NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal

Tadalafil for the treatment of symptoms associated with benign prostatic hyperplasia

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of tadalafil within its licensed indication for the treatment of symptoms associated with benign prostatic hyperplasia.

Background

Benign prostatic hyperplasia (BPH) is noncancerous enlargement of the prostate. It can be associated with lower urinary tract symptoms that impact negatively on quality of life. Symptoms may reflect difficulties when emptying the bladder (weak urine flow, hesitancy, straining and incomplete emptying) or bladder storage problems (frequency, urgency and nocturia). The precise relationship between symptoms and prostate enlargement is not clear as only 25–50% of people with BPH have symptoms.

The prevalence of BPH increases with age and troublesome lower urinary tract symptoms occur in up to 30% of men older than 65 years. Around 40% of men aged 50 years have histological evidence of BPH, rising to 90% for men in their 80s. Some US studies have suggested that the prevalence of BPH is significantly higher in black people. Black people are at increased risk of requiring surgery to treat BPH.

In 2008–9 there were approximately 39,000 inpatient admissions due to BPH in England, accounting for around 76,000 bed days.

BPH is known to be the most common cause of lower urinary tract symptoms. Guidance on ‘Lower urinary tract symptoms: the management of lower urinary tract symptoms in men’ (NICE clinical guideline 97) recommends several possible drug treatments. People with moderate to severe symptoms suggestive of BPH can be offered an alpha blocker (alfuzosin, doxazosin, tamsulosin or terazosin). If they also have an enlarged prostate or raised prostate-specific antigen (PSA) levels, they can be offered a combination of an alpha blocker and a 5-alpha reductase inhibitor (finasteride or dutasteride). A 5-alpha reductase inhibitor may be offered to people with symptoms suggestive of BPH who have an enlarged prostate or raised PSA levels, and who are considered to be at high risk of progression (for example, older people).

The technology

Tadalafil (Cialis; Lilly) is a selective, reversible inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5). It is thought that inhibition of PDE5 reduces BPH symptoms through smooth muscle relaxation and increased blood flow to the bladder, prostate and urethra. Tadalafil is administered orally.

Tadalafil does not currently have a UK marketing authorisation for the treatment of the symptoms of benign prostatic hyperplasia. It has been studied in clinical trials in comparison with placebo, and with tamsulosin as an active control, for the treatment of symptoms of BPH in men with and without erectile dysfunction.

Tadalafil has a UK marketing authorisation for the treatment of erectile dysfunction in men.

Intervention(s)	Tadalafil
Population(s)	People with moderate to severe symptoms of benign prostatic hyperplasia
Comparators	Alpha blockers
Outcomes	The outcome measures to be considered include: • acute and long-term symptoms (for example, frequency and urgency of urination) • physiological measures (for example, peak urinary flow rate and post-void residual urine volume) • erectile function • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.

Other considerations	Guidance will only be issued in accordance with the marketing authorisation. If the evidence allows, the following subgroups will be considered: • presence or absence of erectile dysfunction (that is, BPH alone or BPH with erectile dysfunction) • symptom severity (moderate or severe).
Related NICE recommendations	Related Guidelines: Clinical Guideline No. 97, May 2010, 'Lower urinary tract symptoms: the management of lower urinary tract symptoms in men'. Review decision date May 2013. Clinical Guideline No. 27, June 2005, 'Referral guidelines for suspected cancer in adults and children'. Under review. Related Interventional Procedures: Interventional Procedure Guidance No. 275, November 2008, 'Laparoscopic prostatectomy for benign prostatic obstruction'.