NHS
Frimley
Clinical Commissioning Group

Medicines Optimisation Position Statement

Position Statement	**Treatments for Erectile Dysfunction**
Number	009
Approved by Medicines Optimisation Group:	July 2022
Date of issue:	July 2022
Date of last review:	Nov 2021: Thames Valley Priorities Committee Policy Statement TVPC34
Date of planned review	July 2024 or in the event of new evidence or new national guidance

The Frimley Medicines Optimisation Group has considered the evidence of clinical and cost effectiveness of treatments for erectile dysfunction in adult patients. The publication of the updated Statutory Instrument 2014/1625 was considered in making the following recommendations[1],[2]

Treatments for erectile dysfunction will be funded after considering the following:

1. First line treatment is the phosphodiesterase type -5 inhibitor, generic sildenafil, at the minimum effective dose for any man presenting with erectile dysfunction with a maximum frequency of two doses per week.

2. Tadalafil, as an alternative phosphodiesterase type-5 inhibitor is recommended only for patients who meet the Government Selected List Scheme (SLS) criteria AND where generic sildenafil is ineffective. Depending on patient choice and lifestyle factors, tadalafil may be prescribed at the minimum effective “when required” dose, with a maximum frequency of two doses per week, or alternatively, due to the availability of a cost effective option, generic once daily 5mg tadalafil may be prescribed if sexual activity is anticipated twice a week or more.

   Note: Tadalafil 2.5mg tablets are not a cost effective option (July 2022) and remain non formulary.

3. Funding for treatment with prostaglandin analogues (alprostadil urethral application, skin application, intracavernosal injection,) are recommended only for patients who meet the SLS criteria AND only if oral phosphodiesterase type-5 inhibitors are contraindicated or ineffective. The maximum frequency of dosing should be four times per month using the drug with the lowest acquisition cost. Treatment with prostaglandin analogues must be initiated under specialist supervision

4. Treatment with vacuum erection devices is not normally funded in view of limited evidence for clinical and cost effectiveness.

5. Penile implants are commissioned by NHS England for end stage erectile dysfunction[3]

6. Treatment with psychosexual interventions is not normally funded in view of limited evidence for clinical and cost effectiveness.

Penile rehabilitation following radical prostatectomy

Due to inadequate evidence of clinical effectiveness and lack of evidence of cost effectiveness, NHS funding for the early regular use of phosphodiesterase-5 (PDE5) inhibitors, alprostadil and vacuum erection devices for penile rehabilitation in patients with prostate cancer after radical prostatectomy are considered interventions not normally funded. NICE guideline [NG131] Prostate cancer: diagnosis and management (Dec 2021), does not make recommendations on treatments specific to penile rehabilitation.

Further Information

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 restrictions for prescribing set out in Statutory Instrument 1999/1627 apply to all phosphodiesterase type-5 inhibitors except generic sildenafil.

Prostaglandin analogues are used in the treatment of erectile dysfunction when delivered locally to penile tissues. There is evidence for the effectiveness of intracavernosal injections 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 (VEDs) are external, mechanical pumps (battery-operated and manually-operated) which are used to help men with erectile dysfunction to get an erection. The erection is sustained with the placement of a constricting band across the base of the penis. The devices work by increasing arterial flow to the corpora cavernosa and by decreasing venous outflow once the constriction ring is applied. Once the band is removed, the penis can return to a flaccid state.

Overall, there is weak evidence suggesting that VED devices may be useful for some patients with erectile dysfunction. Inclusion criteria varied and limited information was reported regarding patient characteristics such as the severity of disease or the presence of comorbidities. Many studies quoted predate PDE5is and no recent systematic reviews or RCTs comparing the effectiveness of VEDs to other interventions could be identified. (Full evidence review contributed to South, Central and West Commissioning Support Unit, SHIP Priorities Committee) [4].

Patients may stop using the pump due to the difficulty or inconvenience of using the device which can lead to potential waste. Most men can use a pump safely, though if prescribed an oral anticoagulant, there may be a higher risk of complications. Adverse events include pain, inability to ejaculate, petechiae, bruising, coldness, and numbness.

Benign Prostatic Hyperplasia: NICE terminated their technology appraisal (TA273) due to receiving no evidence from the manufacturer. In NICE CG97: Lower Urinary Tract Symptoms in Men NICE state that there is not enough evidence to recommend phosphodiesterase inhibitors in routine clinical practice.

NOTES:

- Potentially, exceptional circumstances may be considered 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.

[1] https://www.legislation.gov.uk/uksi/2004/629/schedule/2/made
[1] https://www.legislation.gov.uk/uksi/2014/1625/pdfs/uksi_20141625_en.pdf
[1] https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/08/clinical-com-pol-16059p.pdf
[1] https://www.hampshiresouthamptonandisleofwightccg.nhs.uk/reports/505-ship-policy-update-erectile-dysfunction-2020-v1-0/file