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

Reference	**120**
Intervention:	**Invicorp™ (aviptadil / phentolamine 25 micrograms / 2mg solution for intracavernosal injection) for the management of erectile dysfunction in adult males**
Date of Decision:	**November 2020**
Date of Issue:	**December 2020**
Recommendation:	**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.**
Further Information:	· Invicorp™ is an intracavernosal injection containing fixed doses of aviptadil and phentolamine and is licensed for the treatment of men ≥ 18 years of age with erectile dysfunction. · Invicorp™ is accepted for use in SEL in line with the agreed pathways for managing erectile dysfunction in primary and secondary care. The following criteria apply to the use of Invicorp™: - Use is restricted as an alternative 2nd line treatment option after intracavernosal alprostadil has been tried but the patient is unable to use it due to pain or intracavernosal doses of alprostadil up to 40mcg are ineffective. - The next option would otherwise be surgery for a penile prosthesis - Additionally, in the interest of consistency with national advice for other similarly administered erectile dysfunction treatments, it has been agreed that locally in SEL, the "selected list scheme" (SLS) criteria for use of erectile dysfunction treatments will also apply to Invicorp™. · Prescribing of Invicorp™ will follow the same due process for initiation and monitoring that is currently used for the intracavernosal alprostadil treatments already included in the SEL formulary (Viridal™ and Caverject™) · Self-administration of Invicorp™ may only be undertaken after proper training. Patients will be trained on the use of the product by the initiating specialist team. · The manufacturer advises patients should be monitored regularly (e.g. every 3 months), particularly in the initial stages of self-injection therapy; careful examination of the penis is recommended to detect signs of penile fibrosis or Peyronie's disease. Treatment should be discontinued in patients who develop penile angulation, cavernosal fibrosis, or Peyronie's disease.
Shared Care/ Transfer of care required:	N/A.
Cost Impact for agreed patient group	· The application predicts that approximately 200 patients might be suitable for treatment in SEL per annum. · As the price is broadly comparable to alternatives that are currently on the formulary, and this treatment is intended to replace another one (therefore costs would be off-set), no increased costs are expected.
Usage Monitoring & Impact Assessment	**Trusts:** · Monitor use and submit usage data and audit reports (against this recommendation and the ED pathways) upon request to the SEL IMOC.
	SEL CCG Borough Medicines Teams: · Monitor EPACT 2 data · Exception reports from GPs if inappropriate prescribing requests are made to primary care.

Evidence reviewed:	**References (from evidence evaluation)** 1. Hackett G, Kirby M, Wylie K, et al. British Society for Sexual Medicine Guidelines on the Management of Erectile Dysfunction in Men—2017. Journal of Sexual Medicine (2018); pages 1-28. 2. European Association of Urology Guidelines 2020. Management of Erectile Dysfunction. Accessed online via: https://uroweb.org/guideline/sexual-and-reproductive-health/#5. Last accessed 18/09/20. 3. National Institute for Health and Care Excellence. Erectile dysfunction: avanafil. Evidence summary [ESNM45] Published date: 12 August 2014. 4. South East London Medicines Formulary. Accessed online via: http://www.selondonjointmedicinesformulary.nhs.uk/default.asp. Last accessed 18/09/20. 5. Scottish Medicines Consortium. Aviptadil / phentolamine 25 micrograms / 2mg solution for injection (Invicorp®) 6. SMC No 1284/17 (November 2017). Accessed via: https://www.scottishmedicines.org.uk/medicines-advice/aviptadilphentolamine-mesilate-invicorp-fullsubmission-128417/. Last accessed 18/09/20. 7. All Wales Therapeutics & Toxicology Centre. Aviptadil/phentolamine mesilate (Invicorp®) 8. 25 micrograms/2 mg solution for injection. Reference number: 3435. Accessed online via: https://awmsg.nhs.wales/medicines-appraisals-and-guidance/medicines-appraisals/aviptadil-phentolamine-invicorp/. Last accessed 18/09/20. 9. Summary of Product Characteristics. Invicorp 25 micrograms / 2 mg solution for injection. Accessed via: https://mhraproducts4853.blob.core.windows.net/docs/4383f63b7de7a90ceb8e8869af2d00161fa6393a. Last revised 13/09/2017. Last accessed 25/09/20. 10. P. J. R. Shah, W. Dinsmore, R. A. Oakes & Geoff Hackett (2007). Injection therapy for the treatment of erectile dysfunction: a comparison between alprostadil and a combination of vasoactive intestinal polypeptide and phentolamine mesilate. Current Medical Research and Opinion; 23:10, pages 2577-2583

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.