HAUTE AUTORITÉ DE SANTÉ

UROLOGY
New medicinal product
February 2017

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

CETINOR (sildenafil), phosphodiesterase type 5 inhibitor

For this generic version of VIAGRA, no clinical added value demonstrated in erectile dysfunction.

Main points

- CETINOR has marketing authorisation in adult men with erectile dysfunction.
- It is a 1st-line medicine that has no clinical added value compared with other phosphodiesterase type 5 inhibitors (CIALIS, LEVITRA, SPEDRA).
- Reimbursement is recommended only in men whose erectile dysfunction is very likely to be causally related to a serious and defined organic disease.

Therapeutic use

- When pharmacological treatment of erectile dysfunction is considered, the 1st-line options are medicines from the phosphodiesterase type 5 (PDE-5) inhibitor class.
- Alprostadil (as a cream, intracavernous injection or urethral stick) is a 2nd-line medicine.
- The non-pharmacological alternatives include medical devices and surgery to fit a penile prosthesis or implant.
- **Role of the medicinal product in the therapeutic strategy**
  Because of its ease of use, orally administered sildenafil (VIAGRA, CETINOR and other generics), together with the other phosphodiesterase 5 inhibitors (CIALIS, LEVITRA, SPEDRA), is preferred to intracavernous injections of alprostadil as 1st-line treatment.

Clinical data

- Sildenafil (CETINOR, VIAGRA) is more effective than placebo at obtaining an erection in men with erectile dysfunction.
- The clinical data do not allow the efficacy of oral sildenafil to be compared with another PDE-5 inhibitor or with intracavernous or locally administered alprostadil.
- Cases of prolonged erections and priapism have been reported on sildenafil but resolved spontaneously in the majority of cases. However, a prolonged erection lasting 4-6 hours occurred in 4% of patients and a painful erection lasting more than 6 hours occurred in 0.4% of patients.

Benefit of the medicinal product

- The actual clinical benefit* of CETINOR is substantial only in adult men with erectile dysfunction associated with one of the following diseases:
  - diabetic neuropathy;
  - paraplegia or tetraplegia;
  - sequelae of abdominal or pelvic surgery (prostate surgery, radical cystectomy and colorectal resection) or radiotherapy;
  - multiple sclerosis;
  - sequelae of priapism;
  - sequelae of vascular surgery (aortic aneurysm);
  - pelvic trauma complicated by urinary disorders;

  and in men with erectile dysfunction caused by long-term antipsychotic treatment.

  In the other situations covered by the marketing authorisation, the actual benefit of CETINOR is insufficient for reimbursement by National Health Insurance.

- CETINOR is a generic that does not provide clinical added value** (CAV V) in comparison with other sildenafil-based medicines.

- Recommends inclusion on the list of reimbursable products for supply by pharmacies and for hospital use only in adult men with erectile dysfunction associated with one of the diseases stated above (where the actual benefit is substantial).

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This document was created on the basis of the Transparency Committee Opinion of 08 February 2017 (CT-15804) and is available at **www.has-sante.fr**

* The actual clinical benefit (ACB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the ACB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means “no clinical added value”.