Regenerative Medicine

Female 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.

<u>General</u>

• 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, to avoid the possibility of medication interactions and to 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 women, a DUTCH test will be recommended periodically - usually after 2-3 months of treatment and yearly thereafter. We will monitor your hormone levels in order to adjust your dosage to optimize your testosterone level and minimize side effects. Once you have shipped your DUTCH test in, it usually takes 2-3 weeks for the results to be reported to our clinic. We recommend setting up an appointment with your provider to discuss the results approximately 1 month after sending the test in. If you have blood drawn, you should hear from one of our staff within 10-14 days of your labs having been drawn- 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. If you have had labs drawn or sent in a DUTCH test and don't have an upcoming appointment within a few weeks, please reach out to our staff so that we can research what is going on with your labs.

Bioidentical Hormone Replacement Therapy in Women

Although most people think of testosterone as a "male hormone", it turns out it is an important hormone in both men and women. In fact, women have more testosterone circulating in their bodies for most of their lives than they do estradiol (what we normally think of as the "female hormone.") As women approach menopause their testosterone levels start to drop and that is frequently when women start to experience "the change" of life -- decreased energy / fatigue, moodiness / irritability, decreased libido, vaginal dryness, weight gain, decreased muscle mass, poor sleep, poor recovery after exercise, loss of vitality / general happiness, etc. Subsequently women's progesterone levels start to drop and sleep worsens, hair / skin / nails start to "age", women can begin feeling anxious or depressed, etc.

As progesterone levels drop and no longer "balance" estrogen (estradiol is the "primary estrogen" in reproductive age women) menstrual cycles can become irregular -- longer, shorter, heavier, lighter, or some combination of all of the above. As a woman's estradiol levels drop and eventually go away, menstrual cycles stop altogether, all of the above symptoms worsen, and hot flashes / night sweats (the so-called "vasomotor symptoms" of menopause begin.

In addition to the symptoms as detailed above, declining hormone levels in women have been linked with the development of cardiovascular disease, osteoporosis, cognitive decline, sarcopenia, and generally worsened quality of life, in addition to the development of some cancers (testosterone has actually been shown to be protective against breast cancer in women.)

Many of these above changes can be prevented, partially reversed, or at the very least slowed down or lessened significantly by careful, knowledgeable bioidentical hormone replacement therapy in women. PRM uses only "bio-identical hormones" when possible -- these are the exact same hormones that your body makes and expects to see. Many women have been worried about the risks of hormone replacement therapy and have heard that cancer is a potential issue. All the studies that have been done point to the fact that replacing a woman's hormones with synthetic compounds like Premarin (conjugated equine estrogen) or Provera (methylprogesterone -- not progesterone) are where the cancer risk comes from. Although there are some cancers that women get that are sensitive to higher levels of either estradiol or progesterone and may grow more / faster in the presence of those hormones, there is absolutely NO EVIDENCE that those hormones actually "cause" or "start" the cancer. With that in mind, it is very important that all our patients continue to get regular cancer screening and immediately inform their provider if they develop cancer or other changes in their general health status.

Although not "FDA approved" for women, testosterone has actually been shown to be protective against breast cancer, and many thousands of practitioners in the United States and worldwide have vast experience prescribing testosterone to women with excellent results, and have shown it to be safe and effective. The primary available delivery methods for testosterone replacement in women 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.

Please note that although we specialize in replacement of hormones in women as they age, our goals are to restore testosterone, estradiol, and progesterone (and other hormones when such a program is chosen) back to near physiologic levels. In some cases testosterone levels may be slightly higher than physiologic due to decreased testosterone receptor density as women age, but we carefully monitor levels and dosages in an attempt to manage side effects.

Bioidentical hormone replacement therapy, like any other medical therapy, must be dosed correctly, used correctly, and monitored carefully. If all those conditions are met then it can be done safely and effectively, giving patients excellent results.

An excellent book on Women's hormone replacement is <u>The Secret Female Hormone</u> by Kathy Maupin, MD. Dr. Maupin also has YouTube videos and lectures that explain how bioidentical hormone replacement, particularly testosterone, can be life-changing for women as they start the process of menopause.

Hormones We Replace and Side Effects

At Prestige Regenerative Medicine we typically replace testosterone, progesterone and sometimes estradiol in women. The reason estradiol replacement is not necessary in all women is because women convert some of their testosterone into estradiol, so in most cases if we get the testosterone level right, giving estradiol is not necessary.

Potential side effects of testosterone replacement in women can include acne, facial hair, and in extreme and very uncommon cases, clitoral enlargement, hypersexuality, and in extreme cases, a deepening voice. These are all dose dependent and are easily managed by decreasing the dose to a more appropriate level. In addition, there are supplements and medications that can help mitigate these side effects should they occur. Other than dose dependent side effects of testosterone replacement as above, there are no known serious risks of testosterone replacement in women. In addition, there may be potential small injection site risks (infection) in the case of injectable testosterone, or application site issues (rash, localized hair growth, intolerance to delivery method or vehicle).

Potential side effects of progesterone replacement in women are rare and usually related to the delivery method (type of therapy) but can include excessive drowsiness, fluid retention, headache, and dizziness. These are extremely rare and progesterone is generally very well tolerated. If a woman has a progesterone receptor positive malignancy (cancer) then it is possible that the cancer could grow faster, so this is a contraindication (reason not to take) progesterone.

Potential side effects of estradiol (estrogen) therapy include breast tenderness, breakthrough bleeding, weight gain, bloating, itching at application site, moodiness or irritability.

Signs / symptoms of Menopause that <u>may be improved</u> by bioidentical hormone replacement therapy (BHRT) in women 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, decreased sexual brain fog, difficulty with focus and / or concentration, and inability to set and achieve goals. In addition, <u>BHRT</u> decreases the 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 your hormones may help mitigate some of these health risks and lower your risk of certain diseases.

Potential risks of BHRT

As above, the risks of appropriate, low dose BHRT in women are believed to be extremely low. There is no evidence that replacement of hormones in postmenopausal women leads to increased cancer risk, and in fact there is some suggestion that it decreases cancer risk.

There are specific risks associated with the different delivery methods for BHRT. 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 BHRT include injection site pain and infection, damage to anatomically deep structures with the injection, or abscess (a collection of infected fluid under the skin.) These risks are very unlikely, and are decreased with proper injection technique and the use of small gauge subcutaneous needles, which is what PRM prescribes.

Women on BHRT, especially those using testosterone, should use contraception and avoid pregnancy. Women being treated with testosterone in particular who become pregnant have a slightly higher risk of "masculinization" of a female fetus. <u>Thus, you agree to use appropriate contraception while on BHRT, and immediately inform your provider should you become pregnant</u>.

<u>Consent</u>

I have read and understood the above. I have been encouraged and have had the opportunity to ask any questions regarding my BHRT. All my questions have been answered to my satisfaction. I understand the importance of regular cancer screening by my primary care provider, specifically screening for breast and gynecologic cancers. I further acknowledge that there may be risks of testosterone therapy that we do not yet know, and that the current known risks and benefits of this treatment have been explained to me and I have been informed and that I may experience complications or side effects, including one or more of those listed above. I accept these risks and benefits and I consent and request the prescription / provision of hormone 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 bioidentical hormone replacement therapy. This consent is ongoing for this and implied for all subsequent therapy.

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Signature / Date