Guidance for prescribing of drugs in erectile dysfunction in primary care (updated 2014)

Summary

BHR CCGs preferred choice of phosphodiesterase-5 (PDE5) inhibitor is generic sildenafil.

There are no restrictions on the quantity or criteria for prescribing generic sildenafil.

For patients who are taking other medicines for erectile dysfunction, prescribers may wish to consider trialling a one-off acute prescription of sildenafil with the proviso that patients can go back to their usual medicine if they still prefer it.

Other drugs for the treatment of erectile dysfunction can be prescribed in line with the Department of Health guidance and must be endorsed 'SLS' on the prescription. One treatment per week will be appropriate for most patients, however, there will be some patients who may be suitable for the once daily preparations but this will be subject to the prescriber's clinical judgement.

1. Background

The purpose of this guidance is to provide an update on the criteria by which drugs used for the treatment of erectile dysfunction (ED) can be prescribed on the NHS and the quantities that can be prescribed.

Since this guidance was first produced in 2012, generic sildenafil has been made available in 2013 and the restrictions for prescribing this have been removed in 2014.

Other non-ED indications which can be treated by these drugs for example, PDE5 inhibitors for benign prostatic hyperplasia are not covered in this document.

2. Choice of medication

BHR CCGs preferred prescribing choice of PDE5 inhibitor is generic sildenafil (25mg, 50mg and 100mg tablets).

Please note that the Revatio® brand of sildenafil (20mg tablet, 10mg/ml oral suspension and 800mcg/ml injection) is only licensed for the treatment of pulmonary arterial hypertension.

Consider switching appropriate patients on tadalafil or vardenafil to generic sildenafil.

3. Prescribing on the NHS

3.1 Criteria

The Department of Health guidance (HSC 1999/115,148)[1,2] states that specified drugs used for the treatment of erectile dysfunction may be prescribed on an NHS prescription for men who:

- Have diabetes, multiple sclerosis, Parkinson's disease, poliomyelitis,
- Have renal failure treated by transplant or dialysis
- Have had radical pelvic surgery; prostatectomy and/or have been treated for prostate cancer (surgery and other treatment)
- Have had severe pelvic injury, single-gene neurological disease, spinal cord injury, spina bifida
- Were not included in the above categories but were receiving Caverject®, MUSE®, Viagra®, or Viridal® for NHS treatment of impotence on 14 September 1998

3.2 Schedule 2 list of medicines that can be prescribed for ED

In 2014, the Department of Health published a government response to the consultation of a proposal[3] to remove the prescribing restrictions for sildenafil because Viagra® lost its UK patent protection in June 2013 and cheaper generic products were now available.

The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004[4] Schedule 2 (Drugs, medicines and other substances that may be ordered only in certain circumstances) list of medicines that can be prescribed for the treatment of erectile dysfunction has now been amended in 2014[5] to:

- Alprostadil (Caverject®, MUSE®, Viridal®, Vitaros®[6])
- Avanafil (Spedra®)- **NEW ENTRY**
- Tadalafil (Cialis®)
- Vardenafil (Levitra®)
- Viagra®

3.3 Prescribing and endorsing SLS

Prescriptions that meet the criteria in 3.1 and include the medicines listed in 3.2 should be endorsed 'SLS' (selected list scheme) [2,7] by the prescriber.

3.4 Prescribing for severe distress

The Department of Health guidance (HSC 1999/177)[8] states that prescribing for the treatment of erectile dysfunction for men diagnosed to be suffering from

severe distress on account of their impotence should be managed within specialist services. Due to amendments to the 2004 regulations[4], it is now possible for patients suffering from severe distress due to ED to be prescribed generic sildenafil from their own GP, rather than attend a specialist service.

3.5 Quantities

The Department of Health Treatment for Impotence: Health Service Circular 1999/148[2] advises that '**One treatment per week will be appropriate for most patients being treated for erectile dysfunction.** If the GP in exercising his clinical judgement considers that more than one treatment a week is appropriate he should prescribe that amount on the NHS.' However in 2009, due to the release of daily dose treatments (Cialis®), the Department of Health clarified that in exercising their clinical judgement, GPs may consider these preparations suitable for a small number of patients[9]. Due to amendments to the 2004 regulations[4], the restriction in the number of treatments do not apply for generic sildenafil and may help in switching appropriate patients on Schedule 2 medicines who are only prescribed one treatment per week.

3.6 Tadalafil

Tadalafil is approved for use in patients post-prostatectomy at BHRUT[10] (Barking Havering Redbridge University Hospital NHS Trust).

3.7 Alprostadil

If the patient is appropriate for treatment with alprostadil, prescribe by brand name because both the injections and the urethral presentations come with special injection devices/applicators for which patients require training to use[3].

3.8 Private Prescriptions

For those NHS patients (excluding those prescribed generic sildenafil) not meeting the NHS criteria, a private prescription should be provided. These should be provided free of a prescription writing charge[2]. Repeats can be provided on private prescriptions. When a private prescription is written the cost of the medication will be determined by the dispensing pharmacy.

3.9 Street Value

Prescribers may also wish to consider the following statement from the Health Service Circular in prescribing these medications[2]: '*[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.'*

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