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TREATMENT FOR IMPOTENCE

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TREATMENT FOR IMPOTENCE

Summary

This circular follows on from HSC 1999/115 which explains the Secretary of State's decisions about the availability of impotence treatments from GPs on NHS prescription. Regulations have now been laid before Parliament to come into effect from 1 July 1999.

This circular:

- sets out the content of the National Health Service (General Medical Services) Amendment (No 2) Regulations 1999, SI 1999/1627, which will come into effect on 1 July 1999;
- provides advice to GPs on frequency of prescribing;
- provides information and advice on implementing the new arrangements; and
- answers some commonly posed questions about HSC 1999/115.

Guidance on the identification and management within specialist services of those men suffering from severe distress on account of their impotence will be issued shortly.

The National Health Service (General Medical Services) Amendment (No2) Regulations 1999

1. These regulations add the treatment of erectile dysfunction with specified drugs to Schedule 11 of the Regulations (drugs to be prescribed under pharmaceutical services only in certain circumstances). The practical effect of the change is that 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. Additionally those men receiving a course of NHS drug treatment for erectile dysfunction condition 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)[1] and sildenafil (Viagra). Non-drug treatments for erectile dysfunction are unaffected by these regulations.

Frequency of Prescribing

4. 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 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.

[1]Moxisylyte hydrochloride is the recommended International Non-proprietary Name (rINN) and thymoxamine hydrochloride is the British Approved Name (BAN)

5. Therefore, the Department advises doctors 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.

Prescribing under Paragraph 44 and Schedule 11 of GPs' Terms of Service

6. Paragraph 44 of the GPs' Terms of Service reads:

> 44.-(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 drug or other substance specified in Schedule 10 to these Regulations but may 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 an entry in column 1 of Schedule 11 to these Regulations unless-
>
> (a) that patient is a person of a description 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 the form with the reference "SLS",
>
> but may otherwise prescribe such a drug for a patient in the course of that treatment.

7. There are two key points to note from the wording of paragraph 44(2): first, a doctor 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 from the doctor), and second, the phrase "but may otherwise prescribe such a drug for a patient in the course of that treatment" means that the doctor can prescribe privately to a patient on his NHS list.

Related Terms of Service issues for GPs

8. Paragraphs 40 and 42 of the Terms of Service prohibit a doctor from charging a patient of his for any prescription and requires him to take all reasonable steps to ensure that no partner, deputy or assistant of his imposes any charge for treating his patients.

9. Paragraph 38 of the Terms of Service prohibits a doctor (with some exceptions) from charging a patient of his for treatment. By virtue of paragraph 42, this prohibition applies equally to partners, deputies and assistants.

10. Dispensing doctors (ie. GPs authorised under regulation 20 of the Pharmaceutical Services Regulations to provide drugs, medicines and appliances to their patients) are specifically exempted (paragraph 38(m) of the Terms of Service) from the paragraph 38 prohibition where they provide a drug or medicine which may not be prescribed under Schedules 10 or 11. See the answer to Q2 in paragraph 13 of this circular.

Implications for Pharmacy Contractors

11. As with other items included in Schedule 11, pharmacy contractors' terms of service will not allow them to dispense a prescription for any of the drugs in question under NHS pharmaceutical services arrangements, unless the prescriber has endorsed it "SLS". Any prescriptions presented which are not marked "SLS" will need to be returned to the prescriber for endorsement.

12. There is nothing to prevent a pharmacy contractor dispensing a private prescription for any of the drugs concerned, but if they do so, this will be entirely outside NHS pharmaceutical services.

Questions and Answers

13. The following section provides answers to questions which have been raised since HSC 1999/115, which outlined Secretary of State's decisions following the period of public consultation, was issued on 7 May.

Q1 Can GPs charge for issuing a private prescription?

A1 No. See paragraph 8-9.

Q2 Can a dispensing doctor charge a patient for a Schedule 11 medicine?

A2 Yes. See paragraph 10. The dispensing doctor may charge a dispensing patient who is not eligible under Schedule 11 for a NHS prescription. (The doctor may charge for supplying the medicine but not for associated prescribing, advice or consultation.)

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

A3 See paragraph 9. The GP may supply medicine to a patient on his NHS list whose circumstances do not fall within the terms of Schedule 11 provided they do so free of charge. Under paragraph 38 of the Terms of Service the GP is prohibited from charging for the treatment and the prohibition includes charging for the medicine.

Q4 A GP considers that his NHS patient, eligible under Schedule 11, needs more than one treatment a week. Can he issue a NHS prescription for one treatment a week, topped up with a private prescription?

A4 No. 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.

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

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

Q6 What if a patient's treatment ended before September 1998, say June 1997?

A6 No. The provision covers those men receiving treatment on 14 September 1998, although that shouldn't be interpreted so restrictively 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 A patient being 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. He was receiving a drug treatment for erectile dysfunction on 14 September.

Q9 Hospital specialist prescribes treatment for erectile dysfunction for a man with severe distress. Can the GP continue to prescribe on the specialist's recommendation?

A9 No. The GP may only prescribe in accordance with Schedule 11. Separate guidance is being issued on the management of men suffering from severe distress.

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 all GPs.

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

A12 PPA will disallow the claim.

Q13 Does the requirement to endorse "SLS" on NHS prescriptions apply to hospital doctors using forms FP10(HP) which are dispensed by pharmacy contractors?

A13 Whilst there is no requirement on hospital doctors to endorse FP10(HP)'s, any prescription not endorsed "SLS" cannot be dispensed by the community pharmacist (see para 11). Local specialists wishing to use form FP10(HP) should be asked to include the endorsement to prevent inconvenience for both patient and pharmacist.

Review

14. The operation of the policy set out in this circular will be reviewed after 1 year.

This circular has been issued by:

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