NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Single Technology Appraisal

Dutasteride for reducing the risk of developing prostate cancer

Final scope

Remit/Appraisal objective

To appraise the clinical and cost effectiveness of dutasteride within its licensed indication for reducing the risk of developing prostate cancer in men who are considered to be at increased risk of developing the disease.

Background

Prostate cancer is a disease in which tumours develop in the prostate, a gland in the male reproductive system. It is the most common cancer in men in the UK, with 32,679 new cases diagnosed in England and Wales in 2007. The incidence of prostate cancer increases with age and is more common in older men, with around 75% of cases occur in men above the age of 65 years. It is also the second most common cause of cancer mortality in men, with 9150 deaths recorded in England and Wales in 2008.

There is no national screening programme for prostate cancer in England and Wales. At present no modifiable risk factor for prostate cancer has been identified and therefore there is insufficient evidence on which to base a prevention strategy. Established risk factors are age, elevated serum PSA family history and ethnicity (men of black African or black Caribbean). Elevated serum PSA is also a marker for the presence of prostate cancer itself.

Currently there is no treatment that is known to prevent the development of prostate cancer. It has been suggested that certain drugs used in the treatment of another condition of the prostate, benign prostatic hyperplasia (BPH), may reduce the overall risk of prostate cancer. BPH is not a precancerous condition.

The technology

Dutasteride (Avodart, GlaxoSmithKline) is a type-1 and type-2 5-alpha reductase inhibitor that inhibits the conversion of testosterone to dihydrotestosterone, a more potent androgen that is thought to be influential in the development of prostate cancer. It is administrated orally as a 0.5mg capsule once daily.

Dutasteride does not currently have a marketing authorisation for use in the prevention of prostate cancer. It is being studied in comparison with placebo in clinical trials in men between the ages of 50-75 with elevated serum PSA concentration who have had a negative prostate biopsy within 6 months prior to enrolment, that is, men considered to be at increased risk of prostate cancer who have not yet known to have developed the disease. Dutasteride

has a marketing authorisation for the treatment of moderate to severe symptoms of BPH.

Intervention	Dutasteride
Population	Men who are at increased risk of developing prostate cancer on the basis of factors such as age, elevated serum PSA concentration, family history, ethnicity or other known risk factors
Comparators	No intervention to reduce the risk of prostate cancer.
Outcomes	The outcome measures to be considered include: • histological grade of tumour at prostate cancer diagnosis • time of diagnosis to prostate cancer • re-biopsy rate • severity • mortality • PSA • need for radical treatment • probable precursor lesions of prostate cancer such as high grade prostatic intraepithelial neoplasia and atypical small acinar proliferation • 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. Costs to the NHS associated with the case finding/serum PSA concentration testing should be included in the economic analysis.

Other considerations	If the evidence allows subgroups based on the level of risk at which intervention with dutasteride is clinically- and cost-effective will be considered. Risk factors may include age, PSA level, body mass index, family history and ethnicity (men of black African or black Caribbean). Guidance will only be issued in accordance with the marketing authorisation
Related NICE recommendations	Related Guidelines: Guidance on Cancer Services, September 2002, Improving outcomes in urological cancers. Clinical Guideline 58, Prostate Cancer: diagnosis and treatment, February 2008.