

PREScribing POLICY: DRUGS AND DEVICES USED IN THE TREATMENT OF ERECTILE DYSFUNCTION

SUMMARY

Where drug treatment is indicated, **generic sildenafil** (at the minimum effective dose) is the **first line choice** of drug to be used in the treatment of erectile dysfunction in the Medway and Swale local health economy.

Where clinically appropriate, generic sildenafil may be prescribed to any man requiring treatment for erectile dysfunction. Prescriptions for generic sildenafil do not need to be endorsed 'SLS'.

Alprostadil, Avanafil, Tadalafil, Vardenafil and Viagra® will only be prescribed at NHS expense, for men who meet the medical conditions and circumstances specified by the Department of Health.

The maximum frequency of dosing will not exceed ONE tablet per week (i.e. four tablets per MONTH).

Where generic sildenafil is ineffective or contra-indicated and the patient does not meet the NHS criteria for drugs other than generic sildenafil, a private prescription can be provided.

Background

This document aims to outline the criteria by which medicines used for the treatment of erectile dysfunction (ED) can be prescribed at NHS expense and the quantities that can be prescribed.

Non-pharmacological interventions¹

Many men experience episodes of ED that improves without the need for treatment.

Self care advice should always be provided for men with ED. Lifestyle changes should always be tried before drug treatment is considered. Recommended lifestyle changes include:

- Weight loss
- Smoking cessation
- Reduction in alcohol consumption
- Increased exercise
- Men who cycle for more than 3 hours per week may be encouraged to trial a period without cycling to see if this improves their ED.

Ensure that other causative factors such as diabetes, drug induced ED are ruled out. The British Society for Sexual Medicine (BSSM) has produced guidance which outlines other investigations that might be undertaken on men newly presenting and provides lists of

medicines known to cause ED. In some cases, treating the underlying condition can lead to a cure for the ED².

If symptoms persist despite lifestyle changes, consider prescribing a Phosphodiesterase Type-5 (PDE-5) inhibitor.

Prescribing of drug treatments for erectile dysfunction on the NHS.

On August 1st 2014, new legislation was introduced removing the restrictions on NHS prescribing of apomorphine hydrochloride, moxislyte hydrochloride, **generic sildenafil** and thymoxamine hydrochloride for the management of erectile dysfunction. Prescriptions for these drugs no longer need to be endorsed 'SLS' and may be prescribed on the NHS for any suitable patient.³

All other products - Alprostadil, Avanafil, Tadalafil, Vardenafil and Viagra® - continue to be restricted and can only be prescribed at NHS expense in line with Department of Health guidance (HSC 1999/115,148)^{4,5}. This guidance states that drugs used for the treatment of ED may be prescribed on an NHS prescription for men who:

- Have diabetes, multiple sclerosis, Parkinson's disease, poliomyelitis, prostate cancer, severe pelvic injury, single gene neurological disease, spina bifida, or spinal cord injury
- Are receiving dialysis for renal failure
- Have had radical pelvic surgery, prostatectomy, or kidney transplant
- Were receiving Caverject®, Erecnos®, MUSE®, Viagra or Virdal® for ED, at the expense of the NHS on 14th September 1998
- Are suffering severe distress as a result of impotence (prescribed in specialist centres only, see British National Formulary).⁶

Only patients who meet the criteria specified above must be issued FP10 prescriptions for these drugs (Alprostadil, Avanafil, Tadalafil, Vardenafil and Viagra®) and the prescription must be endorsed 'SLS' (selected list scheme). If the patient is not eligible for the ED medicines mentioned above on the NHS then a private prescription should be provided.

Choice of medication

Phosphodiesterase Type-5 (PDE-5) inhibitors are by far the most convenient treatment for erectile dysfunction. Although other treatments are effective, they are usually more difficult and less pleasant to use. The PDE-5 inhibitors include sildenafil (Viagra®), tadalafil (Cialis®), vardenafil (Levitra®) and avanafil (Spedra®).

Step 1: Where a PDE-5 inhibitor is indicated, **generic sildenafil should be used first line at the lowest effective dose.** (Note: Revatio® brand 20mg tablet of sildenafil is only licensed for the treatment of pulmonary arterial hypertension).

Treatment failure:¹

If treatment has not been satisfactorily effective:

- Counsel about the appropriate use of phosphodiesterase-5 (PDE-5) inhibitors. Ensure that the man is aware that PDE-5 inhibitors are not initiators of erection but require sexual stimulation in order to facilitate erection.
- Reconsider comorbidities and treat where possible. In particular, consider the possibility of hypogonadism (which makes PDE-5 inhibitors ineffective).
- Consider increasing to the maximum dose, or switching to an alternative PDE-5 inhibitor. (The effect of PDE-5 inhibitors are partly dose-dependent, so increasing the dose may overcome lack of effect). If this fails, consider referral.

A person with erectile dysfunction should receive eight doses of a PDE-5 inhibitor at a maximum dose with sexual stimulation before being classified as a non-responder.

Second line PDE-5 inhibitors¹: There is anecdotal evidence that a man may respond to a different PDE-5 inhibitor, therefore it is worth trialling a different drug before classing PDE-5 inhibitors as ineffective.

Before deciding which medication to prescribe, the characteristics of the PDE-5 inhibitors listed in the table below should be taken into consideration and an informed choice of drug be made with the patient.

Table 1: Summary of pharmacokinetic properties of PDE-5 inhibitors⁷				
Properties	Sildenafil	Vardenafil	Tadalafil (on demand)	Avanafil
Half life	2.5-3.5hrs	3-4hrs	17.5hrs	4-6hrs
Onset of action	30-60mins	30mins	30mins-2hrs	30mins-45mins
Affected by food	Yes	Yes	No	No
Price (4 tablet pack as at Drug Tariff Sept 2014)	£1.05 - £1.20	£7.56 - £14.08	£26.99	£10.94 - £39.40
Suitable patient cohort			Consider for use only if a longer acting preparation is required e.g. may be an option in young patients	

Daily preparations are currently not on formulary and should not be routinely prescribed.

Quantities that can be prescribed

The Department of Health Treatment for Impotence: Health Service Circular 1999/148⁴ advises that 'one treatment per week will be appropriate for most patients being treated for erectile dysfunction'.

This advice is based on research evidence about the frequency of sexual intercourse which showed that the average frequency of sexual intercourse in the 40-60 age range is once a week. It is also based on the fact that some treatments for impotence have been found to have a "street value" for men who consider, rightly or wrongly, that these treatments will enhance their sexual performance and that excessive prescribing could therefore lead to unlicensed, unauthorised and possibly dangerous use of these treatments.

In light of the pressure on NHS budgets, patients who are eligible for NHS treatment should be prescribed the lowest effective dose, with a maximum frequency of dosing of ONE tablet per week (i.e. FOUR tablets per MONTH).

Private prescriptions

For those NHS patients not meeting the NHS criteria for drugs other than generic sildenafil, a private prescription can be provided. These should be provided free of a prescription writing charge. Repeats can be provided on private prescriptions. When a private prescription is written the cost of the medication will be determined by the pharmacy at which it is presented. Dispensing doctors may charge for supplying the medicine, but not for associated prescribing, advice or consultation.

Vacuum pumps

Vacuum pumps are to be initiated in secondary care as assessment of the condition and training on the use of the device is undertaken in secondary care. Penile constrictor rings (replacement rings for use with vacuum pumps) may be prescribed in primary care following specialist initiation.

References

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