

Prescribing of generic sildenafil

Key message: generic sildenafil, prescribed for the treatment of erectile dysfunction (ED), is not subject to the SLS restrictions for NHS prescribing and dispensing. This is our formulary choice product.

The DH removed sildenafil from its selected list scheme (SLS) on August 1st 2014 in an [amendment](#) to the NHS Prescription of Drugs Regulations 2014. However, Viagra® has been added to the list, and so must be annotated 'SLS' in order for NHS prescriptions to be valid.

SLS criteria for erectile dysfunction applies to men who have at least one of the following:

- Have diabetes, multiple sclerosis, Parkinson's disease, poliomyelitis, prostate cancer, severe pelvic injury, single-gene neurological disease (for example Huntington's disease), spina bifida, or spinal cord injury.
- Are receiving renal dialysis for renal failure.
- Have had radical pelvic surgery, prostatectomy (including transurethral resection of the prostate), or a kidney transplant.
- Were receiving Caverject®, Erechnos®, MUSE®, Viagra®, or Viridal® at the expense of the NHS on 14 September 1998.

Implications for GP practices

1. Prescribers do not need to endorse FP10 prescriptions for generic sildenafil with 'SLS', though prescriptions for other phosphodiesterase type-5 inhibitor (PDE-5) drugs, including Viagra®, remain under SLS regulation. **Generic sildenafil is the Sheffield Formulary choice.**

2. Sheffield Area Prescribing Group (APG) recommends that no more than 4 tablets of generic sildenafil are prescribed each month, but clinicians retain clinical freedom to consider larger quantities for patients where it is considered appropriate, whilst balancing the risks of potential misuse or street value.

3. Generic sildenafil may be prescribed in primary care to patients suffering severe distress as a result of their erectile dysfunction. Referral to specialist services, however, ensures that these men continue to receive psychological treatments. All other PDE-5 inhibitor drugs, including Viagra® are not prescribable on FP10 prescriptions for severe distress, as this is not one of the SLS criteria. Specialist centres, however, can prescribe all PDE-5 inhibitors on the NHS.

See page 2 for more detailed information

Further information

Sildenafil was first introduced in 1998 and the cost of the drug has fallen substantially following introduction of generics in 2013. After a [consultation](#) in 2014, and in the light of the reduced cost, it was concluded by the DH that generic sildenafil should be made available to men with ED on an NHS prescription without them having to meet the criteria for SLS prescribing.

Patients suffering from severe distress

Severe distress is not included in the legislation as one of the SLS criteria for which GPs can prescribe drug treatments for ED on the NHS.

Specialist centres, however, can prescribe all PDE-5 inhibitors and other drugs for ED on the NHS if the man is 'suffering severe distress as a result of impotence' that causes:

- Significant disruption to normal social and occupational activities.
- A marked effect on mood, behaviour, social, and environmental awareness.
- A marked effect on interpersonal relationships.

Treatment with PDE-5 inhibitors for severe distress at Sheffield's Relationship and Sexual Service is given alongside psychosexual therapies.

Prescription quantity

Guidance from the DH recommends that one treatment a week for ED is appropriate for most patients, as research evidence suggests that the frequency of sexual intercourse in the 40–60 age range is once a week. However, this can be increased if, in the clinical judgement of the GP, more frequent use is appropriate.

This guidance is not part of the NHS regulations and no update has been issued following the removal of the SLS criteria for generic sildenafil. This has been reviewed by Sheffield APG (October 2014) who advises that the recommendations on quantity should continue to apply to generic sildenafil. The APG were mindful that the local restriction may assist prescribers in making difficult decisions about appropriate prescribing for some patients; and that, as there is an illicit market for sildenafil, prescribed product may be diverted.

NICE Clinical Knowledge Summary

Additional guidance can be found in the NICE CKS on [Erectile Dysfunction](#)

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