



## Consent for Testosterone Replacement Therapy and Off Label Use

It is important to understand that there are risks associated with undergoing Testosterone Replacement Therapy as there are risks in any medical treatment or procedure. The results of treatment exist on a spectrum and vary from patient to patient. NextGen Male Medical will carry out your treatment in your best interests, but we cannot guarantee the absence of negative side effects or exact results.

This consent is also to inform you of “off-label” use. When a drug is approved by the FDA, physicians and manufacturers will produce a label to explain its use. Once that drug is approved by the FDA, physicians and health care providers may use it off label for other purposes if they are well educated and informed about the product. They may also base its use on the scientific method and sound medical evidence and maintain records of its use and effects. “Off Label” prescribing is a **legal** and very common practice by health care providers in the United States.

You should be educated on the risks of undergoing Testosterone Replacement Therapy and aware that there are alternatives that do not include testosterone treatment. If you have any questions, please ask our medical staff.

### **READ EACH POINT BELOW AND NOTE ANY QUESTIONS YOU MAY HAVE FOR YOUR MEDICAL PROVIDER**

- I consent to medical treatment by NextGen Male Medical.
- I understand that there are risks and possible complications associated with Testosterone Replacement Therapy.
  - Acne
  - Breast Enlargement
  - Mood Swings
  - Extra Fluid in the Body (Be especially aware of this potential side effect if you have heart, kidney, or liver disease)
  - Sleep Apnea (Most common in patients with lung disease or obesity)
  - Prostate Enlargement (may cause trouble with urination)
  - Changes in cholesterol levels, red blood cell counts, PSA levels, and liver function enzymes as well as other hormone levels which will be monitored with periodic blood tests
  - Localized irritation, swelling, warmth, or redness of skin surrounding injection site
- Testosterone Replacement Therapy may cause severe complications or death in patients with heart disease. If you are under 65 with a history of heart disease, you must be cleared by a cardiologist or your primary care provider before receiving treatment.
- You will have regular blood tests conducted to monitor the effects of Testosterone Replacement Therapy. Drawing blood can be painful and potentially cause bruising.
- Testosterone treatments can result in blood clots leading to Deep Vein Thrombosis or Venous Thromboembolism.
- There is no warranty or guarantee of results.
- It is important that you are thorough in disclosing your medical history including past or present injuries. Please ask any questions you may have about risks associated with any of your pre-existing conditions or current state of health.
- Please ask any questions you may have about alternatives to Testosterone Replacement Therapy.
- NextGen Male Medical’s exam does not replace a full physical exam performed by your primary care provider.

- You are responsible for seeing your primary care provider for a full physical annually while you are undergoing Testosterone Replacement Therapy. You should have tests including a digital rectal exam, lipid profile, cholesterol levels, hematocrit levels and a metabolic panel done at these annual appointments.
  - In the case of high hematocrit levels, you may be asked to do phlebotomy therapy.
- Testosterone Replacement Therapy may impact fertility and/or result in testicular atrophy.
- HCG is typically given in our protocol once a week to reduce testicular atrophy and increase fertility while undergoing Testosterone Replacement Therapy.
- Normal levels of testosterone are generally established by referencing morning levels as men's testosterone levels decrease naturally in the afternoon.
- Men's testosterone levels can vary significantly between tests even when the tests are conducted at the same time of day.
- **Testosterone Replacement Therapy is recommended by NextGen Male Medical Clinic when a male patient has a total testosterone level of less than 350 nanograms per deciliter, less than 440 nanograms per deciliter if certain symptoms are present, or 500 nanograms per deciliter if free testosterone is less than 12 nanograms per deciliter. The FDA Diagnosis for being testosterone deficient is a total testosterone below 300 nanograms per deciliter. The amount of testosterone you receive during your therapy will be decided by your testosterone level and symptoms. I also understand that a total testosterone level typically has to be below 300 nanograms per deciliter to be covered by most insurance companies.**

On January 31st, 2014 the FDA issued a safety announcement stating they were investigating the risk of stroke, heart attack, and death in men taking FDA-approved testosterone products. The announcement stresses that the FDA has not concluded that FDA-approved testosterone increases these risks and that patients should not stop taking prescribed testosterone products without first consulting their health care providers.

Testosterone Cypionate was only approved by the FDA for use in men who lack or have low testosterone in connection with an associated medical condition such as failure of the testicles to produce testosterone because of genetic problems or chemotherapy, or problems with the hypothalamus or pituitary gland which are brain structures that control the production of testosterone by the testicles.

**BY SIGNING BELOW, YOU ACKNOWLEDGE THAT YOU UNDERSTAND THE STATEMENTS MADE ABOVE AND ARE EDUCATED IN THE RISKS AND ADVERSE EFFECTS OF TESTOSTERONE REPLACEMENT THERAPY. YOU ARE ALSO CONSENTING TO TESTOSTERONE REPLACEMENT THERAPY PROVIDED BY NEXTGEN MALE MEDICAL.**

Patient

Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_