

**South East London Integrated Medicines Optimisation Committee  
(SEL IMOC, formerly the SEL Area Prescribing Committee)  
Formulary recommendation**

<b>Reference</b>	<b>121</b>
<b>Intervention:</b>	<b>Alprostadil 3mg/g cream (Vitaros™) for the management of erectile dysfunction in adult males</b>
<b>Date of Decision:</b>	<b>November 2020</b>
<b>Date of Issue:</b>	<b>December 2020</b>
<b>Recommendation:</b>	<b>Amber 2 – specialist initiation prescription/supply. GP may be requested to continue prescribing once the patient has been trained on appropriate use (including patient training on dose titration) by the specialist team.</b>
<b>Further Information:</b>	<ul style="list-style-type: none"> <li>· Alprostadil 3mg/g cream (Vitaros™) is accepted for use in SEL in line with the agreed <a href="#">pathways</a> for managing erectile dysfunction in primary and secondary care.</li> <li>· Alprostadil cream may be considered as a 2<sup>nd</sup> line option after the failure of “when required” or “on demand” PDE5 inhibitor therapy, as an alternative to intracavernosal alprostadil (Caverject™, Viridal™), intraurethral alprostadil (MUSE™), and intracavernosal phentolamine/aviptadil (Invicorp™).</li> <li>· Alprostadil cream is restricted for use as an alternative preparation for patients who are unlikely to comply with the instructions for the use of intracavernosal or intraurethral alprostadil preparations or likely to experience unacceptable pain with the use of these treatments.</li> <li>· This is because whilst alprostadil cream may offer advantages over the other formulations of alprostadil (intracavernosal or intraurethral) in terms of ease of use, patient acceptability and convenience, indirect data comparisons suggest it has lower efficacy compared to other formulations.</li> <li>· Patients will be trained on the use of the preparation by the initiating specialist team.</li> <li>· The national “selected list scheme” (SLS) <a href="#">criteria</a> for use of erectile dysfunction treatments apply to alprostadil cream.</li> </ul>
<b>Shared Care/ Transfer of care required:</b>	N/A.
<b>Cost Impact for agreed patient group</b>	<ul style="list-style-type: none"> <li>· The application predicts that approximately 250 patients might be suitable for treatment in SEL per annum.</li> <li>· As the price is broadly comparable to alternatives that are currently on the formulary (slightly cheaper than intraurethral treatment, slightly more expensive than lower doses of intracavernosal injections), no increased costs are expected.</li> </ul>
<b>Usage Monitoring &amp; Impact Assessment</b>	<b>Trusts:</b> <ul style="list-style-type: none"> <li>· Monitor use and submit usage data and audit reports (against this recommendation and the ED pathways) upon request to the SEL IMOC.</li> </ul>
	<b>SEL CCG Borough Medicines Teams:</b> <ul style="list-style-type: none"> <li>· Monitor EPACT 2 data</li> <li>· Exception reports from GPs if inappropriate prescribing requests are made to primary care.</li> </ul>

<b>Evidence reviewed:</b>	<b>References (from evidence evaluation)</b> <ol style="list-style-type: none"> <li>1. Does alprostadil cream hit the spot? Drug and Therapeutics Bulletin 2015 Volume 53 issue 2.</li> <li>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.</li> <li>3. Male Sexual Dysfunction. European Association of Urology. Available online at: <a href="https://uroweb.org/guideline/male-sexual-dysfunction/#3">https://uroweb.org/guideline/male-sexual-dysfunction/#3</a> (accessed 23/09/2020)</li> <li>4. Alprostadil topical cream – Evidence Summary New Medicine. National Institute for Health and Care Excellence 2014.</li> <li>5. Vitaros, Summary of product Characteristics. Available online at: <a href="https://www.medicines.org.uk/emc/medicine/28866">https://www.medicines.org.uk/emc/medicine/28866</a> (accessed 23/09/2020).</li> <li>6. Vitaros 200 micrograms and 300 micrograms, cream. Public Assessment Report of the Medicines Evaluation Board in the Netherlands, November 2013.</li> <li>7. Padma-Nathan H, Yeager JL. An integrated analysis of alprostadil topical cream for the treatment of erectile dysfunction in 1732 patients. Urology 2006; 68: 386–91.</li> <li>8. Rooney M, Pfister W, Mahoney M et al. Long-term, Multicenter Study of the Safety and Efficacy of Topical Alprostadil Cream in Male Patients with Erectile Dysfunction. J Sex Med 2009;6:520–534.</li> </ol>
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**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.**