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BIOTE MALE NEW PATIENT PACKET

The contents of this package are your first step to restore your vitality.
Please take time to read this carefully and answer all questions.
Please submit the completed packet to our office BEFORE your initial consultation.

Thank you for your interest in BioTE Medical®. In order to determine if you are a candidate for bio-identical testosterone pellets we need your laboratory results and the completion of this packet. We will evaluate your information to determine if BioTE Medical® can help you live a healthier life. If after reviewing your information our providers find you are not a good candidate for BioTE they can discuss alternative hormone replacement therapies with you.

YOU MAY NOT BE A CANDIDATE FOR BIOTE THERAPY IF:

- You currently have, or were diagnosed with, cancer during the past 24 months
- You have had a serious cardiovascular event (stroke, heart attack, pulmonary embolus, cardiothoracic surgery) within the past 24 months
- You have epilepsy or an uncontrolled seizure disorder (seizure within the past 12 months)
- Your PSA test result is 2.5 or greater (will require urology evaluation and clearance before BioTE treatment could be approved by our providers)

INSTRUCTIONS FOR PRE-TREATMENT (EVALUATION) LAB WORK

Visit our website www.NovaWellnessCenter.com and click the "schedule an appointment" button to schedule an appointment for a **BLOOD DRAW.** You will receive a text message confirming your appointment. There is no charge to reserve your blood draw appointment, **payment of $325 for your lab work and provider appointment will be collected when your blood is drawn at our office.** Fasting for 8 hours prior to your blood draw is preferred but NOT required. You may take all medications as you normally do. Please drink plenty of water prior to your blood draw.

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BIOTE FINANCIAL POLICY- You will be responsible for payment in full for the services provided. These services are not covered by traditional health insurance in most cases, but you may use a health savings account (HAS) or flexible spending account (FSA) to pay for your treatment. You may request paperwork to submit to your insurance company if you would like to try filing for reimbursement. We are unable to assist you in obtaining reimbursement other than providing invoices and proof of payment for the services you receive. We accept the following forms of payment: MasterCard, Visa, Discover, American Express, CareCredit or Cash.

COST FOR INITIAL EVALUATION- *Initial evaluation to assess your health and determine whether BioTE is a viable option for you.*

Comprehensive Health & Hormone Assessment- $325 *(includes):*

- **Comprehensive lab work:** complete metabolic panel (liver and kidney function, blood sugar and electrolytes), complete blood count, PSA, vitamin D level, vitamin B12 level, thyroid function profile, testosterone level, and sex hormone binding globulin level.
- **Best-selling book *"Age Healthier, Live Happier"*** written by Dr. Gary Donovitz
- **Consultation with one of our BioTE providers** (via phone or in the office): This is typically a 30-minute appointment to discuss your lab results, symptoms and medical history to determine whether or not you are a candidate for BioTE therapy. If you are not a candidate for pellet therapy, or decide it is not for you, other hormone replacement options may be discussed with you.

TREATMENT COST - If your provider determines you are a candidate for pellet therapy and you elect to begin treatment the cost will be as follows.

Start-up Package- $1099 *(includes the **first 6 months'** worth of hormone treatment, follow up lab work, supplements and provider follow up visits)*

- Office visit with a BioTE provider to discuss your individualized treatment plan immediately prior to the insertion of your pellets
- Initial insertion of hormone pellets (up to a maximum dose of 2400 mg of testosterone)
- Access to Dr. Lisa Sachdev's mobile phone number for 24-hour text support
- Follow up lab work and symptom assessment (one month after pellet insertion)
- In office consultation with a BioTE provider to review your lab results and assess your response to treatment (30 min office visit, 6 weeks after pellet insertion)
- Insertion of additional testosterone pellets (booster) if indicated at the 6-weeks visit
- First 6 months' supply of EstroDIM 150 mg capsule supplement (take 1 capsule 2x/day)

Maintenance Cost- $750 per pellet insertion (typically every 4-6 months). Does not include supplements.

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If you are currently receiving hormone pellet therapy and wish to transfer your care to our facility contact our office manager for assistance, this page will not apply to you.

STEPS FOR INITIAL EVALUATION:

- ✓ Review the medical conditions that may make you ineligible for BioTE therapy (see pg 1)
- ✓ Complete the BIOTE MALE NEW PATIENT PACKET that is available on our website
- ✓ Visit our website to schedule a BLOOD DRAW for your pre-evaluation lab work. The evaluation fee of $325 will be collected at our office immediately prior to your blood draw.
- ✓ After your blood is drawn our staff will schedule your CONSULT with a BioTE provider to review your lab results and medical history. This appointment may be either a telemedicine or office visit, whichever you prefer.

STEPS TO BEGIN TREATMENT:

- ✓ If after your consult you elect to begin therapy our staff will schedule your first pellet insertion (This is 60-minute office appointment). The startup fee of $1099 which covers the first six months of treatment will be due at this time.
- ✓ At the beginning of your pellet insertion appointment a provider will discuss your individualized treatment plan with you. She will explain the procedure, including after-care instructions and answer any questions you might have. This typically takes 30-45 minutes. The insertion will occur immediately after the treatment plan is discussed with you. Pellet insertion typically takes 10-15 minutes.
- ✓ Visit our website to schedule a BLOOD DRAW for your follow up lab work, your blood should be drawn 4 weeks after your 1st pellet insertion. The cost for lab work is included in your startup fee.
- ✓ After your blood is drawn our staff will schedule a FOLLOW UP OFFICE VISIT for you with your provider 1-2 weeks later. During this visit your provider will discuss your lab results and symptomatic response to treatment. Additional pellets may be inserted (called a booster dose) at the end of your follow up visit if indicated. The cost for your appointment and additional pellets (if needed) is included in your startup fee.

HOW TO MAINTAIN PELLET THERAPY:

When your initial symptoms begin to return you will know it is time to have your pellets replaced, for most men this occurs 4-6 months after insertion. Go to our website and schedule a BIOTE MALE PELLET INSERTION. Payment of $750 will be collected when you reserve your appointment online. You will receive a text message confirming your appointment time.

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Commonly Asked Questions Regarding Treatment

Q**. What is BioTE®?** A. BioTE® is a Bio-Identical form of hormone therapy that seeks to return the hormone balance to youthful levels in men and women.

Q**. How do I know if I'm a candidate for pellets?** A. Please review the conditions that may exclude your eligibility for treatment listed on page 1 of our New Patient Packet or on our website www.NovaWellnessCenter.com. If none of the excluding conditions apply one of our providers will review your lab work and medical information to determine if BioTE is right for you.

Q. **Do I have blood work done before each treatment?** A. No, only initially and again 4-6 weeks after your 1st pellet insertion. Additional lab work may be ordered per the discretion of your provider if any modifications are made to your treatment plan.

Q. **What are the pellets made from?** A. They are made from wild yams and soy. Wild yams and soy have the highest concentration of hormones of any substance. There are no known allergens associated with wild yams and soy, because once the hormone is made it is no longer yam or soy. The pellets are all natural and bio-identical which means they are an exact replication of what the body normally makes.

Q. **How long will the treatment last?** A. Every 4-6 months depending on the person. Everyone is different so it depends on how you feel and what your provider determines is right for you. If you are really active, you smoke, are under a lot of stress or it is extremely hot your treatment may not last as long.

Q. **Is the therapy FDA approved?** A. What the pellets are made of is FDA approved and regulated, the process of making pellets is regulated by the State Pharmacy Board, and the distribution is regulated by the DEA and Respective State Pharmacy Boards. The PROCEDURE of placing pellets is NOT FDA approved because the treatment is individualized for every patient.

Q. **How are they administered?** A. Your practitioner will implant the pellets into the fatty layer underneath the skin of the hip, or lower abdomen. A small incision is made prior to pellet insertion, stitches are rarely required.

Q. **Does it matter if I'm already on therapy to manage low testosterone levels?** A. No, your provider can determine what your hormone needs are and transition you from your previous therapy to the BioTE method.

Q. **Are there any side effects?** A. The majority of side effects are temporary and typically only happen after the first dose. All symptoms are very treatable

Q. **What if I've had prostate or some other form of cancer?** A. Cancer survivors or those with a family history of cancer may still be candidates, discuss this with your BioTE provider.

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BioTE Male New Patient Questionnaire & History

Name: _____Today's Date: _____
(Last) (First) (Middle)

Date of Birth: _____ Age: _____ Occupation: _____

Home Address: _____

City: _____ State: _____ Zip: _____

Cell Phone: _____ Work Phone: _____

E-Mail Address: _____ May we contact you via E-Mail? ( ) YES ( ) NO

In Case of Emergency Contact: _____ Relationship: _____

Cell Phone: _____ Work Phone: _____

Primary Care Physician's Name: _____ Phone: _____
Address:

_____
(Address) (City) (State) (Zip)

Marital Status (check one): ( ) Married ( ) Divorced ( ) Widow ( ) Living with Partner ( ) Single

In the event we cannot contact you by the mean's you've provided above, we would like to know if we have permission to speak to your spouse or significant other about your treatment. By giving the information below you are giving us permission to speak with your spouse or significant other about your treatment. _____ NO; <or> ____YES (please complete below):

Spouse's Name: _____ Relationship: _____

Cell Phone: _____ Work Phone: _____

Social:
( ) I am sexually active.
( ) I want to be sexually active.
( ) I have completed my family.
( ) I have used steroids in the past for athletic purposes.

Habits:
( ) I smoke cigarettes or cigars
( ) I drink alcoholic beverages _____X per week.
( ) I drink more than 10 alcoholic beverages a week.
( ) I use caffeine _____X a day.

Any known drug allergies: _____, No known allergies: _____

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Have you ever had any issues with anesthesia? ( ) Yes ( ) No. If yes please explain:

_____

Medications Currently Taking:

_____
_____
_____
_____

Current Hormone Replacement Therapy: _____

Past Hormone Replacement Therapy: _____

Nutritional/Vitamin Supplements: _____

Surgeries, list all and when:

_____
_____
_____
_____

Other Pertinent Information:

_____
_____
_____

Treatment Consent: I understand that if I begin testosterone replacement with any testosterone treatment, including testosterone pellets, that I will produce less testosterone from my testicles and if I stop replacement, I may experience a temporary decrease in my testosterone production. Testosterone Pellets should be completely out of your system within 12 months of discontinuing therapy.

By beginning treatment, I accept all the risks of therapy stated herein and future risks that might be reported. I understand that higher than normal physiologic levels may be reached to create the necessary hormonal balance.

Name (print): _____ Date: _____

Signature: _____

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PRE- TREATMENT HEALTH ASSESSMENT FOR MEN

Name: _____ Date: _____ DOB: _____

Current Hormone Treatment Modality (if applicable): _____

Symptom: (please rate each symptom with an "X")	**MILD**	**MODERATE**	**SEVERE**
Decline in general well being			
Joint pain or muscle aches			
Excessive sweating			
Joint problems			
Increased need for sleep			
Irritability			
Depressed mood			
Exhaustion/lacking vitality			
Decreased mental focus or concentration			
Feeling you have passed your peak			
Feeling burned out or "hit rock bottom"			
Decreased muscle strength			
Belly fat or inability to lose weight			
Breast development			
Shrinking testicles			
Rapid hair loss			
Decrease in beard growth			
New migraine headaches			
Decreased desire for sex (low libido)			
Decreased morning erections			
Decreased ability to perform sexually (ED)			
Infrequent or absent ejaculations			
Poor results from erectile dysfunction Rx			

NOTES:

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THINGS TO KNOW BEFORE YOU COME FOR YOUR PELLET INSERTION:

WHAT TO WEAR:

Wear loose, comfortable clothing whenever you come for a pellet insertion, preferably something that has an elastic waistband. Jeans or tight pants are not recommended attire to wear on the day you have pellets inserted. We recommend applying a small ice pack to the pellet area for the first 48 hrs after your insertion. We will provide you with gel packs that you may freeze and apply to the area.

RETURNING TO WORK:

You may return to work or other activities immediately after your insertion as long as you avoid straining your lower body. Most men prefer taking the rest of the day off to rest and recover as much as possible, a physician's excuse may be provided if needed.

ACTIVITY LIMITATIONS:

You will not be able to swim or sit in water for one week after your insertion, the incision needs time to heal. You should not perform any strenuous activity that might cause inflammation or delay healing in the area where your pellets are placed for approximately 2-3 weeks.

DISCOMFORT:

It is normal to experience swelling and tenderness in the area where the pellets were placed for a few weeks after insertion, the most significant discomfort will be during the first 48 hours. You may take Tylenol or Motrin for discomfort. You may apply an ice pack to the area of swelling as needed during the day. If an ice pack is inconvenient you may apply lidocaine 4% patches to the area may help ease discomfort, these patches are available over the counter at your local pharmacy and provide pain relief for 12 hours after application.

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WHAT MIGHT OCCUR AFTER A PELLET INSERTION (MALE)

A significant hormonal transition will occur in the first four weeks after the insertion of your hormone pellets. Therefore, certain changes might develop that can be bothersome.

• **FLUID RETENTION:** Testosterone stimulates to the muscle grow and retain water which may result in a weight change of two to five pounds. This is only temporary. This happens frequently with the first insertion, and especially during hot, humid weather conditions.

• **SWELLING of the HANDS & FEET:** This is common in hot and humid weather. It may be treated by drinking lots of water, reducing your salt intake, taking cider vinegar capsules daily, (found at most health and food stores) or by taking a mild diuretic, which the office can prescribe.

• **MOOD SWINGS/IRRITABILITY:** These may occur if you were quite deficient in hormones. They will disappear when enough hormones are in your system.

• **FACIAL BREAKOUT:** Some pimples may arise if the body is very deficient in testosterone. This lasts a short period of time and can be handled with a good face cleansing routine, astringents and toner. If these solutions do not help, please call the office for suggestions and possibly prescriptions.

• **HAIR LOSS:** Is rare and usually occurs in patients who convert testosterone to DHT. Dosage adjustment generally reduces or eliminates the problem. Prescription medications may be necessary in rare cases.

• **HAIR GROWTH:** Testosterone may stimulate some growth of hair on your chin, chest, nipples and/or lower abdomen. This tends to be hereditary. You may also have to shave your legs and arms more often. Dosage adjustment generally reduces or eliminates the problem.

Name (print): _____ Date: _____

Signature: _____

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Testosterone Pellet Insertion Consent Form (MALE)

Bio-identical testosterone pellets are hormone, biologically identical to the testosterone that is made in your own body. Testosterone was made in your testicles prior to "andropause." Bio-identical hormones have the same effects on your body as your own testosterone did when you were younger. Bio-identical hormone pellets are plant derived and bio-identical hormone replacement using pellets has been used in Europe, the U.S. and Canada since the 1930's. Your risks are similar to those of any testosterone replacement but may be lower risk than alternative forms. During andropause, the risk of not receiving adequate hormone therapy can outweigh the risks of replacing testosterone.

Risks of not receiving testosterone therapy after andropause include but are not limited to: Arteriosclerosis, elevation of cholesterol, obesity, loss of strength and stamina, generalized aging, osteoporosis, mood disorders, depression, arthritis, loss of libido, erectile dysfunction, loss of skin tone, diabetes, increased overall inflammatory processes, dementia and Alzheimer's disease, and many other symptoms of aging.

Benefits of testosterone pellets include: Increased libido, energy, and sense of well-being; increased muscle mass and strength and stamina; decreased frequency and severity of migraine headaches; decrease in mood swings, anxiety and irritability (secondary to hormonal decline); decreased weight (increase in lean body mass); decrease in risk or severity of diabetes; decreased risk of Alzheimer's and dementia; and decreased risk of heart disease in men less than 75 years old with no pre-existing history of heart disease. On January 31, 2014, the FDA issued a Drug Safety Communication indicating that the FDA is investigating risk of heart attack and death in some men taking FDA approved testosterone products. The risks were found in men over the age of 65 years old with pre-existing heart disease and men over the age of 75 years old with or without pre-existing heart disease. These studies were performed with testosterone patches, testosterone creams and synthetic testosterone injections and did not include subcutaneous hormone pellet therapy.

Side effects may include: Bleeding, bruising, swelling, infection, pain, reaction to local anesthetic and/or preservatives, lack of effect (typically from lack of absorption), thinning hair, male pattern baldness, increased growth of prostate and prostate tumors, extrusion of pellets, hyper sexuality (overactive libido), ten to fifteen percent shrinkage in testicle size and significant reduction in sperm production. There is some risk, even with natural testosterone therapy, of enhancing an existing current prostate cancer to grow more rapidly. For this reason, a prostate specific antigen blood test is to be done before starting testosterone pellet therapy and will be conducted each year thereafter. If there is any question about possible prostate

cancer, a follow-up with an ultrasound of the prostate gland may be required as well as a referral to a qualified specialist. While urinary symptoms typically improve with testosterone, rarely they may worsen, or worsen before improving. Testosterone therapy may increase one's hemoglobin and hematocrit, or thicken one's blood. This problem can be diagnosed with a blood test. Thus, a complete blood count (Hemoglobin and Hematocrit.) should be done at least annually. This condition can be reversed simply by donating blood periodically.

Consent for treatment: I consent to the insertion of testosterone pellets in my hip or abdomen area. I have been informed that I may experience any of the complications to this procedure as described below. Surgical risks are the same as for any minor medical procedure.

I agree to immediately report to my practitioner's office any adverse reactions or problems that may be related to my therapy. Potential complications have been explained to me and I agree that I have received information regarding those risks, potential complications and benefits, and the nature of bio-identical and other treatments and have had all my questions answered. Furthermore, I have not been promised or guaranteed any specific benefits from the administration of bio-identical therapy.

I certify this form has been fully explained to me, and I have read it or have had it read to me and I understand its contents. I accept these risks and benefits and I consent to the insertion of hormone pellets under my skin. This consent is ongoing for this and all future insertions.

I understand that payment is due in full at the time of service. I also understand that it is my responsibility to submit a claim to my insurance company for possible reimbursement. I have been advised that most insurance companies do not consider pellet therapy to be a covered benefit and my insurance company may not reimburse me, depending on my coverage**.**

I acknowledge that my provider has no contracts with any insurance company and is not contractually obligated to pre-certify treatment with my insurance company or answer letters of appeal.

Name (print): _____ Date: _____

Signature: _____

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HIPAA Information and Consent Form

PRIVACY PROTECTION POLICIES (HIPAA)

The Health Insurance Portability and Accountability Act (HIPAA) provides safeguards to protect your privacy. Implementation of HIPAA requirements officially began on April 14, 2003. Many of the policies have been our practice for years. This form is a "friendly" version. A more complete text is posted in the office.

What this is all about: Specifically, there are rules and restrictions on who may see or be notified of your Protected Health Information (PHI). These restrictions do not include the normal interchange of information necessary to provide you with office services. HIPAA provides certain rights and protections to you as the patient. We balance these needs with our goal of providing you with quality professional service and care. Additional information is available from the U.S. Department of Health and Human Services. www.hhs.gov

We have adopted the following policies:

1. Patient information will be kept confidential except as is necessary to provide services or to ensure that all administrative matters related to your care are handled appropriately. This specifically includes the sharing of information with other healthcare providers, laboratories, health insurance payers as is necessary and appropriate for your care. Patient files may be stored in open file racks and will not contain any coding which identifies a patient's condition or information which is not already a matter of public record. The normal course of providing care means that such records may be left, at least temporarily, in administrative areas such as the front office, examination room, etc. Those records will not be available to persons other than office staff . You agree to the normal procedures utilized within the office for the handling of charts, patient records, PHI and other documents or information.

2. It is the policy of this office to remind patients of their appointments. We may do this by telephone, e-mail, U.S mail, or by any means convenient for the practice and/or as requested by you. We may send you other communications informing you of changes to office policy and new technology that you might find valuable or informative.

3. The practice utilizes a number of vendors in the conduct of business. These vendors may have access to PHI but must agree to abide by the confidentiality rules of HIPAA.

4. You understand and agree to inspections of the office and review of documents which may include PHI by government agencies or insurance payers in normal performance of their duties.

5. You agree to bring any concerns or complaints regarding privacy to the attention of the office manager or the doctor.

6. Your confidential information will not be used for the purposes of marketing or advertising of products, goods or services.

7. We agree to provide patients with access to their records in accordance with state and federal laws.

8. We may change, add, delete or modify any of these provisions to better serve the needs of the both the practice and the patient.

9. You have the right to request restrictions in the use of your protected health information and to request change in certain policies used within the office concerning your PHI. However, we are not obligated to alter internal policies to conform to your request.

I, _____ (name)_____ (date) do hereby consent and acknowledge my agreement to the terms set forth in the HIPAA INFORMATION FORM and any subsequent changes in office policy. I understand that this consent shall remain in force from this time forward.