Erectile Dysfunction –Primary care prescribing advisory summary

NHS
Bath and North East Somerset, Swindon and Wiltshire
Integrated Care Board

Key points:

- **Sildenafil may be prescribed generically on FP10 for erectile dysfunction (ED) in any clinically eligible patient.**
- **Tadalafil may be prescribed in line with selected list scheme "SLS" criteria[1].**
- **Prescribe "ONE TREATMENT PER WEEK" in line with DoH guidance[2].**

SLS criteria (also see purple box P3)

- **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[1].
- **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.

BSWFormulary Status for PDE-5is and other ED treatment options

Sildenafil 25mg, 50mg and 100mg tablets (generic) 1st line
Tadalafil 10mg and 20mg tablets (generic) – 2nd line [SLS criteria apply]
Specialist initiated treatment options [SLS criteria apply] Patients must receive assessment and device training from an appropriately qualified practitioner Caverject®,Viridal Duo®, MUSE®, Vitaros®, Invicorp and ED vacuum pumps. 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 are iMEDicare *SomaErect Response II* and iMEDicare *SomaCorrect Xtra.* GPs may also prescribe replacement constrictor ring sets.
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, including branded sildenafil (Viagra®) and other PDE-5is, meet SLS criteria[1]. Patients not meeting these criteria should be prescribed treatment privately, if clinically appropriate.
- **Review any patients prescribed daily tadalafil or non-formulary PDE-5is (vardenafil and avanafil) for ED** and prescribe formulary alternative if clinically appropriate.

Frequency of Prescribing

- National advice regarding the quantity to prescribe remains unchanged from the Health Service Circular HSC 1999/148 which recommends one treatment per week at NHS expense, based on research evidence in the 40-60 year age group, but does allow GPs to use clinical judgement to prescribe more than one treatment per week[2,3]. Availability of generics has since brought weekly sildenafil/tadalafil prices down significantly but, in line with many other areas, **BSW ICB continue to recommend prescribers follow the DoH's original guidance that one treatment per week will be appropriate for most patients.**

bswicb.prescribing@nhs.net

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- If the GP considers that more than one treatment a week is appropriate, they may prescribe this on FP10 but should be aware this is considered a low value clinical intervention. It is not appropriate to prescribe 'top-ups' privately[2].
- 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 any deviation from the DoH guidance of one treatment per week.**

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** document 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 ED and for benign prostatic hypertrophy (BPH)

- BSW ICB continues to support the position outlined in *NHSE: Items which should not routinely be prescribed in primary care 2019*[4] which recommends primary care should not initiate once daily tadalafil for any new patient. While the 5mg tablets have dropped in price since the NHSE publication, the 2.5mgs remain comparatively expensive so BSW ICB retain the message that **daily tadalafil remains non-formulary until NHSE review the national position.**
- 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**[5] and is not on BSWformulary for this indication.

References and other information

1. NHS Drug Tariff Part IXA NHS Electronic Drug Tariff (nhsbsa.nhs.uk)
2. Male sexual dysfunction: Prescqipp Bulletin 73 (2015) https://www.prescqipp.info/umbraco/surface/authorisedmediasurface/index?url=%2fmedia%2f1439%2fb73-sildenafil-and-other-ed-drugs-20.pdf
3. NHS Health Service Circular HSC 1999/148 HSC 1999/148
4. NHSE: Items which should not routinely be prescribed in primary care 2019
5. NICE Clinical Guideline CG97. Lower urinary tract symptoms in men: management (2015) https://www.nice.org.uk/guidance/cg97

See also:

- British Society of Sexual Medicine. Guidelines on the management of erectile dysfunction in men - 2017. https://www.bssm.org.uk/wp-content/uploads/2018/09/BSSM-ED-guidelines-2018-1.pdf
- NICE Clinical Knowledge Summaries. Erectile Dysfunction Last revised July 2020. http://cks.nice.org.uk/erectile-dysfunction
- SPS article May 2019 What rationale, guidance and evidence is there for the use of phosphodiesterase-5 inhibitors as supportive therapy to rehabilitate erectile function after nerve sparing radical prostatectomy?

Costs based on Drug Tariff August 2022

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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 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?

YES

Maintain treatment via FP10.

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

NO

Does patient meet SLS criteria?

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 weekly 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 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

NO

Only prescribe generic sildenafil on NHS

If needs other ED treatments, offer private prescription.

- BSW ICB 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'.
- Daily tadalafil should not routinely be prescribed.

Approved at BSWAPC Oct 2022

bswicb.prescribing@nhs.net