



## Male Non-Pellet Membership Information and Consent Form

Welcome to the Prestige Regenerative Medicine (PRM) practice. We are excited to get you started on your journey to optimal health and vitality.

This document contains information on our standard operations and procedures, in addition to some important medical information about your program, including the potential risks and benefits of testosterone replacement therapy. We encourage you to read it carefully and make sure to discuss any questions or concerns you may have with our program director, one of our staff members, or your provider. Your signature indicates you have read the form and agree with its contents, and would like to proceed with therapy.

### General

- PRM does not provide primary care services -- our providers specialize in hormone replacement therapy and sexual wellness treatments.
- PRM recommends all our patients have a local Primary Care Provider (PCP) to help manage important routine healthcare needs, including cancer screening. On occasion, PRM Providers will advise patients to seek follow-up with a PCP and / or have their PCP coordinate referral to specialists for other conditions. PRM Providers will cooperate and coordinate with your PCP and provide necessary records as needed. By signing this form you acknowledge the need for a PCP and that you will seek follow up with a PCP or other specialists as advised by PRM Providers.
- Although extremely rare, there may be situations that your PRM provider will refer you to seek emergency care -- you agree to do so if advised.
- By signing this form you give consent to PRM to electronically obtain your medication / prescription history. This is important for providing you the best care and to avoid the possibility of medication interactions and minimize side effects.

### Laboratory Work

- At Prestige Regenerative Medicine (PRM) our goal is to provide you with premium, concierge level service that optimizes your health outcome and minimizes hassle and out-of-pocket costs. **Quest Diagnostics** is our exclusive provider for blood based lab work.
- Please do not give any insurance information to Quest. We have excellent pricing through Quest which allows us to obtain your lab work at a fraction of standard pricing (for either you or your insurance company). In our experience, billing labs through insurance usually results in a (large) surprise bill to the patient. Your standard labs are covered by PRM and included in your membership.
- For men, lab tests through Quest will be necessary periodically -- typically twice per year. We will monitor your testosterone and estradiol levels in order to adjust your dosage to optimize your testosterone level and minimize side effects. We also monitor your CBC / hemoglobin / hematocrit to ascertain if blood donation or therapeutic phlebotomy is required, and we need to monitor your Prostate Specific Antigen (PSA) at least yearly. If you have blood drawn, you should hear from one of our staff within 10-14 days of your labs having been drawn (unless you have an upcoming appointment to discuss them), otherwise please call our staff. Although labs are supposed to automatically be transferred to our Electronic Medical Record system, occasionally they don't make it. We have no way of knowing when you have had them drawn, but can research it if there is an issue.

## **Testosterone Replacement Therapy**

Testosterone replacement therapy is prescribed to replace the testosterone loss that occurs with normal aging in men. Some men have a more rapid drop in testosterone levels than others, and that can lead to many symptoms of a condition that is referred to as “andropause.”

Testosterone replacement therapy has been used in the United States and worldwide for many years and has been widely proven to be both safe and effective. The primary available delivery methods for testosterone replacement include topical, injectable, and pellet therapy. Because of the virtual nature of this telemedicine program, we are unable to provide testosterone pellet therapy unless you visit one of our clinics.

### **Signs / symptoms of Andropause that may be improved by testosterone therapy include but are not limited to:**

Low energy, depressed mood, anxiety, poor sleep, inability to gain and retain muscle mass, insulin resistance, weight gain, joint aches and pains, difficulty healing, decreased libido, erectile dysfunction, brain fog, difficulty with focus and / or concentration, and inability to set and achieve goals. In addition, low testosterone levels have been shown to increase risk of all-cause mortality, certain types of cancer, atherosclerosis / cardiovascular disease, unhealthy lipid (cholesterol) patterns, generalized aging, osteoporosis, diabetes, increased overall inflammatory disorders, dementia, Alzheimer’s disease, and many other symptoms of aging. Replacing testosterone may help mitigate some of these health risks and lower your risk of certain diseases.

Benefits of testosterone therapy are dose dependent but appear to plateau between total testosterone blood levels of 1000 and 1200 ng/dl. At PRM, we typically attempt to optimize your free and bioavailable testosterone levels (these closely track each other), but at no time will we attempt to dose your therapy to get blood levels of total testosterone higher than 1200 ng/dl. Please note that testosterone therapy is prescribed by PRM to treat medical symptoms associated with Andropause / Relative Androgen Deficiency, and not for sports performance enhancement or bodybuilding.

### **Potential risks of Testosterone Replacement Therapy (TRT)**

There are specific risks associated with the different delivery methods for testosterone therapy. Specifically, the risks of topical therapy include hair growth at application sites and transfer to partners, children, or pets. Due to the inherent nature of dermal absorption it may be difficult to maintain consistent or steady levels and / or control some of the byproduct hormones of normal testosterone metabolism in the skin.

Risks specific to injectable testosterone include injection site pain and infection, damage to anatomically deep structures with the needle or injection, or abscess (a collection of infected fluid under the skin.) These risks are all extremely small and unlikely, and are decreased with proper injection technique and the use of small gauge subcutaneous needles, which is what PRM prescribes.

Men on testosterone replacement therapy may experience slight (usually 10-15%) shrinkage of the testes. This is due to the fact that once adequate testosterone levels are present the pituitary gland decreases your own testosterone production (which is carried out in the testes). This is primarily a cosmetic issue, but if it bothers you please talk to your practitioner as there are ways that we can help maintain normal testicular volume (clomiphene and gonadorelin).

TRT may also cause a significant reduction in sperm production and / or fertility (again, due to the pituitary gland downregulating stimulation of the testes). If you would like to maintain your potential fertility, there are methods to help raise your testosterone without potentially impairing fertility, or additional treatments that can be given (typically oral clomiphene).

There is some theoretical risk, even with bio-identical testosterone therapy, of enhancing an existing current prostate cancer to grow more rapidly. However, the most recent literature suggests that testosterone therapy may be protective against high grade prostate cancer and that once your level is above a certain rather low point there is no additional

cancer risk (the “saturation hypothesis”). Many urologists now recommend testosterone replacement where indicated even in patients with a history of treated or even active prostate cancer.

To monitor this situation, a Prostate Specific Antigen (PSA) blood test will usually be done prior to starting testosterone therapy and will be conducted at least annually thereafter. If there is any question about a possible prostate cancer, a follow-up with an ultrasound or other imaging of the prostate and referral to a urologist may be indicated. It is recommended that you have a prostate examination before starting therapy (see your primary care physician) and at least yearly thereafter. It is your responsibility to notify your practitioner of any changes in your prostate status or symptoms potentially related to prostate gland problems (changes in urinary stream strength, more frequent night time urination, etc.)

Testosterone therapy may increase one’s hemoglobin and hematocrit (“thicken” one’s blood). Note that this is more common with injectable testosterone than other replacement methods, and can be diagnosed with a blood test, which will be done periodically (Complete Blood Count (CBC)). This condition is treated by periodically donating blood if it occurs, or by therapeutic phlebotomy if you are not eligible to donate blood.

Testosterone is a major substrate or “building block” for estrogen. All men convert some portion of their testosterone to estradiol (the primary “estrogen hormone”). This conversion rate increases with age and percentage of body fat. Symptoms of excess estrogen include fluid retention, bloating, anxiety, irritability, breast pain, or weight gain. An estrogen blocker, anastrozole, may be prescribed and can either be compounded with your injectable testosterone or taken orally (usually once per week). The use of anastrozole in this fashion is “off-label” but has been widely proven to be safe and effective in thousands of men. There are alternative methods to decrease aromatase activity if you prefer – please discuss with your practitioner if you have questions.

In some cases, other supplements may be recommended for specific purposes. For example, Saw Palmetto can decrease the conversion of testosterone to dihydrotestosterone, which can stimulate prostate enlargement and potentiate hair loss in some men. DIM (Di-indolyl-methane) may be recommended by your practitioner to improve estradiol metabolism in certain cases.

Testosterone Replacement Therapy may suppress the body’s normal production of testosterone. In general you will only be prescribed TRT if your testosterone levels are very low and your symptoms indicate you might benefit. You can choose to stop TRT at any time and should expect your testosterone levels to return within a several weeks or a few months to very close to where they were prior to you starting TRT.

## **Consent**

I have read and understood the above. I have been encouraged and have had the opportunity to ask any questions regarding my testosterone replacement therapy. All my questions have been answered to my satisfaction. I understand that the use of anastrozole to treat men is “off-label” use as per the FDA, but has been shown safe and effective. I further acknowledge that there may be risks of testosterone therapy that we do not yet know now, and that the current known risks and benefits of this treatment have been explained to me and I have been informed that I may experience complications, including one or more of those listed above. I accept these risks and benefits and I consent and request the prescription of testosterone replacement therapy. I release my practitioner and the employees, officers, and owners of Prestige Regenerative Medicine and Prestige Restorative Management of any liability should any hormone related cancer occur in my case, and I assume responsibility for any and all recommended screenings for such. **By signing this document I have consented to proceed with testosterone replacement therapy. This consent is ongoing for this and implied for all therapy.**

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Signature Date