Erectile Dysfunction –Primary care guidance

Key points:

- **Sildenafil may be prescribed generically on FP10 for erectile dysfunction (ED) in any clinically eligible patient 1st line.**
- **Daily tadalafil 5mg may be prescribed in line with selected list scheme "SLS" criteria[1].**

Erectile Dysfunction (ED)

Erectile Dysfunction (ED) has been defined as the persistent inability to attain and/or maintain an erection sufficient to permit satisfactory sexual performance. Although ED is not perceived as a life-threatening condition, it is closely associated with many important physical conditions and may affect psychosocial health.
ED is a CV risk factor equivalent to smoking (hazard ratio [HR] 1.46)[1].
Local specialist advice is that with the growth of obesity there is a huge increase in functional secondary hypogonadism. More than 60% of pts with T2DM have testosterone deficiency and specialist services see very late referrals to endocrinology. In abdominal obesity total testosterone is not reliable, as in many obese men SHBG is low which results in low total testosterone, but normal free testosterone. Measuring only total testosterone in obese men results in over diagnosing of hypogonadism. Therefore, in all men with erectile dysfunction it would be strongly advisable to request FASTING 8-10 am testosterone, SHBG and albumin to get free testosterone to avoid unnecessary referrals to endocrinology and be sure there is no hypogonadism.

Lifestyle & patient advice- in conjunction with treatment

Encourage weight loss if this is a factor, smoking cessation, reduce alcohol consumption, stress, stop any illicit drug use and increase exercise.
Stopping cycling for a trial period, if the patient regularly cycles for more than 3 hours a week. If this is not possible, advise to use a properly fitted bicycle seat and ride with the seat in a suitable position[2].
Erectile dysfunction treatments are widely counterfeited, ensure patients are obtaining from legitimate sources if purchasing.

Initial assessment

- For detailed advice, see: Assessment | Diagnosis | Erectile dysfunction | CKS | NICE[2]
- Assessment should include patient's medical history (including any medication prescribed for co-morbidities), patient's report of previous and present erectile quality, lifestyle, physical examination, 10-year cardiovascular risk, and testosterone screening.
- Before prescribing any medication, complete a cardiac risk assessment, such as QRisk, including a blood pressure check and ED blood screen on ICE (if available at the acute trust pathology lab) It is important to note that ED may have organic, psychogenic causes and/or be drug-induced (e.g. diuretics, antidepressants, H2 antagonists). ED is a marker for cardiovascular disease and is included in QRisk3.
- Ensure all patients with type 2 diabetes are screened for ED on an annual basis and offered treatment as appropriate.

Medication- 1st line: generic sildenafil.
For a full list of cautions/contraindications/drug interactions please refer to individual SPCs

Offer to prescribe generic sildenafil (unless contraindicated) when required, on the NHS, for all patients as the first line treatment where clinically appropriate. Generic sildenafil tablets can be prescribed on the NHS to ANY patient with ED regardless of cause. Usual starting dose is 50mg approximately 1 hour before sexual activity, increasing to 100mg if ineffective or decreasing to 25mg if necessary. Discuss the need for sexual stimulation and the delay in onset of action.

Common adverse effects:

Back pain, dizziness, dyspepsia, flushing, migraine, myalgia, nasal congestion, nausea, and vomiting.

Approved at BSWAPC Feb 2025. Updated to add daily tadalafil 5mg, quantity of sildenafil allowed on FP10 plus extra clinical information. Consultation with all three local acute trust urology teams.

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Cautions:

- Cardiovascular disease. Consider the potential cardiac risk of sexual activity in men with pre-existing cardiovascular disease before prescribing a PDE-5 inhibitor. Refer to NICE CKS Cardiac risk stratification section for further information.
- Left ventricular outflow obstruction (for example aortic stenosis and idiopathic hypertrophic subaortic stenosis).
- Anatomical deformation of the penis (for example angulation, cavernosal fibrosis, or Peyronie's disease).
- A predisposition to priapism (for example in sickle-cell disease, multiple myeloma, or leukaemia).
- Prescribe sildenafil with caution to men with active peptic ulceration or bleeding disorders.

Contraindications: Do not prescribe a PDE-5 inhibitor to a patient with any of the following co-morbidities:

Hypotension (systolic BP<90/50 mmHg)	**Loss of vision in one eye due to non-arteritic anterior ischaemic optic neuropathy (NAION)**	**Recent MI** (within past 90 days)
Recent stroke (within past 6 months)	**Sever/unstable heart disease** (vasodilation/sexual activity not recommended)	**Taking nitrate medications**
Unstable angina/angina during sexual intercourse	**Hereditary degenerative retinal disorders**	**Severe Hepatic impairment**
New York Heart Association (NYHA) class II or greater heart failure (within the last 6 months)	**Uncontrolled arrhythmias**	**Uncontrolled hypertension**

Key: BLUE = both PDE-5 Inhibitors ORANGE – Sildenafil only GREEN – Tadalafil only

Most common drug interactions:

- **Nitrates —** GTN, isosorbide mononitrate, or isosorbide dinitrate, nicorandil, or amyl nitrate ('poppers' used for recreation) are absolutely contraindicated.
- **Alpha-blockers —** can increase the risk of postural hypotension as both are vasodilators.
- **Cytochrome P450 (CYP) 3A4 and 2C9 inhibitors** (e.g. ritonavir, ketoconazole, itraconazole, erythromycin, cimetidine, and grapefruit juice) - co-administration should be avoided if possible.
- **CYP3A4 inducers** (e.g. rifampicin, phenobarbital, phenytoin, and carbamazepine) - co-administration should be avoided if possible.

Review (6-8 weeks) 2nd line: generic 5mg daily tadalafil (must fit SLS criteria)

- Assess the efficacy and safety of the treatment as well as patient satisfaction.
- Is the dose adequate
- Has the patient waited the required length of time between taking the medication and engaging in sexual activity?
- Discuss the need for sexual stimulation
- Re-consider testosterone measurements
- **If treatment is not tolerated/ ineffective/contraindicated after dose titration, change patient to 5mg daily tadalafil (generic) if they fit SLS criteria.** Up to 57% of men with an unsuccessful response to on-demand therapy will respond to daily tadalafil 5mg. Only 8–12% will achieve success with a second on-demand medication (see CKS).
- If treatment failure on two oral PDE-5 inhibitors, consider alternative therapy options as per the following page or via specialist advice (e.g. injections).

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When to refer

Admit to hospital
- Priapism (warn patients to seek advice if erection lasting longer than 4 hours).

Refer to ED clinic
- Contra-indication to use of PDE-5i in patient (e.g. patient taking nitrates)

Refer to urology
- Abnormality of the penis or testicles is found on examination (including Peyronie's Disease)
- History of trauma / surgery (e.g. to genital area, pelvis, or spine).
- Young men who have always had difficulty in obtaining or maintaining an erection.
- Where the underlying cause is psychogenic.

Refer to endocrinology:
- Hypogonadism (abnormal testosterone, follicle-stimulating hormone, luteinizing hormone, or prolactin levels).

Refer to cardiology:
- Severe cardiovascular disease that would make sexual activity unsafe or contraindicates PDE-5i inhibitor use.

SLS criteria (also see purple box in flowchart p5)

- **SLS criteria** describe the conditions under which a man may be prescribed ED treatment on the NHS. These criteria are described in the NHS Drug Tariff Part IXA[3].
- **SLS restrictions were removed from generic sildenafil making it available on the NHS for all clinically eligible patients for ED**. SLS criteria remain in place for branded Viagra® and all other PDE-5is.

BSW Formulary Status for PDE-5is and other ED treatment options

Sildenafil 25mg, 50mg and 100mg tablets (generic) 1st line for non-SLS patients
Tadalafil 5mg daily or 10mg/20mg tablets (generic) "on demand" – alternative formulary option for patients that fit SLS criteria
Arrangements for supply of ED vacuum pumps should be agreed locally; **primary care may prescribe initial or replacement device on FP10 where clear instruction has been provided in writing by specialist.** Preferred devices used by local urology teams include iMEDicare *SomaErect Response II*, iMEDicare *SomaCorrect Xtra, Osbon Erecaid & classic version, and VaxAid.* Acute trusts may have different arrangements for training & provision of pumps. GPs may also prescribe replacement constrictor ring sets.
Specialist initiated treatment options [SLS criteria apply] Patients must receive assessment and device training from an appropriately qualified practitioner Alprostadil injection (note that Caverject® is discontinued but generic available), MUSE® (alprostadil urethral suppository), Vitaros® (alprostadil cream), and Invicorp (aviptadil/phentolamine mesylate).
Vardenafil (Levitra® or generic) and avanafil (Spedra®) are not included on BSWformulary and should not be prescribed on FP10

Recommended Actions

- Ensure patients are **prescribed generic sildenafil** as the **most cost-effective** PDE-5i unless contraindicated/not tolerated/ineffective. All patients should try generic sildenafil first-line.
- Ensure patients prescribed alternative pharmacological treatment options for ED on FP10, meet SLS criteria[1]. Patients not meeting these criteria should be prescribed treatment privately, if clinically appropriate.

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Erectile Dysfunction –Primary care guidance

- **Review any patients prescribed non-formulary PDE-5is (vardenafil and avanafil) for ED** and prescribe formulary alternative if clinically appropriate.
- Do not prescribe sildenafil or tadalafil by brand (Viagra® or Cialis®) this incurs significant cost with no extra benefit.

Frequency of Prescribing

- One treatment per week of an on-demand regimen should be appropriate for most patients. However, If the GP considers that more than one treatment a week of an on-demand regimen with sildenafil is appropriate, they may prescribe this on FP10 e.g. couples who consider 2-3 attempts at sexual intercourse per week could be supplied with up to 8-12 tablets on-demand per month.
- **For patients that meet the SLS criteria, Tadalafil 5mg daily is an alternative option rather than higher quantities of sildenafil.**
- It is not appropriate to prescribe 'top-ups' privately.
- Bear in mind excessive prescribing could lead to off-label use, diversion and possibly dangerous use. GPs should document in the patients' medical records their reasoning for larger quantities of supply.
- **Please note that Tadalafil 2.5 mg tablets are NOT on the BSW formulary and are more expensive than the 5mg tablets.**

Private Prescribing

- GPs may **prescribe a PDE-5i privately** for patients with ED who do not meet SLS criteria, but they **may not charge for providing the consultation or prescription** if the patient is on the practice registered list[2].
- GPs should not prescribe ED medication privately for NHS patients who meet "SLS" criteria[2].

Daily tadalafil for benign prostatic hypertrophy (BPH)

- Tadalafil 5mg once daily is also licensed for benign prostatic hypertrophy (BPH). Due to a lack of evidence about the effectiveness of PDE-5Is for treating lower urinary tract symptoms in men who do not have ED, it **is not recommended by NICE CG97**[4] and is not on BSWformulary for this indication.

References

1. Erectile dysfunction: is the NHS men's health friendly? - Hackett - 2020 - Trends in Urology & Men's Health - Wiley Online Library
2. NICE Clinical Knowledge Summaries. Erectile Dysfunction Last revised October 2024. Erectile dysfunction | Health topics A to Z | CKS | NICE
3. NHS Drug Tariff Part IXA NHS Electronic Drug Tariff (nhsbsa.nhs.uk)
4. NICE Clinical Guideline CG97. Lower urinary tract symptoms in men: management (2015) https://www.nice.org.uk/guidance/cg97

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

Does patient have ED?
See NICE CKS Erectile Dysfunction: How should I assess a man with ED

Choose **generic sildenafil via FP10** as first line treatment for ALL patients regardless of cause (whether meets NHS SLS criteria 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 or maximum 8-12 tablets per month.

Is treatment effective?

YES → **Maintain treatment via FP10.**

NO → **Does patient meet SLS criteria?**

NO → Only prescribe generic sildenafil on NHS → If needs other ED treatments, offer private prescription.

YES →

Prescribe ALL treatments on NHS if patient meets SLS criteria

1st line: generic sildenafil
2nd line: if not tolerated or contraindicated or in-effective, then use 5mg daily generic tadalafil.

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

3rd line: alprostadil preparations or Invicorp® or ED vacuum pumps or as per specialist input.

Private prescription 'top-ups' are not acceptable

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
- Receiving treatment for renal failure by renal dialysis
- After prostatectomy
- After radical pelvic surgery
- After renal failure treated by transplant

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