

National Horizon Scanning Centre

Dutasteride (Avodart) for prevention of prostate cancer

April 2008



This technology summary is based on information available at the time of research and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes.

Dutasteride (Avodart) for prevention of prostate cancer

Target group

- Men identified as at risk of developing prostate cancer.

Technology description

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

Dutasteride is licensed in the EU for:

- Treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH).
- Reduction in the risk of acute urinary retention (AUR) in patients with moderate to severe symptoms of BPH.
- Reduction in the risk of surgery in patients with moderate to severe symptoms of BPH.

Finasteride, a type-2, 5-alpha reductase inhibitor, is in phase III development in the USA for prostate cancer prevention.

Innovation and/or advantages

As there is currently no licensed pharmacotherapy for the prevention of prostate cancer, this would be a significant new indication.

Developer

GlaxoSmithKline Plc.

Availability, launch or marketing dates, and licensing plans:

In phase III clinical trials.

NHS or Government priority area:

This topic is relevant to the NHS Cancer Plan (2000).

Relevant guidance

- NICE clinical guideline. Prostate cancer: diagnosis and treatment. 2008¹.
- NICE clinical guideline. Referral for suspected cancer. 2005².
- NICE cancer service guidance. Improving outcomes in urological cancers - Manual. 2002³.

Clinical need and burden of disease

Prostate cancer is the most common cancer in men. In 2004 there were 31,679 new cases diagnosed in England and Wales (an incidence of 139 per 100,000 men). In 2005 there were 9,013 registered deaths in England and Wales (a mortality rate of 35 per 100,000 men). The risk of prostate cancer increases with age and around 60% of cases occur in men aged over 70. Men of African descent have an increased risk, as do those with a family history of the disease⁴.

There are no routinely collected data in England and Wales on testing for prostate cancer. In the year 2001/2002 the annual rate of PSA testing in asymptomatic men was estimated to be 6 per 100 men⁵. An estimate of 56,000-89,000 needle biopsies performed in England and Wales per year¹.

Efficacy and safety

Trial code, name, phase	NCT00056407; REDUCE: phase IIIb ⁶ .
Sponsor	GlaxoSmithKline
Status	Ongoing
Location	Worldwide
Design	Randomised, double blind, placebo controlled.
Participants in trial	n = 8000 (planned); adults 50-75 years; one negative prostate biopsy within 6 months prior to enrolment; PSA >2.5 and <10.0 ng/mL if 50-60 years of age or >3.0 and <10.0 ng/mL if 60+; international prostate symptom score (IPSS) less than 25 and peak urinary flow rate (Qmax) more than 5mL/sec or more; prostate volume less than 80mL; Randomised to dutasteride 0.5mg or matching placebo.
Follow-up	4 years
Primary outcome	Biopsy detectable prostate cancer.
Secondary outcomes	Overall survival; adverse events; Gleason grade at diagnosis; high grade prostatic intraepithelial neoplasia (HGPIN); number of cancer positive cores; % of core involved at diagnosis; treatment alteration score; intervention (surgical and non-surgical) for prostate cancer; IPSS; prostate volume; urine flow; alpha blockers for symptom control; acute urinary retention; urinary tract infections; quality of life; serum testosterone (Serum T) and dihydrotestosterone (DHT); post-biopsy macroscopic haematuria/haemospermia; clinical laboratory evaluations (haematology, biochemistry, PSA [free and total]).

Estimated cost and cost impact

The cost of the treatment for the prevention of cancer has not yet been assessed, but dutasteride (Avodart) at a dosage of 0.5mg daily costs £300 per annum.

Patients

- | | | |
|---|---|---|
| <input checked="" type="checkbox"/> Reduced morbidity | <input checked="" type="checkbox"/> Reduced mortality or increased survival | <input checked="" type="checkbox"/> Improved quality of life for patients and/or carers |
| <input type="checkbox"/> Quicker, earlier or more accurate diagnosis or identification of disease | <input type="checkbox"/> Other: | <input type="checkbox"/> None identified |

Services

- | | | |
|---|--|---|
| <input type="checkbox"/> Increased use | <input type="checkbox"/> Service reorganisation required | <input type="checkbox"/> Staff or training required |
| <input checked="" type="checkbox"/> Decreased use: diagnosis and treatment of prostate cancer | <input type="checkbox"/> Other: | <input type="checkbox"/> None identified |

Costs

- | | | |
|--|---|---|
| <input type="checkbox"/> Increased unit cost compared to alternative | <input type="checkbox"/> Increased costs: more patients coming for treatment | <input type="checkbox"/> Increased costs: capital investment needed |
| <input checked="" type="checkbox"/> New costs: | <input checked="" type="checkbox"/> Savings: diagnosis and treatment costs of prostate cancer | <input type="checkbox"/> Other: |

References

- ¹ National Institute for Health and Clinical Excellence. Prostate cancer: diagnosis and treatment. Clinical guideline CG58. February 2008.
- ² National Institute for Health and Clinical Excellence. Referral for suspected cancer. Clinical guideline CG27. June 2005.
- ³ National Institute for Health and Clinical Excellence. Improving outcomes in urological cancers - Manual. Cancer service guidance. September 2002.
- ⁴ Cancer Research UK. CancerStats key facts on prostate cancer. Available at: <http://info.cancerresearchuk.org/cancerstats/types/prostate/> (Accessed 06/03/08).
- ⁵ NHS Cancer Screening Programmes. Prostate specific antigen (PSA) tests. Available at: <http://www.cancerscreening.nhs.uk/prostate/psa-tests.html> (Accessed 15/02/08).
- ⁶ Clinical trials. NCT00056407. "REDUCE" - A clinical research study to reduce the incidence of prostate cancer in men who are at increased risk. Available at: <http://clinicaltrials.gov/show/NCT00056407> (Accessed 07/02/08).

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