

**POLICY FOR THE PRESCRIBING OF
PHOSPHODIESTERASE TYPE-5 INHIBITORS FOR THE TREATMENT OF ERECTILE
DYSFUNCTION**

Author(s)	Medicines Optimisation Team, Manx Care
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Intended audience	Primary and Secondary Care Prescribers	
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Stakeholders consulted prior to ratification	GP Representatives, GPs, Urology Department Nobles Hospital, Chief Pharmacist Nobles Hospital	
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1. INTRODUCTION

1.1 Purpose

This policy covers the prescribing of the following drugs for the treatment of Erectile Dysfunction:

- Avanafil
- Sildenafil
- Tadalafil
- Vardenafil

1.2 Scope

All clinicians who prescribe for men with Erectile Dysfunction within the Health Service

2. POLICY

Manx Care recommends SILDENAFIL as the first-choice phosphodiesterase type-5 inhibitor (PDE-5 inhibitor) for the treatment of erectile dysfunction.

PDE-5 inhibitors (sildenafil, tadalafil, vardenafil, and avanafil) are currently recommended as first-line treatments for erectile dysfunction in Primary Care.¹ A CVD risk assessment should be completed, lifestyle changes and risk factor modification must precede or accompany treatment. This may include consideration of referral for psycho-sexual counselling.

Sildenafil has been chosen as the first-line PDE-5 inhibitor for erectile dysfunction (ED). Where sildenafil is not suitable, the second choice of PDE-5 inhibitor should preferably be one with the least acquisition cost, currently “as required” generic tadalafil (10mg or 20mg). Initiation of once-daily tadalafil (2.5mg or 5mg) is restricted to Secondary Care Only (as per DROP list CRC policy).

2.1 Frequency of Prescribing

Manx Care recommends that 1 TREATMENT PER WEEK (4 per month) should not be exceeded.

If a patient requests extra, GPs can provide a private prescription if appropriate. GPs **must not** charge for writing a private prescription for these drugs.

Sildenafil is available for purchase in pharmacy, following a consultation with the pharmacist, for ED.

2.2 Indications for Prescribing

Restrictions on prescribing PDE-5 inhibitors for ED on the NHS, as detailed below, have been removed for sildenafil, and so it can be prescribed to any man who in their clinical judgement are suffering from erectile dysfunction and are suitable candidates for PDE-5 inhibitors.

All other PDE-5 inhibitors are subject to restrictions, with NHS prescriptions (endorsed “SLS”) only issued to those men who in their clinical judgement are suffering from erectile dysfunction **and who**:

- have diabetes, multiple sclerosis, Parkinson’s disease, poliomyelitis, prostate cancer, severe pelvic injury, single gene neurological disease, spina bifida, or spinal cord injury
- are receiving dialysis for renal failure
- have had radical pelvic surgery, prostatectomy, or kidney transplant
- or were receiving alprostadil (Caverject[®], MUSE[®] Viridal[®]), moxisylyte (Erecnos[®]), apomorphine (Uprima[®]) tadalafil (Cialis[®]), thymoxamine hydrochloride (Erecnos[®]) or sildenafil (Viagra[®]) at the expense of the NHS on 14 September 1998.

Initiation of medications for erectile dysfunction for the indication of severe distress can be made by GPs, urologists, psychiatrists, or other clinicians experienced in assessing mental health issues, following the criteria below as guidance:

- Significant disruption to normal social and occupational activities
- A marked effect on mood, behaviour, social and environmental awareness
- A marked effect on interpersonal relationships

2.3 Effectiveness

There is substantial evidence from randomized controlled trials (RCTs) that PDE-5 inhibitors are effective in the treatment of erectile dysfunction. The four PDE-5 inhibitors marketed in the UK (avanafil, sildenafil, tadalafil, and vardenafil) are likely to be equally effective, although there is a lack of direct head-to-head RCTs to verify this.

Treatment failure should not be presumed for any type until at least 4 attempts at the maximum dose have been tried. Occasionally patients may respond to one drug when another has failed.

If the patient does not respond to all four types of PDE5 inhibitor, after a gap of a few months and if the patient is willing to try again, anecdotally some patients do respond to a second trial of these medications. A second trial of PDE5 inhibitors should not be prescribed under the NHS as it lacks a clear evidence base.

2.4 Patient Factors

Several measures are described in the literature to salvage patients clearly identified as non-responders:

- Counsel again on proper use, including dietary advice
- Optimise treatment of concurrent diseases and frequently re-evaluate for new risk factors
- Consider treatment of concurrent hypogonadism

It is well established that testosterone regulates the expression of PDE-5 and the responsiveness of PDE-5 inhibitors in the corpus cavernosum. Several studies have shown that patients can be salvaged by treating low or low-normal levels of testosterone.

2.5 Additional Notes for Prescribers

- All consultations involving initiation of PDE-5 inhibitors should explicitly state the indication for prescribing relating to the above-noted restrictions
- Prescribers are reminded to ensure that all patients that receive an NHS prescription for PDE-5 inhibitors are eligible
- IT systems should clearly identify a private prescription so that it cannot be inadvertently re-issued as an NHS prescription

- Audit is required to support the effective implementation of this guidance and to promote equality of access to treatment

3. REFERENCES AND/OR RESOURCES

- NICE Clinical Knowledge Summaries. Erectile Dysfunction Prescribing Information. July 2020.
<https://cks.nice.org.uk/topics/erectile-dysfunction/prescribing-information/phosphodiesterase-5-pde-5-inhibitors/> (Accessed 15/06/2021)
- Isle of Man DHSC. DHSC 54: Primary Care Prescriptions (DROP List). 01/12/2018.
<https://www.gov.im/about-the-government/departments/health-and-social-care/dhsc-clinical-commissioning/dhsc-clinical-commissioning-policies/> (Accessed 15/06/2021)
- NHSBSA, NHS Prescription Services. Electronic Drug Tariff. Part XVIII B – Drugs, Medicines and Other Substances that may be ordered only in certain circumstances In Wales. <https://www.drugtariff.nhsbsa.nhs.uk/#/00804172-DD/DD00803636/In%20Wales> (Accessed 14/06/2021)

Acknowledgements

- Pan Mersey Area Prescribing Committee
Prescribing Policy Statement
<https://www.panmerseyapc.nhs.uk/media/2039/phosphodiesterase5inhibitors.pdf> (Accessed 14/06/21)
- Buckinghamshire Formulary
CCG125FM.1 Treatment of erectile dysfunction in primary care
http://www.bucksformulary.nhs.uk/docs/Guideline_CCG125FM.pdf (Accessed 22/06/21)
- All Wales Guidance on Prescribing for Erectile Dysfunction
All Wales Medicines Strategy Group
<https://awmsg.nhs.wales/files/guidelines-and-pils/all-wales-guidance-on-prescribing-for-erectile-dysfunction-pdf/> (Accessed 22/06/21)
- Northern Ireland Formulary
7.4.5 Drugs for erectile dysfunction
<https://niformulary.hscni.net/formulary/7-0-contraception-gynaecology-and-urinary-tract-disorders/7-4-drugs-for-genito-urinary-disorders/7-4-5-drugs-for-erectile-dysfunction/> (Accessed 22/06/21)