

## PDE5 INHIBITORS PRESCRIBING GUIDANCE

### Background

Within Cumbria CCG, £449K was spent on oral phosphodiesterase type-5 (PDE5) inhibitors (brand plus generic) for erectile dysfunction(ED) from Oct 2013 to Sep 2014. Sildenafil came off patent in June 2013 and the cost of generic tablets has fallen considerably. Sildenafil is now prescribable for any patient with ED on the NHS.

### Key Points

- Sildenafil is no longer restricted in the treatment of ED so is now prescribable for any patient on the NHS.
- Generic sildenafil should be FIRST LINE.
- Sildenafil should be prescribed for all new patients if a PDE5 inhibitor is considered appropriate after full investigation of underlying causes.
- The prescribing of branded treatments for erectile dysfunction on the NHS is still based on Department of Health guidance (1999), which restricts who can receive treatment.
- The recommendation of one treatment per week for the majority of patients is based on the Health Service Circular(1999) and is still in place.
- Avanafil (Spedra) is black in the Traffic Light Classification.
- Daily tadalafil (Cialis) is black in the Traffic Light Classification .
- Consider changing appropriate patients taking tadalafil or vardenafil to generic sildenafil.

### What are the costs?

	Price (Drug Tariff Apr 2015)	Amount spent in Cumbria CCG (Oct13-Sep14)
Sildenafil 25mg,50mg,100mg tabs (4)	£1.09,£1.15,£1.23	£26,469.02
Viagra 25mg,50mg,100mg tabs (4)	£16.59,£21.27,£23.50	£8,886.14
Vardenafil (generic+brand)5mg,10mg, 20mg tabs (4)	£7.56,£14.08, £23.48	£24,976.76
Tadalafil (generic+brand) 10mg,20mg tabs (4)	£26.99	£297,440.28
Tadalafil (generic+brand) 2.5mg,5mg tabs (28) (BLACK: These medicines are not recommended and should not be prescribed in any setting).	£54.99	£91,650.65
Avanafil (generic+brand) (4) 50mg, 100mg & 200mg tabs (BLACK: These medicines are not recommended and should not be prescribed in any setting).	£10.94, £14.08 ,£21.90	£18.23 (8 pack of 50mg)

### Supporting Information

- The British Society for Sexual Medicine recommends PDE5 inhibitors as 1st line treatments for ED and states they all have proven efficacy and safety in men with ED. (BSSM SEP 2013)
  - There are no meaningful head-to-head studies between the oral PDE5 inhibitors.
  - The NNT is 2. (cks)
- There are some differences between agents in how they are taken:
- They are taken 60 minutes (sildenafil), 25-60 minutes (vardenafil) or at least 30 minutes (tadalafil) before anticipated sexual activity (BNF).
  - Tadalafil has a longer serum half-life (17.5 hours) than sildenafil and vardenafil (4 hours).
  - Tadalafil has a longer duration of effectiveness (up to 36 hours) compared with 4-5 hours for sildenafil and vardenafil. (SPC)
  - Tadalafil is licensed for daily dosing; however this is black in the traffic light classification.

Department of Health guidance recommends one treatment per week at NHS expense.

### Appropriate prescribing of PDE5 inhibitors

Ensure that any patient receiving an in-patient or branded PDE5 inhibitor meets "SLS" criteria:

a) **Only** prescribe branded PDE5 inhibitors on the NHS if the patient suffers from the following:

- Diabetes
- Multiple Sclerosis
- Parkinson's Disease
- Poliomyelitis
- Prostate cancer
- Severe pelvic injury
- Single gene neurological disease
- Spina bifida
- Spinal cord injury

b) Or patient is receiving treatment for renal failure by dialysis.

c) Or has had the following surgery:

- Prostatectomy (including TURP)
- Kidney transplant
- Radical pelvic surgery

d) Were receiving NHS prescriptions for ED for alprostadil (Caverject<sup>®</sup>, Muse<sup>®</sup>, Viridal Duo<sup>®</sup>), apomorphine hydrochloride (Uprima<sup>®</sup>), Moxisylyte hydrochloride/ thymoxamine hydrochloride (Erecnos<sup>®</sup>), sildenafil (Viagra<sup>®</sup>), tadalafil (Cialis<sup>®</sup>), on or before the 14th September 1998 (Drug tariff Apr 2015).

All other patients should be prescribed generic sildenafil. Those wishing to receive branded PDE5 inhibitors should receive a private prescription.

### References:

Summary of Product Characteristics. Sildenafil. Electronic Medicines Compendium (eMC). <http://www.medicines.org.uk/emc/>

Clinical Knowledge Summaries <http://cks.nice.org.uk>

Traffic light classification

<https://www.networks.nhs.uk/nhs-networks/nhs-cumbria-ccg/medicines-management/traffic-light-classification>

Lothian Joint formulary [www.ljf.scot.nhs.uk](http://www.ljf.scot.nhs.uk)

BNF 68 March- September 2014

Drug tariff Apr 2015 <http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx>

British Society for Sexual Medicine. Guidelines on the Management of Erectile Dysfunction, 2009 (updated Sep2013). [www.bssm.org.uk](http://www.bssm.org.uk)

HSC 1999/115: Treatment for Impotence. NHS Executive.

HSC 1999/148: Treatment for Impotence. NHS Executive.

Newcastle, North Tyneside, Northumberland and Gateshead Guidelines for Management of Erectile Dysfunction in adults > 18 years. Aug 2014

Based on Lancashire North CGG prescribing guideline.