Guidelines for the management of erectile dysfunction in adults

Erectile dysfunction (ED) is defined as the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual performance. Individuals presenting with ED should be assessed to determine any underlying cause and their cardiac risk of sexual activity.

Before pharmacological treatments are considered for ED, clinicians should:

- Discuss and advise on lifestyle changes that may help with symptoms (e.g. weight loss, regular exercise, smoking cessation, alcohol reduction)
- Optimise management of any underlying conditions (e.g. diabetes, cardiovascular disease)
- Consider whether the patient may be suffering from medication-induced ED

PDE-5 Inhibitors

1st line – Generic sildenafil – 50 mg when required (based on efficacy and tolerability, the dose may be increased to 100mg or decreased to 25mg)

2nd line - Generic tadalafil or generic vardenafil

- **On-demand tadalafil** – 10mg when required (based on efficacy and tolerability, this can be increased to the maximum dose of 20mg) **or**
- If a short-acting drug is preferred – **Vardenafil 10mg** when required (based on efficacy and tolerability, the dose may be increased to 20mg or decreased to 5mg)

NOTE: Once daily tadalafil (2.5mg and 5mg) is **not recommended** for prescribing for erectile dysfunction.

If treatment failure with at least 2 different oral PDE-5 inhibitors, **refer to a specialist** for consideration of alternative treatment options. A patient should receive 8 doses of a PDE-5 inhibitor at a maximum tolerated dose with sexual stimulation before treatment is classified as non-effective.

Selected List Scheme (SLS)

Prescribing drugs for ED, except generic sildenafil, is restricted nationally under the Selected List Scheme (SLS). Patients with any of the following conditions meet SLS criteria for the treatment of ED:

- Diabetes
- Multiple Sclerosis
- Parkinson's disease
- Poliomyelitis
- Prostate cancer
- Severe pelvic injury
- Single gene neurological disease
- Spina bifida
- Spinal cord injury
- A man who is receiving treatment for renal failure by dialysis
- A man who has had the following surgery –
  - Prostatectomy
  - Radical pelvic surgery
  - Renal failure treated by transplant

For further information on SLS, refer to Part XVIIIB of the Drug Tariff

Private prescriptions for PDE-5 inhibitors (except generic sildenafil) can be considered for patients that do not meet the SLS criteria.

Over the counter purchase - Sildenafil 50 mg tablets and tadalafil 10mg tablets can be purchased from pharmacies and do not need a prescription.

Prescription quantities

The recommended quantity of on-demand PDE-5 inhibitors to be prescribed is 4 tablets per month

- This advice is based on research by the Department of Health (DoH) on impotence which showed that the average frequency of sexual intercourse in the 40-60 age range is once a week.
- Prescribers should be aware of the risks of excessive prescribing which can lead to unlicensed, unauthorised, diversion of supply (PDE-5 inhibitors have "street value") and/or possible dangerous use.
- However, if the clinician in exercising their clinical judgement considers that more than one treatment a week is appropriate, then the clinician can prescribe that amount on the NHS.

Patient advice

- PDE-5 inhibitors have no effect in the treatment of ED in the absence of sexual stimulation.
- ED usually responds well to a combination of lifestyle changes and drug treatment. Lifestyle changes include (where applicable) losing weight, reducing stress, stopping smoking, reducing alcohol consumption, stopping illicit drug use and regular exercise.
- There is often a delay in onset of action with "when required" PDE-5 inhibitors (see below)

	Sildenafil	**Tadalafil (on demand)**	**Vardenafil**
Time taken before sexual activity	1 hour	At least 30 minutes	25–60 minutes
Time to onset of effect	25 minutes (range 12–37 minutes)	16 minutes to 36 hours	25 minutes (range from 15 minutes)
Duration of action	4–5 hours	Up to 36 hours	4–5 hours
Effect of food intake	Rate of absorption reduced by mean of 60 minutes when taken with food	Not affected	Rate of absorption reduced by median of 60 minutes when taken with high fat meals

Alternative options for the treatment of ED (specialist initiation only)

- Topical preparations and injectable therapies are alternatives to PDE-5 inhibitors for the treatment of ED for patients who have a contra-indication, intolerance or treatment failure with at least 2 oral PDE-5 inhibitors.
- Initiated by specialists following assessment with appropriate training and counselling provided.
- Primary care can be requested to continue prescribing once the patient is stabilised, and efficacy and tolerability have been confirmed.

Drug/Device	**Formulation**	**Brand name**	**Formulary**
Alprostadil	Topical cream	Vitaros®	✓
	Intraurethral application	MUSE®	✓
	Intracavernosal injection	Generic alprostadil powder for solution for injection	✓
		Caverject® Dual Chamber	✓
		Viridal® Duo	✓ 40mcg strength only
Aviptadil with phentolamine mesylate	Intracavernosal injection	Invicorp®	✓

All products listed above must only be prescribed on FP10 for patients who fulfil the NHS SLS criteria.

- In line with other on-demand ED treatments – 1 treatment per week is appropriate for most men.
- Combining alprostadil or Invicorp® with other ED treatments is <u>not</u> recommended.

Hertfordshire and West Essex Integrated Care System

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Erectile Dysfunction Prescribing Flow Chart

Confirm diagnosis of Erectile Dysfunction in adults over 18 years old

Assess for causative factors, offer lifestyle advice and assess cardiac risk.
Optimise management of comorbidities.

Are PDE-5 inhibitors clinically appropriate for the patient?

Yes

No

Seek specialist advice and refer as appropriate

Prescribe generic sildenafil on FP10

Usual starting dose is 50mg when required, increasing to 100mg or decreasing to 25mg based on efficacy and tolerability.
Refer to SPC for full dosing information, contraindications, and drug interactions.

Note: All treatments for ED (except for generic sildenafil) require an SLS endorsement to be prescribed on the NHS.

Follow up after 6–8 weeks

Review response to treatment. **Is treatment effective* and tolerated?**
*(*A patient should receive 8 doses of sildenafil at a maximum tolerated dose with sexual stimulation before treatment is classified as non-effective)*

Yes

Continue sildenafil treatment on FP10

No

Does patient meet the SLS criteria?

Yes

No

Consider offering alternative PDE-5 inhibitor treatment on a private prescription

Trial an alternative PDE-5 inhibitor on FP10

- **Generic tadalafil**
  - **On-demand –** Usual starting dose is 10mg when required, increasing to 20mg based on efficacy and tolerability.
- **Generic vardenafil** if a **short-acting drug is preferred**
  - Usual starting dose is 10mg when required, increasing to 20mg or decreasing to 5mg based on efficacy and tolerability.

NOTE: Once daily tadalafil is **not recommended** for prescribing for erectile dysfunction.

Refer to SPCs for full dosing information, contraindications, and drug interactions

Yes

Is treatment effective?

No

If treatment failure with at least 2 oral PDE-5 inhibitors, refer to specialist to consider alternative therapy options

Continue tadalafil or vardenafil on FP10
(provided the patient continues to meet SLS criteria)

SECONDARY CARE INITIATION – see page 2 for further details

- **Alprostadil** – Topical, intraurethral application and intracavernosal injection
- **Aviptadil / Phentolamine Mesilate** intracavernosal injection (Invicorp®)

References:

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8. NHS England (October 2023) Items which should not routinely be prescribed in primary care: policy guidance
9. Department of Health, NHS Executive Health Service Circular 1999/148 June1999 https://eclipsesolutions.org/UploadedFiles/166_HSC%201999%20Erectile%20Dysfunction.pdf

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