

Erectile Dysfunction (ED) Practical Prescribing

Medicines Management Team Statement

Step 1: Offer generic sildenafil on the NHS for all patients as first-line treatment for ED. Private prescriptions are not necessary or appropriate. Viagra Connect available OTC.

Step 2: If ineffective, consider alternative PDE5 inhibitor, generic tadalafil. Prescribe on the NHS if patient meets SLS criteria. Offer a private prescription, if patient does not meet SLS.

WCCG supports DoH recommendations on quantity (ONE treatment per week).

**Daily tadalafil tablets (2.5mg and 5mg) are not on local formularies.
DO NOT PRESCRIBE in primary care.
DO NOT prescribe sildenafil or tadalafil by brand (Viagra or Cialis)
- incurs significant costs with no extra benefits.**

Introduction

- Medication can be used to successfully manage erectile dysfunction (ED) in at least two-thirds of men. Phosphodiesterase-5 inhibitors (PDE5 inhibitors) are the first line recommended pharmacological treatment.
- Vacuum pumps and alprostadil preparations are alternatives to PDE5 inhibitors for the treatment of ED, offered by secondary care. Patients should be assessed for suitability for these devices, and initial supply should be given by a specialist. Prior PDE5 treatment is needed before any referral.
- Since August 2014, generic sildenafil tablets can be prescribed on the NHS for ANY patient with ED, regardless of cause.
- Once-weekly tadalafil (prescribe generically) is the second-line treatment choice in primary care.
- If patient meets SLS criteria, can be prescribed on the NHS; if not, consider private prescription.
- Viagra Connect (sildenafil) is available April 2018 for purchase over-the-counter.

Once daily Tadalafil

Daily tadalafil (Cialis) is non-formulary across all there Wiltshire formularies. There is no specific evidence of benefit of once daily over weekly use for ED or any other indication like penile rehabilitation post radical prostatectomy.

The NHS England review of Low Value Medicines concludes daily tadalafil is not suitable for prescribing in primary care.

PrescQIPP Patient Information Leaflet: [Changes to once daily tadalafil prescribing](#)

Action: No new patients to be initiated on once daily tadalafil.

Identify all existing patients and switch to once weekly or PRN tadalafil (even if initiated by Urology specialists) and treat as per usual ED guidance.

Formulary Status

GWH	BCAP	ICID
Sildenafil (generic) 1 st Line		
Tadalafil (generic, once weekly only) 2 nd Line		
Alprostadil (Caverject, MUSE)	Alprostadil (Caverject, MUSE, Viridal Duo)	Alprostadil (Caverject, Viridal Duo, MUSE, Vitaros)
ED vacuum pumps (specialists issue first device)		
Vardenafil or Avanafil – non-formulary		

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Quantity

- Advice regarding the quantity of medication to prescribe remains unchanged from that outlined by the Department of Health (Health Service Circular HSC 1999/148) based on research evidence in the 40-60 year age group,
- The recommended quantity is ONE treatment per week.
- If the GP considers that more than one treatment a week is clinically appropriate then that amount should be prescribed on the NHS. **GPs should document in patients' medical record their clinical judgement for any deviation from the DoH guidance.**
- Advise patient of availability of Viagra Connect from pharmacies (£19.99 for 4 x 50mg tablets).
- The prescriber needs to be aware of the risks of excessive prescribing could lead to unlicensed, unauthorized, diversion of supply (tablets have a recognizable street value) and/or possibly dangerous use. As well, one treatment per week is deemed to provide an equitable quantity with respect to our population needs.
- **It is not appropriate to prescribe 'top-ups' privately if the patient is already receiving NHS prescriptions.**

Private Prescriptions

- GPs may prescribe non-generic-sildenafil PDE-5 inhibitors privately for those patients that do not meet the SLS criteria.
- The patient cannot be charged a fee for either providing the consultation or writing the private prescription, if the patient is on the practice registered list.
- GPs cannot prescribe any ED medication privately for their NHS patients who meet the 'SLS' criteria.

Comparison

	Sildenafil	Tadalafil
Maximum frequency	Once daily	Once daily
Time taken before actual sexual activity	1 hour	At least 30 minutes
Tmax	30 – 120 minutes (median 60 mins)	2 hours (median)
Time to erection	25 minutes (range 12-37 minutes)	16 minutes – 36 hours
Time still able to produce erection post dose	4-5 hours	Up to 36 hours
Effect of food intake	Rate of absorption reduced by mean 60 minutes when consumed with food	Not affected

Cost Issues

- Prescribe on demand, once a week sildenafil or tadalafil generically.
- Cialis, prescribed by brand, costs 10 x more than the generic versions. Compare £28.88 for 4 tablets with £3.17 (20mg) or £2.13 (10mg).
- All prescriptions for Cialis can now be prescribed as generic tadalafil to maximise cost-savings to the NHS.

At least £58,000 could be saved by WCCG if all prescriptions for once daily tadalafil were stopped.

References

1. Male sexual dysfunction. PrescQipp Bulletin 73 (2015) <https://www.prescqipp.info/resources/send/145-male-sexual-dysfunction/1780-b73-sildenafil-and-other-ed-drugs>
2. Treatment for impotence, Health Service Circular:NHS Executive (1999)
3. NHS Drug Tariff PartXVIII B [http://www.drugtariff.nhsbsa.nhs.uk/#/00475250-DA_1/DA00474692/In England:](http://www.drugtariff.nhsbsa.nhs.uk/#/00475250-DA_1/DA00474692/In%20England)
4. Erectile Dysfunction, Clinical Knowledge Summaries (2014) <https://cks.nice.org.uk/erectile-dysfunction#!topicsummary>
5. NHS England Consultation Report on Findings 30 November 2017 available from <https://www.england.nhs.uk/publication/items-which-should-not-be-routinely-prescribed-in-primary-care-consultation-report-of-findings/>

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Primary care prescribing of PDE-5 Inhibitors (and other treatments) for Erectile Dysfunction (ED).

Does patient have ED?
(Assess for causative factors, offer lifestyle advice & assess cardiac risk)

Choose **generic sildenafil via FP10** as first line treatment for ALL patients regardless of cause (whether meets NHS criteria/SLS or not).
Usual starting dose 50mg when required (increasing to 100mg if ineffective, or decreasing to 25mg if needed).
Quantity of ONE treatment per week.

Is treatment effective?

Maintain treatment via FP10.

- Document clinical reason if quantities are above DoFH recommendations.
- Advise available for purchase OTC via pharmacy.

NO YES

Does patient meet SLS criteria?

YES

NO

Only prescribe generic sildenafil on NHS

If needs other ED treatments, offer private prescription.

Prescribe ALL treatments on NHS if patient meets SLS criteria

1st line: generic sildenafil
2nd line: if not tolerated/contraindicated/ineffective, then use weekly generic tadalafil.

REFER to secondary care ONLY after PDE-5 trial (min 4-8 tablets or 1-2 months treatment).

3rd line: alprostadil injections or ED vacuum pumps as per specialist input (specialists to supply initial treatment)

NHS SLS criteria

(Drug Tariff part IXA)

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

QUANTITIES

- Separate decision from 'NHS vs private' or 'SLS vs non-SLS'.
- No daily prescribing – once daily tadalafil is non-formulary, not suitable for primary care prescribing.
- WCCG supports DoH recommendations of 'ONE treatment per week'.
- If additional quantities are required; prescriber must document reason for extra supply citing clinical reasoning/appropriateness. No private 'top-ups'.