion of the treating health care provider that the medical literature strongly contradicts the FDA



warnings about the use of testosterone in men. Specifically, there is medical evidence to suggest that bio-identical testosterone therapy:

Reduces the risk of coronary artery and other cardiovascular diseases

Reduces the risk of osteoporosis and the risk of death from osteoporosis related fractures

Reduces the risk of age related dementias and Alzheimer's disease

Reduces the risk of certain cancers

Reduces the risk of "all-cause mortality"; meaning that men who are hormone balanced live longer lives

Reduces the risk of the decline in sexual responsiveness

Reduces the effects of age related/hormone mediated psychogenic symptoms and improves libido and sex drive

Improves physical stamina, endurance and results of exercise

Improves muscle bulk and tone

Improves lipid metabolism

Improves glucose/sugar metabolism and reduces the risk of type 2 diabetes

Provides a more beneficial hormonal environment for weight management

Overall, it is the opinion of the treating health care provider that the risks of prolonged hormone imbalance in the aging years is far greater than any risk shown to be associated with the use of bio-identical hormone therapy. That is, the risks of illness and dying early is greater if treatment is withheld as opposed to initiating and continuing bio-identical hormone therapy through the aging years.

I understand that the treating health care provider cannot guarantee any positive results or that there will be no side effects or harm. The goal and potential benefit of this therapy is to prevent, reduce or control the symptomatic dysfunction and physiologic imbalance that occurs as a result of testosterone deficiency or the aging process and the low testosterone production that occurs in aging males.

Bio-identical testosterone therapy is available in various forms including pills, capsules, sublingual drops, troches, topical creams, pellets and injection.

I understand that typical side effects associated with the use of Testosterone might include oily skin, acne, moodiness, irritability, chronic priapism (persistent, abnormal erection of the penis), change in libido, hirsutism (facial hair growth) and scalp hair loss, hair growth where topical Testosterone is applied, voice changes, water retention, slight bruising or infection at the injection/pellet insertion site (if injection or pellet therapy is used), increased hematocrit in the blood count, alteration of lipid profile, changes in blood pressure, and insulin sensitivity changes.

I agree to cease using the testosterone and contact my provider and if necessary, seek immediate medical attention, in the event I knowingly develop any adverse side effects.

I understand that when Testosterone is applied topically as a cream or a gel, it may cause transference to others resulting in hair growth or other signs of Testosterone excess in those to whom the transference has occurred.

I understand that the conventional medical community and many medical doctors believe that Testosterone supplementation is contra-indicated in a patient with past history of a variety of different prostate disease states including but not limited to Prostate Hypertrophy (BPH) and prostate Cancer. I have been fully informed, and I am totally satisfied with my understanding that this proposed treatment



may be viewed by the conventional medical community as new, controversial or detrimental, and/or unnecessary by the Food and Drug Administration. I am also aware that there is a substantial body of evidence that supports Testosterone supplementation in appropriate male patients.

While a study published in the New England Journal of Medicine, January 2004, reviewed 72 medical studies and found no evidence that testosterone therapy causes prostate cancer, I understand that questions have been raised about Testosterone as a cause of prostate cancer, since it is an anabolic hormone and has previously been thought to increase the growth rate of cancer cells.

I understand that the long-term use of exogenous testosterone may result in a mild to moderate testicular atrophy (shrinkage) and a lowered sperm count, and that my ability to father children may be lessened or permanently impaired.

I understand the importance of maintaining a healthy lifestyle with the use of Testosterone and agree to continue with a recommended program of healthful nutrition, regular exercise, stress management and nutritional supplementation with the use of Testosterone. I further agree to continue any other hormone replacement therapies recommended by my physician.

I understand that careful monitoring is crucial with Testosterone replacement therapy and agree to comply with the following monitoring recommendations while receiving Testosterone replacement therapy:

- Total and Free Testosterone levels, PSA, CBC, CMP, Thyroid panel, Vitamin D Level, IGF-I level and DHEA-S level are measured initially, then at appropriate intervals thereafter.
- PSA is measured every 6-12 months in men over the age of 40
- Other hormone levels may be monitored, as well as other blood tests appropriate for treatment.
- Assessment for physical side effects 4-8 weeks after initial replacement and regularly thereafter.
- Annually: Physical examination, baseline blood testing, baseline prostate exams and digital prostate exams.

Statement of Patient:

I understand that along with the benefits of any medical treatment or therapies, there are both potential risks and complications to treatment. Those risks and complications have been explained to me and I agree that I have received information regarding those risks, complications and benefits, and the nature of bio-identical and other hormone treatments and have had all my questions answered. I have not been promised or guaranteed any specific benefit from the administration of these therapies and no warranty or guarantee has been made regarding the results of treatment. By signing below, I agree and give my consent to proceed with treatment and to comply with recommended dosages.

I agree to comply with requests for ongoing testing to assure proper monitoring of my treatments that may include laboratory evaluation of all aforementioned hormone levels or other diagnostic testing by a Wellness and Age Management physician, my primary care physician, or other specialist, I agree to see my primary care physician, or other practitioner for regular monitoring and for preventative measures that may include but are not limited to complete physicals, rectal examinations and/or colonoscopy, EKG, prostate exams, PSA levels, etc. at least on a yearly basis.

I agree to immediately report to my physician any adverse reaction or problem that might be related to my therapy.



Treating Provider Initials _____

Patient Initials _____

I certify this form has been fully explained to me. I have read it or have had it read to me and that I understand its contents. I agree not to undergo any treatments unless I fully understand the treatment and have discussed possible risks and benefits. I agree to Testosterone therapy as described above. I have been educated on the benefits, risks, and possible adverse reactions associated with bio-identical hormone replacement therapy.

Signature of Patient **Date**

Print Name

Notice About Prostate Exam (Digital Rectal Exam-DRE):

In many circles, it is considered the standard of care for all men undergoing Testosterone therapy to have a Digital Rectal Exam performed prior to the initiation of therapy and then at least annually thereafter. The rationale for this had been the concern that Testosterone therapy could be an inciting or aggravating factor in prostate cancer. However, recent literature seems to indicate no further support of the notion that Testosterone therapy aggravates or incites prostate cancer. In addition, even with DRE, a substantial number of prostate cancers are missed due to (a) they are not of a substantial size to be detected, (b) the



exam can be ineffective in detecting any potential tumor. Thus, DRE is no longer perceived to be the gold standard in diagnosing prostate cancer.

It is the practice of this office to offer DRE to all men who would like to have this screening test carried out before the initiation of testosterone therapy.

I DECLINE A DRE EXAMINATION AT THIS TIME_____ (Initials)

I WOULD LIKE TO HAVE A DRE EXAMINATION PRIOR TO THE INITIATION OF TESTOSTERONE THERAPY_____ (Initials)

I WILL CONTINUE TO HAVE MY PROSTATE HEALTH MONITORED BY MY PRIMARY CARE PHYSICIAN_____ (Initials)

This consent is ongoing for this and all future BHRT Treatments.

Signature of Patient

Date