East Lancashire Health Economy Medicine Management Board

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Lancashire Medicines Management Group NHS

Erectile Dysfunction Guidance

Sharon Andrew

Midlands and Lancashire CSU

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VERSION CONTROL

Version Number	Date	Amendments made
1.0	08/10/15	First version agreed at LMMG
1.1	14th April	Updated with tadalafil daily commissioning position
1.2.	26/7/17	Updated to include Invicorp - Reserved for patients not responding or intolerant to Alprostadil, as an option before referral for surgical procedure (section 4.3.3)

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1. INTRODUCTION

Erectile Dysfunction (ED), previously known as impotence, is the persistent inability to get and maintain an erection that is sufficient to permit satisfactory sexual performance. It is a very common condition, and it is estimated that ~50% of all men between the ages of 40 and 70 are affected. ED can have a significant impact on quality of life of both patients and their partners.[1-3,10]

The primary goal in the management strategy of a patient with ED is to determine the cause and treat it when possible. Modifiable risk factors, including lifestyle or drug-related factors, may be addressed either before, or at the same time that other ED specific interventions are used. As a rule, ED can be treated successfully, but can only be cured in limited circumstances, i.e. psychogenic ED, post-traumatic ED in young patients, and hormonal causes for ED (e.g. hypogonadism and hyperprolactinaemia). Most men with ED will be treated with therapeutic options that are not cause specific, allowing a structured treatment strategy to be adopted.[3,10]

2. PURPOSE AND SUMMARY

This guidance includes a flow chart indicating a stepwise approach to the management of ED, with additional treatment notes that have been developed to guide prescribers

3. SCOPE

This guidance covers the principals of prescribing for Erectile Dysfunction in primary and secondary care organisations.

Specifically

- The initial patient assessment.
- First and second line treatments including the evidence base and rationale behind potential therapies.
- Treatment options for erectile dysfunction post prostatectomy.
- Department of Health prescribing restrictions.
- Appropriate quantities of supply on NHS prescriptions.

4. GUIDANCE

4. 1 Initial Patient Assessment

New Patient with Erectile Dysfunction (ED)[1,2,3]

Take a History

Medical- Check for co-morbidities and any previous trauma or surgery. Establish if there is a history of abnormal bending when erect, a filling defect i.e. rigidity/not full erection, or difficulty with penetration. Ensure complaint is not premature ejaculation

Sexual- Clarify onset and duration of ED, relationship issues, loss of desire

Psychosocial- Asses stress, life changes, and anxiety

Reversible risk factors- Check for anabolic steroid use, smoking, alcohol, illicit drugs, prescribed medications, cycling

Likely primary psychogenic cause if[3]:
Symptoms variable
Sudden onset
Presence of early morning, nocturnal, spontaneous or self-stimulated erections

Likely primary organic cause if[3]:
Symptoms constant
Gradual onset
Absence or altered early morning, nocturnal, spontaneous or self-stimulated erections

Carry out Investigations for Underlying Disease

- Fasting blood glucose & HbA_{1c} [2]
- Lipid profile
- eGFR
- LFTs (Gamma GT if indicated)
- Total serum testosterone (morning sample) if low (<12nmol/L) repeat sample after 2-3 weeks and refer to endocrinology if consistently low. [2]
- Prolactin – check if patient complains of lack of desire
- CV risk
- BP
- BMI
- HR and rhythm
- External genitalia
- Secondary sexual characteristics
- Lower limb pulses.

Ensure 'curable' causes of ED are treated (refer to specialist services as appropriate)

e.g. Hormonal, post-traumatic, arteriogenic ED in young patients, psychological causes, partner sexual problems, radical prostatectomy and drug-induced ED.

Review medications which are known to cause ED

- Antihypertensives. (B-blockers, verapamil & methyldopa)
- Diuretics (thiazides & spironolactone)
- Antidepressants (SSRIs TCAs, MAOIs, lithium)
- Antipsychotics (neuroleptics)
- Antiandrogens
- Cardiac (digoxin)
- H2 antagonists (cimetidine & ranitidine)
- Recreational drugs

Advise on lifestyle changes and risk factor modification

e.g. weight loss, smoking cessation, reduced alcohol consumption, increased exercise and stress management.
For men who cycle more than 3 hours/week, encourage a trial period without cycling to see if this improves their erectile function.[3]

Provide education and counselling to patients and partners

Identify patient needs and expectations

Offer conjoint psychosocial and medical treatment

Referral Criteria[3]

Admit to hospital if there is priapism

Refer to Urology

- Young men who have always had difficulty obtaining or maintaining an erection
- Men with a history of trauma, if an abnormality of the penis or testicles is found on examination

Refer to Endocrinology/Andrology

- Hypogonadism (characterized by abnormal testosterone, FSH, LH or prolactin levels)

Refer to Cardiology

- CV disease that would make sexual activity unsafe

Refer to Psychosexual services

- If severe distress is suspected. The following criteria should be taken into account:
  - significant disruption to normal
  - social and occupational activity
  - marked effect on mood, behaviour, social and environmental awareness
  - marked effect on interpersonal relationships

Consider referral for psychological assessment

- Men with a psychogenic underlying cause of ED

4.2 Primary Care Medical Management of Erectile Dysfunction[1,2,3]

1st line PDE5 inhibitor: Generic Sildenafil* 50mg on demand[4]

Dose can be increased to 100mg according to response or reduced to 25mg if required e.g. if eGFR <30ml/min or in hepatic impairment
(nb. manufacturer advises to avoid in severe hepatic impairment)

Provide instructions on use and counselling

- Should be taken ~1hr prior to sexual activity
- Duration of action ~ 4hrs
- Possible interaction with food resulting in delayed absorption
- Ensure patient understands that PDE5i's are not initiators of erection and sexual stimulation is required.[1,2]

* **Generic Sildenafil can be provided to all patients on the NHS, regardless of the cause of ED, patients who require other treatments must meet NHS criteria. Those with severe distress who require alternative treatments should be referred to specialist services** . Use of branded sildenafil (Viagra ®) or branded generics is not recommended; they offer no advantage over the generic product but are considerably more expensive.

If a PDE-5 inhibitor is contraindicated [3,5]

E.g.

- Use of nitrates
- Recent MI
- Recent stroke
- Unstable angina
- Non-arteritic anterior ischaemic optic neuropathy
- Hypotension
- if vasodilation of sexual activity is not recommended

Consider a trial of:

A Vacuum Pump

(Only for initiation in non-specialist services by clinicians with experience in use)

Or

Alprostadil Cream (Vitaros®)[16]

Usual dose 300mcg, (can be reduced to 200mcg if the patient experiences local side-effects).

Administration:

- Use 5-30 mins prior to intercourse
- Supplied as single dose containers (discard after use)
- The tip of the container should be placed over the opening of the penis and the plunger pushed down until all the cream is expelled into the penis opening and surrounding skin. The penis should then be held upright for 30 seconds to allow the cream to penetrate
  Nb: The tip of the container should NOT be inserted into the opening of the penis
- Duration of affect is 1-2 hrs
- Maximum frequency is once per 24hr period and no more than 2-3 times per week

The initial prescription should be for 1 pack of 4x single doses, after which the patient should be reviewed to assess treatment effect prior to further prescriptions being provided

For Further Information See the SPC

Assess therapeutic outcome
Erectile response, side-effects and patient satisfaction with treatment
Assess use of treatment
If needed provide instructions and counselling. Ensure patient understands that PDE5i's are not initiators of erection and sexual stimulation is required.
Consider re-trial
If there is no response after at least six (preferably eight) doses of an oral PDE5 inhibitor at a maximum tolerated dose with sexual stimulation, a second line PDE-5 inhibitor should be used.[1,2] (~40% of men discontinue the 1st line PDE5 because of lack of efficacy).[1]

2nd line PDE5 inhibitor: Tadalafil 10mg on demand[9]

Dose can be increased to 20mg according to response.
Max dose 10mg if eGFR < 30ml/min and in hepatic impairment
(nb. manufacturer advises to avoid in severe hepatic impairment)

- Should be taken at least 30 mins prior to sexual activity
- Duration of action ~36hrs
- Can be taken with or without food
- Useful treatment option if patient is anxious about timing relative to intercourse

Patients must meet NHS criteria for ED medication. **For those not meeting NHS criteria a private prescription can be offered.[2]**

The DoH recommends that **ONE TREATMENT PER WEEK** is sufficient for most patients. **See also quantity of supply on NHS prescription**

Assess therapeutic outcome and use of treatment. (See above)
If unsatisfactory response refer to specialist services

See also general Referral Criteria

NOTE: Tadalafil Daily Tablets are not recommended for use in primary care for the treatment of erectile dysfunction i.e. Black Colour Classification

For a very specific group of patients with significant performance anxiety or who require erection support as part of a masturbatory/behavioural programme, tadalafil daily tablets are recommended where treatment is provided, as part of a discrete programme by specialists under a Sexual Health Service. i.e. Red Colour Classification. (See LMMG New Medicine Recommendation for full details)

4.3 Alternative Treatments to PDE5 Inhibitors

4.3.1 Vacuum Pumps[1-2]

May be Suitable for Patients Who:

- Do not respond to PDE5 inhibitors or other treatments.[3]
- Require non-invasive, non-drug treatment.[2] e.g. older patients who have certain co-morbidities and infrequent sexual intercourse.[1]

They are most efficacious if the patient has a positive attitude to the use of the device, have been counselled appropriately and had sufficient demonstration of their use.[10]

Information on the principals of treatment, equipment and technique is available from the British Journal of Urology[11]

Referral to a specialist may be required for assessment and treatment initiation. In this instance the specialist should provide the initial device as cost is included in the treatment tariff.[10]

Efficacy (in terms of producing erection satisfactory for intercourse), is reported to be up to 90% regardless of the cause of ED. However satisfaction rates vary considerably.[1]

Long term use of devices decreases to 50-64% after 2 years. Most men who discontinue use do so after 3 months, leading to potential waste.[1]

Safety: Tension rings should not be worn for more than 30mins and European Association of Urology states that devices should not be used in patients with bleeding disorders or taking anticoagulants.[1]

Choice of Vacuum Pump: Only CE marked devices listed in the Drug Tariff Part IXA are prescribable on NHS prescription.

In the absence of trial data or evidence of individual device effectiveness. Choice should be based on costs and prescriber or organisational satisfaction of the device safety and effectiveness. (A healthcare organisation could be held responsible, under health and safety law and civil liability in the event that a patient or member of personnel died or suffered personal injury or damage, as a result of inappropriate purchase or prescription of a device).[12]

In order to assist organisations with device rationalisation, a number of manufactures were asked to provide safety data and evidence of compliance with European CE conformity and with BS EN 62366:2008 'Medical devices. Application of usability engineering to medical devices.' [12]
The requested confirmation of safety and compliance with standards was received from Eurosurgical (only), producers of **Pos-T-Vac AVP 1000** battery operated £127.00[6] and **Pos-T-Vac MVP 700** Manual £98.00[6]. The company also provides patients with a user manual and DVD instructions which may reduce the need for follow up demonstration appointments.

4.3.2 Alprostadil – Available as 3 different presentations

Intracavernous injection is recommended by the European Association of Urology as 2nd line therapy (after PDE5 inhibitors) for ED.[1] Less invasive formulations of alprostadil may be preferable for some patients but are also less effective.[1]

	Intracavernous injection Caverject ®, Viridal ®	**Urethral sticks** Muse ®	**Cream** (3mg/g) Vitraos ® [24]
Dose [13-16]	2.5-40 micrograms	250-1000 micrograms	200-300 micrograms
Frequency of Administration[13-15]	**On demand** Max Once daily/ 3 doses per week	**On demand** Max 2 doses/day 7 doses/week	**On demand** Max Once daily and 2-3 doses per week
Efficacy [1] Rigidity sufficient for penetration	>70% Does not require an intact nerve supply. Can be highly effective after spinal cord injuries or major pelvic surgery e.g. radical prostatectomy.	30-66%	An increase of ~15% is reported see LMMG Alprostadil cream review for more details.
Comments[1]	**The injection and Urethral sticks** come with special injection devices/applicators for which patients require training to use and should be **prescribed by brand**		
Colour Classification	**AMBER 0** Requires specialist initiation, for training and dose titration.		**Amber 0** For patients resistant to treatment with PDE5 inhibitors (Specialist review advised) **Green** For patients who in whom PDE5 inhibitors are not tolerated or contra-indicated.

4.3.3 Aviptadil (VIP) 25micrograms / Phentolamine Mesilate 2mg (Invicorp) solution for injection[17] is indicated for the symptomatic treatment of erectile dysfunction in adult males due to neurogenic, vasculogenic, psychogenic, or mixed aetiology. LMMG have approved its use within licensed indication, but its use is to be **reserved for patients not responding or intolerant to alprostadil, as an option before referral for surgical procedure**.

4.4 Treatment of ED in Patients Post Radical Prostatectomy (RP)

ED is a common complication following prostatectomy due to cavernosal nerve damage, causing hypoxia, apoptosis, venous leak and fibrosis of the corpora cavernosa.[18] Although there is evidence that, following an initial loss of erectile function, spontaneous improvements will occur in a proportion of men without specific intervention, most men who undergo radical treatment for prostate cancer experience ED and this is a cause of distress for the majority.[1]

NICE CG175 recommends[19]**:**

- That post prostatectomy men have early and ongoing access to specialist ED services.
- Men with prostate cancer who experience loss of erectile function should be offered treatment with PDE5 inhibitors (1st line) to improve their chance of spontaneous erections.
- If PDE5 inhibitors fail to restore erectile function or are contraindicated, men should be offered, vacuum devices, intraurethral inserts/penile injections, or penile prostheses as an alternative.

Within the Lancashire Health Economy, it is recommended that patients are treated with generic sildenafil 1st line post-prostatectomy (unless PDE5 inhibitors are considered inappropriate). Tadalafil daily is **not recommended** i.e. Black colour classification, but tadalafil on demand may be used as a 2nd line PDE5 inhibitor (if considered appropriate by specialist ED services).

Nb. Intracavernous injections do not require an intact nerve supply and can therefore be highly effective after spinal cord injuries and after major pelvic surgery such as after radical prostatectomy.[1]

It has been hypothesised that regular treatment (rather than on demand) with a PDE5 inhibitor or use of longer acting treatments may facilitate recovery of natural erectile function. However, to date convincing evidence has remained lacking and there is no consensus on the most effective treatment strategy post prostectomy.[18&20]

The evidence and rationale for PDE 5 inhibitors post prostatectomy has been summarised by UKMI as follows[18]**:**

- PDE5 inhibitors promote corporal smooth muscle relaxation and blood flow and early use of these agents following prostatectomy can reverse or minimise these adverse effects.
- **All four PDE-5 inhibitors have been used successfully post-radical prostatectomy**, with greater success following nerve sparing radical prostatectomy.
- **Sildenafil is the most widely studied PDE5 inhibitor for ED following prostatectomy** but few trials have studied daily dosing.
- Supportive therapy to rehabilitate erectile function should, ideally, be started as soon as possible following surgery. In the studies, regular PDE5 inhibitor dosing was started up to 6 weeks after surgery and continued for up to 12 months. On-demand dosing was used in other studies, with initiation ranging from the day after surgery to over 24 months later.
- Few studies enrolled men after unilateral Nerve Sparing Radical Prostatectomy (NSRP); this is associated with a higher risk of losing erectile function completely, compared with bilateral NSRP.

- Both regular (daily or three-times a week) and on-demand (prior to sexual activity) doses were effective but the studies are not designed well enough to draw firm conclusions which regimens offer the best treatment outcomes. There are conflicting results from studies comparing the two treatment regimens possibly due to differences in study designs.
- Treatment should be started early and may need to be continued for 24-36 months to allow full recovery of erectile function.

See also comment from European Association of Urology[20]

4.5 Supporting Information

4.5.1 Criteria for Providing ED medications on NHS Prescription [10, ,21,22,23]

1. **All patients diagnosed with ED (regardless of cause) can be provided with generic sildenafil on the NHS, if clinically appropriate.**
2. **Alprostadil, Aviptadil (VIP) / Phentolamine Mesilate and all other PDE5 inhibitors, including branded sildenafil (Viagra®) can only be prescribed on the NHS to patients who meet one of the following criteria:**
   a. **Are suffering from any of the following**
      - Diabetes
      - Multiple sclerosis
      - Parkinson's disease
      - Poliomyelitis
      - Prostate cancer
      - Severe pelvic injury
      - Single gene neurological disease
      - Spina bifida
      - Spinal cord injury

   b. **Are receiving treatment for renal failure by dialysis**
   c. **Have had the following surgery**
      - Prostatectomy
      - Radical pelvic surgery
      - Kidney transplant

   d. **Were receiving NHS prescriptions for one of these drugs on 14th September 1998**

   Prescriptions which meet the criteria outlined above should be endorsed 'SLS' by the prescriber.
3. **Prescribing for Severe Distress.**
   Severe distress is not one of the 'SLS' criteria for provision of ED treatments on NHS prescription.
   However, patients suffering from severe distress as a result of ED can be treated in primary care with generic sildenafil (on NHS prescription) where it is clinically appropriate.[23]
   Patients requiring different pharmacotherapy should be referred to a specialist for treatment on the NHS.[23] The DOH specifies that patients who are prescribed treatment for ED as per Health Service Circular 1999/177 '*would need to* ***continue to receive their treatment through specialist services.'*** It further states that '*arrangements for follow-up and the provision of further treatment, should be determined according to the needs of each patient. These may include arrangements for repeat prescriptions which may or may not include a full outpatient appointment.'* [25]

If an FP10 form is used it should be endorsed 'SLS' otherwise the community pharmacist will be unable to supply the medicine[25]

4.5.2 Private Prescriptions

For those NHS patients not meeting NHS criteria (excluding those prescribed generic sildenafil) a private prescription should be provided.

These should be free of a prescription writing charge. Repeats can be provided on a private prescription. The cost of the medication will be determined by the dispensing pharmacy.

4.5.3 Quantity of Supply on NHS Prescriptions[21,22]

The Department of Health advises that **'One treatment per week will be appropriate for most patients being treated for erectile dysfunction**. If the GP in exercising his clinical judgement considers that more than one treatment a week is appropriate they should prescribe that amount on the NHS.'

The restriction in the number of treatments do not apply for generic sildenafil.

Frequency of treatment will need to be considered on a case by case basis, but **prescribers may find it helpful to bear in mind that:**

- Research shows that the average frequency of sexual intercourse in the 40–60 age range is once a week.[21]
- Some treatments for impotence have a **"street value"** for men who consider, rightly or wrongly, that they will enhance their sexual performance. Excessive prescribing could therefore lead to unlicensed, unauthorised and possibly dangerous use of these treatments.

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Name the person / people and their role who have written the original document that this document is based on; or who have contributed to this document in a significant way

This guidance does not override the individual responsibility of health professionals to make decisions in exercising their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer. For full prescribing information please refer to the BNF and SPC ensuring correct SPC according to dose is consulted.

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