

## LTC Pharmacy



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# Addressing Andropause in Older Men in Long-Term Care

**D**uring an initial medication assessment, MC, a 94-year-old man new to the assisted living facility, presented with a chief complaint of “sweats” that he said he had treated at home with a lotion. His primary care provider confirmed that MC had a history of hypertension, osteoporosis, and prostate cancer, but the doctor was unaware that MC was on testosterone replacement treatment (TRT) and was concerned.

The case raises important questions: How well are we recognizing and addressing andropause in older men in postacute/long-term care, and what is the state of the science with the various TRT options?

Andropause, or age-related hypogonadism, increases with age and is difficult to recognize because the signs and symptoms are often nonspecific and confused with other symptoms of aging. The condition is associated with fatigue, changes in mood and cognition, and a decrease in libido and sexual function, lean body mass, muscle strength, and bone density. In addition to blood tests, questionnaires such as the Saint Louis University Androgen Deficiency in the Aging Male and Aging Male Symptom rating can be used, but caution exists with their specificity (Eur. Geriatr. Med. 2012;3:368–73).

Only 5% of older men receive appropriate treatment for andropause, and it often has to do with prescriber concerns with TRT safety and efficacy. That is why it's critical that older men undergo a comprehensive pretreatment assessment to exclude systemic illness, eating disorders, and the use of drugs such as marijuana, opiates, and alcohol. Additionally, a testosterone level should be measured, preferably in the morning, using the lower limit of testosterone such as 300 ng/mL or the reference range per the laboratory assay (Best Pract. Res. Clin. Endocrinol. Metab. 2011;25:251–70). Ongoing monitoring is essential to avoid potential adverse consequences of TRT.

TRT is contraindicated in the following situations:

- ▶ Prostate cancer.
- ▶ Prostate-specific antigen (PSA) >4 ng/mL or PSA >3 ng/mL in men at high risk of prostate cancer (African Americans, men with a first-degree relative with prostate cancer) without urological assessment.
- ▶ Prostate nodule without urological assessment.
- ▶ Severe symptoms of low urinary tract.
- ▶ Hematocrit more than 50%.
- ▶ Uncontrolled congestive heart failure.
- ▶ Ischemic heart disease in the preceding 6 months (e.g., myocardial infarction,

acute coronary event, unstable angina, coronary revascularization procedure).

- ▶ Severe obstructive sleep apnea without treatment.

### TRT Modalities

A recent report noted a three-fold increase in TRT among men 40 years or older (JAMA Intern. Med. 2013;173[15]:1465–6). The researchers reported that almost 20% of all new users received TRT for 30 days or less and that most men didn't clearly have an appropriate clinical indication.

TRT modalities are numerous, and they all have advantages and disadvantages in terms of safety, convenience, efficacy, ability to mimic physiologic levels, and adverse effects. When choosing a TRT, take into account the patient's age, existing medical conditions and medications, previous and current response to treatment, preference, and cost. The formulations consist of buccal, oral, parenteral, transdermal, and subcutaneous pellets.

The various transdermal preparations are more widely used. These prescriptions must be accompanied by MedGuides because of potential harm from transfer to another person.

### Transdermal Patch

In 1995, the Food and Drug Administration approved a testosterone transdermal system (Androderm). In 2011, 2 mg/day and 4 mg/day patches replaced the original patch strengths of 2.5 mg and 5 mg. The advantages to this formulation are that it closely mimics normal diurnal change in testosterone levels, and it's convenient to use. Its most significant disadvantage is skin irritation.

If you are monitoring blood testosterone levels, a level should be taken 3 to 12 hours after application of the patch, meriting the importance of dating the patch, noting the time of application, and tracking its location.

### Transdermal Gels

Currently, four transdermal gels are available in the United States. The advantages to using gels are that they provide therapeutic levels without large fluctuations, are easy to use, and produce less skin irritation than patches do. Two strengths of the same agent, testosterone gel (AndroGel 1% and 1.62%), are available for topical use, and each has distinct implications for administration and safety concerns with transfer of gel or solution. Next are highlights of each of the formulations and considerations for administration and testosterone monitoring.

### Testosterone Gel 1%

This testosterone formulation has been FDA approved since 1953. The starting dose of testosterone gel 1% is 50 mg of testosterone (four pump actuations, two 25 mg packets, or one 50 mg packet) applied once daily in the morning. The gel must be applied to clean, dry, intact skin of shoulders and upper arms and/or abdomen. Don't apply testosterone gel 1% to any other part of the body, including the genitals, chest, and back. After applying, wash hands immediately with soap and water.

Furthermore, cover the application site with clothing after the gel has dried. Wash the application site thoroughly with soap and water prior to any situation where skin-to-skin contact of the application site with another person is anticipated, to avoid transfer of medication. It's imperative that any direct care staff member (e.g., a nurse) wear gloves when applying or removing the topical preparation.

**Ongoing education and monitoring will be needed across PA/LTC as increasing attention is given to andropause in men.**

### Testosterone Gel 1.62%

Noteworthy differences from the above formulation are the starting dose and sites of application. Testosterone gel 1.62% is 40.5 mg of testosterone (two pump actuations or a single 40.5 mg packet) applied topically once daily in the morning. Apply to clean, dry, intact skin of the shoulders and upper arms, but don't apply testosterone gel 1.62% to any other part of the body, including the abdomen and the genitals. Bioavailability of this formulation is reduced when it is applied to the abdomen.

### Testosterone Gel 2% (Fortesta)

This gel formulation has a starting dose of 40 mg of testosterone (four pump actuations) applied topically once daily in the morning. This formulation must be applied to clean, dry, intact skin of the thighs. Don't apply this gel to the genitals or other parts of the body.

### Testosterone Gel 1% (Testim)

The recommended starting dose for adult males is 50 mg of testosterone (one tube) applied topically once daily.

This formulation must be applied to clean, dry, intact skin of the shoulders and/or upper arms. Don't apply to the genitals or abdomen.

The various testosterone gels just mentioned aren't interchangeable. Wait at least 7-14 days after initiation before monitoring testosterone levels.

### Transdermal Solution (Axiron)

Testosterone topical solution 30 mg/1.5 mL is mentioned in direct-to-consumer advertising as the “only underarm low-T treatment.” It is similar to the TRT formulations previously mentioned with respect to safety. However, it is applied to the axilla in the morning. The starting dose is 60 mg of testosterone (one pump actuation of 30 mg of testosterone to each axilla) applied once daily at the same time each morning.

Apply to clean, dry intact skin of the axilla, not to any other part of the body, including the abdomen or genitals. Serum testosterone blood draw should be obtained 2-8 hours after application and at least 14 days after starting treatment or following dose adjustments.

### Implications for PA/LTC

Safety of the resident, but also the staff and family, is a foremost consideration. Direct-care staff must be cognizant of the potential transfer of TRT, especially if they're women of childbearing years. Precautions need to be in place for the administration, storage, and disposal of the medication. Furthermore, the medical team needs to assess for appropriateness and have ongoing monitoring in place for both efficacy, as well as adverse consequences.

With respect to MC, the health care team consulted with him and his family. They decided that the risks of TRT outweighed the benefits, in light of his past history of prostate cancer and oversight of medications from nursing.

Ongoing education and monitoring will be needed across PA/LTC, as increasing attention is given to andropause in men. Additional evidence will be obtained from a large-scale, multicenter, randomized, double blind, placebo-controlled trial currently being conducted by the National Institute of Aging, examining the effect of testosterone therapy in older men. Results of this trial are expected in 2015.

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