Prescribing Policy: Drugs used for the treatment of erectile dysfunction

Policy Statement: Date of Approval: 10th December 2009

This policy defines the decision made by the NHS Western Cheshire Clinical Commissioning and Strategy Committee.

Drugs for erectile dysfunction will only be prescribed under the NHS for men meeting the conditions specified by the Department of Health.

The Department of Health guidance to prescribe a maximum of one treatment weekly will be adhered to.

GPs will not assess patients suffering severe emotional distress.

Note:
Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy.

Individual cases will be reviewed at the PCT Bespoke Care Panel upon receipt of a completed application form from the Patient’s GP, Consultant or Clinician. Applications can not be considered from patients personally.

<table>
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<th>Version</th>
<th>1.0</th>
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<tr>
<td>Approved by (committee)</td>
<td>Clinical Commissioning and Strategy Committee</td>
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<tr>
<td>Date Approved:</td>
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<td>Prescribing policy development group</td>
</tr>
<tr>
<td>Telephone: 01244 650316 Email: <a href="mailto:barbara.perry@wcheshirepct.nhs.uk">barbara.perry@wcheshirepct.nhs.uk</a></td>
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Version Control:

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<td>0.1</td>
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<td>Nëse keni pyetje ose komente në lëdhje me këtë informacion ose dëshironi t’a keni atë të përktërher në gjuhën tuaj, ju lutemi telefonon në 01244 650368. Ju lutemi thoni emrin e gjuhës tuaj tre herë, së bashkë me numrin tuaj telefonik. Ne do të marrim masa që një përktëherë përmes telefonit t’ju telefonojë juve.</td>
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<tr>
<td>Arabic</td>
<td>إن كان يوجد لديك أي أسئلة أو ملاحظات حول هذه المعلومات أو إذا أردت ترجمة لها في لغتك الخاصة، يرجى الاتصال بالرقم 01244 650368. نرحب أن تعطي اسم لغتك ثلاثة مرات سوية مع رقم هاتفك. سوف نقوم بعد ذلك بالطلب من مترجم لعيد الاتصال بك.</td>
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<td>Bengali</td>
<td>আপনার মধ্যে এই তথ্য সম্পর্কে কোন প্রশ্ন অথবা অভিমত থাকে অথবা সেটা যদি আপনার মাতৃভাষায় অনুবাদ করানো চান তাহলে অনূর্ধ্ব করে 01244 650368 নম্বরে টেলিফোন করুন। আপনার টেলিফোন নম্বর বর্তুন ও আপনার ভাষার নাম তিনবার অনূর্ধ্ব করে বর্তুন। আপনাকে পুনরায় ফেনার বা কল ব্যাক করার জন্যো আমরা একজন দোভাষীর বাবস্থা করবো।</td>
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<td>Cantonese</td>
<td>如果你對本資訊有任何疑問或意見，或者你希望將它翻譯成你的母語版本，請致電 01244 650368。請在電話中說明你所需的語言，以及你的電話號碼（請重複表述三次）。我們會在回復你的電話時安排電話口譯服務。</td>
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<td>Gujarati</td>
<td>જો તમને આ માહિતી વિશે કોઈ પણ પ્રશ્ન અથવા વિષય ચિંતા છે, તો તમને 01244 650368 નંબરે ટેલિફન કરી શકી શકો છે. તમને આ માહિતી વિશે વાંચવા માટે વિભાગી વચ્ચેની લાભો પહોંચાવેલી સંપર્ક વધુ પણ ચિંતાઓ અને પ્રશ્નોને મામલે આપણી સાથે પ્રસ્તુત પ્રતિસ્પર્દાતા અને તમારી સ્થિતિ અને તમામ વિષયક ડીટ્યું પ્રાપ્ત કરી શકો છો. તેમણે તમને વાંચવા માટે ટેલિફન કરી શકે છે.</td>
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**Mandarin**


**Polish**

नेहान निम्नलिखिते वर घसे डुकडॅ भेठी सुचारू नत नं केही टिपटी हो तां कुमारं हिंदी उल्लभ भाषी क्रम ललचाची चर्चा देते हों विलय करते 01244 650368 'उं टेलीफोने करो विलय भाषी क्रम ललचाची चर्चा टेलीफोने हेच देते रुप विलय करते। अभी टेलीफोने चर्चा देते डुकडॅ विलय चर्चा तेलीफोने बनाने।

**Punjabi**

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**Urdu**
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The following terms are used in this document
Drugs used in the treatment of erectile dysfunction

1. Summary

Erectile dysfunction causes distress amongst its sufferers and is known to affect self-esteem and relationships. Severe dysfunction occurs in up to 10% of men aged 40 to 70 years.

A comprehensive literature search was performed to find published literature concerned with prescribing policies and the economics of the oral anti-impotence drugs.

Phosphodiesterase type-5 inhibitors are effective agents for the treatment of erectile dysfunction although they are contra-indicated in patients taking nitrates and those with severe cardiac disease. Side effects are generally mild and transient and include headache, facial flushing, dyspepsia, nasal congestion and abnormal vision.

Shortly after the launch of the first PDE-5 inhibitor (sildenafil), the Department of Health issued a health circular which specifies the conditions under which drug treatments can be prescribed on the NHS. GPs are permitted to prescribe for men with diabetes, multiple sclerosis, Parkinson’s disease, poliomyelitis, prostate cancer, severe pelvic injury, single –gene neurological disease (eg Huntingdon’s), spina bifida or spinal cord injury. Prescribing is also approved for men receiving renal dialysis, following radical pelvic surgery, prostatectomy or a kidney transplant.

In addition, the Department of Health specifies that men who suffer severe distress as a result of their erectile dysfunction can also receive drug treatment from a commissioned specialist service. The criteria to define “severe distress” are listed in the relevant health circular.

The prescribing costs for sildenafil (and other anti-impotence drugs) in Western Cheshire is currently around £300k per annum. There is the potential for this to rise to £1.35m if all men with severe dysfunction were to receive treatment.

It is suggested that NHS Western Cheshire should implement the guidance given in the Department of Health’s circular on anti-impotence drugs. This will involve active promotion of the permitted prescribing categories and also commissioning of a specialist service. Men who fall outside these categories can be issued with a private prescription.
2. INTRODUCTION / METHOD

Erectile dysfunction has been defined as the inability to achieve, or maintain, an erection sufficient for satisfactory sexual performance. The condition is known to cause severe distress amongst its sufferers and affects self-esteem and relationships.

Around 10% of men aged 40-70 years are thought to have complete erectile dysfunction and up to 52% of men in the same age bracket might report erectile dysfunction of any severity. Worldwide, the incidence has been predicted to double from 1995 to 2025 as a result of the ageing population.

Search strategy
A search of Pharm-line® and DH-DATA was performed using the search terms, “erectile dysfunction”, “sildenafil” (and other oral anti-impotence drugs), “National Health Service” and “Prescribing policy.” A second search was also carried out on Medline, Embase and Pharm-line with the addition of the terms “cost”, “economics” and “pharmacoeconomics.”

Other databases searched included the National Institute for Health and Clinical Excellence (NICE), Scottish Intercollegiate Guidance Network (SIGN), the British Medical Journal and the Cochrane database. NHS Evidence was also searched for examples of local policies on management of erectile dysfunction.

3. SAFETY and EFFICACY

Sildenafil belongs to a group of drugs known as the Phosphodiesterase -5 (PDE-5) inhibitors. Inhibition of this enzyme reduces the breakdown of cyclic guanosine monophosphate which allows relaxation of the smooth muscle in the corpus cavernosum.

A recent meta-analysis has shown this group of drugs to be highly effective in the management of erectile dysfunction. Sildenafil, in particular, has been proven more effective than placebo in improving erections and allowing successful penetrative sexual intercourse. In other studies, these oral drugs were deemed effective in 75% of participants with an improvement in self-esteem, confidence and satisfaction with sexual relationships.

Side effects, generally transient and mild, include headache, facial flushing, dyspepsia, nasal congestion and abnormal vision. They are absolutely contra-indicated in patients taking nitrates and those with severe cardiac disease.
Lifestyle issues
When sildenafil was first introduced in the late 1990s, there was some discussion as to whether the medication was a lifestyle drug because erectile dysfunction was considered a normal part of ageing.\textsuperscript{10,11} On balance, the general public and political opinion came down in favour of restricting funding.\textsuperscript{12} This view is reflected in the Department of Health guidance which restricts the issue of anti-impotence drugs to men with certain co-morbidities and in those in whom erectile dysfunction is causing significant psychological distress.

Department of Health prescribing guidance
The Department of Health issued guidance (HSC 1999/115,148) which states that GPs can only prescribe oral anti-impotence drugs on an NHS prescription to men who:-

- Have diabetes, multiple sclerosis, Parkinson’s disease, poliomyelitis, prostate cancer, severe pelvic injury, single-gene neurological disease (eg Huntington’s), spina bifida or spinal cord injury.
- Are receiving renal dialysis
- Have had radical pelvic surgery, prostatectomy (including Trans Urethral Resection Prostate) or a kidney transplant
- Were receiving Caverject, Erecnos, MUSE, Viagra or Viridal at the expense of the NHS on 14th September 1998.

Patients outside of these categories can also receive a prescription from a specialist if they are suffering severe distress as a result of impotence. The Department of Health has issued further guidance (HSC 1999/177) which defines “specialist” services and “severe distress.”

Thus, specialist services (which should be delivered via a service agreement) are those commissioned by the (former) Health Authorities and Primary Care Groups. The Department of Health suggests that mental health services, sexual dysfunction services, urology services or genito-urinary medicine services might be involved in the care of these patients.

In this context, GP referral would be appropriate if the man is suffering severe distress which is manifested by:-

- A significant disruption to normal social and occupational activity
- A marked effect on mood, behaviour, social and environmental awareness
- A marked effect on interpersonal relationships

The specialist centre will decide if the patient’s presentation warrants prescribing of sildenafil. Follow up treatment is expected to be provided through the specialist centre.

All of the guidance described above is repeated in the appropriate section of the NHS Clinical Knowledge Summaries (formerly Prodigy).\textsuperscript{13}
4. COSTS

Shortly after the launch of sildenafil, recorded cases of erectile function more than doubled. Estimates of potential costs of sildenafil across the UK were from £100m to £1000m. In one (former) health district, an economic analysis of the costs of erectile dysfunction treatment showed a 70% reduction in the cost of specialist care yet a doubling of primary care costs when sildenafil was first introduced. The approximate costs of sildenafil alone were around £216k per annum (1999 – 2000). Locally, the prescribing data for erectile dysfunction drugs in general practice are given below.

Figure 1: Prescribing costs for erectile dysfunction drugs in general practice in Western Cheshire 2005/6 to 2008/9

Source: ePACT data
Figure 2: Prescribing data (number of items) for erectile dysfunction drugs in general practice in Western Cheshire 2005/6 to 2008/9

Source: ePACT data

Figure 1 shows that prescribing costs for erectile dysfunction drugs in general practice in western Cheshire have increased from £206,406 in 2005/6 to £293,701 in 2008/9 – an increase of 30%. The number of items has increased by 23% in the same time period (figure 2). Thus, costs have increased by approximately 10% each year.

Prescribing outside Department of Health guidance
NHS Wirral’s erectile dysfunction prescribing policy allows GPs to take on the role of “specialist” services i.e. GPs decide whether men are suffering “extreme distress” as a result of erectile dysfunction and thus eligible for drug treatment under the NHS. This is clearly outside Department of Health guidance (above).
Data from the North West Public Health Observatory show that Wirral has one of the highest erectile dysfunction drug prescribing rates in the country (table 1).

Table 1: Prescribing rates for erectile dysfunction drugs 2002-5

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<td>Wirral</td>
<td>102.4</td>
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<tr>
<td>Chester</td>
<td>70.0</td>
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<tr>
<td>Ellesmere Port &amp; Neston</td>
<td>92.6</td>
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<td>England</td>
<td>69.4</td>
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Source: Sexual and Reproductive Health Indicators for the North Wes. Centre for Public Health, 2006, Liverpool

It is not clear the impact Wirral’s prescribing policy has had on this prescribing rate but it is likely that this will be maintained at a high level. Table 1 shows that Wirral’s prescribing rate is almost 50% higher than Chester’s.

Potential prescribing costs in Western Cheshire

In July 2009, there were 53,711* males aged 40 -70 years registered with western Cheshire Primary Care Trust. Assuming an incidence of 10% of men with severe erectile dysfunction, this would cost the Primary Care Trust £1,350,376** per annum for sildenafil prescribing alone. This assumes all men receive treatment at a rate of one tablet per week.

5. CONCLUSIONS

Evidence suggests that current drug treatments for erectile dysfunction are safe and effective. Sildenafil is generally used as the first line agent of choice.

The cost of erectile drug prescribing in western Cheshire has been rising by approximately 10% every year since 2005 and is currently almost £300,000 per annum. If all men with severe dysfunction were given treatment, this would cost the Primary Trust over £1.3m per year. Clearly, if men with less severe problems were also given therapy, the costs would be significantly higher. There is a danger that if prescribing in this area is not controlled, costs will escalate to unacceptable levels.

* Source: NHAIS (Open Exeter) GP List Sizes, July 2009
** BNF edition 57 costs.
Data suggest that Primary Care Trusts with GP-led prescribing of erectile dysfunction drugs experience high (and costly) prescribing rates. The Department of Health has issued clear guidance on erectile dysfunction drug prescribing which still remains current.

6. RECOMMENDATIONS

1. NHS Western Cheshire should endorse the prescribing guidance from the Department of Health.
2. This will involve restricting GP prescribing to the Department of Health’s designated groups.
3. It would be useful to perform an audit of current GP prescribing.
4. NHS Western Cheshire should commission specialist prescribing services for those men with “severe distress” with agreed criteria on how this “distress” will be measured.
5. GPs should be encouraged to prescribe sildenafil on a private prescription for those men outside these categories where appropriate.

7. REFERENCES

(1) Ashton K. UK Department of Health guidance on prescribing for impotence following the introduction of sildenafil: potential to contain costs in the average health authority district. Pharmacoeconomics 2002; 20(12):839-846.


(4) Aytac IA, McKinley JB, Krane RJ. The likely worldwide increase in erectile dysfunction between 1995 and 2025 and some possible policy consequences. BJU International 1999; 84:50-56.


8. RESPONSIBILITY FOR IMPLEMENTATION

Responsibility for implementation lies with the Practice Based Commissioning Consortium and the Area Prescribing Committee.
9. ROUTE FOR POLICY DEVELOPMENT AND RATIFICATION

Evidence researched by Public Health Specialist

Evidence reviewed by Task & Finish Group and draft policy developed

Draft policy reviewed and agreed by Area Prescribing Committee

Draft policy finalised and ratified by Clinical Commissioning and Strategy Committee

Policy distributed to relevant stakeholders and uploaded on the PCT extranet and website