

**South East London Area Prescribing 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™ 50mg in 5 grams) (Testosterone is the primary male sex hormone)
Date of Decision:	June 2019
Date of Issue:	July 2019
Recommendation:	Amber 2 – initiation and first prescription supplied by the gynaecology team
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™ (50mg in 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 one week (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. The patient must also be provided with the local patient information leaflet. • 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). <p>*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.</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. A local patient information leaflet is also available and should be provided to the patient.
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.
Usage Monitoring & Impact Assessment	Acute Trusts: <ul style="list-style-type: none"> • Monitor use and submit usage data and audit reports upon request to the APC.
	CCGs: <ul style="list-style-type: none"> • Monitor EPACT 2 data. • Exception reports from GPs if inappropriate prescribing requests are made to primary care.

Evidence reviewed	References (from evidence evaluation)
	<ol style="list-style-type: none"> 1. NICE Clinical Knowledge Summaries: Menopause. Available online at: https://cks.nice.org.uk/menopause (accessed 30/01/18) 2. 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 3. 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) 4. Uptodate. Overview of androgen deficiency and therapy in women. Laurence C Udoff, online [Accessed on:07/02/2018] 5. 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] 6. 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] 7. 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. <i>Maturitas</i> 2006;53(1):11–8. 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. <i>Journal of Clinical Endocrinology and Metabolism</i> 2005;90(9):5226–33. 9. Davis SR et al. Testosterone for low libido in postmenopausal women not taking estrogen. <i>N Engl J Med</i> 2008 Nov 6; 359:2005. 10. Somboonporn W, Bell RJ, Davis SR. Testosterone for peri and postmenopausal women (Review) [published online April 17, 2007]. <i>Cochrane Database Syst Rev.</i> 2009; 3. 11. 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. <i>The Journal of Clinical Endocrinology and Metabolism.</i> 2014; 99(10):3543-3550. doi:10.1210/jc.2014-2262.

NOTES:

- a) Area Prescribing Committee recommendations and minutes are available publicly on the APC website.
- b) This Area Prescribing Committee 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.
- c) **Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**