BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

VITAROS cream (alprostadil), medicine used to treat erectile dysfunction

No clinical benefit demonstrated in the treatment of erectile dysfunction due to organic causes over the available alternatives

Main points
- VITAROS cream has Marketing Authorisation in the treatment of erectile dysfunction in adults.
- It only concerns erectile dysfunctions due to organic causes.
- This is a new alternative to the currently available alprostadil-based proprietary medicinal products for the symptomatic treatment of erectile dysfunction due to organic causes.
- The studies provided, versus placebo only, did not enable to demonstrate a benefit compared with the other already-available proprietary medicinal products.

Therapeutic use

Oral phosphodiesterase type 5 (PDE5) inhibitors (sildenafil, tadalafil, vardenafil, avanafil) are the first-line pharmacological treatment of erectile disorders.

Alprostadil administered via the intracavernous route or as a urethral stick is used in second-line treatment after failure of oral treatments.

Non-medicinal alternatives are the VACUUM medical device and surgically fitted penile implants as the last treatment option.

Role of the medicinal product in the therapeutic strategy
VITAROS is an alternative to alprostadil-based medicinal products administered via the intracavernous route in the event of unresponsiveness or contraindication to PDE5s.

Clinical data
- In two 12-week studies in patients with erectile dysfunction of various etiologies, including dysfunction secondary to organic diseases or who have failed treatment with sildenafil, VITAROS at doses of 200 and 300 µg showed modest efficacy compared with placebo on the erectile function score for the IIEF questionnaire (ranging from 0 to 30):
  - + 2.5 points and + 3.1 points in the alprostadil 200 and 300 µg groups versus - 0.5 points in the placebo group in one study;
  - + 2.4 points and + 1.7 points in the alprostadil 200 and 300 µg groups versus - 0.9 points in the placebo group in another study.

The percentage of patients with an improvement of +3 points in the IIEF score was 53.4% (pooled analysis) in the VITAROS groups versus 32.7% in the placebo groups (post-hoc analysis).
- The Transparency Committee regrets the absence of a study versus another active treatment for erectile dysfunction, particularly a PDE5i or inhibitors of PDE5.
- The most commonly reported adverse events were a transient local urogenital reaction (feeling of warmth or burning in the penis, penile pain or rash in 36% to 43% of patients) and a local vaginal reaction in the partner (5% to 9%). One case of priapism was reported.
Benefit of the medicinal product

- The actual benefit* of VITAROS is low as a second-line treatment for erectile dysfunctions due to organic causes covered by the request for reimbursement:
  - paraplegia and tetraplegia regardless of the cause;
  - pelvic trauma complicated by urinary disorders;
  - surgery sequelae (aortic aneurysm; radical prostatectomy, radical cystectomy and colorectal resection) or abdominopelvic radiation therapy;
  - priapism sequelae;
  - known diabetic neuropathy;
  - multiple sclerosis.

- VITAROS does not provide clinical added value** (CAV V) in the therapeutic strategy.

- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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* The actual benefit (AB) 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 AB, which can be substantial, moderate, low or insufficient for reimbursement by National Health Insurance.

** 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”.

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