All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

All Wales Guidance on Prescribing for Erectile Dysfunction

October 2012

CONTENTS

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1.0 SUMMARY

The All Wales Medicines Strategy Group (AWMSG) has endorsed the following recommendations:

- For patients who have been assessed as suffering from severe distress as a result of erectile dysfunction, guidance is amended to remove the restriction of specialist service supply, enabling general practitioners (GPs) to prescribe the medication.
- The assessment of severe distress resulting from erectile dysfunction may be undertaken by GPs or specialist teams. All health boards should have clearly defined commissioning arrangements for this assessment. A commissioned, specialist-led service will support equality of access to therapy and minimise conflict in the doctor-patient relationship.
- Once-daily preparations should only be considered in patients who anticipate frequent use of single dose preparations (i.e. at least twice-weekly). This should be based on the clinician's judgement.

2.0 BACKGROUND

Drug treatments for erectile dysfunction may only be prescribed on the NHS under certain circumstances. The British National Formulary (BNF) cites Department of Health guidance, which recommends that treatment should be available from specialist services when the condition is causing severe distress[1]. Welsh Health Circular (WHC) (99) 148, published by the National Assembly for Wales in 1999, provided guidance for the NHS on the identification and management within specialist services of men diagnosed as suffering severe distress resulting from erectile dysfunction[2]. The All Wales Prescribing Advisory Group (AWPAG) reviewed this guidance and formed recommendations, which have subsequently been endorsed by AWMSG, regarding the prescribing of treatments for erectile dysfunction.

3.0 AWMSG RECOMMENDATIONS

3.1 GP prescribing of drug treatments for erectile dysfunction

AWPAG did not consider that the medications reached the AWMSG criteria for shared care or hospital-only prescribing. It was concluded that it is appropriate for GPs to prescribe drug treatments for erectile dysfunction following the initial assessment.

3.2 The initial assessment of severe distress resulting from erectile dysfunction

The assessment of severe distress resulting from erectile dysfunction may be undertaken by GPs or specialist teams.

All health boards should have clearly defined commissioning arrangements for this assessment.
A commissioned, specialist-led service will support equality of access to therapy and minimise conflict in the doctor–patient relationship.

Patients presenting with erectile dysfunction should be appropriately assessed for underlying causes. GPs may issue NHS prescriptions (endorsed "SLS") to men that in their clinical judgement are suffering from erectile dysfunction and have any of the specified medical conditions (listed in the BNF)[1,3,4]. It should be noted that any patient who does not adhere to a category may have the drug prescribed privately[1].

3.2.1 Current practice

As previously noted, it has been recommended that treatment should be available from specialist services when the condition is causing severe distress[1]. Variation in interpretation of this regulation has resulted in heterogeneous service provision across Wales:

- A survey of current practice in Wales shows that medications for erectile dysfunction *for medical causes* are initiated by both GPs and specialist teams. Several health boards have flowcharts recommending initial assessment, investigation and treatment of erectile dysfunction by GPs.
- Initiation of medications for erectile dysfunction *for the indication of severe distress* varies across health boards, with initiation via urologists, psychiatrists, GPs, on the advice of psychosexual teams or via a GP-led specialist service (see section 3.2.2). There are few examples of services providing expertise in both urological assessment and psychological assessment.

GPs are experienced in assessing mental health issues, and some will have expertise in assessing erectile dysfunction. If GPs are commissioned to provide the assessment of severe distress, the criteria below provides guidance; however, variations in the provision of care should be monitored.

The following criteria should be considered when assessing severe 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.

It has been noted that the "watch list" of falsified medicines consists largely of treatments for erectile dysfunction. There is a risk that patients denied access to treatment by GPs or specialist services will seek to obtain treatments elsewhere, and these sources may not be regulated. Similarly, there is a risk that overprescribing or inappropriate prescribing can lead to diversion.

AWPAG considered that the emphasis should be on an effective assessment of the condition and psychological impact. Given the above considerations, directive national guidance on the location and personnel providing this assessment is not appropriate. It is, however, important that there are clearly defined commissioning arrangements at health board level.

3.2.2 Example of good practice

The Cardiff and Vale University Health Board discussed the treatment of erectile dysfunction with a group of stakeholders including clinicians that provide the severe distress service, secondary care clinicians (cardiology, urology and psychology), general practice and public health. The purpose of the multidisciplinary meeting (which took place September 2011) was to discuss the results of an audit undertaken in primary care, which assessed prescribing against the NHS criteria and WHC severe distress guidance, and to consider equity of access to NHS specialist services (for severe distress) across the health board. Attendees considered that initiation via a GP-led specialist service remained appropriate. They also noted the link between erectile dysfunction and cardiovascular disease (CVD), and the need for lifestyle advice, CVD risk assessment and alternatives to pharmacological therapy for these patients.

3.3 Once-daily preparations

AWPAG has not reviewed the guidance relating to frequency of prescribing of ”on demand” treatments; WHC (99) 125 states:

> ***“Frequency of Prescribing***
>
> *4. The 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 evidence about the frequency of sexual intercourse (Johnson A, Wadsworth J, et al, Sexual Attitudes and Lifestyles Survey, UK 1990-91, 1994) 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.*
>
> *5. Therefore, the [National Assembly for Wales advises prescribers] 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.“*[3]

While there are currently no formal restrictions in relation to prescribing once-daily preparations for erectile dysfunction by Welsh Government, prescribers should refer to their health board formulary and guidance.

Prescribers and commissioners should note changes in patents that will alter the cost-effectiveness assessment of available preparations. Expected patent expiry dates for all phosphodiesterase type-5 inhibitors currently licensed for the treatment of erectile dysfunction are as follows:

- Sildenafil (Viagra®) – June 2013[5];
- Tadalafil (Cialis®) – November 2017[5];
- Vardenafil (Levitra®) – October 2018.

The recommendation that once-daily preparations should only be considered in patients who anticipate frequent use of single dose preparations (i.e. at least twice-weekly) reflects the current marketing authorisation for tadalafil (Cialis®). The Summary of Product Characteristics (SPC) for tadalafil notes that the dose may be decreased based on individual tolerability, and that the appropriateness of continued use of the daily regimen should be reassessed periodically[6].

4.0 RELEVANT PUBLICATIONS

- National Assembly for Wales. Welsh Health Circular (99) 125: Treatment for impotence (1999)[3].
- National Assembly for Wales. Welsh Health Circular (99) 148: Treatment for impotence – Patients with severe distress (1999)[2].
- Health Service Circular. Treatment for impotence (1999)[7].
- Scottish Government NHS Circular. Treatment of erectile dysfunction: Patients with severe distress (2011)[8].
- AWMSG. Prescribing dilemmas: A guide for prescribers (2011)[4].

5.0 ADDITIONAL NOTES FOR PRESCRIBERS AND COMMISSIONERS

- Practice audits have shown both a lack of documentation regarding the underlying diagnosis and variation in the numbers of patients prescribed medication for erectile dysfunction diagnosed as causing severe distress.
- Prescribers are reminded to ensure that all patients that receive an NHS prescription for phosphodiesterase inhibitors are eligible to receive these treatments on the NHS.
- IT systems should clearly identify a private prescription so that it cannot be inadvertently re-issued as an NHS prescription.
- Audit is required to support the effective implementation of this guidance and to promote equality of access to treatment

References

1 British Medical Association, Royal Pharmaceutical Society. *British National Formulary. No. 63.* Mar 2012.

2 National Assembly for Wales. Welsh Health Circular (99) 148: Treatment for impotence - Patients with severe distress. 1999. Available at: http://howis.wales.nhs.uk/doclib/WHC(99)148.htm. Accessed Dec 2011.

3 National Assembly for Wales. Welsh Health Circular (99) 125: Treatment for impotence. 1999. Available at: http://howis.wales.nhs.uk/doclib/WHC(99)125.htm. Accessed Feb 2012.

4 All Wales Medicines Strategy Group. Prescribing dilemmas: A guide for prescribers. 2011. Available at: http://www.wales.nhs.uk/sites3/page.cfm?orgid=371&pid=56066. Accessed Jan 2012.

5 Intellectual Property Office. Online patent services. 2012. Available at: http://www.ipo.gov.uk/home.htm. Accessed Feb 2012.

6 Eli Lilly and Company Ltd. CIALIS®. Summary of Product Characteristics. 2011. Available at: http://www.medicines.org.uk/EMC/medicine/11363/SPC/Cialis+2.5mg%2c+5mg%2c+10mg+%26+20mg+film-coated+tablets. Accessed Jan 2012.

7 Department of Health. Health Service Circular 1999/148: Treatment for impotence. 1999. Available at: http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4012086.pdf. Accessed Dec 2011.

8 The Scottish Government. Treatment of erectile dysfunction: patients with severe distress. NHS Circular PCA(M)(2011)4. 2011. Available at: http://www.sehd.scot.nhs.uk/pca/PCA2011(M)04.pdf. Accessed Dec 2011.

This report has been prepared by the All Wales Prescribing Advisory Group (AWPAG) with support from the All Wales Therapeutics and Toxicology Centre (AWTTC), and has subsequently been endorsed by the All Wales Medicines Strategy Group (AWMSG). Please direct any queries to AWTTC:

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