The specialist authority for menopause & post reproductive health

British Menopause Society

Testosterone replacement in menopause

Is testosterone a female hormone?

Yes – premenopausal women produce both testosterone and estrogen physiologically. Androgens, including testosterone, are essential for development and maintenance of female sexual anatomy and physiology, and modulation of sexual behaviour.

What happens to testosterone levels with age?

The decline in testosterone levels appears to be age related at least partly due to loss of ovarian function, but can also occur more profoundly due to iatrogenic menopause which may be medical or surgical.

Should testosterone be replaced just because levels are low?

No. Many women with low systemic testosterone levels do not complain of distressing low libido or other symptoms, even on direct questioning.

Why do systemic testosterone levels not always correlate directly with Hypoactive Sexual Desire Disorder (HSDD), the American Psychiatric Association's definition of distressing low libido?

The intracrinological metabolism of testosterone may be more important than the circulating levels. This may be particularly important in the central nervous system where DHEA is converted to testosterone in the brain.

Who should be offered testosterone?

Testosterone supplementation should only be considered in women who complain of low sexual desire after a biopsychosocial approach has excluded other causes such as relationship, psychological and medication related HSDD, e.g. SSRIs/SNRIs. However, combined hormonal and psychosexual approaches may be beneficial in cases with mixed etiologies.

Should testosterone be prescribed on its own or with HRT?

The NICE Menopause Guideline (NG23) and the BMS recommend that a trial of conventional HRT is given before testosterone supplementation is considered.

Oral estrogens, especially conjugated estrogens, can reduce the effectiveness of testosterone by increasing sex hormone binding globulin (SHBG) levels. Switching women with HSDD from oral to transdermal estrogen can be beneficial as this can increase the proportion of circulating free testosterone without requiring exogenous testosterone.

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It is important that any genitourinary symptoms of menopause are also adequately treated if testosterone is being considered for HSDD. Although studies have shown that testosterone can be beneficial in women not using concomitant estrogen containing hormone therapy, the incidence of adverse androgenic effects such as acne and excess hair growth is higher; this strategy is therefore not usually recommended in routine clinical practice.

What about the potential wider benefits of testosterone?

Randomised clinical trials (RCTs) of testosterone to date have not demonstrated the beneficial effects of testosterone therapy for cognition, mood, energy and musculoskeletal health. Further, better designed studies are required with these health issues as primary outcome measures, as some individuals report improvement of these symptoms.

A testosterone supplementation trial funded by the National Institute for Health and Care Research (NIHR) called "Evaluating the clinical and cost-effectivenesS of TEstosteronE to improve Menopause-related quality of life" (ESTEEM) has just commenced to investigate menopause quality of life (MENQOL) as the primary outcome measure in 400 women. Until data from this, and other such trials are available, the primary indication for testosterone should therefore remain HSDD following a biopsychosocial approach.

Are there side effects and risks?

Adverse effects of testosterone in women are uncommon if levels are maintained within the female physiological range. The most common effects are excess hair growth, acne and weight gain, which are usually reversible with reduction in dosage or discontinuation. Alopecia, deepening of voice and clitoral enlargement are rare with physiological testosterone replacement.

More data are required for the long-term effects on cardiovascular and breast outcomes but short-term data from recent RCTs and meta-analyses are reassuring.

Why is it not licensed for women except in one country?

Although there is a lack of long-term safety data for cardiovascular and breast outcomes, an equally important factor is the reluctance of the pharmaceutical industry thus far to finance further clinical studies to achieve licensing of female androgenic products.

The recent licensing of 1% testosterone cream in Australia, New Zealand, South Africa and the UK is an encouraging development; it is hoped that regulators in other countries may be encouraged by this enlightened approach by the regulators of these countries who have recognised the unmet need and the large body of efficacy and safety data already available for testosterone in women.

How long should testosterone be prescribed for?

It may take 3-6 months to fully evaluate the efficacy of treatment. There should be at least an annual re-evaluation of ongoing usage based on the same criteria that would be used for standard hormone therapy, i.e. carefully weighing up the benefits and risks of long-term usage.

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Monitoring?

General information

- It is recommended that total testosterone levels are checked before treatment to establish a baseline for future monitoring and to ensure that levels are not in the upper range before treatment is commenced.
- Ideally total testosterone should be measured by Liquid Chromatography-Tandem Mass Spectrometry, although direct assays can also be used in clinical practice to exclude high baseline concentrations and supraphysiological concentrations during treatment.
- It is recommended by some guidelines that testosterone levels are reassessed at 3-6 weeks after treatment is commenced but given that most National Health Service (NHS) clinics review patients after 2-3 months it is recognised that this is an aspirational goal and that testing should be performed as close to this timeline as possible.
- It is important that testosterone level monitoring continues every 6-12 months to ensure that levels remain within the female physiological range in order to minimise adverse effects.
- Unlike male testosterone replacement (usually at much higher doses), there is no need for routine monitoring of other safety parameters such as FBC or lipids.
- It should be feasible for prescribing and monitoring to occur in primary care, depending on a healthcare professional's level of expertise and the resources available. It is recognised that on occasion, the initial decision to start treatment may need to be made jointly between a woman's general healthcare professional and specialist menopause services.

What should be measured?

- Total testosterone levels provide a more accurate representation of therapeutic response than free testosterone or the calculated Free Androgen Index (FAI).
- Free testosterone assays are not recommended, as correlation with biological activity of free testosterone has not been confirmed.
- Recent evidence suggests that not only free but also some protein bound testosterone may be bioavailable, and also that not all free testosterone is biologically active.
- Assessment of the proportion of total testosterone binding to SHBG, albumin and other proteins, e.g. by FAI, may not give an accurate reflection of testosterone which is available to activate testosterone receptors and, by extrapolation, influence clinical response.
- In day-to-day practice, assessment of clinical response to testosterone supplementation in women (i.e. HSDD benefits and/or androgenic adverse effects, e.g. excess hair growth, acne), should be of primary importance, supported by data for total testosterone, measured by Liquid Chromatography-Tandem Mass Spectrometry, in preference to FAI or free testosterone.
- The aim should be to achieve total testosterone levels within the normal physiological range for women using the laboratory reference range where the test is carried out.

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- In certain circumstances, SHBG levels may be helpful as additional supportive information:
  - Where SHBG levels are high, e.g. due to high dose oral estrogen therapy, especially conjugated estrogens. This may explain lack of therapeutic response to physiological testosterone replacement, despite normal total testosterone levels.
  - Conversely, when SHBG levels are very low. This may explain why androgenic adverse effects with testosterone replacement have occurred, despite normal total testosterone levels.

What are the available treatment options?

Most testosterone products remain off licence for female usage and may not always be available. The regulatory advice regarding use of compounded medications advises against their use unless an equivalent alternative is not available. The General Medical Council (GMC) supports off licence prescribing when there is sufficient efficacy and safety evidence and experience to support the use of the medication. In most countries and settings, including the UK, there are licensed male testosterone preparations that can be down titrated to female doses (typically 1/10th).

In some countries, oral Dehydroepiandrosterone (DHEA) is more commonly used than testosterone; however further research is required before this product can be recommended, as clinical trials and meta-analyses have not definitively proven the benefits for sexual function in women with normal adrenal function.

This list is an example of some of the more commonly used products in current clinical practice:

- Tostran (2% testosterone gel in a canister containing 60g): starting dose 1 metered pump of 0.5 g = 10 mg on alternate days – each canister should last 240 days.
- Testogel (2.5 g sachets containing 40.5 mg testosterone): starting dose 1/8 of a sachet/day = approx. 5 mg/day, i.e. each sachet should last 8 days. (new formulation)
- AndroFeme cream (1% testosterone 10 mg/ml cream in 50 ml tubes with screw cap): starting dose 0.5 ml/day = 5 mg /day, i.e. each tube should last 100 days.
- Testosterone implants (100 mg implanted pellets) – imported from USA.

Prescribing notes

1. Androfeme is currently licensed in Australia, New Zealand and South Africa for female usage and imported to the UK for private use under special MHRA license. Recent granting of full UK marketing authorization by the MHRA was contingent on availability of the product as a pump pack, and it is hoped this will be available in 2026.
2. Testosterone implants are currently unlicensed in the UK and can only be used privately or through agreement of the local formulary committee with appropriate monitoring of hormone levels and adverse effects. Designed for female usage. These are not currently available in the UK due to a quality control recall of the product although no clinical issues have been reported.

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3. Tibolone is weakly androgenic, progestogenic and estrogenic – although it is an oral option for women with low sexual desire, it is not sufficiently androgenic nor estrogenic in many women. The progestogenic effect is not required in hysterectomised women and may cause unnecessary adverse effects.
4. Compounded bioidentical testosterone preparations are not recommended by the regulatory authorities or the menopause societies.
5. When treating low sexual desire/arousal it is also important that urogenital tissues are adequately estrogenised in women with genitourinary symptoms of menopause, e.g. through use of vaginal estrogen, to avoid dyspareunia.
6. This BMS Tool for Clinicians refers to testosterone replacement in menopause, both natural and surgical. There are very few data for testosterone replacement in premenopausal women which remains a controversial area requiring more research.
7. Oral androgens are not recommended as they are difficult to monitor, and oral testosterone can lead to adverse lipid effects.
8. It is recommended that with support from this prescribing tool, the appropriate prescribing of testosterone can take place in primary care, with support from secondary care/menopause specialist services where required, through management care pathways.

How should testosterone gel/cream be used?

Testosterone gel/cream should be applied to clean dry skin (lower abdomen/upper thighs) and allowed to dry before dressing. Skin contact with partners or children should be avoided until dry and hands should be washed immediately after application. The area of application should not be washed for 2-3 hours after application. It is advised to regularly change the site of application to avoid unwanted hair growth in that area.

When should testosterone be avoided or used with caution?

- During pregnancy or breastfeeding
- Active liver disease
- History of hormone sensitive breast cancer – off licence exceptions to this may be agreed in fully informed women with intractable symptoms not responding to alternatives
- Competitive athletes – care must be taken to maintain levels well within the female physiological range
- Women with upper normal or high baseline total testosterone levels

Audit and research

In order to achieve global licensing of testosterone use in women, more long-term data are not only desirable but are essential. In the absence of long-term prospective randomised controlled trials, the best ways to gather these data are through service evaluation and prospective quality data collection through registries.

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Next research steps in special populations

More data are particularly required in:

- Women with Premature Ovarian Insufficiency (POI)
- Women with Hypothalamic Amenorrhoea
- Premenopausal women, especially those on SSRIs and combined hormonal contraception
- Women with hormone sensitive malignancy, e.g. breast cancer

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Further reading

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MHRA: Off-label or unlicensed use of medicines: prescribers' responsibilities
https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities

Cardiff University ESTEEM trial
https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/esteem

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This BMS Tool for Clinicians will be updated when guidance changes and/or new data becomes available.

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