Bedfordshire, Luton and Milton Keynes Area Prescribing Committee (BLMK APC) – Formulary Subgroup

Testosterone Gel for low sexual desire in post-menopausal women – Fact Sheet

Version 1.1, April 2022

Version Control	
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Review	April 2024

Change control

Update:	Date:
Testogel strength and dosing advice updated following discontinuation of 50mg/5g strength (replaced with 40.5mg in 2.5mL over 8 days)	22.4.22

The following organisations contribute to and participate in the BLMK APC – Bedfordshire, Luton and Milton Keynes Clinical Commissioning Group; Bedfordshire Hospitals NHS Foundation Trust; Cambridgeshire Community Services NHS Trust; Central and North West London NHS Foundation Trust; East London NHS Foundation Trust; Milton Keynes University Hospital NHS Foundation Trust

Testosterone Gel for low sexual desire in post-menopausal women – Fact sheet

Background

The Bedfordshire, Luton and Milton Keynes (BLMK) Formulary Subgroup to the Area Prescribing Committee (APC) agreed the following recommendations in September 2021 (These recommendations have been ratified by the APC):

- The committee agreed that Testosterone gel (Testogel®/Tostran®) for treating the symptom of low sexual desire in post-menopausal women is added to both Joint Formularies in accordance with the recommendations included in NICE Guideline 23 i.e. if HRT alone is not effective.
- GPs may continue therapy after initiation and stabilisation by a clinician with expertise in the treatment of the menopause (Defined as a Consultant Endocrinologist/Gynaecologist or a Primary Care Clinician who has relevant experience and is clinically competent to prescribe).
- Notes to be added to each formulary to clarify the meaning of 'specialist' (see above).
- Fact sheet to be developed to assist GPs in taking over prescribing, including guidance regarding blood monitoring requirements and patient counselling.
- No prescribing until fact sheet developed and agreed.

Formulary status:

- Bedfordshire and Luton – Amber
- Milton Keynes - Amber 3

Further information relating to the use of testosterone gel for treating symptoms of low sexual desire in post-menopausal women can be accessed from the British Menopause Society (BMS) Tool kit. **Click here** to access it.

Click here for a patient information leaflet produced by the British Menopause Society

Medicine (Generic and Brand name)	Testosterone gel (Testogel® or Tostran®)
Strength and formulation	Testogel® 40.5mg/2.5g transdermal gel in sachets Tostran® 2% Gel in a canister containing 60g
Intended indication	Low sexual desire in postmenopausal women (administered on expert advice) - NB this is an 'off label' use of testosterone gel. For use as outlined in NICE Guideline 23 – Menopause: diagnosis and management:- **Altered sexual function** 1.4.8 Consider testosterone supplementation for menopausal women with low sexual desire if HRT alone is not effective. The NICE Guidance also states: **If a woman has menopausal symptoms, consider arranging referral to a healthcare professional with expertise in menopause if:** The women has persistent altered sexual function and hormonal and/or non-hormonal, or non-drug treatments are ineffective: • Seek specialist advice regarding the use of testosterone supplementation (off-label use) • Consider referral for psychosexual counselling, depending on the woman's wishes.

Safety and side effects	• Testosterone is well tolerated in the short term - symptoms of androgen excess, such as hirsutism and acne, are common with testosterone therapy, although these effects are often mild. • If adverse effects are thought to be linked to testosterone gel usage, the dosage used should be reduced or treatment stopped. Where increased body hair occurs at the site of application – spread more thinly, vary the site of application, reduce dosage. • The safety of long-term testosterone therapy has not been established, particularly with regard to lipids, cardiovascular disease and breast cancer. It should be noted that many of the clinical trials excluded women with cardiometabolic risk.
When should testosterone be avoided or used with caution?	• During pregnancy or breastfeeding • Active liver disease • History of hormone sensitive breast cancer – off label 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 testosterone levels / FAI.
Dose and administration	**For Adults** **Testogel®:** Apply 40.5 mg over an 8 day period, the contents of a 2.5g sachet to be divided for daily dosing and applied to non-hairy areas, such as the abdomen or upper thighs. **Tostran®:** Starting dose 1 metered pump or 0.5g =10mg on alternate days. Each canister should last 240 days The testosterone gel should be to 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. When treating low sexual desire /arousal it is also important that urogenital tissues are adequately oestrogenised in women with vulvovaginal atrophy / genitourinary syndrome of the menopause e.g. through use of vaginal oestrogen, to avoid dyspareunia. *Ref: British Menopause Society update on HRT supply Last updated: 12 April 2022* *British Menopause Society update on HRT supply - British Menopause Society (thebms.org.uk)* *Ref - Testosterone replacement in menopause, tools for clinicians, British Menopause Society Published February 2019* *https://thebms.org.uk/publications/tools-for-clinicians/testosterone-replacement-in-menopause/* *Ref – Electronic BNF – accessed 16/08/21 (and checked 11/10/21)* *https://bnf.nice.org.uk/drug/testosterone.html#indicationsAndDoses*
Patient monitoring	NICE Guideline 23 recommends that each treatment for short-term menopausal symptoms should be reviewed: • At 3 months to assess efficacy and tolerability. • Annually thereafter unless there are clinical indications for an earlier review (such as treatment ineffectiveness, side-effects or adverse events). The BMS recommends a 3-6 month trial of therapy. Duration of use should be individualised and evaluated at least on an annual basis, weighing up pros and

<table>
<tr><td></td><td>cons according to benefits and risks, as per HRT advice from all menopause societies.</td></tr>
<tr><td>Blood Test Monitoring</td><td>
<table>
<tr><th rowspan="2">Recommended Monitoring</th><th rowspan="2">Total Testosterone</th><th colspan="2">SHBG and FAI (Free Androgen Index)
(*If locally available*)</th></tr>
<tr><th>Testosterone < 1.7nmol/L</th><th>Testosterone > 1.7nmol/L</th></tr>
<tr><td>Baseline (before initiation of therapy)</td><td>Yes</td><td>Yes</td><td>Yes</td></tr>
<tr><td>After initiation or increase in dosage</td><td>At 6 weeks, 6 months and 12 months, then annually if stable (every 6 months if overuse suspected)</td><td>No</td><td>Yes</td></tr>
<tr><td>After downward dose titration (if total testosterone high, even if no androgenic side-effects)</td><td>At 2-3 weeks, then at 3 months, 6 months and 12 months, then annually if stable (every 6 months if overuse suspected)</td><td>No</td><td>Yes</td></tr>
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Local labs check SHBG automatically when Total Serum Testosterone >1.7 nmol/L

References: The above information is based on two consensus guidance documents, the ‘International Society for the Study of Women's Sexual Health Clinical Practice Guideline for the Use of Systemic Testosterone for Hypoactive Sexual Desire Disorder in Women’ (The Journal of Sexual Medicine, April 2021, https://www.jsm.jsexmed.org/article/S1743-6095(20)30982-6/fulltext) and ‘Global Consensus Position Statement on the Use of Testosterone Therapy for Women’ (J Clin Endocrinol Metab. Sep 2019, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6821450/), and the publication ‘Testosterone replacement in menopause’ (BMS, Feb 2019, https://thebms.org.uk/publications/tools-for-clinicians/testosterone-replacement-in-menopause /)
</td></tr>
<tr><td>Availability of Blood test monitoring</td><td>The relevant assays are available at both local Trusts. For Bedfordshire Hospitals, the assays for Sex Hormone Binding Globulin (SHBG) and Free Androgen Index (FAI – total testosterone/SHBG x 100) are not routinely carried out if testosterone levels are requested.</td></tr>
<tr><td>Prescribing and monitoring Responsibilities</td><td>As patient assessment and selection is key, treatment should be initiated and stabilised by an expert (Defined as a Consultant Endocrinologist/Gynaecologist or a primary care clinician who has relevant experience and is clinically competent to prescribe) in treatment of the menopause. GP to continue therapy after the patient is stabilised on therapy, typically after a 6 month trial and conduct the patient annual review (unless there are clinical indications for an earlier review). All blood test monitoring (see above) will be undertaken by the clinician who is prescribing for the patient.</td></tr>
<tr><td>Criteria for seeking further advice/referral back to expert in the treatment of the menopause</td><td>The following are examples:

• Adverse Drug Reaction
• Advice on Blood test monitoring
• Diagnosis of new complex medical conditions</td></tr>
<tr><td>Private to NHS Care</td><td>As per the BLMK policy on Defining the Boundaries between NHS and Private Healthcare, after recommendations from a private consultant/specialist, GPs should only take on prescribing of testosterone Gel for low sexual desire in post-menopausal women if the patient’s clinical circumstances meet the initiation criteria</td></tr>
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	set out in NICE CG 23 and this bulletin. GPs should also be sure that the private consultant/specialist has expertise in managing the menopause and is following the prescribing and monitoring responsibilities set out in this bulletin. As with all recommendations to prescribe from a private consultant/specialist, GPs do also not have to take on prescribing if in the exercise of their clinical discretion they do not think it is medically appropriate for the patient, the testosterone preparation is not listed on the BLMK formulary or they are unwilling to accept clinical responsibility for prescribing the medication. We are aware of requests made by private consultants/specialist and patients following a private consultation for GPs to prescribe *AndroFeme [Lawley Pharma] (1% testosterone cream).* AndroFeme is not currently available on the NHS and is being imported from Western Australia by special license from the MHRA. Therefore, patients will have to continue to fund this privately or the private consultant/specialist will need to recommend an alternative.