



Health Department
Directorate of Primary Care

NHS Management Executive
St Andrew's House
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Dear Colleague

TREATMENT FOR ERECTILE DYSFUNCTION

Summary

1. This letter follows on from the Chief Medical Officer's letter of 7 May 1999 (SODH/CMO(99)4) and provides guidance on the prescribing and dispensing of drug treatments for erectile dysfunction under the NHS. The attached Guidance and Annex:

- set out the content of the National Health Service (General Medical Services) (Scotland) Amendment (No 3) Regulations 1999 (copy of the amendment Regulations to follow under separate cover);
- provides advice to General Medical Practitioners and Pharmacy Contractors on the prescribing and dispensing of drug treatments for erectile dysfunction;
- answers some commonly posed questions about SODH/CMO(99)4.

2. Separate guidance will be issued in due course on the identification and management within specialist services of men suffering from severe distress because of erectile dysfunction.

Action

3. Primary Care Trusts are requested to send copies of the attachments to this letter as soon as possible to Pharmacy Contractors and to each GP on their Health Board's medical list and to the Area Medical Committee for the attention of the Secretary of the GP Sub-Committee.

Yours sincerely

AGNES ROBSON
Director of Primary Care

July 1999

Addressees

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BACKGROUND

THE NATIONAL HEALTH SERVICE (GENERAL MEDICAL SERVICES) (SCOTLAND) AMENDMENT (NO 3) REGULATIONS 1999

1. These Amendment Regulations add the treatment of erectile dysfunction with specified drugs to Schedule 11 ie drugs to be prescribed under pharmaceutical services only in certain circumstances. From 1 July 1999, GPs are limited in their use of NHS prescriptions for the treatment of this condition. They may issue NHS prescriptions (endorsed "SLS") to those men whom in their clinical judgement are suffering from erectile dysfunction and have any of the following medical conditions:-

- diabetes
- multiple sclerosis
- Parkinson's disease
- poliomyelitis
- prostate cancer
- prostatectomy
- radical pelvic surgery
- renal failure treated by dialysis or transplant
- severe pelvic injury
- single gene neurological disease
- spinal cord injury
- spina bifida

2. In addition those men receiving a course of NHS drug treatment for erectile dysfunction on 14 September 1998 will continue to be eligible to receive a drug treatment from their GP.

3. The drug treatments affected are alprostadil (Caverject, MUSE and Viridal), moxisylyte hydrochloride: thymoxamine hydrochloride (Erecnos) and sildenafil (Viagra). Non-drug treatments for erectile dysfunction are unaffected by these Regulations.

Prescribing Under Paragraph 31 and Schedule 11 of GPs' Terms of Service

4. Paragraph 31 of the GPs' Terms of Service reads:-

"31 - (1) In the course of treating a patient to whom he is providing treatment under these terms of service, a doctor shall not order on a prescription form a scheduled drug, but may with the consent of the patient otherwise prescribe such a drug or other substance for that patient in the course of that treatment.

- (2) In the course of treating such a patient, a doctor shall not order on a prescription form a drug specified in Schedule 11 unless –
- (a) that patient is a person mentioned in column 2 of that entry; and
 - (b) that drug is prescribed for that patient only for the purpose specified in column 3 of that entry; and
 - (c) the doctor endorses the face of that form with the reference "SLS"

but may with the consent of the patient otherwise prescribe such a drug for that patient in the course of that treatment."

5. To comply with paragraph 31(2) a GP who has prescribed a drug specified in Schedule 11 must endorse the prescription form "SLS" (the community pharmacist will not be able to dispense such a medicine without the necessary endorsement). Also, the statement "*but may with the consent of the patient otherwise prescribe such a drug for that patient in the course of that treatment*" means that the GP can prescribe privately to a patient on his/her NHS list.

Related Terms of Service Issues for GPs

6. Paragraph 36 of the Terms of Service prohibits a doctor from charging his/her patient for any treatment rendered or any drug supplied and requires him/her to take all reasonable steps to ensure that no partner, deputy or assistant imposes any charge for treatment his/her patient.

7. Dispensing doctors (ie GPs authorised under Regulation 34 to provide drugs, and appliances to their patients) may charge a dispensing patient who is ineligible under Schedule 11 for his medicine and for dispensing it but not for prescribing it.

Frequency of Prescribing

8. The frequency of treatment will need to be considered on a case by case basis, but doctors 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 199081, 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. Also, 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. Excessive prescribing could therefore lead to unlicensed, unauthorised and possibly dangerous use of these treatments. In these circumstances the Department advises GPs that no more than one treatment a week will be appropriate for most patients treated for impotence. If the GP in exercising his/her clinical judgement considers that more than one treatment a week is appropriate he should prescribe that amount on the NHS.

Implications for Pharmacy Contractors

9. As with other items included in Schedule 11, pharmacy contractors' terms of service will not allow them to dispense any of the drugs in question under NHS pharmaceutical services arrangements, unless the prescriber has endorsed the prescription "SLS". Prescriptions (forms GP10 or HBP) not marked "SLS2 will need to be returned to the prescriber for endorsement.

10. There is nothing to prevent a pharmacy contractor dispensing a private prescription for any of the drugs concerned. However, this will be an arrangement entirely outside NHS pharmaceutical services and any fees or charges are a matter for the pharmacy and the patient concerned.

This Annex provides answers to commonly asked questions about the availability on NHS prescription of drug treatments for erectile dysfunction.

Q1. Can GPs charge for issuing a private prescription to his/her own NHS patient?

A1. No.

Q2. Can a dispensing GP charge a patient for a Schedule 11 medicine?

A2. Yes. The dispensing GP can charge a dispensing patient who is not eligible under Schedule 11 for a NHS prescription. (The GP can charge for supplying the medicine, but not for associated prescribing, advice or consultation).

Q3. Can a non-dispensing GP supply these medicines to patients on his/her NHS list who are not eligible under Schedule 11?

A3. Yes – provided they do so free of charge. Under paragraph 36 of the Terms of Service, GPs are prohibited from charging for treatment and this includes charging for medicine.

Q4. If a GP considers that his/her NHS patient, eligible under Schedule 11, needs more than one treatment a week can the patient be issued both a NHS prescription (for the one treatment) topped up by a private prescription?

A4. No. If, in the GP's clinical judgement a patient requires more than one treatment a week, then the treatment should be prescribed on the NHS.

Q5. Is a patient who was receiving private treatment on 14 September 1998 eligible under Schedule 11?

A5. No. The 14 September 1998 provision relates to the NHS treatment from a GP or hospital, and includes patients receiving treatment under a clinical trial undertaken by NHS doctors.

Q6. Is a patient whose treatment ended before 14 September 1998 eligible under Schedule 11?

A6. No. The provision covers only those men receiving treatment on 14 September 1998. However, that should not be interpreted so restrictively as to mean that a man has to have injected himself with, for example, alprostadil on that day. GPs should be able to establish eligibility from patient records.

Q7. What if the patient first saw his doctor after 14 September 1998.

A7. No. The GP may only prescribe in accordance with Schedule 11.

Q8. If a patient treated with alprostadil on 14 September 1998 was switched to sildenafil and has since received continuing treatment. Is he allowed to continue receiving this treatment?

A8. Yes.

Q9. If a hospital specialist prescribes treatment for impotence for a man with severe distress, can the GP continue to prescribe on the specialist's recommendation?

A9. No. A GP can only prescribe in accordance with Schedule 11. Separate guidance will be issued on the management of men suffering from severe distress because of erectile dysfunction.

Q10. Does prostatectomy include transurethral resection of the prostate (TURP)?

A10. Yes.

Q11. What guidance is available to GPs on the prescribing of these treatments?

A11. The British National Formulary and the Summaries of Product Characteristics are available to GPs.

Q12. What will happen if a pharmacy contractor submits a prescription for pricing which has not been endorsed "SLS"?

A12. The Pharmacy Practice Division (PPD) will disallow the claim.

Q13. Does the requirement to endorse "SLS" on NHS prescriptions apply to hospital doctors using form HBP which are subsequently presented for dispensing by pharmacy contractors?

A13. Whilst there is no requirement on hospital doctors to endorse these prescriptions, pharmacy contractors cannot dispense the medicine. Specialists wishing to use HBP form should be asked to include the endorsement to prevent inconvenience for both patients and pharmacists.