

Guidance for prescribing of drugs in erectile dysfunction in primary care

Summary

- BHR CCGs preferred choice of phosphodiesterase-5 (PDE5) inhibitor is generic sildenafil (25mg/50mg/100mg) OR tadalafil (10mg/20mg)
- There are no restrictions on the quantity or criteria for prescribing generic sildenafil
- Prescribing of generic tadalafil (10mg/20mg) and other drugs for the treatment of erectile dysfunction can be prescribed in line with the Department of Health guidance and must be endorsed 'Selected List Scheme (SLS)' on the prescription

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) OR generic tadalafil (10mg or 20mg). Viagra Connect® is available OTC. 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 and should not be prescribed in primary care.

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

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 proposal³ 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 2004⁴ 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 2014⁵ to:

- Alprostadil (Caverject[®], MUSE[®], Viridal[®], Vitaros^{®6})
- Avanafil (Spedra[®])
- 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 by the prescriber.

3.4 Prescribing for severe distress

The Department of Health guidance (HSC 1999/177)⁷ 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 regulations⁴, 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 1999/148² advises that '**One treatment per week will be appropriate for most patients being treated for erectile dysfunction.** However, the guidance also states that if the GP, in exercising their clinical judgement, consider that more than one treatment per week is appropriate, then that amount may be prescribed on the NHS. When prescribing these products please consider that these drugs do have a street value and quantities should be agreed after a discussion with the patient assessing realistic needs.

3.6 Tadalafil

Following the NHS England guidance "items which should not be routinely be prescribed in primary care: Guidance for CCGs⁵ (version 2, June 2019) the decision to stop Tadalafil (2.5mg/5mg) **once daily** applies to ALL patients across Barking and Dagenham, Havering and Redbridge. BHR CCGs have agreed NO exceptions to this recommendation.

3.7 Vacuum Pumps and Alprostadil preparations

These are alternatives to PDE5 inhibitors for the treatment of ED offered by secondary care. Patients should be assessed for suitability by the specialist and prior PDE5 treatment is required before referral to the specialist services. 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 use³.

3.8 Private Prescriptions

For those NHS patients not meeting the NHS criteria, a private prescription can be provided. These should be provided free of a prescription writing charge². Repeats can be provided on private prescriptions. When a private prescription is written the cost of the medication will be determined by each pharmacy on an individual basis.

References

1. Department of Health, NHS Executive Health Service Circular 1999/115 May 1999
http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012070.pdf
2. Department of Health, NHS Executive Health Service Circular 1999/148 June 1999
http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012086.pdf
3. Department of Health, Proposed Changes to NHS availability of erectile dysfunction treatments: changing prescribing restrictions for sildenafil: government response to consultation. June 2014
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/322464/ED_Cons_response.pdf
4. National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 No 629 National Health Service, England
http://www.legislation.gov.uk/uksi/2004/629/pdfs/uksi_20040629_en.pdf
5. NHS England and NHS Improvement. Items which should not routinely be prescribed in primary care: Guidance for CCGs. Version 2, June 2019. Publishing approval reference 000608 <https://www.england.nhs.uk/publication/items-which-should-not-be-routinely-prescribed-in-primary-care-guidance-for-ccgs/>
6. The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2014 No 1625 National Health Service, England
http://www.legislation.gov.uk/uksi/2014/1625/pdfs/uksi_20141625_en.pdf
7. Department of Health, NHS Executive Health Service Circular 1999/177 August 1999
http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012101.pdf
8. DH clarify guidance around new daily dose treatments for impotence. On the Horizon Stop Press. National Prescribing Centre. 9 March 2009
<http://www.npc.nhs.uk/rapidreview/?p=292>