Guidelines for the Management of Erectile Dysfunction in Primary Care

Background

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.

The principal aim of these guidelines is to enable physicians and other healthcare professionals to manage ED in line with recent evidence, modern research and clinical opinion, while adhering to the correct interpretation of current Department of Health regulations (see Appendix 1).

Adapted from British Society for Sexual Medicine Guidelines on the Management of Erectile Dysfunction and Clinical Knowledge Summaries – Assessment and Management of ED (NICE 2014)

Assessment (see Flowchart on page 5 or https://cks.nice.org.uk/erectile-dysfunction)

Patient should be assessed to determine whether nature of dysfunction is physical or pathophysiological. 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.

Referral

- 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)
  - Where patient does not meet “SLS” criteria as condition causes “severe distress” (requires prescriptions from specialist centre)
  - Failure to respond to the maximum dose of at least two phosphodiesterase-5 inhibitors (PDE-5i)
- 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).
    (N.B. Alternate guideline available for Erectile Dysfunction following Radical Prostatectomy)
  - Young men who have always had difficulty in obtaining or maintaining an erection.
- Refer for psychosexual counselling
  - Where the underlying cause is psychogenic. (Refer to Relate 01482 329621)
- 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.
Recommended treatment for erectile dysfunction

For information on contraindications, cautions, drug interactions, and adverse effects, see the electronic Medicines Compendium (eMC) (http://emc.medicines.org.uk), or the British National Formulary (BNF) https://www.medicinescomplete.com

N.B. NHS treatment (excluding generic sildenafil) must meet DoH criteria (see Appendix 1 and prescriptions endorsed “SLS”).

ALL PATIENTS: Lifestyle advice

➢ Lose weight (important), stop smoking, reduce alcohol consumption, and increase exercise.
➢ Men who cycle for more than 3 hours per week should be encouraged to trial a period without cycling to see if this improves their erectile function.
➢ Further advice and support is also available from the Sexual Dysfunction Association www.sda.uk.net.

1st line treatment:

➢ Sildenafil 50mg ONCE WEEKLY when required (initial dose 25 mg if patient has co-morbidities).
➢ Review and titrate dose as necessary (from 25mg to 100mg once weekly as required)
➢ A man with erectile dysfunction should receive eight doses of a PDE-5i at a maximum dose with sexual stimulation before being classified as a non-responder

2nd line treatment: where no response to sildenafil at 100mg when required,

➢ Tadalafil 10mg ONCE WEEKLY when required for 1 month
   Review and if necessary increase to 20mg once weekly when required
   OR

➢ Vardenafil tablets – 10 mg ONCE WEEKLY when required for 1 month (5mg for patients on alpha blocker)
   Review and titrate dose as necessary (from 5mg to 20mg once weekly when required)

N.B. With the exception of treatment for Erectile Dysfunction following Radical Prostatectomy (see separate guidelines) drug treatment at a frequency of more than once weekly (including more than once weekly of when required preparations or the use of once daily preparations) is not routinely commissioned. An exceptional treatment request may be made to the appropriate CCG.
3rd line: REFER TO ED CLINIC

Where patient has failed to respond to the maximum dose of at least two oral PDE-5 inhibitors refer to specialist.

Treatments suitable for prescribing by general practitioner, following initiation by specialist include (in no particular order):

- Vacuum erection devices (sometimes used in combination with PDE-5i)
- Alprostadil cream, 200 – 300 micrograms sachet once weekly when required
- Intracavernous alprostadil (*Caverject or Viridal Duo*)
  - Usual dose 5-20 micrograms (max 60 micrograms) when required once weekly
    - [Rarely used in combination with PDE-5i, unlicensed indication]
- Intraurethral alprostadil (*MUSE*) – usual dose 125 micrograms – 1 mg when required once weekly
- Invicorp® (aviptadil 25micrograms and phentolamine 2mg) solution for intracavernosal injection. Use once weekly when required
  (See Appendix 2 for more details)

Treatments for prescription by specialist only [unlicensed drugs, alone or in combination]

- Intracavernous phentolamine: Dose 250 micrograms – 2mg when required

References

1. NHS Executive (June 1999) HSC Circular 1999/148 Treatment for impotence
2. NHS Executive (Aug 1999) HSC Circular 1999/177 Treatment for impotence: Patients with severe distress
## APPROVAL PROCESS

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Appendix 1 – Summary of Department of Health Guidance


Limitation to prescribing (excluding generic sildenafil)
GPs are limited in their use of NHS prescriptions for the treatment of erectile dysfunction. They may issue NHS prescriptions (endorsed “SLS”) to treat erectile dysfunction in men 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 (including transurethral resection of the prostate), or renal transplant.
- were receiving alprostadil (Caverject®, MUSE® and Viridal®), moxisylyte hydrochloride (thymoxamine hydrochloride, Erconos®) or sildenafil (Viagra®) for erectile dysfunction, at the expense of the NHS, on 14 September 1998.
- are suffering severe distress as a result of impotence (prescribed in specialist centres only, see notes below).

Frequency of Prescribing
The frequency of treatment will need to be considered on a case by case basis, but doctors may find it helpful to bear in mind that research evidence¹ about the frequency of sexual intercourse shows that the average frequency of sexual intercourse in the 40-60 age range is once a week. This evidence is confirmed by research from the USA. They may also wish to bear in mind that some treatments for impotence have been found to have a “street value” for men who consider, rightly or wrongly, that these treatments will enhance their sexual performance and that excessive prescribing could therefore lead to unlicensed, unauthorised and possibly dangerous use of these treatments.

Therefore, the DH advises doctors that one treatment a week will be appropriate for most patients treated for erectile dysfunction. If the GP in exercising his clinical judgement considers that more than one treatment a week is appropriate he should prescribe that amount on the NHS.


Treatment of impotence where condition causes severe distress
Department of Health (also recommends that treatment should also be available from specialist centres when the condition is causing severe distress.

The following criteria should be considered when assessing distress:

- significant disruption to normal social and occupational activities;
- a marked effect on mood, behaviour, social and environmental awareness;
- a marked effect on interpersonal relationships.

When prescribing specialist centres will issue an FP10 and endorse the form issued ‘SLS’ if the treatment is to be dispensed in the community.
Appendix 2: Erectile Dysfunction Shared Care Management in General Practice—Hull and East Riding of Yorkshire

(Written by Dr U Y Joshi May 2013 – updated by Marie Miller in line with commissioning decision)

- Evidence of primary psychogenic problems
- Full history and relevant examination
- Evidence of organic disease
  - Investigations: FBC, biochemical profile, Fasting P Glucose/Hba1c & S Lipids profile, S Testosterone, Pictactin and SHBG.PSA if >50 years old, Urinalysis
  - Take appropriate action or refer to relevant service
  - Results normal
    - Yes
      - Shared decision making with patients
      - Offer oral therapy (PDE5 inhib): make sure patient is not on nitrates
      - Discuss various options of oral therapy ie Sildenafil 50-100mg (first line), Tadalafil 10-20mg, Vardenafil 10-20mg
    - No
      - Optimise management of diabetes cardiovascular status (table 1) and consider alternative to current medication where indicated Ref to appropriate specialty if indicated
      - Refer to Erectile Dysfunction Clinic, Conifer House, 01482 336336 for further assessment and care ie topical, intracavernous injection, intraurethral therapy, vacuum therapy

Eligibility of NHS treatment under Schedule II Diabetes Mellitus, Multiple Sclerosis, Parkinson’s Disease, poliomyelitis, prostate cancer, severe pelvic injury, single gene neurological disease, spina bifida or spinal cord injury, receiving dialysis, prostatectomy, or renal transplant, were receiving treatment before 14th Sep 1998