

Changes to the prescribing regulations for generic sildenafil For erectile dysfunction

Key Message

Generic sildenafil is now no longer in the SLS list (Part XVIII B of the Drug Tariff) meaning that restrictions on its use are lifted. It no longer needs to be annotated “SLS” and can be prescribed by GPs on FP10 for any indication for erectile dysfunction including severe distress. Guidance on suggested quantities to prescribe has not changed. The most cost effective treatment for erectile dysfunction at present is generic sildenafil.

Background

As of 1st August 2014, changes to the SLS regulations for England means that **generic sildenafil** has been removed from the list of medicines that may be prescribed only where they meet the SLS requirements. This means that generically written prescriptions for sildenafil no longer require the prescriber to annotate them with the letters “SLS”. The generic drugs apomorphine hydrochloride, moxislyte hydrochloride and thymoxamine hydrochloride are also all removed from the list and can be prescribed in their generic form without annotating “SLS”. Viagra and also avanafil have been *added to the SLS list*, and so must be annotated “SLS” in order to be valid. (NB there is no formal commissioning position for avanafil at present in VoY therefore it should not be prescribed).

What does this mean for my patient?

The restricted list of indications no longer applies to generic sildenafil (or apomorphine, moxislyte or thymoxamine) and therefore can be prescribed on FP10 by GPs without the need for “SLS” endorsement. This enables GPs to prescribe on FP10 for those who previously may not have been eligible for treatment under the NHS criteria such as those who may have been receiving a prescription privately or those attending specialist service/clinics to receive treatment on the basis of suffering severe distress as a result of erectile dysfunction.

What if the patient cannot tolerate generic sildenafil and requests Viagra?

Viagra can only be prescribed on the NHS according to the criteria in the SLS guidance in the Drug Tariff and must then be endorsed “SLS”. This is an important distinction with the new national guidance. CCGs may have their own commissioning guidance on the use of branded drugs where generic versions are available. Viagra remains significantly more expensive than generic sildenafil (average cost £20 per 4 tablets compared to £1.10 for generic sildenafil).

What quantity of tablets should be issued on prescription?

National advice regarding suggested quantities (i.e. one treatment per week) has not changed.

What are the criteria for prescribing under SLS requirements?

The criteria for prescribing treatment for ED on the NHS under SLS are laid down in HSC 1999/115⁸ and are also available in the BNF. Broadly they include the following:

- men who have had radical pelvic surgery; men who have had their prostate removed and / or have been treated for prostate cancer (surgery and other treatment); treated for renal failure (transplant and dialysis); spinal cord and severe pelvic injury; diabetes; multiple sclerosis; single gene neurological disease, poliomyelitis, spina bifida and Parkinson's disease.
- men not included in the above categories but who were receiving treatment for impotence on 14 September 1998.
- men diagnosed to be suffering from severe distress on account of their impotence should be referred to specialist services who will prescribe treatment if it is considered appropriate.

Drugs for erectile dysfunction that are prescribable on the NHS **as SLS** are alprostadil (MUSE, Caverject, Viridal), avanafil, Erecnos, tadalafil (Cialis), vardenafil and Viagra - please see CCG website for current commissioning positions: <http://www.valeofyorkccg.nhs.uk/rss/prescribing>

If patients require a private prescription for their ED treatment can I charge them for writing a private prescription?

GPs should not charge for writing a private prescription.

What does the practice need to do now?

- Be aware that sildenafil (and apomorphine, moxislyte and thymoxamine for ED treatment) prescriptions do not need to be annotated SLS (prescribing systems will be updated accordingly)
- Review patients that are receiving sildenafil on private prescription and transfer to FP10 (being mindful of advice on quantities)
- Ensure that patients who are being seen by specialist services (e.g. in secondary care) for severe distress are now managed in primary care and receive their prescriptions for sildenafil on FP10. The rules require that patients who need ED drugs that remain on the SLS list and when used for severe distress still need to be managed by the specialist services.

Where do I find further up to date information on this?

The September Drug Tariff has been updated to reflect these changes.
<http://www.nhsbsa.nhs.uk/924.aspx>