

Tadalafil use in Benign Prostatic Hyperplasia

Recommendation

Due to the lack of a NICE recommendation, the cost implication and the similar efficacy to the other drug treatments Tadalafil should not be prescribed for use in BPH.

Generic prescribing of existing drug treatments should continue to be used.

Background

5mg Tadalafil (Cialis) once daily has been licenced for the treatment of the signs and symptoms of benign prostatic hyperplasia in adult malesⁱ. The phosphodiesterase 5 inhibitor is thought to relieve BPH symptoms by relaxing smooth muscle and increasing blood flow to the bladder, prostate and urethraⁱⁱ.

It is the first PDE5 to be licenced for BPH thus it offers a new drug treatment to the existing drug management options.

Existing Drug Treatment

1. Alpha blockers (alfuzosin, doxazosin, tamsulosin or terazosin)ⁱⁱⁱ
2. 5-alpha reductase inhibitors (5ARIs)ⁱⁱⁱ
3. Combination alpha blockers and 5ARIsⁱⁱⁱ

Currently NICE is unable to recommend the use in the NHS of tadalafil for the treatment of symptoms associated with the BPH^{iv} as the TA273 appraisal was terminated in September 2012.

Cost comparison

Drug	Dose	Cost for 1 year treatment (Drug Tariff Apr13)
Tadalafil 5mg tabs	OD	£714.87
Dutasteride 500mcg caps	OD	£361.21
Dutasteride 500mcg/Tamsulosin 400mcg caps	OD	£240.24
Alfuzosin MR 10mg	OD	£151.79
Indoramin 40mg	OD	£148.26
Tamsulosin MR 400mcg tabs	OD	£127.04
Alfuzosin 7.5mg tabs	OD	£121.94
Prazosin 4mg	OD	£83.96
Tamsulosin Mr 400mcg caps	OD	£65.76
Terazosin 5mg	OD	£32.63
Finasteride 5mg Tabs	OD	£21.97
Doxazosin 4mg tabs	OD	£15.21

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Efficacy

Tadalafil has not been directly compared with established treatments for LUTS/BPH^v. When the International Prostate Symptom Score (IPSS) from different studies are compared they indicate that tadalafil has a similar efficacy to the other drug treatments available.

Drug	Reduction in IPSS
Tadalafil 5mg	-5.6 ^{vi}
Alpha blockers	-6.3 ^{vii}
Fenasteride	-4.1 ^{vii}

Recommendations

Due to the lack of a NICE recommendation, the cost implication and the similar efficacy to the other drug treatments Tadalafil cannot be recommended for use in BPH. EKHUFT consultant view is that they would support the use of generic standard options of existing treatments first, then recommend referral onto urology. They would not support GPs using Tadalafil for management of BPH symptoms in someone failing treatment with ordinary medication. This would not make financial sense considering the price of daily Tadalafil and its limited efficacy compared to surgical options.

ⁱ<http://www.medicines.org.uk/emc/medicine/11363/SPC/Cialis+2.5mg%2c+5mg%2c+10mg+%26amp%3b+20mg+film-coated+tablets#INDICATIONS>

ⁱⁱ <http://www.mims.co.uk/more/LicenceChanges/rss/article/1164519/Cialis-first-PDE5-inhibitor-licensed-benign-prostatic-hyperplasia/>

ⁱⁱⁱ National Institute for Health and Clinical Excellence. The management of lower urinary tract symptoms in men. Clinical guideline CG97. London: NICE; May 2010.

^{iv} National Institute for Health and Clinical Excellence. Tadalafil for the treatment of symptoms associated with BPH (terminated appraisal). Technology appraisal TA273. London: NICE; Sept 2012.

^v Regional Drug and Therapeutics Centre. Tadalaphil for BPH. New Drug Evaluation #126. Newcastle upon Tyne: RDTC;Apr2013.

^{vi} Porst H, Kim ED, Casabe AR, et al; for the LVHJ study team. Efficacy and Safety of tadalafil once daily in the treatment of men with lower urinary tract symptoms suggestive of benign prostatic hyperplasia: results of an international randomized, double-blind, placebo-controlled trial. *Eur Urol.* 2011;60(5):1105-1113.

^{vii} Hutchison A, Farmer R, Verhamme K, Berges R, Navarrete RV. The efficacy of drugs for the treatment of LUTS/BPH, a study in 6 European countries. *Eur Urol.* 2007 Jan;51(1):207-15.