

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

Reference	152
Intervention:	Daily tadalafil 5mg tablets for the treatment of erectile dysfunction (ED) (Tadalafil is a phosphodiesterase type 5 enzyme [PDE5] inhibitor)
Date of Decision:	October 2024
Date of Issue:	November 2024
Recommendation:	Amber 1 – initiation in primary care on the recommendation of the specialist urology team
Further Information	<ul style="list-style-type: none"> • Daily tadalafil 5mg tablets are accepted for use in SEL as a treatment option for the management of erectile dysfunction in men: <ul style="list-style-type: none"> - who have unsuccessfully tried on demand (or when required) sildenafil and - have planned sexual activity more than twice a week. • There should be regular review of patients (at least 3 months after initiation) to ensure ongoing effectiveness. • Prescribing should be in line with the erectile dysfunction treatment pathway* contained in the SEL Acute Provider Collaborative (APC) Urology Guidelines. • Further information on 5mg daily tadalafil can be found in the relevant summary of product characteristics (SPC). • Prescribing in primary care should be in line with the Selected List Scheme (SLS) criteria for the treatment of erectile dysfunction. <p>Note: Daily tadalafil was removed from the NHS England low value medicines guidance in 2023 following a national review due to its price now being comparable with the “as required” treatment.</p> <p>*An update to the erectile dysfunction pathway to reflect this formulary recommendation is in progress at time of writing.</p>
Shared Care/ Transfer of care required:	N/A
Cost Impact for agreed patient group	<ul style="list-style-type: none"> • The cost impact from the use of 5mg daily tadalafil is expected to be negligible. • Tadalafil 5mg daily has a similar cost profile to on demand (or when required) tadalafil and sildenafil, resulting in a negligible cost difference. • The availability of tadalafil 5mg daily could also prevent the need for more costly and invasive locally administered treatments (such as intracavernosal or intraurethral injections), potentially resulting in cost savings.
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	References (from evidence evaluation)
	<ol style="list-style-type: none"> 1. Does alprostadil cream hit the spot? Drug and Therapeutics Bulletin 2015 Volume 53 issue 2. 2. Hackett G, Kirby M, Wylie K et al. British Society for Sexual Medicine Guidelines on the Management of Erectile Dysfunction in Men—2017. The Journal of Sexual Medicine 2018 p1-28. 3. Male Sexual Dysfunction. European Association of Urology. Available online at: EAU-Guidelines-on-Male-Sexual-Dysfunction-2019.pdf (accessed 02/10/2024). 4. Items which should not be routinely prescribed in primary care: policy guidance. NHS England 2023. Available online at: NHS England » Items which should not routinely be prescribed in primary care: policy guidance – frequently asked questions (accessed 02/10/2024). 5. Erectile Dysfunction - Prescribing guidelines in primary care for adults aged 18 years and above. NHS South West London. Available at Erectile-Dysfunction-management-guidelines-in-primary-care-for-adults-aged-18-years-and-above-V3.pdf (icb.nhs.uk) (accessed 02/10/2024). 6. Cialis. Public Assessment Report 2005. European Medicines Agency. Available online at: https://www.ema.europa.eu/en/documents/scientific-discussion/cialis-epar-scientific-discussion_en.pdf (accessed 02/10/2024). 7. Cialis. Public Assessment report – Variation 2007. European Medicines Agency. Available online at: https://www.ema.europa.eu/en/documents/scientific-discussion-variation/cialis-h-c-436-ii-46-epar-scientific-discussion-variation_en.pdf (accessed 02/10/2024). 8. Cialis 5 mg. Summary of Product Characteristics. Available online at: https://www.medicines.org.uk/emc/product/7432/smpc (accessed 02/10/2024). 9. Alprostadil topical cream – Evidence Summary New Medicine. National Institute for Health and Care Excellence 2014. 10. Porst H, Giuliano F, Glina S, et al. Evaluation of the efficacy and safety of once-a-day dosing of tadalafil 5 mg and 10 mg in the treatment of erectile dysfunction: results of a multicenter, randomized, double-blind, placebo-controlled trial. Eur Urol 2006;50: 351–9. 11. Rajfer J, Aliotta PJ, Steidle CP, Fitch III WP, Zhao Y, Yu A. Tadalafil dosed once a day in men with erectile dysfunction: a randomized, double-blind, placebo-controlled study in the US. Int J Impot Res 2007;19:95–103. 12. Hatzichristou D, Gambla M, Rubio-Aurioles E, et al. Efficacy of tadalafil once daily in men with diabetes mellitus and erectile dysfunction. Diab Med 2008;25:138–46. 13. Porst H, Gacci M, Buettner H et al. Tadalafil once daily in men with erectile dysfunction: an integrated analysis of data obtained from 1913 patients from six randomized double-blind placebo controlled clinical studies. European Urology 2013. Available online at http://dx.doi.org/10.1016/j.eururo.2013.09.037 (accessed 02/10/2024). 14. Peng Z, Yang L, Dong Q et al. Efficacy and safety of tadalafil once-a-day versus tadalafil on-demand in patients with erectile dysfunction: a systematic review and meta-analysis. Urologia Internationalis 2017 doi 10.1159/000477496 15. Zhou Z, Chen H, Wu J et al. Meta-analysis of the long-term efficacy and tolerance of tadalafil daily compared with tadalafil on-demand in treating men with erectile dysfunction. Sexual Medicine 2019 7 p282-291. 16. Brock G, Ni X, Oelke M et al. Efficacy of continuous dosing of tadalafil once daily vs tadalafil on demand in clinical subgroups of men with erectile dysfunction: a descriptive comparison using the integrated tadalafil databases. The Journal of Sexual Medicine 2016 13 p860-875. 17. Bolat M, Cinar O, Akdeniz E et al. Low dose daily versus on-demand high dose tadalafil in diabetic patients with erectile and ejaculatory dysfunction. International Journal of Impotence Research 2018 30 p102-107. 18. Mohamed Gharib T, Abdel-AI I, Elatreisy A, Kandeel W, El-Shaer W, Abdrabuh AM, Mohamed Salih E, Sebaey A. Short- and long-term follow-up results of daily 5-mg tadalafil as a treatment for erectile dysfunction and premature ejaculation. Arab J Urol. 2022 Jan 23;20(1):49-53. 19. Rhoden, E., Telöken, C., Sogari, P. et al. The use of the simplified International Index of Erectile Function (IIEF-5) as a diagnostic tool to study the prevalence of erectile dysfunction. Int J Impot Res 14, 245–250 (2002). https://doi.org/10.1038/sj.ijir.3900859

NOTES:

- a) SEL IMOC recommendations and minutes are available publicly via the [website](#).
- b) 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.
- c) **Not to be used for commercial or marketing purposes. Strictly for use within the NHS**