

**South East London Integrated Medicines Optimisation Committee
Formulary recommendation**

Reference:	105
Intervention:	Testosterone in topical gel formulation for use in women with decreased libido in the menopause (Tostran™ 2% gel and Testogel™ 40.5mg in 2.5 grams) (Testosterone is the primary male sex hormone)
Date of Decision:	June 2019. Updated September 2022 due to the discontinuation of Testogel™ 50mg in 5 grams, replaced by Testogel™ 40.5mg in 2.5 grams. Updated May 2024 – recategorised from Amber 2 to Amber 1 to align to the SEL Primary Care Menopause guideline
Date of Issue:	July 2019, Re-issued September 2022, Re-issued May 2024
Recommendation:	Amber 1 – Initiation in primary care on the advice of a gynaecology specialist or a GP with an extended role in gynaecology
Further Information	<ul style="list-style-type: none"> • Testosterone topical gel is accepted for use in SEL as an option for the management of decreased libido in women in the menopause if hormone replacement therapy (HRT) alone is not effective. Testosterone gel is used in addition to HRT in this setting. • Two gel formulations of testosterone are supported: Tostran™ (2% gel) and Testogel™ (40.5mg in 2.5 grams gel sachets). • Tostran™ is the first line option and Testogel™ will be reserved for women who experience application site reactions to Tostran™. • The above testosterone gel products are not licensed* for use in this setting. Informed consent should be gained from the patient before treatment is started. • The dosing regimen followed for the use of testosterone gel in this setting will be different to the dosing used in the licensed indications. In summary: <ul style="list-style-type: none"> – Tostran™ 2% is a gel in a pump dispenser, and one measured pump (which contains 10 milligrams of testosterone) is usually used three times a week. – Testogel™ is a testosterone product that is formulated as a gel in a sachet. One sachet is usually used over the course of 8 days (given as a daily dose of a small portion of the pack). • As instructions on the use of testosterone gel in this setting are different to the licensed indications, patients must be counselled on their use by the initiating gynaecology service. • There should be regular review of patients (at least every 6 months once stable) to ensure ongoing effectiveness. • It should be noted that testosterone gel products are Schedule 4 (part 2) controlled drugs (anabolic steroids). • September 2022: Testogel™ 50mg in 5mg grams is being discontinued and replaced with Testogel™ 40.5mg in 2.5 grams. • Testogel™ 40.5 mg in 2.5 grams is a more concentrated gel than Testogel™ 50 mg in 5 grams. This means patients require less volume of gel to apply the recommended dose. • Dosing based on one Testogel™ 50 mg in 5 grams sachet is equivalent to one Testogel™ 40.5 mg in 2.5 grams sachet. • The application sites differ between the two formulations; it is important patients are counselled on this difference: <ul style="list-style-type: none"> - Testogel™ 40.5 in 2.5 grams: applied onto clean, dry, healthy skin over right and left upper arms and shoulders - Testogel™ 50 mg in 5 grams (now discontinued): applied onto clean, dry, healthy skin over both shoulders, or both arms or the abdomen. • For more information, please refer to the SPC for Testogel® 40.5mg in 2.5 grams • Please refer to the SEL Acute Provider Collaborative Primary Care (APC) Menopause guidelines for further information. <p><small>*Tostran™ 2% gel and Testogel™ are both licensed as testosterone replacement therapy for male hypogonadism when testosterone deficiency has been confirmed by clinical features and biochemical tests.</small></p>

Shared Care/ Transfer of care required:	N/A – continuation in primary care under an individual management plan (for example, a detailed clinic letter) between specialist and the GP. Links to patient information can be found in the SEL APC Menopause guideline .
Cost Impact for agreed patient group	<ul style="list-style-type: none"> The application proposed that 100 women would require testosterone treatment per year in addition to their existing systemic HRT regime. The additional cost per year for SEL would be approximately between £4,000 and £7,500 depending on the preparation used. As there is historic use of testosterone in this setting, much of this spend is already likely to be occurring. September 2022: The price of Testogel™ 40.5mg in 2.5 grams is the same price as Testogel™ 50mg in 5 grams. The switch to Testogel™ 40.5mg sachet is cost neutral
Usage Monitoring & Impact Assessment	<p>Acute Trusts:</p> <ul style="list-style-type: none"> Monitor use and submit usage data and audit reports upon request to the Committee. <p>SEL Borough Medicines Teams:</p> <ul style="list-style-type: none"> Monitor ePACT2 data. Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	<p>References (from evidence evaluation)</p> <ol style="list-style-type: none"> NICE Clinical Knowledge Summaries: Menopause. Available online at: https://cks.nice.org.uk/menopause (accessed 30/01/18) The British Menopause Society & Women’s Health Concern 2016 recommendations on hormone replacement therapy in menopausal women. H Hamoda, N Panay, R Arya, M Savvas. The British Menopause Society and Women’s Health Concern. Post Reproductive Health. Vol 22, Issue 4, pp. 165 – 183. 2016 NICE Guidelines: Menopause NG23 Full Guideline. Updated: 12-Nov-2015. Available online at: https://www.nice.org.uk/guidance/ng23/evidence/full-guideline (accessed 30/01/18) Uptodate. Overview of androgen deficiency and therapy in women. Laurence C Udoff, online [Accessed on:07/02/2018] Summaries of product characteristics Tostran 2% gel. Last updated on eMC: 20 Feb 2017. Kyowa Kirin Ltd. Available at: http://www.medicines.org.uk/emc/ [Accessed on: 04/02/18] Summaries of product characteristics Testogel. Last updated on eMC: 12 Dec 2017. Besins Healthcare Ltd. Available at: http://www.medicines.org.uk/emc/ [Accessed on: 04/02/18] Nathorst-Boos J, Floter A, Jarkander-Rolff M, Carlstrom K, Schoultz B. Treatment with percutaneous testosterone gel in postmenopausal women with decreased libido--effects on sexuality and psychological general well-being. Maturitas 2006;53(1):11–8. Simon J, Braunstein G, Nachtigall L, Utian W, Katz M, Miller S, et al. Testosterone patch increases sexual activity and desire in surgically menopausal women with hypoactive sexual desire disorder. Journal of Clinical Endocrinology and Metabolism 2005;90(9):5226–33. Davis SR et al. Testosterone for low libido in postmenopausal women not taking estrogen. N Engl J Med 2008 Nov 6; 359:2005. Somboonporn W, Bell RJ, Davis SR. Testosterone for peri and postmenopausal women (Review) [published online April 17, 2007]. Cochrane Database Syst Rev. 2009; 3. Elraiyah T, Sonbol MB, Wang Z, et al. The Benefits and Harms of Systemic Testosterone Therapy in Postmenopausal Women with Normal Adrenal Function: A Systematic Review and Meta-analysis. The Journal of Clinical Endocrinology and Metabolism. 2014; 99(10):3543-3550. doi:10.1210/jc.2014-2262. Testogel™40.5mg transdermal gel in sachet Medicines Information Letter, Besins Healthcare Summary of product characteristics, Testogel™40.5mg transdermal gel in sachet. Last updated 29/06/202. Available at: http://www.medicines.org.uk/emc/ [Accessed on: 05/08/22]

NOTES:

- SEL IMOC recommendations and minutes are available publicly via the [website](#).
- This SEL IMOC recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.
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