

County Durham and Darlington Commissioning Policy Statement (EXTRACT)

Policy No. CL01: Erectile Dysfunction

Agreed by Executive Committee(s): 25 July 2017, 10 October 2017

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The County Durham and Darlington Clinical Commissioning Groups have considered the evidence of clinical and cost effectiveness of treatments for erectile dysfunction in adult patients. The publication of the updated Statutory Instrument 2014/16251¹ was taken into account in making the following recommendations.

NHS funded prescribing will not be routinely commissioned except in accordance with the criteria listed below:

1. NHS treatment with the phosphodiesterase type -5 inhibitor, generic sildenafil, at the minimum effective dose is **recommended** for any man presenting with erectile dysfunction with a frequency of dosing of four times per month².
2. Other phosphodiesterase type-5 inhibitors** (tadalafil* and avanafil) are only recommended **for patients who meet the Government Selected List Scheme (SLS) criteria*** AND where generic sildenafil is ineffective**, with a frequency of dosing of four times per month using the drug with the lowest acquisition cost.

* Daily dosing of PDE-5 inhibitors (e.g. tadalafil once daily) is not approved in County Durham and Darlington³.

** Vardenafil is not approved for use in County Durham and Darlington.

*** Psychological distress is not considered for NHS treatment as set out in Part XVIII B of the Drug Tariff (Drugs, medicines and other substances that may be ordered only in certain circumstances) and in keeping with the North East and Cumbria Regional Policy for VBCC *“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*

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2014/1625 part 1: <http://www.legislation.gov.uk/ukxi/2014/1625/regulation/2/made> refers to the deletion of generic sildenafil (amongst others) and replacement with Viagra and Avanafil

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http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012086.pdf Health Service Circular HSC 1999/148 refers to research re frequency of treatment

³ See <http://ntag.nhs.uk/docs/rec/NTAG-Decision-Summary-PDE5-inhibitors-for-ED-following-treatment-for-prostate-cancer-final.pdf>

policy as psychological distress unfortunately does not constitute clinical exceptional circumstance.”

Government Selected List Scheme (SLS) criteria

The following patients with erectile dysfunction

- a) a man with erectile dysfunction who on 14 September 1998 was receiving a course of treatment under the Act, the National Health Service (Scotland) Act 1978(a) or the Health and Personal Social Services (Northern Ireland) Order 1972(b) for this condition with any of the following drugs -
 - Alprostadil (Caverject), (MUSE), (Viridal)
 - Apomorphine Hydrochloride (Uprima)
 - Moxisylyte Hydrochloride (Erecnos)
 - Sildenafil (Viagra)
 - Tadalafil (Cialis)
 - Thymoxamine Hydrochloride (Erecnos); or
 - b) a man who is a national of an EEA State who is entitled to treatment by virtue of Article 7(2) of Council Regulation 1612/68(c) as extended by the EEA Agreement or by virtue of any other enforceable Community right who has erectile dysfunction and was on 14 September 1998 receiving a course of treatment under a national health insurance system of an EEA State for this condition with any of the drugs listed in sub-paragraph (a); or
 - c) a man who is not a national of an EEA State but who is the member of the family of such a national who has an enforceable Community right to be treated no less favourably than the national in the provision of medical treatment and has erectile dysfunction and was being treated for that condition on 14 September 1998 with any of the drugs listed in sub-paragraph (a); or
 - d) a man who is 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; or
 - e) a man who is receiving treatment for renal failure by dialysis; or
 - f) a man who has had the following surgery -
 - prostatectomy
 - radical pelvic surgery
 - renal failure treated by transplant.
3. NHS treatment with prostaglandin E1 intracavernosal injections and intraurethral instillations is **only recommended for patients who meet the SLS criteria**

AND only if oral phosphodiesterase type-5 inhibitors are contraindicated or ineffective. The maximum frequency of dosing should be four times per month using the drug with the lowest acquisition cost.

4. Treatment with Alprostadil cream is not approved for use in County Durham and Darlington and **not routinely commissioned** in view of limited evidence for clinical and cost effectiveness.
5. Treatment with vacuum erection devices is **only recommended for patients who meet the SLS criteria AND only if oral phosphodiesterase type-5 inhibitors are contraindicated or ineffective.** VEDs may be the treatment of choice in well-informed older patients with infrequent sexual intercourse and comorbidity requiring non-invasive, drug-free management of ED but only after specialist initiation.
6. Treatment with penile implants is commissioned by NHS England (Specialised Commissioning) for patients with end-stage ED. NHS England will fund the implantation of penile prosthesis in patients fulfilling the criteria set out in their policy⁴ only via local commissioning teams.
7. Treatment with psychosexual interventions is **not routinely commissioned** in view of limited evidence for clinical and cost effectiveness.
8. This policy does not cover post prostatectomy once daily prescribing of PDE5 inhibitors for patients who have undergone a prostatectomy recommended by Urology. The policy for this is currently under review.

Phosphodiesterase type-5 inhibitors (sildenafil, avanafil and tadalafil) are oral drugs that enable a penile erection with sexual stimulation. There is evidence for the effectiveness of these drugs in men with erectile dysfunction of varying causes. The effectiveness of individual drugs is comparable and generic sildenafil has been shown to be cost-effective. The SLS restrictions set out in Statutory Instrument 1999/1627⁵ apply to all phosphodiesterase type-5 inhibitors except generic sildenafil.

Prostaglandin E1 is used in the treatment of erectile dysfunction when delivered locally into penile tissues. There is evidence for the effectiveness of intra-cavernosal injections of prostaglandin E1 in those unresponsive to oral drugs.

Psychosexual interventions such as counselling and psychotherapy comprise a group of techniques with limited evidence for effectiveness and no evidence of cost-effectiveness.

Vacuum erection devices are mechanical devices for producing an erection that is sustained with the placement of a constricting band across the base of the penis. Caution should be applied for patients with bleeding disorders or on anticoagulant therapy.

Penile implants can be surgically inserted into the penis for treating erectile dysfunction. If first and second line treatments are ineffective at allowing penetrative

⁴ <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/08/clinical-com-pol-16059p.pdf>

⁵ 1999: 1672 part 2: <http://www.legislation.gov.uk/uksi/1999/1627/regulation/2/made> is the addition of the PDE-5 to the SLS scheme

intercourse, patients are considered to have end stage erectile dysfunction and will be referred for consideration of penile prosthesis in a tertiary urology centre