NHS
Cheshire and Merseyside

Clinical Commissioning Policy

CMICB_Clin110
Erectile Dysfunction – secondary care referral

Category 2 Intervention - Only routinely commissioned when specific criteria are met

Contents

Last Reviewed: March 2024

This policy statement will be reviewed 5 years from the date of the last review unless new evidence or technology is available sooner.

1. Policy statement

1.1 Some important causes of erectile dysfunction may be cardiovascular-related (e.g. hypertension or hyperlipidaemia), neurogenic (e.g. multiple sclerosis or diabetes mellitus), or hormonal (e.g. hypogonadism).

1.2 Initial management should include advice on lifestyle changes (e.g. weight loss, stopping smoking, reducing alcohol consumption and increasing physical activity if appropriate).

1.3 Majority of men with erectile dysfunction can be managed in primary care using an oral phosphodiesterase (PDE5) inhibitor according to the local formulary administered at the correct dosage. Links to the relevant formulary are given below[1]

1.4 Referral to secondary care for erectile dysfunction is not routinely commissioned unless one of the following criteria is met:

- Young men who have never been able to obtain or maintain an erection.
- Laboratory-confirmed history of hypogonadism.
- History of trauma to the genital area, pelvis or spine.
- An abnormality of the penis or testicles is found on examination (e.g. suspicion of Peyronie's disease)
- Patients with diabetes where treatment with a phosphodiesterase (PDE5) inhibitor has been unsuccessful or is contraindicated.
- Patients who have had radical prostate surgery and haven't responded to a phosphodiesterase (PDE5) inhibitor or where this is contraindicated.
- Men who wish to be considered for injectable agents, vacuum devices and/or other surgical procedures.

2. Exclusions

2.1 None.

3. Core Eligibility Criteria

3.1 There are several circumstances where a patient may meet a 'core eligibility criterion' which means they are eligible to be referred for this procedure or treatment, regardless of whether they meet the policy statement criteria, or the procedure or treatment is not routinely commissioned.

3.2 These core clinical eligibility criteria are as follows:

- Any patient who needs 'urgent' treatment will always be treated.
- All NICE Technology Appraisals Guidance (TAG), for patients that meet all the eligible criteria listed in a NICE TAG will receive treatment.
- In cancer care (including but not limited to skin, head and neck, breast and sarcoma) any lesion that has features suspicious of malignancy, must be referred to an appropriate specialist for urgent assessment under the 2-week rule.
  NOTE: Funding for all solid and haematological cancers are now the responsibility of NHS England.
- Reconstructive surgery post cancer or trauma including burns.

[1] **FORMULARY** links available here: East Cheshire and West Cheshire

- Congenital deformities: Operations on congenital anomalies of the face and skull are usually routinely commissioned by the NHS. Some conditions are considered highly specialised and are commissioned in the UK through the National Specialised Commissioning Advisory Group (NSCAG). As the incidence of some cranio-facial congenital anomalies is small and the treatment complex, specialised teams, working in designated centres and subject to national audit, should carry out such procedures.
- Tissue degenerative conditions requiring reconstruction and/or restoring function e.g. leg ulcers, dehisced surgical wounds, necrotising fasciitis.
- For patients expressing gender incongruence, further information can be also be found in the current ICB gender incongruence policy and within the NHS England gender services programme - https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/

4. Rationale behind the policy statement

4.1 The policy statement has been developed to align with recommendations from NICE and the British Society for Sexual Medicine.

4.2 In addition, the policy was also ratified by two urologists with a specialism in erectile dysfunction.

5. Summary of evidence review and references

5.1 Erectile dysfunction (ED) is usually defined as the inability to achieve or maintain an erection sufficient for satisfactory sexual performance. [1] The pathophysiology may be vasculogenic, neurogenic, anatomical, hormonal, drug-induced and/or psychogenic.[2] Worldwide, the number of men with ED is expected to increase to 322 million by the year 2025 (this has doubled from 152 million in 1995). [1] In the USA (estimated population 330 million), it is estimated more than 3 million men are affected every year.[3] A large European study of men aged 30 – 80 years reported a prevalence of 19%. [4]

5.2 Although age is one of the key associations, other risk factors include diabetes, cardiovascular disease, depression and benign prostatic hyperplasia (BPH). ED may also be a predictor of cardiovascular disease (CVD), dementia and all-cause mortality. [1] Writing for the British Society for Sexual Medicine, Hackett concluded there is now overwhelming evidence that erectile dysfunction is strongly associated with cardiovascular disease such that newly presented patients should be thoroughly evaluated for cardiovascular and endocrine risk factors. Further, measurement of fasting serum glucose, lipid profile and morning total testosterone should be considered mandatory in all newly presenting patients. [4]

5.3 In terms of treatment, the most common option is the phosphodiesterase type 5 inhibitor (PDE5) which has proven successful in up to 65% of men. Other options include the vacuum erection device or intracavernosal injection therapy using vasodilators which should be considered in men with contraindications or non-responders to PDE5. Apart from penile implants, other therapies such as penile vascular surgery, extracorporeal shockwave therapy and intracavernosal stem cell therapies are novel and should be considered investigational due to lack of evidence supporting their long-term safety and efficacy.[3]

5.4 A recent review on the health economics of ED treatment concluded that evaluation of PDE5 inhibitors, particularly sildenafil (Viagra), is well described. However, there has been minimal research on intracavernosal injections, intra-urethral suppositories, penile prosthesis surgery, vacuum erection devices and other techniques. The authors concluded that substantial research is needed to evaluate the cost effectiveness of these ED treatments across different populations, countries and reimbursement systems.[5]

5.5 In 1999, a suite of Department of Health circulars and government regulations were published to restrict the use of sildenafil which at that time was not available generically. Prescribing was restricted to men who had had radical pelvic surgery, prostatectomy, prostate cancer, renal failure, spinal cord/pelvic injury, diabetes, multiple sclerosis, single gene neurological disease, poliomyelitis, spina bifida and Parkinson's disease. All other men could receive private prescriptions and men suffering from severe distress were to be included in the future.[6,7] Modern day authors have commented that the 1999 circular was non-evidence based and it defined guidance for good clinical practice based largely on economic grounds. The National Institute for Health and Care Excellence has never been asked to review this topic. However, although ED is not perceived to be a life-threatening condition, it is closely associated with many important physical conditions which may affect psychosocial health and so it can have a significant impact on the quality of life of both patients and their partners.[4]

5.6 National guidance on ED published by the British Society for Sexual Medicine (2018) suggested that specialised investigations are not required for most patients. However, the Society suggested that the indications for specialist investigations should include: young people who have always had difficulty in obtaining and/or sustaining an erection, trauma, abnormality of the testicles or penis and patients unresponsive to medical therapies who may desire surgical management. [4] NICE recommend specialist referral in a number of different scenarios. These include:

- men with type 2 diabetes for management of erectile dysfunction where treatment with a PDE5 inhibitor has been unsuccessful.[8]
- men with type 1 diabetes were treatment with a PDE 5 inhibitor has been unsuccessful or is contraindicated.[9]
- men who have had radical treatment for prostate cancer and also the same men who haven't responded to PDE5 inhibitors or have contraindications.[10]

REFERENCES

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8. Type 2 diabetes in adults: management. Nice guideline. London: National Institute for health and care excellence, 2015:NG 28.
9. Type 1 diabetes in adults: diagnosis and management. Nice guideline. London: National Institute for health and care excellence, 2015:NG 17.
10. Prostate cancer: diagnosis and management. Nice guideline: National Institute for health and care excellence, 2019:NG 131.

6. Advice and Guidance

6.1 **Aim and Objectives**

- This policy aims to ensure a common set of criteria for treatments and procedures across the region. This is intended to reduce variation of access to NHS services in different areas and allow fair and equitable treatment for all patients.

- This policy relates to the commissioning of interventions which optimise clinical effectiveness and represent value for money.

- This document is part of a suite of policies which the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy is a separate public document in its own right but should be considered alongside all the other policies in the suite as well as the core principles outlined.

- At the time of publication, the evidence presented per procedure/treatment was the most current available.

- The main objective for having healthcare commissioning policies is to ensure that:
  - Patients receive appropriate health treatments
  - Treatments with no or a very limited evidence base are not used; and
  - Treatments with minimal health gain are restricted.

- Owing to the nature of clinical commissioning policies, it is necessary to refer to the biological sex of patients on occasion. When the terms ‘men’ and ‘women’ are used in this document (unless otherwise specified), this refers to biological sex. It is acknowledged that this may not necessarily be the gender to which individual patients identify.

6.2 **Core Principles**

- Commissioning decisions by ICB Commissioners are made in accordance with the commissioning principles set out as follows:

  - Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment.
  - Commissioners require clear evidence of cost effectiveness before NHS resources are invested in the treatment.
  - Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment.
  - Commissioners will balance the needs of an individual patient against the benefit which could be gained by alternative investment possibilities to meet the needs of the community.
  - Commissioners will consider all relevant national standards and consider all proper and authoritative guidance.
  - Where a treatment is approved Commissioners will respect patient choice as to where a treatment is delivered, in accordance with the ‘NHS Choice’ framework.
  - Commissioning decisions will give ‘due regard’ to promote equality and uphold human rights. Decision making will follow robust procedures to ensure that decisions are fair and are made within legislative frameworks.

6.3 **Individual Funding Requests (Clinical Exceptionality Funding)**

- If any patients are excluded from this policy, for whatever reason, the clinician has the option to make an application for clinical exceptionality. However, the clinician must make a robust case to the Panel to confirm their patient is distinct from all the other patients who might be excluded from the designated policy.

- The ICB will consider clinical exceptions to this policy in accordance with the Individual Funding Request (IFR) Governance Framework consisting of: IFR Decision Making Policy; and IFR Management Policy available on the C&M ICB website: https://www.cheshireandmerseyside.nhs.uk/your-health/individual-funding-requests-ifr/

6.4 **Cosmetic Surgery**

- Cosmetic surgery is often carried out to change a person's appearance to achieve what a person perceives to be a more desirable look.

- Cosmetic surgery/treatments are regarded as procedures of low clinical priority and therefore not routinely commissioned by the ICB Commissioner.

- A summary of Cosmetic Surgery is provided by NHS Choices. Weblink: http://www.nhs.uk/conditions/Cosmetic-surgery/Pages/Introduction.aspx and http://www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Procedures.aspx

6.5 **Diagnostic Procedures**

- Diagnostic procedures to be performed with the sole purpose of determining whether or not a restricted procedure is feasible should not be carried out unless the eligibility criteria are met, or approval has been given by the ICB or GP (as set out in the approval process of the patients responsible ICB) or as agreed by the IFR Panel as a clinically exceptional case.

- Where a General Practitioner/Optometrist/Dentist requests only an opinion the patient should not be placed on a waiting list or treated, but the opinion given and the patient returned to the care of the General Practitioner/Optometrist/Dentist, in order for them to make a decision on future treatment.

6.6 **Clinical Trials**

- The ICB will not fund continuation of treatment commenced as part of a clinical trial. This is in line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki which stipulates that the responsibility for ensuring a clear exit strategy from a trial, and that those benefiting from treatment will have ongoing access to it, lies with those conducting the trial. This responsibility lies with the trial initiators indefinitely.

7. Monitoring and Review

7.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance or other national directive relating to this intervention, or to alternative treatments for the same condition.

7.2 This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.

7.3 This policy may be subject to continued monitoring using a mix of the following approaches:
- Prior approval process
- Post activity monitoring through routine data
- Post activity monitoring through case note audits

7.4 This policy will be kept under regular review, to ensure that it reflects developments in the evidence base regarding effectiveness and value.

8. Quality and Equality Analysis

8.1 Quality and Equality Impact Analyses have been undertaken for this policy at the time of its review.

9. Clinical Coding

9.1 **Office of Population Censuses and Surveys (OPCS)**
N32.4 Injection of therapeutic substance into penis
(Primary position)

9.2 **International classification of diseases (ICD-10)**
With or without
F52.2 Failure of genital response

Document Control

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