



CONSENT FOR TREATMENT

Bioidentical Hormone Replacement Therapy

PURPOSE AND BACKGROUND

As a patient of Nourished MedSpa and Wellness Center, I have requested hormone replacement therapy, which is used to treat hormone dysfunction. The procedure requires multiple sequential treatments. These hormones are typically used to treat symptoms of PMS, pre-menopause, peri-menopause, menopause, post-menopause, andropause (male menopause), thyroid dysfunction and adrenal fatigue. Other symptoms and health concerns may also be treated with BHRT.

I understand that it is my responsibility to have an annual physical examination, annual gynecological exam/breast exam/mammogram or equivalent (for males, i.e. prostate exam), including any suggested laboratory tests to ensure that I have no disease(s) which might make natural BHRT inappropriate for my condition. I also understand that BHRT requires laboratory monitoring as prescribed by my primary care physician or healthcare provider.

I realize in the past athletes have abused testosterone. When they took large quantities of synthetic testosterone, they may have incurred heart problems, elevated cholesterol, and other health problems. However, low dose, non-oral, natural testosterone that is used in bio-identical hormonal therapy has NOT been associated with these problems.

I understand that bioidentical estrogen theoretically has the same cancer risk as the estrogen produced within my own body and should never be used without bioidentical progesterone. Personal family history of breast, ovarian, or endometrial (uterine) cancer should be discussed with your primary healthcare provider as well as Dr. Carter. For male patients, studies have shown testosterone does not increase risk of prostate cancer. Although some studies have shown an increased risk of heart attack and stroke with Testosterone Replacement Therapy, a large majority of studies show improved heart health, and decreased risk.

I understand that Estriol is the protective estrogen, thought to reduce the risk of breast cancer or recurrence. Estriol is a much safer form of estrogen because it isn't metabolized into other hormones, keeping its unique identity. Estriol does not stimulate growth of breast tissue in physiologic doses.

Testosterone cypionate is an injectable prescription medication formulated to treat a condition known as 'hypogonadism' or 'andropause' (where the body doesn't create enough testosterone). Low testosterone levels in males can lead to mood changes, poor concentration, erectile dysfunction (trouble getting or keeping an erection), and low sex drive. It can also cause reduced growth of penis and testicles, gynecomastia (breast growth), loss of body hair and muscle mass, anemia, and osteoporosis.

I understand that BHRT does not increase heart disease if given at the proper dosage and ratio. Patients with previous deep vein thrombosis (DVT), or blood clots, require careful monitoring if they are taking oral estrogen. Women or men with known heart disease or other serious illness need routine evaluation and annual labs including cholesterol levels, EKG, and other necessary tests. Patients are encouraged to follow up with their primary care physician for these conditions. BHRT taken transdermally (through the skin) does not increase risks of blood clots or DVT.

PROCEDURE

You have been diagnosed with a relative or absolute deficiency of estrogen, testosterone, or progesterone or a combination thereof. You may potentially benefit from hormonal supplementation. Nourished MedSpa and Wellness Center and Dr. Carter have recommended treatment with BHRT which consists of either progesterone and/or testosterone and/or estradiol. The goal is to provide you with the most up-to-date therapy options. You need to be sure you understand the reason that this therapy is being prescribed, the potential risks of therapy and the potential risk of declining treatment.

We also feel it is important that you know there are significant controversies regarding the best method to diagnosis and treat symptoms related to perimenopause and menopause, the best methods of treatment, and the most appropriate way to monitor therapy. This is especially true when "standard" blood tests look "normal". Thus, you may consult another doctor who does not agree with the recommendations for therapy.

Do not undergo therapy until you have reviewed this document with your provider, thoroughly understand the potential risks and benefits of treatment, and have all your questions answered. The diagnosis and treatment used may be considered non-conventional, complementary or alternative. Other physicians may disagree with the need for treatment, the method of treatment and dosing, and/or the methods of monitoring. You agree to undergo testing as recommended and report any potential side effects immediately.

RISKS AND COMPLICATIONS

Route of Administration

- I understand that the general risks of subdermal pellet insertion and injections may include, but are not limited to bleeding, bruising, scarring, extrusion, soreness or long-term pain, and infection. In general, pellets cannot be removed after insertion.
- Topical creams can be transferred to other family members and result in a local skin reaction or side effects.

Benefits and Potential Risks/ Side Effects of Individual Hormones

Testosterone:

- A prescription hormone given by subdermal pellet, injection, troche, or transdermal cream.
- It is not FDA approved for women and is considered “off-label” use for symptomatic improvement in women
- Potential benefits: increased libido, energy and sense of well-being, decreased frequency/severity of headaches, increased energy, decreased hot flashes, increase in muscle mass and decrease in visceral fat, improved insulin sensitivity, improved lipid panel, decreased risk of dementia, decreased bone loss, improved cognition and memory and help with sleep issues, reduced risk of reproductive cancers, reduced risk of cardiovascular disease.
- Risks of testosterone replacement may include, but are not limited to: an increase in red blood cells (erythrocytosis) reduced insulin requirements in insulin-dependent diabetics, increased estradiol levels, edema (fluid retention), reproductive cancers, cardiovascular disease, enlargement of male prostate gland resulting in frequent need to urinate. All males on testosterone treatment require annual PSA checks annually while using the medication. You affirm that you do not have a history of prostate issues or prostate cancer before beginning treatment.
- Side effects may include, but are not limited to: enlarged clitoris, hair loss, temporary water retention, acne, irritability, and voice changes. These are mostly dose related and usually resolve with reduction in dose. Premenopausal females MUST use birth control. Theoretically, testosterone can masculinize a female fetus.

Estrogen (estradiol and/or estriol):

- A prescription hormone, given by subdermal pellet, oral tablet, cream, patch, or troche.
- Potential benefits: increased libido, sense of well-being, increased energy, decreased hot flashes/night sweats, decreased vaginal dryness, decreased risk of heart disease and cardiovascular disease when started in the first 1-2 years of menopause, decreased risk of dementia, decreased bone loss, improved cognition and memory, help with sleep issues, and help with urinary incontinence.
- Risks of estrogen replacement include, but are not limited to: heart attacks, blood clot formation, stroke, breast cancer, liver disease, gallstones, increased risk of uterine cancer, and fibroid tumors.
- Side effects may include, but are not limited to: increased body fat, bloating, breast swelling/tenderness, fluid retention, uterine bleeding, depression, headaches, impaired glucose tolerance and aggravation of migraines.

Progesterone:

- A prescription hormone, given orally or by transdermal cream.
- Potential benefits: protection from estrogens’ effect on the uterus and breast thereby reducing risk of endometrial (uterine) and breast cancer, treatment of irregular menstruation, improved sleep quality, improved anxiety.
- Side effects can include, but are not limited to: acne, drowsiness or dizziness.
- Progesterone has not been shown to cause any risks or increase the risk of thrombosis or breast cancer in the medical literature. However, long term risks of breast cancer or other medical problems have not been definitively proven

Dehydroepiandrosterone- DHEA:

- DHEA is classified as a dietary supplement given orally or by transdermal cream.
- Risks of DHEA replacement include but are not limited to: worsening of certain cancers and should be avoided in women with breast cancer.
- Side effects of DHEA replacement are generally dose related and may include but are not limited to: acne or oily skin, hair growth on the face, arms or legs, acne in women, prostate enlargement in men, male pattern baldness, decreased HDL cholesterol, fatigue, mood changes, weight gain and insomnia.

BENEFITS

- Control of symptoms associated with declining hormone levels.

- May help prevent, reduce or control physical diseases and dysfunction associated with declining hormone levels.
- I understand that my healthcare provider cannot guarantee any health benefits or that there will be no harm from the use of hormone replacement therapy.

ALTERNATIVES

This is strictly a voluntary cosmetic procedure. No treatment is necessary or required. Other alternative treatments which vary in sensitivity, effect and duration include:

- Leaving the hormone levels as they are and doing nothing. Risks may include, but are not limited to: experiencing symptoms of hormone deficiency, and increased risk for aging-related diseases or dysfunction resulting from declining hormone levels. This alternative may result in the need to treat diseases or dysfunctions associated with declining hormone levels.
- Treating the symptoms of declining hormone levels as they develop with non-hormonal therapies such as SSRI's (antidepressants), sleeping pills, and herbal therapies, essential oils, lifestyle modifications such as weight loss, stress reduction, yoga, etc.
- Many of these hormones are used "off-label", which means they are not FDA approved. Many of these hormones are made by a compounding pharmacy. Off-label refers to use of, relating to or being an approved drug legally prescribed for a purpose for which it has not been specifically approved.
- Seeing another provider who believes in using non-identical synthetic hormones such as Premarin and Prempro or other therapies FDA approved therapies for menopause.

I understand that neither Nourished MedSpa and Wellness Center nor Dr. Jason Carter can guarantee any results or that there will be no harm. The potential health risks and benefits of using BHRT have been explained to me to my satisfaction.

QUESTIONS

This procedure has been explained to me by the staff of Nourished MedSpa and Wellness Center. I have had an opportunity to ask any questions and research the procedure to my satisfaction.

CONSENT

I understand that my consent and authorization for this procedure is strictly voluntary. I have already read and signed the Clinic's general consent and understand that it is still in effect. By signing this informed consent form, I hereby grant authority to Nourished MedSpa and Wellness Center and Dr. Jason Carter, MD (or other delegated medical providers for Nourished MedSpa and Wellness Center) to perform bioidentical hormone replacement therapy and/or administer any related treatment as may be deemed necessary or advisable in the diagnosis and treatment of my condition. For purposes of advancing medical education, I consent to the admittance of observers to the treatment room.

The nature and purpose of this procedure and the complications and side effects have been fully explained to me. Alternative treatments and their risks and benefits have been explained to me and I understand that I have the right to refuse treatment. I agree to adhere to all safety precautions and instructions after the treatment. I have been instructed in and understand post treatment instructions and have been given a written copy of them. I understand that no refunds will be given for treatments received. No guarantee has been given or implied by anyone as to the results that may be obtained from this treatment.

I have read this informed consent and certify that I understand its contents in full. All of my questions have been answered to my satisfaction and I consent to the terms of this agreement. I have had enough time to consider the information given me by my physician/practitioner and feel that I am sufficiently advised to consent to this procedure. I accept the risks and complications of the procedure. I certify that if I have any changes occur in my medical history I will notify Nourished MedSpa and Wellness Center immediately.

I hereby voluntarily consent to this procedure and release Nourished MedSpa and Wellness Center, medical staff, and all associated professionals from liability associated with the procedure. I certify that I am a competent adult of at least 18 years of age and am not under the influence of alcohol or drugs. This consent form is freely and voluntarily executed and shall be binding upon my spouse, relatives, legal representatives, heirs, administrators, successors and assigns.

Patient Name (please print) **Patient Signature** **Date**

Performed by (please print name and title) **Practitioner Signature** **Date**



PRE/POST TREATMENT INSTRUCTIONS

Bioidentical Hormone Treatment

APPLICATIONS OF CREAMS OR GELS

APPLY this to the bend of your arms, the fat at the back of your upper arms, the inner thigh, the back of the knees, the abdomen, the buttocks, or to the vaginal labia. The larger the area of application the better absorption will be. RUB the cream in until it disappears, then rub for 60 seconds more. DO NOT mix the testosterone cream or layer it over the progesterone or estrogen creams. DO NOT bathe for 40 minutes after applying hormones. DO NOT exercise for 2 hours after applying hormones, doing so might cause you to sweat the hormones out of the fat base. Cover the area of application with clothing if you are in direct skin-to-skin contact with others until most of it is absorbed (1 hour). Use a separate hand towel than your housemates.

Dr. Carter normally writes the prescription as applying 1 time per day (beginning with the lowest dose). If your symptoms are resolved at this dose in two weeks, then remain at this dose. If you still are symptomatic, increase your dose to 2 times per day. Try this for 2 weeks. Continue to increase as necessary until a maximum dose of 4 times per day. If this dose does not relieve your symptoms, then a cream is likely not the best choice for you. We would recommend a return visit at that time. Please, use the lowest effective dose, as this is the safest dose with the lowest risk of side effects. Taking too much of the hormone will eventually give you the same symptoms as deficiency of the hormone. Be careful, you'll feel better in the short term, but eventually the symptoms will come back with a vengeance and we'll have to start over.

REPEAT TESTING AND FOLLOW UP CARE

- After beginning hormone replacement therapy, we recommend follow up lab work for your safety.
- It is recommended that testing of hormones be repeated at 3 months, 6 months and then yearly or as needed. Also, a careful analysis of symptoms can also be very helpful in determining hormone dosing levels.
- If you are a menstruating woman, then testing is completed on day 21 of you cycle assuming you have a 28-day cycle. (Day 1 is the first day of your menstrual cycle)
- On the day of testing it is recommended to test first thing in the morning before you apply hormones or 3-4 hours after hormone application.

Patients New to Bio-HRT

HOT FLASHES

Causes of hot flashes, especially in early to mid peri-menopause include:

- Low Progesterone Excessive Progesterone
- High or Low Cortisol
- Insulin resistance
- Low thyroid function
- Excessive estrogen
- Endogenous level not balanced by progesterone
- Excessive exogenous and/or environmental estrogen
- Exposure to pseudo-estrogens and xeno-estrogens
- Poor estrogen elimination

RISK FACTORS

Bio-identical hormones are considered safer than traditional synthetic hormones but still harbor risks and side effects especially if used in excess.

TESTOSTERONE

- Androgens may decrease blood glucose lowering insulin requirements in a diabetic patient as well as lowering blood pressure. Adjustments may need to be made in medications.
- Androgens increase hemoglobin and hematocrit increasing the risk of clotting. For this reason, a CBC is repeated on follow-up lab work.
- Testosterone can change anti-coagulant therapy, so those monitoring their INR will need to check this more regularly.
- Symptoms that may result from Testosterone use include acne, clotting disorders, deepening of the voice, an enlarged clitoris, hair loss, hair growth on the face, changes in sex drive (normally an increase in sex drive), anger or hostility, shrinking in the size of the testicles, reduction in sperm production.

ESTROGEN

No long-term studies on the use of bio-identical hormone replacement therapy are available. Risks are based on studies of synthetic conjugated estrogens. However, since these are the only studies we have, Dr. Carter wants you to be aware of potential risks. HRT has been associated most frequently with the following medical problems:

- Cancer of the uterus may be slightly increased. Using estrogen alone causes the lining of the uterus to grow and can increase the risk of endometrial cancer. To reduce this risk, Dr. Carter prescribes progesterone. Do not confuse this with Progestin, which has multiple serious side effects. Most studies with serious side effects were conducted using Progestins.
- Development of blood clots is slightly increased. When blood clots form in blood vessels, the blood clots can cut off blood flow to organs like the lung or brain and lead to severe damage of these organs.
- Breast cancer may be increased. Some research studies suggest that the use of HRT may increase the risk of breast cancer. However, other research studies suggest there is not association. No definitive statements can be made about these issues. The use of Estriol (E3) and Progesterone with Estradiol (E2) is believed to reduce this risk.
- The risk for ovarian cancer is slightly increased. Researchers calculated that for every 8,300 women, hormone therapy would result in one extra case of ovarian cancer a year. These studies, again, were concluded with the use of Progestins. The use of Estriol (E3) and Progesterone with Estradiol (E2) is believed to reduce this risk.

PROGESTERONE

Recent research suggests a relationship between Progestin and Cancer. Progestin is a synthetic Progesterone and is not the same as natural Progesterone. There has been no research to support the relationship between natural Progesterone and cancer.

Female Symptoms

Estrogen Deficiency

- Hot flashes • Night sweats • Sleep disturbances • Vaginal dryness/atrophy • Dry skin • Headaches • Foggy thinking
- Memory lapses • Heart palpitations • Yeast infections • Painful intercourse
- Depression • Low libido • Bone loss

Estrogen Excess

- Water retention • Heavy, irregular menses • Breast swelling and tenderness • Fatigue
- Craving for sweets • Weight gain • Fibrocystic breasts • Mood swings • Uterine fibroids • Low thyroid symptoms • Nervousness/anxiety/irritability

Progesterone Deficiency

Many of the symptoms of Estrogen Excess, including:

- Swollen breasts • Weight gain • Headaches • Low libido • Anxiety • Mood swings • Irregular menses • Depression
- Cramping • PMS • Infertility • Fuzzy thinking • Acne • Joint pain

Progesterone Excess

- Somnolence • Gastrointestinal bloating • Mild depression • Breast swelling • Candida exacerbations • Exacerbates symptoms of estrogen deficiency

Testosterone Deficiency

- Fatigue, prolonged • Mental fuzziness • Memory problems • Depression • Decreased libido
- Blunted motivation • Muscle weakness • Diminished feeling of well-being • Heart palpitations • Thinning skin • Bone loss • Vaginal dryness • Incontinence • General aches/pains

Testosterone Excess

- Acne • Male-pattern hair growth • Deepening of voice • Clitoral enlargement • Irritability/moodiness • Insomnia • Loss of scalp hair

Low Cortisol

- Fatigue • Allergies • Cravings for sweets • Irritability • Chemical sensitivities • Symptoms of hypothyroidism • Symptoms of low progesterone

High Cortisol

Same symptoms as low cortisol, including

- Bone loss • Anxiety • Sleep disturbances • Depression • Low libido • Hair loss • Anxiety • Elevated triglycerides

Low Thyroid Function

- Fatigue (especially evening) • Low stamina • Cold extremities • Low body temperature
- Low libido • Headaches • Dry skin • Intolerance to cold • General aches and pains • Weight gain • Depression • Anxiety • Scalp hair loss • Swollen, puffy eyes • Brittle nails • Decreased swelling • Low pulse rate/blood pressure • Poor concentration • Memory lapses • High cholesterol • Heart palpitations • Infertility • Constipation • Fibromyalgia

Male Symptoms

Basic Hormone Imbalance

• Burned out feeling • Irritable • Decreased mental sharpness • Night sweats • Sleep disturbances/ Insomnia • Hot flashes • Decreased stamina • Weight gain waist • Erectile dysfunction, Decreased erections • Infertility problems • Decreased libido • Increased urinary urge /Decreased urine flow/ Prostate problems • Oily Skin • Decreased muscle mass

Adrenal Hormone Imbalance

• Aches and pain/Fibromyalgia • Morning fatigue/Evening fatigue • Susceptibility to infections • Sleep disturbances • Depression/Anxiety • Lack of motivation • Bone loss • Weight gain waist • Prostate problems • Decreased erections • Infertility • Blood sugar imbalance • Elevated triglycerides • Allergic conditions • Autoimmune illness • Chronic illness • Stress

Thyroid Hormone Imbalance

• Low libido • Depression • Cold body temperature • Decreased erections • Foggy thinking • Infertility • Headaches • Sleep disturbances • Constipation • Fatigue • Lack of motivation • Inability to lose weight

Please contact our office at 903-357-5108 with any questions or concerns. If you have an emergency or urgent pressing clinical issue, call Dr. Carter at 903-818-3467. Texting is the best way to reach Dr. Carter.

Please make an appointment for follow-up and reassessment in 4 weeks.

Patient Name (please print)

Patient Signature

Date



PRE-TREATMENT INSTRUCTIONS

Bioidentical Hormone Pellet Procedure

- Wear loose comfortable clothing the day of the procedure
- Stop aspirin, ibuprofen, and fish oil 3 days prior to the procedure
- Eat a small meal prior to pellet insertion
- Wear comfortable clothing
- An area on the back of your hip will be numbed. You may experience a small pin prick at the start of the procedure from the needle to inject the anesthetic agent, or a slight “stinging” sensation as the anesthetic is introduced. A small puncture is made, and pellets are inserted into the subcutaneous tissue using a disposable trochar.
- Steri-strips are placed over the incision.
- You may experience a small pin prick at the start of the procedure from the needle to inject the anesthetic agent, or a slight “stinging” sensation as the anesthetic is introduced.
- Please call to reschedule if you experience flu-like symptoms or a respiratory infection the day prior to treatment. Also call to reschedule if you notice any type of skin condition on the area to be treated.

Please contact our office at 903-357-5108 with any questions or concerns.



POST-TREATMENT INSTRUCTIONS

Bioidentical Hormone Pellet Procedure

1. Remove clear protective covering after 24 hours
2. Keep wound completely dry until the following day. After that, showering is OK. Avoid soaking in tubs, pools, or baths for at least 3 days.
3. Put a fresh Band-Aid over the wound for a few days to catch any oozing that might occur.
4. Leave steri-strip or foam tape on wound until it falls off (usually 2-3 days).
5. Avoid vigorous exercise for 72 hours to reduce chance of bruising, oozing, or infection, or delayed wound healing. Avoid massage therapy at pellet site.
6. A little redness, bruising, and swelling for 3-4 days is normal. The area may be tender for 4-14 days (possibly more for men).
7. If you have continued bleeding, significant redness, pain (without putting pressure on the wound), warmth, or pus from the wound, call us immediately—you might need an antibiotic. This happens rarely, but infection is always a possibility with any kind of invasive procedure.
8. Optimal results are achieved with clients who continue treatments routinely. Most patients will receive pellet implants every 3-4 months.
9. Inform our office immediately if a reaction has occurred. If immediate care is needed, call Dr. Carter, proceed to the nearest emergency room, or call 911.

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