

**TESTOSTERONE 2% GEL (TOSTRAN[®]) REPLACEMENT THERAPY
IN MALE HYPOGONADISM.**

RECOMMENDED

Name: generic (trade)	What it is	Indication	Date decision last revised	Decision status	NICE / SMC Guidance
Testosterone 2% gel (Tostran [®])	Androgen	Testosterone replacement therapy in male hypogonadism	November 2012	Final	NICE – None SMC – recommended for restricted use

HMMC Recommendation: Testosterone 2% gel (Tostran[®]) is **RECOMMENDED for secondary and primary care prescribing.**

<p><u>EFFICACY</u></p> <ul style="list-style-type: none"> • The Times 2 study randomised 220 men with hypogonadism and type 2 diabetes and/or metabolic syndrome. • Patients received either 60mg metered dose of testosterone (3g of Tostran[®]) [n=108] or placebo [n=112] once daily. • Over the six month study period, patients on testosterone treatment had significant reductions in insulin resistance, total and LDL cholesterol, lipoprotein A and improvements in sexual health. 	<p><u>SAFETY</u></p> <ul style="list-style-type: none"> • Appears to be well tolerated. • The most commonly reported adverse reactions are application site reactions including pruritus and rash. These are mainly mild to moderate in severity and diminish or clear on continued use.
<p><u>COST</u></p> <ul style="list-style-type: none"> • Annual primary care expenditure on testosterone gel in NHS Hertfordshire (October 2011-September 2012) was £105k. 	<p><u>PATIENT FACTORS</u></p> <ul style="list-style-type: none"> • Tostran[®] is available in a pump dispenser. Other testosterone gel preparations are available in sachets which may complicate up titration of dose.

Assessment against Ethical Framework

Evidence of clinical effectiveness

- As above. The Times 2 study covered a small population and the statistical significance of improved outcomes was not maintained at the 12 month analysis (possibly because of smaller group size at 12 months due to drop-outs and allowed use of concomitant medication after 6 months). However, even after loss of participants, the treatment group stratification and characteristics of the patients in the groups did not change at 12 months.
- The British Society for Sexual Medicine Guideline does not differentiate between the various preparations of testosterone transdermal gel formulations.

Cost of treatment and cost effectiveness :

- Tostran[®] gel is cheaper than alternative testosterone preparations when used at maximum doses (but not at initial doses) for both primary and secondary care.
- Scottish Medicines Consortium recommendation considered that Tostran[®] is a cost effective use of NHS resources.

The needs of the population

- Approximately 125 patients in a population of 500,000 are estimated to receive treatment with testosterone replacement.
- The needs of the population appear to be low as alternative preparations are available.
- However, the pump dispenser of Tostran[®] may provide an easier method of dose titration than other preparations

The needs of the community

- Changing to an alternative testosterone replacement gel is unlikely to have a significant impact on the local health economy.

Equity

- No impact anticipated.

Policy drivers

- Specialists within West Hertfordshire Hospitals NHS Trust have requested use of Tostran[®] as testosterone replacement gel of choice. Tostran is already on the formulary at East and North Herts NHS Trust.

Implementability:

- No issues expected

References

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10. Jones TH. Testosterone replacement therapy – Drug Focus. British Journal of Hospital Medicine, October 2007; 68 (10): 547-553