

GUIDANCE FOR PRESCRIBING OF DRUGS IN ERECTILE DYSFUNCTION IN PRIMARY CARE

KEY PRESCRIBING MESSAGE

- Generic sildenafil is the first line treatment choice for Erectile Dysfunction (ED).
- New patients requiring a Phosphodiesterase type-5 Inhibitors (PDE5-I) for erectile dysfunction should be commenced on generic sildenafil.
- Patients currently prescribed a PDE5 inhibitor for erectile dysfunction other than generic sildenafil should, if appropriate, be switched to sildenafil written generically taking account of individual patient circumstances.
- There are no longer any prescribing restrictions for the use of generic sildenafil in ED
- It is recommended that four tablets per month be prescribed when prescribing PDE5-I for ED.
- Tadalafil ONCE DAILY is **not recommended**.
- Treatment for penile rehabilitation is not supported in General Practice and any request to prescribe should be referred back to secondary care. Use in this indication is unlicensed and would fall outside the requirements of the 'SLS' list.

PDE5 inhibitor(ED treatment)	Doses recommended	SLS endorsement required
Sildenafil Generic	4 doses per month	NO
Sildenafil (Viagra®)	4 doses per month	YES
Tadalafil (Cialis®)	4 doses per month	YES
Tadalafil (Cialis®) 'once daily'	Not recommended (see below)	YES
Avanafil (Spedra®)	4 doses per month	YES
Vardenafil (Levitra®)	4 doses per month	YES

BACKGROUND

The following Phosphodiesterase type-5 Inhibitors (PDE5-I) are licensed for treatment of erectile dysfunction (ED)¹

- Sildenafil **Generic** and branded Viagra®
- Tadalafil (Cialis®)
- Alprostadil (Caverject®, MUSE®, Viridal®, Vitaros®),
- Avanafil (Spedra®)
- Vardenafil (Levitra®)

In June 2014, the Department of Health published a government response to the consultation for the proposal to remove the prescribing restrictions for sildenafil². This was because Viagra® lost its UK patent protection in June 2013 and cheaper generic products were now available.

These changes came into effect on the 1st August 2014 and this meant **no restrictions** or applied criteria was needed for the prescribing generic sildenafil for patients with erectile dysfunction i.e. generic sildenafil tablets are no longer restricted to the selected list scheme. Prescribers should ensure that generic sildenafil tablets 25, 50 and 100mg tablets are always considered first line for the treatment of erectile dysfunction.

All other PDE5-Is and branded Viagra® may be issued on an NHS prescription** to those men who are diagnosed with erectile dysfunction **and** have any of the following medical conditions listed below³:

- Diabetes
- Multiple sclerosis
- Parkinson's disease
- Poliomyelitis
- Prostate cancer
- Prostatectomy
- Radical pelvic surgery
- Renal failure treated by dialysis or transplant
- Severe pelvic injury
- Single gene neurological disease
- Spinal cord injury
- Spina bifida

****The prescriber must endorsed with the abbreviation for the Selective List Scheme- 'SLS' on prescriptions for this cohort of patients. A prescription not containing this endorsement will not be reimbursed by the Prescription Pricing Division.**

Loosening of national restrictions on generic sildenafil tablets now enables NHS prescribing of generic sildenafil for severe distress. All other formulations of sildenafil or brands remain under the control of Part XVIII of the Drug Tariff and can only be prescribed within that context. NHS prescription continuation for these patients should be reviewed when patients circumstances change.

Drug treatment may be prescribed privately by the prescriber when an NHS prescription is no longer appropriate for the patient³.

THE FREQUENCY

Department of Health advises that **one treatment a week** will be appropriate for most patients treated for erectile dysfunction after the initial stabilisation. If prescribers in exercising their clinical judgment considers that more than one treatment a week is appropriate they should prescribe that amount on the NHS.

It should also be remembered that PDE5-I have a "street value" so excessive prescribing could lead to unlicensed, unauthorised and possibly dangerous use³.

CHOICE OF THERAPY

Generic Sildenafil is to be used as the 1st line PDE5-I in NHS Waltham Forest CCG for ED. Sildenafil came off patent in June 2013 and as such the price dropped significantly when compared to other PDE5-I Drugs thus all initiations should be with generic sildenafil.

Patients who are currently prescribed another PDE5-I and have not previously tried sildenafil should be reviewed and switched to generic sildenafil unless clinically inappropriate.

As there are no comparative trials between the different drugs the following equivalent doses are based on licensed dosage ranges, not necessarily therapeutically equivalent doses⁴.

The BSSM guidelines⁵ notes that treatment failure should only be considered after a patient has received eight doses of PDE5-I at maximum dose with sexual stimulation.

Drug	Switch to Generic
Tadalafil 10mg 'when required dose'	Sildenafil 50-100mg
Tadalafil 20mg 'when required dose'	Sildenafil 50-100mg
*Tadalafil 2.5mg and 5mg 'once daily dose' - Not recommended	Sildenafil 50-100mg 8 per month (NB high dose chosen to compensate for loss of daily dosage)
Vardenafil 5mg	Sildenafil 25mg
Vardenafil 10mg	Sildenafil 50-100mg
Vardenafil 20mg	Sildenafil 50-100mg

TADALAFIL ONCE DAILY

***Waltham Forest CCG does not recommend the prescribing of Tadalafil once daily (Cialis® once-a-day) for erectile dysfunction in new patients.** This is in line with the guidance given following the NHS England consultation published in November 2017⁷. The guidance states that there is not enough robust evidence to routinely recommend once daily preparations in preference to 'when required' products particularly with the availability of generic 'when required' preparations. For existing patients on Tadalafil once daily it is recommended that deprescribing is considered where appropriate.

REFERENCES

1. British National Formulary 72, September 2017- March 2018 section 7(4.1)
2. Proposed changes to NHS availability of erectile dysfunction treatments-changing prescribing restrictions for generic sildenafil <https://www.gov.uk/government/consultations/nhs-availability-of-erectile-dysfunction-drugs-proposed-changes>
3. Department of Health, NHS Executive Health Service Circular 1999/115 May - August 1999
Department of Health, NHS Executive Health Service Circular 1999/148 (amended 2009)
4. UKMI Trent Medicines information service. QIPP detail aid support document. Sildenafil – a generic opportunity available from <http://www.midlandsmedicines.n.uk/filestore/Sildenafil-SD.pdf> Accessed 30/05/2014
5. British Society for Sexual Medicine Guidelines on the management of erectile dysfunction 2009 (available from http://www.bssm.org.uk/downloads/BSSM_ED_Management_Guidelines_2009.pdf, Accessed 30/05/2014)
6. The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2014. 2014 No.1625
7. NHS England consultation for items which should not be routinely prescribed in primary care <https://www.engage.england.nhs.uk/consultation/items-routinely-prescribed/>
8. NHS Drug Tariff Oct 2017 www.nhsbsa.nhs.uk