

## Testosterone Replacement Therapy for Men Through Subcutaneous Pellets:

### *“Why pellets?”*

In my other materials on testosterone replacement therapy I discuss extensively the potential benefits of TRT. Presently, there are no good studies comparing the different forms of TRT, so it is not possible to claim that TRT through subcutaneous pellets offers superior effectiveness. On the other hand, as with every other form of currently available form of medical therapy, the biggest factor limiting effectiveness of therapy is compliance. Whether using once daily gels or patches or weekly injections, compliance is a common problem which quickly results in re-emergence of symptoms. On the other hand, even with perfect compliance patients on weekly injections may experience reemergence of symptoms 48 hours prior to their next injection. Pellet therapy offers an opportunity to obtain a smooth, consistently effective treatment that eliminates the problem of compliance.

### *“What are testosterone pellets and how large are they?”*

Testosterone pellets are small, compressed cylinders of testosterone, with the size of the pellet varying with the milligram strength of the pellet, but with no pellets larger than a Tic-Tac.

### *“How are the pellets administered?”*

The pellets are injected into subcutaneous fat (fat beneath the skin) of the buttock just below the waistline. To accomplish this, with the patient lying on their side, the skin is anesthetized with an injection of a small amount of Xylocaine anesthetic. After the area is anesthetized a small 5 mm incision is made by a sterile blade. A stainless steel trocar, which looks like a metal syringe, is then inserted through this incision. Once in place in the subcutaneous fat the needle is removed from the trocar so that testosterone pellets can be placed inside the barrel of the trocar followed by a plunger that allows them to be inserted into the subcutaneous fat. Once this is completed the trocar is removed and the wound is covered by a series of bandages; there is no stitching involved in closing the wound to minimize scar. The whole procedure lasts 10 to 15 minutes.

### *“How do you decide on how much of a dose to use?”*

Most men will utilize 1200 to 1600 mg of testosterone (6 to 8 pellets) though the dose will be individualized to your needs based on your blood levels of testosterone achieved and your clinical response.



*“How long does it take to work and how often will I require pellet insertions?”*

It may require three to four weeks before patients notice an improvement in their symptoms though it may require adjustments over the first three to six insertions to determine your ideal, long term dose (maintenance dose). Insertions the first year are every three months with the time interval widened to four to six months thereafter depending upon the patient’s response. Based on the inherent properties of the pellet and the results of clinical studies utilizing pellets, it is expected that the average patient will require insertions every four months during maintenance.

*“If I am currently on another form of TRT, will I experience a recurrence of symptoms after starting pellet therapy while I am waiting for my levels to build up?”*

In patients being switched from another form of TRT, it is possible that such patients could experience an increase in symptoms during the first three weeks of pellet therapy. However, there are various options available to try and minimize such recurrent symptoms which will be discussed with you prior to starting pellet therapy.

*“How often will I require other office visits and blood work?”*

Once your maintenance dose has been determined (usually after 12-18 months of therapy) lab work and office visits (excluding pellet insertion visits) may be as little as once a year. However, this is individualized based on the patient’s other medical problems and course of therapy. Patients with chronic medical diseases or treated for other conditions will require office visits and lab work based on what is recommended for such therapy. While your optimal, long term dose is being determined during the first 12 to 18 months of pellet therapy, blood levels will be taken at four weeks (peak levels) and at 10-14 weeks (trough levels) after each insertion. Office visits will be scheduled six weeks after each insertion to review your clinical improvement and blood levels. This will allow for continued, methodical adjustment of your dosing until your ideal maintenance dose is determined. Scheduling a teleconference for these six week follow-up visits is an option. However, Medicare patients may not utilize this option because government regulations do not allow Medicare patients to pay for teleconference care (see Office Policy Handbook).

*“Are there any special preparations required prior to my insertion?”*

When medically appropriate we ask that patients stop aspirin therapy at least one week prior to insertions. In all patients taking any form of blood thinner, we require that you discuss this with the prescribing doctor so that they can determine the appropriateness of stopping such medication and the timing of such. In some cases, like patients who have cardiac stents and/or artificial valves, it is not appropriate under any circumstances to stop such blood thinners. Such patients may want to consider an alternate form of TRT.



*“Are there any special instructions or down time after insertion?”*

You will be given instructions that explain clearly how to handle the bandages utilized to cover the wound. Though you may shower, we request that you not soak in a bath tub until one week after the procedure. We also request that there be no vigorous exercise for three days following an insertion, though routine activities of daily life can be maintained.

*“Are there any complications particular to the insertion procedure?”*

As with all surgical procedures involving the skin and subcutaneous fat, wound infection is a rare but real possibility. Further, the physician will occasionally injure a more prominent blood vessel resulting in more blood and a larger bruise at the site. Very rarely, a hematoma, which is a collection of blood under the skin, may form at the wound site. Again, this is very rare and usually happens in patients on some form of blood thinner. Finally, pellets may rarely extrude (back out of the wound) and be lost.

*“How much does it cost?”*

All discussions of cost must be done with the understanding that insurance coverage varies between companies and plans and is constantly changing. To assess this more appropriately, patients are always encouraged to ask their insurance company directly about payment for such services. The CPT (procedure code) code for pellet insertion is 11980 and the ICD-9 diagnosis code for hypogonadism is 257.2. Our most recent analysis suggests that most of the major insurance carriers, including Medicare, reimburse at their typical, negotiated level of reimbursement for the procedure code, associated office visits, and labs. The level of reimbursement for such, and the portion which you are required to pay, will vary depending on your plan. While coverage for the procedure and the associated office visits and labs has been encouraging to date, all carriers, including Medicare, have denied payment for the pellets. For men at the doses noted above, this usually will result in a monthly cost of \$75 to \$100 for pellets. While this seems expensive, it is cheaper than the typical out-of-pocket cost for either the transdermal gel or patches for TRT. The transdermal systems typically run between \$120 and \$400 per month depending on the dose utilized. On the other hand, most major carriers are now covering the testosterone gel and patches but recent increases in co-pays have resulted in monthly co-pays of \$40 to \$80 for many of our patients. For patients receiving weekly injections of depo-testosterone in an office setting, the expenditure is likely similar to that which they would be paying for pellets. For those rare practices that train patients to do home, self-injection of weekly depo-testosterone, this continues to be the cheapest form of TRT available, with average maintenance costs of around \$25 per month.