

Tadalafil 5mg tablets (Cialis®) for lower urinary tract symptoms (LUTS) in adult men

NHS Devon

Commissioning policy

The routine commissioning of tadalafil 5mg tablets is not accepted in Devon for lower urinary tract symptoms (LUTS) in adult men. The Formulary Interface Group should not include this in locally defined treatment recommendations.

Rationale for the decision

Tadalafil is a phosphodiesterase-5 inhibitor which is licensed for oral use to treat the signs and symptoms of benign prostatic hyperplasia (BPH) in adult men. National Institute for Health and Care Excellence (NICE) clinical guideline CG97 states “do not offer phosphodiesterase-5-inhibitors solely for the purpose of treating lower urinary tract symptoms in men, except as part of a randomised controlled trial.”

Clinical trial data from a number of randomised, controlled trials (RCTs) have been published and subject to multiple meta-analyses. These meta-analyses consistently report no clinically important difference between tadalafil and placebo at 12 weeks in the efficacy measure of change from baseline in total International Prostate Symptom Score (IPSS). Similarly, no clinically important difference between tadalafil and placebo at 12 weeks was seen in the efficacy measure of change from baseline in quality of life (IPSS QoL).

In subgroups of men with comorbid LUTS and erectile dysfunction (ED), meta-analyses reported no clinically important difference between tadalafil and placebo at 12 weeks in change from baseline in total IPSS.

Analysis by NICE also concluded that there is no difference in the effects of tadalafil compared to alpha blockers for the outcomes of IPSS symptom score or IPSS QoL, which they considered were the critically important outcomes. However, NICE noted

that the evidence was not sufficiently powered or analysed as a non-inferiority (or equivalence) trial and therefore cannot be interpreted as showing that PDE5 inhibitors are as effective as alpha blockers.

The annual acquisition cost of tadalafil 5mg tablets is higher than that of other established oral treatments for LUTS/BPH. Given that tadalafil does not appear to be more effective than placebo or alpha blockers, and is more expensive, it is not considered to be value for money for the NHS.

Guidance notes on exceptionality

This general policy does not replace clinical judgement on the appropriate treatment of an individual patient.

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