

# Drugs used in Primary Care for the treatment of erectile dysfunction (ED)

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# **Document Amendment History**

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The formally approved version of this document is that held on the NHS Shropshire, Telford and Wrekin CCG website: www.shropshiretelfordandwrekinccg.nhs.uk

Printed copies or those saved electronically must be checked to ensure they match the current online version.

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# 1 Commissioning Statement

Shropshire, Telford and Wrekin Clinical Commissioning Group (CCG) support the prescribing of the following treatments for erectile dysfunction (ED) in line with the criteria outlined by this policy:

PDE-5 inhibitors are currently recommended as first-line treatment for ED: 1

- Generic sildenafil should be used first line, at the lowest effective dose. (NB: Revatio® brand (20mg tablet) of sildenafil is only licensed for the treatment of pulmonary arterial hypertension)
- Tadalafil on demand (10mg or 20mg tablets) is the second line formulary choice for a PDE-5 inhibitor and should only be prescribed at NHS expense for men who meet the specific conditions as defined by the Selected List Scheme- see below. Prescriptions must be endorsed "SLS".
- Prescribing of ONCE DAILY tadalfil for ED is not supported in-line with <u>NHSE guidance</u>:
   "Items which should not routinely be prescribed in primary care"

Several treatments for erectile dysfunction are available in secondary care, although none are as convenient or well tolerated as PDE-5 inhibitors: 1

• Formulary choice for specialist initiated or recommended treatment is alprostadil as an intracavernous injection (Caverject®, Viridal®Duo) or an intraurethral application (MUSE®, limited to 4 urethral sticks per month).

### 2 Clinical criteria

Many men experience episodes of ED that improves without the need for treatment. Where possible, any reversible or modifiable risk factors including lifestyle or drug-related factors should be identified and managed prior to commencing pharmacological interventions.

### Non-pharmacological interventions <sup>1</sup>

### Recommended lifestyle changes include:

- Smoking cessation
- Weight loss
- Increased physical activity
- Dietary changes to reduce saturated fat and cholesterol levels
- Reduction in stress
- 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 erectile dysfunction

Ensure that any underlying conditions, such as diabetes and some cardiovascular problems (for example hypertension, hyperlipidaemia), are well controlled. In some cases, treating the underlying condition can lead to a cure for the ED.

### Drugs associated with ED include: 1

- Antihypertensives: Beta-blockers, verapamil, methyldopa, and clonidine.
- Diuretics: Spironolactone and thiazides
- Antidepressants: Tricyclics, monoamine oxidase inhibitors, selective serotonin reuptake inhibitors

- Antiarrhythmic drugs: Digoxin, amiodarone.
- Antipsychotics: Chlorpromazine, haloperidol.
- Hormones and hormone-modifying drugs: Antiandrogens (flutamide, cyproterone acetate), luteinising hormone releasing hormone agonists (leuprorelin, goserelin), corticosteroids, 5-alpha reductase inhibitors (for example finasteride).
- Histamine (H2)-antagonists: Cimetidine, ranitidine.
- Recreational drugs: Alcohol, heroin, cocaine, marijuana, methadone, synthetic drugs, anabolic steroids.

Where pharmacological intervention is required, treatments for ED should be prescribed in line with the following clinical criteria:

On the 1st August 2014 new legislation was introduced removing the restrictions on the prescribing of generic sildenafil for the management of erectile dysfunction. Generic sildenafil may now be prescribed, where clinically appropriate, to any man requiring treatment for erectile dysfunction. Prescriptions for generic sildenafil no longer need to be endorsed 'SLS'.

All other formulary drug treatments (alprostadil, tadalafil, and branded Viagra®) cannot be prescribed at NHS expense except for men who meet certain medical conditions as listed in part XVIIIB of the Drug Tariff. <sup>2</sup> In these cases, prescriptions must be endorsed "SLS". The medical conditions listed are:

- Diabetes
- Multiple sclerosis
- Parkinson's disease
- Poliomyelitis,
- Prostate cancer,
- Severe pelvic injury
- Single-gene neurological disease (for example Huntington's disease)
- Spina bifida, or spinal cord injury
- Renal failure treated with dialysis or transplant
- Radical pelvic surgery
- Prostatectomy (including transurethral resection of the prostrate)

Additionally those men receiving a course of NHS drug treatment who were not included in the above categories but were receiving Caverject®, MUSE®, Viagra®, or Viridal® for NHS treatment for ED on 14 September 1998 will continue to be eligible to receive drug treatment at NHS expense.

Only patients who meet the criteria specified above must be issued FP10 prescriptions for these drugs 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.

## 3 Prescribing guidance

### 3.1 Quantities to be prescribed

The Department of Health Treatment for Impotence: Health Service Circular 1999/148<sup>3</sup> advises that 'One treatment per week will be appropriate for most patients being treated for erectile dysfunction'.

Patients who are eligible for NHS treatment should be prescribed the lowest effective dose, with a maximum frequency of ONE dose per week (i.e. FOUR tablets per MONTH).

Prescribers may also wish to consider the following statement from the Health Service Circular in prescribing these medications: '[Prescribers] may also wish to bear in mind 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'

### 3.2 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.

# 4 Summary of recommendations

- Where clinically appropriate generic sildenafil may be prescribed to any man requiring treatment for ED. Prescriptions for generic sildenafil do not need to be endorsed 'SLS'.
- All other drug treatments cannot be prescribed at NHS expense except for men who meet certain medical conditions as listed in part XVIIIB of the Drug Tariff. In these cases, prescriptions must be endorsed "SLS".<sup>2</sup>
- Identify and, where possible, manage any reversible or modifiable risk factors including lifestyle or drug-related factors.<sup>1</sup>
- Where drug treatment on prescription is indicated, **generic sildenafil (at the minimum effective dose) is the first line formulary choice** of drug to be used in the treatment of ED.
- Where generic sildenafil is inappropriate or ineffective and the patient does not meet the NHS criteria for drugs other than generic sildenafil, a private prescription can be provided.
- Tadalafil on demand (10mg or 20mg tablets) is the second line formulary choice for a PDE-5 inhibitor and should only be prescribed at NHS expense for men who meet the medical conditions and circumstances specified by the Department of Health.<sup>3</sup>
- Prescribing of ONCE DAILY tadalfil is not supported for the treatment of ED in line with <a href="NHSE guidance">NHSE guidance</a>: "Items which should not routinely be prescribed in primary care"
- Formulary choice for specialist initiated or recommended treatment is alprostadil as an intracavernous injection (Caverject®, Viridal®Duo) or an intraurethral application (MUSE®).
- Quantities to be prescribed: The Department of Health's original guidance on frequency of
  use advises that one treatment per week will be appropriate for most patients. It is therefore
  recommended that the usual frequency of dosing should not exceed one treatment per week.

### 5 Advice

For further advice on this document please contact:

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### 6 References

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- 2. https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff
- 3. Department of Health. Treatment of impotence. NHS Executive Health Service Circular 1999/148 June 1999