

BOB ICB and Frimley ICB Priorities Committee Clinical Commissioning Policy Statement

Policy Number/ Name	BOBFPC34 Erectile Dysfunction
Date of BOB ICB Adoption	March 2024

The Buckinghamshire, Oxfordshire, and Berkshire West ICB and Frimley ICB Priorities Committee has considered the evidence of clinical and cost effectiveness of treatments for erectile dysfunction in adult patients. The publication of the updated Statutory Instrument 2014/1625¹ was taken into account in making the following recommendations:

- 1. Funding for treatment with the phosphodiesterase type -5 inhibitor, generic sildenafil, at the minimum effective dose is **recommended** for any man presenting with erectile dysfunction with a frequency of dosing of four times per month.
- 2. Funding for all other phosphodiesterase type-5 inhibitors (vardenafil, tadalafil and avanafil) is only recommended for patients who meet the Government Selected List Scheme (SLS) criteria^{1,2} AND where generic sildenafil is ineffective. Tadalafil can be prescribed with a frequency of four doses per month and should be the second line choice. Vardenafil and avanafil would be 3rd and 4th line choice respectively with a frequency of dosing of two times per month.
- 3. Tadalafil 5mg Once daily can be considered for patients who anticipate sexual activity at least twice a week or other phosphodiesterase type-5 inhibitor ineffective or not tolerated, or for patients with concomitant lower urinary tract symptoms and erectile dysfunction.
- 4. Funding for treatment with prostaglandin E1 intracavernosal injections and intraurethral instillations is only recommended for patients who meet the SLS criteria^{1,2} AND only if oral phosphodiesterase type-5 inhibitors are contraindicated or ineffective. The maximum frequency of dosing should be two times per month using the drug with the lowest acquisition cost.
- 5. Funding for the treatment with Invicorp[®] (Aviptadil with phentolamine) is only recommended for patients who meet the SLS criteria^{1,2} who have not responded to oral phosphodiesterase type-5 inhibitors or are contraindicated AND alprostadil injections are contraindicated, ineffective or cause significant pain. The maximum frequency of dosing should be two times per month.
- 6. Treatment with Alprostadil cream is **not normally funded** in view of limited evidence for clinical and cost effectiveness.

- 7. Treatment with penile implants is not normally funded by the ICB. Penile Prosthesis surgery for end stage erectile dysfunction is commissioned by NHS England, please see <u>NHS England Clinical Commissioning policy (2016)</u>
- 8. Treatment with psychosexual interventions is **not normally funded** in view of limited evidence for clinical and cost effectiveness.

Phosphodiesterase type-5 inhibitors (sildenafil, vardenafil and tadalafil) are oral drugs that enable a penile erection with sexual stimulation. There is evidence for the effectiveness of these drugs in men with erectile dysfunction of varying causes. The effectiveness of individual drugs is comparable and generic sildenafil has been shown to be cost-effective. The SLS restrictions set out in Statutory Instrument 1999/1627² apply to all phosphodiesterase type-5 inhibitors except generic sildenafil.

Prostaglandin E1 is used in the treatment of erectile dysfunction when delivered locally into penile tissues. There is evidence for the effectiveness of intra-cavernosal injections of prostaglandin E1 in those unresponsive to oral drugs.

Psychosexual interventions such as counselling and psychotherapy comprise a group of techniques with limited evidence for effectiveness and no evidence of cost-effectiveness.

Vacuum erection devices are mechanical devices for producing an erection that is sustained with the placement of a constricting band across the base of the penis. There is limited evidence for the effectiveness of these devices and no evidence of cost-effectiveness.

Penile implants can be surgically inserted into the penis for treating erectile dysfunction. There is limited evidence of effectiveness with a high proportion of patients having major complications.

NOTES:

- Potentially exceptional circumstances may be considered by a patient's ICB where there is evidence of significant health status impairment (e.g. inability to perform activities of daily living) and there is evidence that the intervention sought would improve the individual's health status.
- This policy was developed and recommended by Thames Valley Priorities Committee which was the predecessor of Buckinghamshire, Oxfordshire, and Berkshire West ICB and Frimley ICB Priorities Committee. Amendments have been approved by BOB APC.
- This policy will be reviewed in the light of new evidence or new national guidance, e.g. from NICE.
- BOBFPC clinical policies can be viewed at <u>Clinical Commissioning Policies & IFRs | BOB ICB</u>

Version	Date	Reason for change
Version 1	July 2016	New policy
Version 2	July 2017	
Version 2.1	January 2019	No changes
Version 3	July 2023	Amendments approved by BOB APC (changes not reviewed by BOBFPC)
Version 4	March 2024	Amendments (inclusion of tadalafil 5mg once daily) approved by BOB APC (changes not reviewed by BOBFPC)

¹ <u>http://www.legislation.gov.uk/uksi/2014/1625/pdfs/uksi_20141625_en.pdf</u>

²<u>http://www.legislation.gov.uk/uksi/1999/1627/pdfs/uksi_19991627_en.pdf</u>