




## Prescribing oral phosphodiesterase type-5 inhibitors for erectile dysfunction

### Phosphodiesterase type-5 inhibitors<sup>1,2,3,4,5</sup>

- Sildenafil, tadalafil, avanafil and vardenafil are phosphodiesterase type-5 inhibitors licensed for the treatment of erectile dysfunction
- These drugs with the exclusion of generic sildenafil<sup>5</sup> should not be prescribed on the NHS , except to treat erectile dysfunction in 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 (including transurethral resection of the prostate), or kidney transplant;
  - were receiving Alprostadil (*Caverject*®), Alprostadil (*MUSE*®), Alprostadil (*Viridal*®), Apomorphine hydrochloride (*Uprima*®), Moxisylyte hydrochloride (*Erecnos*®), Sildenafil (*Viagra*®), Tadalafil (*Cialis*®), Thymoxamine hydrochloride (*Erecnos*®) for erectile dysfunction, at the expense of the NHS, on 14 September 1998;
  - are suffering severe distress as a result of impotence (**prescribed in specialist centers only**, see below)
- The prescription must be endorsed 'SLS' (Selected List Scheme) except for generic sildenafil<sup>5</sup>

### Prescribing on the NHS – Key Points from the Health Service Circulars 1999/148 and 1999/177

- Drug treatments excluding generic sildenafil<sup>5</sup> for erectile dysfunction may only be prescribed on the NHS under certain circumstances<sup>1,4</sup>
- The regulations which came into effect on 1<sup>st</sup> July 1999 limit the use of NHS prescriptions by GPs for the treatment of impotence<sup>3</sup>
- The frequency of treatment will need to be considered on a case by case basis, but doctors may find it helpful to bear in mind the research evidence (*Johnson A, Wadsworth J, et al, Sexual Attitudes and Lifestyle Survey, UK 1990-91, 1994*) which shows that the average frequency of sexual intercourse in the 40-60 age range is once a week. The Department of Health advises doctors that one treatment a week will be appropriate for most patients treated for erectile dysfunction<sup>3,4</sup>
- Generic sildenafil is available for the treatment of erectile dysfunction on the NHS and therefore GPs must not prescribe generic sildenafil on private prescription for their own patients for the treatment of erectile dysfunction

### Referral to specialist centers

- Treatment may be available from specialist services (commissioned by Health Authorities and Clinical Commissioning Groups, and operating under local agreement) for those men who are not eligible for NHS prescriptions from their GP to treat their impotence<sup>3</sup>
- The decision about referral of individual patients for specialist services is a matter for the clinical judgement of the GP concerned who may arrange for the referral of patients as appropriate<sup>3</sup>
- The Department of Health recommends that a referral should be made where the GP is satisfied that the man is suffering from impotence and that this impotence is causing him severe distress<sup>3</sup>

- In determining whether a patient is suffering from severe distress it is recommended that the following criteria should be taken into account<sup>3</sup>:
  - significant disruption to normal social and occupational activity
  - marked effect on mood, behavior, social and environmental awareness
  - marked effect on interpersonal relationships
- Patients who are prescribed treatment for impotence causing severe distress on the NHS by specialist centers would need to continue to receive their treatment through the specialist services<sup>3</sup>
- Where the GP or specialist determines that NHS prescriptions are not appropriate for individual patients, drug treatment may be prescribed privately by the GP<sup>3</sup>
- If GPs have been asked to prescribe a phosphodiesterase type-5 inhibitor for impotence that is causing severe distress *at the request of a consultant specialist*, then they should use the attached WSCCG Prescribing Responsibility Form to defer the prescribing back to secondary care:

<http://www.westsuffolkccg.nhs.uk/wp-content/uploads/2013/01/Prescribing-responsibility-form.pdf>

- The full Health Service Circular documents and Statutory Instruments are available here:

<http://www.westsuffolkccg.nhs.uk/wp-content/uploads/2013/01/Change-to-Sildenafil.pdf>

<http://www.westsuffolkccg.nhs.uk/wp-content/uploads/2013/01/HSC-1999-148-Treatment-for-Impotence.pdf>

<http://www.westsuffolkccg.nhs.uk/wp-content/uploads/2013/01/HSC-1999-177-Treatment-for-Impotence.pdf>

NHS WSCCG Traffic Light System September 2014		
Drug or therapy area	Decision	Indication
Erectile dysfunction excluding generic sildenafil <sup>5</sup>	Double red - No prescribing	Patients not covered by the Health Service Circular 1999/177 ( <i>as detailed above</i> )
Erectile dysfunction excluding generic sildenafil <sup>5</sup>	Red - Hospital only	Patients with "severe distress" ( <i>including on-going treatment, as detailed above</i> )
Erectile dysfunction excluding generic sildenafil <sup>5</sup>	Primary Care	Patients covered by the Health Service Circular 1999/177 for this category ( <i>as detailed above</i> )
Generic sildenafil	Primary Care	Erectile dysfunction

Choice of phosphodiesterase type-5 inhibitor <sup>1,2</sup>											
Avanafil			Sildenafil			Tadalafil*			Vardenafil		
Brand	Strength	Cost for once weekly treatment <sup>1</sup> (4tablets/month)	Brand	Strength	Cost for once weekly treatment <sup>1</sup> (4tablets/month)	Brand	Strength	Cost for once weekly treatment <sup>1</sup> (4tablets/month)	Brand	Strength	Cost for once weekly treatment <sup>1</sup> (4tablets/month)
Spedra®	50mg 100mg 200mg	£10.94 £14.08 £21.90	Viagra®	25mg 50mg 100mg	£16.59 £21.27 £23.50	Cialis®	10mg 20mg	£26.99 £26.99	Levitra®	5mg 10mg 20mg	£7.56 £14.08 £23.48
Generic	Strength	Cost for once weekly treatment <sup>1</sup> (4tablets/month)	Generic	Strength	Cost for once weekly treatment <sup>1</sup> (4tablets/month)	Generic	Strength	Cost for once weekly treatment <sup>1</sup> (4tablets/month)	Generic	Strength	Cost for once weekly treatment <sup>1</sup> (4tablets/month)
Not yet available	-	-	Available since July 2014	25mg 50mg 100mg	£1.23 £1.08 £1.15	Not yet available	-	-	Not yet available	-	-

Generic sildenafil is currently the most cost-effective oral phosphodiesterase type-5 inhibitor for the treatment of erectile dysfunction. The WSCCG advocates the prescribing recommendation “≥ 80% of all oral erectile dysfunction drug items to be prescribed as generic sildenafil”; further cost-effective drug options may be included in this prescribing recommendation as patents expire.

\*Note: Tadalafil (Cialis®) once-a-day 2.5mg and 5mg tablets are not recommended as they are not cost-effective in most patients. Cialis® on-demand 10mg or 20mg tablets are the preferred option, with a maximum supply of 4 doses per month. Patients currently receiving Cialis® once-a-day 2.5mg or 5mg tablets should be considered for a switch to the on-demand 10mg or 20mg tablets, taken on a ‘when required’ intermittent basis, with a maximum supply of 4 doses per month. The WSCCG procedure to assist doctors/pharmacists/technicians with this switch is available here:

<http://www.westsuffolkccg.nhs.uk/wp-content/uploads/2013/01/Tadalafil-once-a-day-v11.pdf>

## References

1. British National Formulary Online April 2014. Ed. Ryan R. BMJ Group and Pharmaceutical Press (<http://www.medicinescomplete.com/mc/bnf/current/>)
2. NHS Electronic Drug Tariff May 2014. NHS Business Services Authority ([http://www.ppa.org.uk/edt/April\\_2013/mindex.htm](http://www.ppa.org.uk/edt/April_2013/mindex.htm))
3. Department of Health, Health Service Circular 1999/177 Treatment for Impotence: patients with severe distress
4. Department of Health, Health Service Circular 1999/148 Treatment for Impotence
5. Department of Health, The National Health Service (General Medical Services Contracts) (Prescriptions of drugs etc.) Amendments Regulations 1st August 2014