NHS
County Durham
Clinical Commissioning Group

Guideline for the management of erectile dysfunction in primary care

This guideline has been prepared and approved for use within County Durham Clinical Commissioning Group

Full details of drug doses, interactions, contra-indications and cautions for individual drugs are available in the BNF or in the Summary of Product Characteristics (available in the Electronic Medicines Compendium)

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Guideline for the management of erectile dysfunction in primary care

1. Background

Erectile Dysfunction (ED) is defined as the persistent inability to attain and/or maintain an erection that is sufficient to permit satisfactory sexual performance.

The aetiology of ED may include multiple factors:

- Organic causes
- Vasculogenic e.g. CVD, hypertension, diabetes mellitus, hyperlipidaemia, smoking and metabolic syndrome
- Neurogenic e.g. Parkinson's disease, multiple sclerosis, alcoholism, stroke
- Anatomical e.g. Peyronie's disease, hypospadias, prostate cancer
- Hormonal e.g. hypogonadism, hyper/hypothyroidism, hyperprolactinaemia, Cushing's disease
- Psychogenic causes
- Situational e.g. due to psychiatric illness such as depression
- Generalised e.g. due to a lack of arousability
- Drug-induced e.g. antipsychotics, antidepressants, antihypertensives, cytotoxics, hormones and hormone-modifying drugs including oestrogens, progesterone, corticosteroids, cyproterone and 5α reductase inhibitors (e.g. finasteride)

2. Scope

This document is designed to guide the history taking, investigation and initial management for patients presenting with erectile dysfunction symptoms. It also provides information on when specialist referral would be appropriate.

This guideline is not exhaustive and does not override the individual responsibility of health professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient.

3. Pathway

3.1 History taking

It is important to take a full history and identify risk factors present within the patient that may prompt additional investigation and result in treatment to correct any underlying problem/pathology that is primary to ED. Where possible, the man's partner should be involved in the discussions.

- Full medical, surgical and psychiatric history current/past, and identification of risk factors for metabolic syndrome e.g. (central) obesity, hypertension, insulin resistance, dyslipidaemia
- Full drug history, including current/previous, prescribed and over-the-counter medicines

- Social history and lifestyle include level of physical exercise and exercise tolerance, use of alcohol, tobacco and illicit drugs, and treatments already tried. Also ask about energy levels, loss of libido, loss of body hair or spontaneous hot flushes (symptoms of hypogonadism)
- Sexual history including:
  - present and previous erection quality, problems with sexual desire and arousal, and concomitant ejaculatory and orgasm dysfunction
  - onset and duration of symptoms
  - any issues regarding relationships (current and past), sexual aversion/pain (both for the patient and for his partner), sexual orientation and gender identity
  - Can use questionnaires for instance the International Index of Erectile Function (IIEF) or the validated shorter version of the Sexual Health Inventory for Men (SHIM).
- Identification of psychological/emotional factors such as anxiety and depression, knowledge and beliefs, including patient's interpretation of the problem.

3.2 Physical Examination

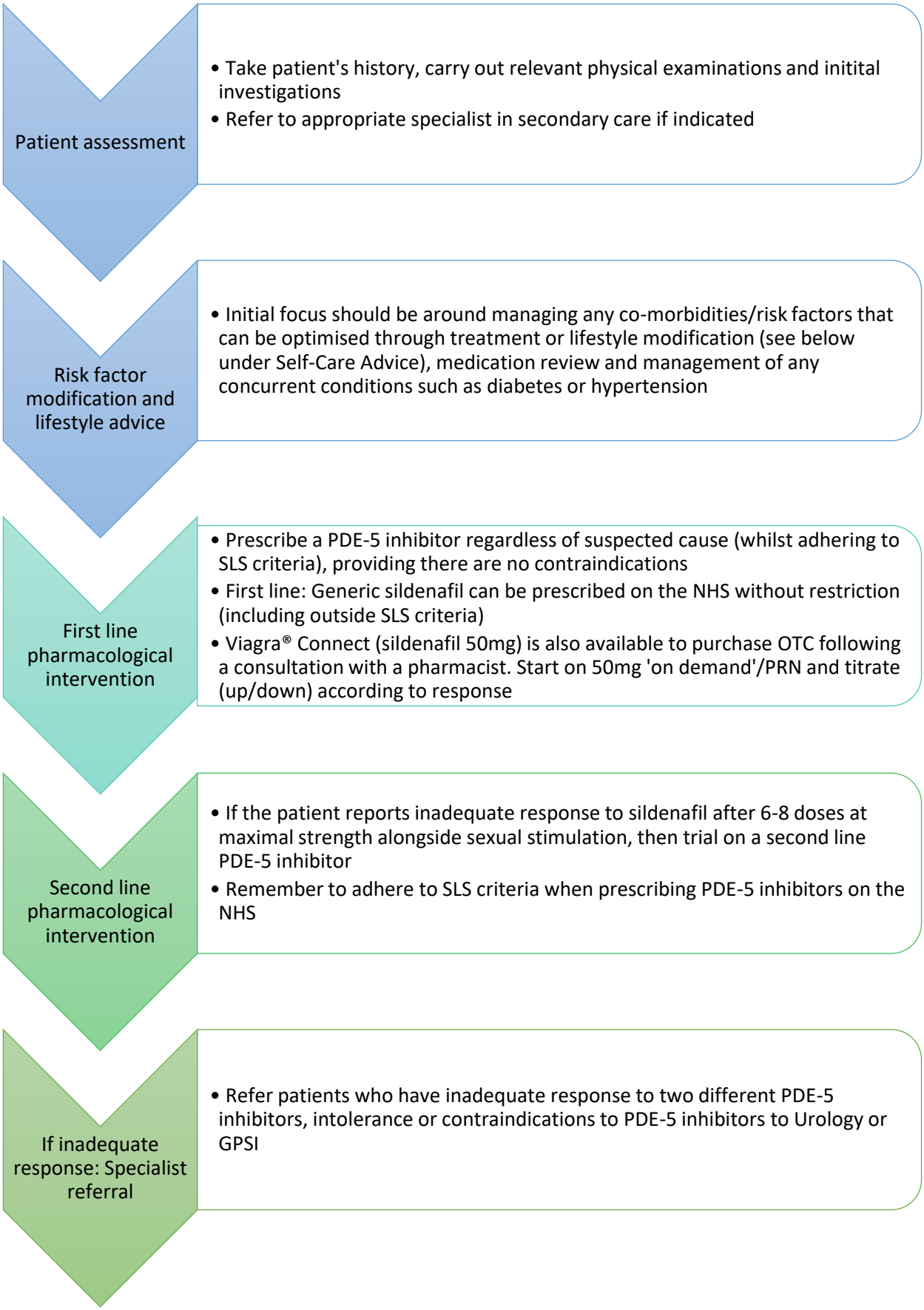
- Cardiovascular risk assessment: Record patient blood pressure, heart rate, height, weight, body mass index, waist circumference, and peripheral pulses. Perform a 10-year cardiovascular risk assessment.
- Genitourinary examination: Detect any abnormalities of penis, testicles and scrotum and retractile foreskin.
- Endocrine examination: Pay attention to sexual development; testes size, assess amount of (reduced) body hair (including facial and pubic), examine for any breast enlargement.
- Digital Rectal Examination – Consider DRE and prostate-specific antigen (PSA) test to assess for prostate cancer in men with any lower urinary tract symptoms such as nocturia, urinary frequency, hesitancy, urgency or retention, or erectile dysfunction, or visible haematuria (NICE NG12)

3.3 Investigations

- Total testosterone (TT) levels (recommended fasting sample) taken between 8-11 am.
  If low, repeat test with Sex Hormone-Binding Globulin (SHBG).
  If TT is lower than 12 nmol/l then follow-up investigations required as per Hypogonadism Guidelines
- Fasting glucose
- HbA1c and lipid profile (if not done in past 12 months)
- LFT
- PSA (as recommended by NICE NG12)
- TFT

3.4 Flow chart

3.5 Secondary care referral



When should I refer a man with erectile dysfunction?

Admit to hospital if there is priapism (persistent erection)

Urology

- Younger men who have always had difficulty obtaining and maintaining an erection
- Men with a history of trauma e.g., to the genital area, pelvis or spine
- Men with an abnormality of the penis or testicles upon physical examination
- Men who report treatment failure on two different PDE-5 inhibitors
- Suspected penile or prostate cancer, Peyronie's disease (moderate/severe)
- Men who do not fit SLS indications and report treatment failure on generic sildenafil and cannot be prescribed an alternative PDE-5 inhibitor by their GP

Endocrinology

- Men with low testosterone levels or abnormal FSH, LH or prolactin levels
- Also see Hypogonadism Guidelines

Cardiology

- Men at increased cardiovascular risk as per CKS Cardiovascular Risk Stratification
- Men with severe/unstable cardiovascular disease that would make sexual activity unsafe, or which contraindicates PDE-5 inhibitor usage e.g. unstable angina, heart failure, high risk arrhythmias or recent myocardial infarction
- Seek specialist advice before formal referral, if necessary

Mental Health Services

There are currently no NHS-funded psychosexual support services in County Durham CCG, however, referrals can be made to private providers. Any mental health issues may also be treated pharmacologically.

4. Self-care advice to the patient

- Lifestyle changes e.g. lose weight, stop smoking, reduce alcohol consumption, increase exercise, reduce stress
- For men cycling > 3 hours per week – advise a trial of reduced cycling to see if this improves the condition. If this is not possible, preventative measures, such as the use of a properly fitted bicycle seat and riding with the seat in a suitable position, may help prevent impairment of erectile function
- Advice and support available from:
  - NHS has useful information on erectile dysfunction
  - The British Association of Urological Surgeons (BAUS) has produced an information leaflet on erectile dysfunction
  - Sexual Advice Association

- Resuming sexual activity while using PDE-5 inhibitors (e.g. OTC Viagra® Connect) is not recommended for men with unstable heart disease, recent myocardial infarction, poorly compensated heart failure, unstable dysrhythmia, taking regular nitrates. These men should be referred to Cardiology – see above.

5. Prescribing

Prescribing considerations

When prescribing a PDE-5 inhibitor, the following should be borne in mind in addition to any clinical considerations:

- First line: generic sildenafil
- County Durham and Tees Valley formulary
- SLS (Selected List Scheme) criteria – also see sections 5.1 and 6

5.1 Patient qualification for NHS prescriptions and the Selected List Scheme (SLS)

SLS defines groups of patients who are eligible to be prescribed a treatment for a specific purpose on an NHS prescription in primary care (England) – also see Drug Tariff part XVIIIB.

The SLS restrictions, set out in Statutory Instrument 1999/16272, apply to all PDE-5 inhibitors with exception of generic sildenafil. In other words, generic sildenafil can be prescribed without restriction on the NHS, whereas Viagra®, tadalafil (Cialis®), avanafil (Spedra®), vardenafil (Levitra® - NB not on formulary) are not prescribable on an NHS prescription *except* for men who fall within the below criteria:

- Men who have diabetes, multiple sclerosis, Parkinson's disease, poliomyelitis
- Men who have renal failure treated by transplant or dialysis
- Men who have had radical pelvic surgery; prostatectomy and/or have been treated for prostate cancer (surgery and other treatment)
- Men who have had severe pelvic injury, single-gene neurological disease, spinal cord injury, spina bifida
- Men who were not included in the above categories but were receiving Caverject®, MUSE®, Viagra®, or Viridal® for NHS treatment of impotence on 14 September 1998

For patients falling in one of these categories, prescribers must endorse prescriptions for these products 'SLS'. If the 'SLS' endorsement is missing, the prescription will not be dispensed. Pharmacy staff cannot make the 'SLS' endorsement on behalf of the prescriber.

As set out in section 5.6 below, severe distress resulting from erectile dysfunction is not considered for NHS treatment (as set out in the NHS BSA Drug Tariff Part XVIIIB).

If the patient does not qualify for receiving a prescription on the NHS, a private prescription may be issued. This also includes treatment options that are not currently included in these guidelines.

5.2 Private prescriptions

Prescribing outside these guidelines may be done privately.
Because, in this case, prescribing is done outside the NHS framework, patients' prescription charge exemptions or NHS prepayment certificates are not valid.

5.3 PDE-5 inhibitor prescribing, monitoring and patient counselling

PDE-5 product choice

Tadalafil 'once daily' 5mg oral tablets have recently been approved locally as an option for the management of erectile dysfunction for patients meeting the SLS criteria (see section 5.1) and have been added to the County Durham and Tees Valley formulary as a GREEN drug, i.e. may be initiated in primary care. Tadalafil 2.5mg tablets are not recommended on the basis of cost.
Please note that tadalafil 'once daily' is not approved for the management of Benign Prostatic Hyperplasia alone. NICE terminated their technology appraisal (TA273) due to receiving no evidence from the manufacturer. In addition, NICE CG97 states that there is not enough evidence to recommend PDE-5 inhibitors in routine clinical management of Lower Urinary Tract Symptoms (LUTS) in men.

Avanafil is not approved for prescribing on the County Durham and Tees Valley formulary.

Prescribing quantities of PDE-5 inhibitors

The frequency of treatment, and therefore the quantity to be prescribed, will need to be considered on an individual basis.

Patient counselling on PDE-5 inhibitors

- Delay in onset of action (around 1-2 hours but dependent on the drug) so take at least 30-60 minutes in advance of sexual activity
- Erotic/sexual stimulation required
- Warn of possible side effects including headache, dyspepsia, visual disturbance and priapism (very rare) – for an overview of possible side effects, please refer to the product's Summary of Product Characteristics or BNF
- Ideally take before a meal but avoid heavy meals and excessive amounts of alcohol
- Encourage occasional "drug holidays"
- Seek advice if the man has an erection lasting longer than 4 hours (rare)

Follow-up and annual review

- Arrange follow-up 6-8 weeks after initiation of treatment to assess the efficacy and safety of the treatment as well as patient satisfaction
- Where possible, involve the man's partner in follow-up appointments
- Check how the patient has been using his PDE-5 inhibitor and that they have been using a licensed product, as there is a large counterfeit market
- Adjust the dose if required

- If patient reports inadequate response after 8 doses at maximal strength alongside sexual stimulation, then may trial on a different PDE-5 inhibitor or if two different PDE-5 inhibitors have been tried, refer to Urology/GPSI
- For people with diabetes, consider referral to Diabetes Clinic if their diabetes is poorly controlled and the patient is not already being followed up
- Continue to monitor any conditions that can contribute to erectile dysfunction

5.4 Vacuum Erection Device (VED) prescribing

Where pharmacological treatment fails, a vacuum erection device (VED) may be considered. VEDs are initiated on recommendation by specialist urology teams, usually as part of a penile rehabilitation protocol following treatments for prostate cancer or following radical pelvic surgery. Treatment with VEDs should only be prescribed on the NHS for patients who meet the SLS criteria and where PDE-5 inhibitors are contraindicated or ineffective. Caution should be applied for patients with bleeding disorders or on anticoagulant therapy.
In order to get maximum benefit, the prescription needs to be issued with appropriate patient education and support. The product is issued on a one-off prescription and usually comes with a 10-year guarantee and support package. Replacement parts and consumables may be required over time. Both VEDs and their consumables may be prescribed in primary care.

5.5 Prosthetic penile implants

Penile implants can be surgically inserted into the penis for treating ED. If first- and second line treatments are ineffective at allowing penetrative intercourse, patients are considered to have end stage ED and can be referred for consideration of penile prostheses in a tertiary urology centre.
Treatment with penile implants is commissioned by NHS England (Specialised Commissioning) for patients with end stage ED. NHS England will fund the implantation of a penile prosthesis in patients fulfilling the criteria set out in their policy only via local commissioning teams.

5.6 Psychosexual counselling

The current CCG recommendation is that psychological distress is not considered for NHS treatment as set out in Part XVIIIB of the NHS BSA Drug Tariff. In line with the North East and North Cumbria CCGs' Value-Based Clinical Commissioning Policies (2020), the following statement is made: *"Accounting for psychological factors in arriving at a decision about eligibility for NHS funding is hard to do in a clear and fair way. These considerations have been removed from this policy as psychological distress unfortunately does not constitute clinical exceptional circumstance"*. Consequently, treatment with psychosexual interventions is not routinely commissioned.

6. Financial implications

Drug and Strength	Drug tariff price	Cost per dose	'SLS' applies?	Formulary status (January 2022)
Sildenafil 25mg	96p for 4	24p	Yes, with exception of *generic* sildenafil	Green
Sildenafil 50mg	95p for 4	24p	Yes, with exception of *generic* sildenafil	Green
Sildenafil 100mg	£1.11 for 4	28p	Yes, with exception of *generic* sildenafil	Green
Tadalafil 10mg	£1.12 for 4	28p	Yes	Green alternative
Tadalafil 20mg	£1.41 for 4	35p	Yes	Green alternative
Tadalafil 5mg daily	£3.02 for 28	n/a as taken continuously	Yes	Green alternative
Avanafil 50mg	£10.94 for 4 £19.70 for 8	£2.74 £2.46	Yes	Non-formulary
Avanafil 100mg	£14.08 for 4 £26.26 for 8	£3.28 £3.52	Yes	Non-formulary
Avanafil 200mg	£21.90 for 4 £39.40 for 8	£4.93 £5.48	Yes	Non-formulary
Vardenafil 5mg	£5.69 for 4	£1.42	Yes	Green alternative
Vardenafil 10mg	£10.59 for 4	£2.68	Yes	Green alternative
Vardenafil 20mg	£2.95 for 4	74p	Yes	Green alternative
Vacuum erection device	one-off purchase £149		Yes	Specialist initiation
Alprostadil 1mg intraurethral application (MUSE®)	£11.56 for 1	£11.56	Yes	Green+
Alprostadil intracavernous 10-40mg injection (Caverject® or Viridal® Duo)		£7.35 to £21.58	Yes	Green+
Aviptadil/phentolamine intracavernous injection (Invicorp®)	£47.50 for 5	£9.50	No	Green+
Prosthetic penile implants	Funded by NHS England (Specialised Commissioning)			

based on NHS BSA Drug Tariff December 2021

Formulary status:

Green = treatment may be initiated and prescribed in primary care

Green+ = following specialist initiation/recommendation, treatment may continue to be prescribed in primary care