



Submission from CancerBACUP to NICE Appraisal Committee on docetaxel for hormone refractory prostate cancer

CancerBACUP welcomes the opportunity to contribute to the appraisal of docetaxel for hormone refractory prostate cancer. As the leading specialist provider of independent information on all types of cancer, CancerBACUP has regular contact with people living with prostate cancer and those caring for them.

CancerBACUP believes that everyone with cancer should be offered the most effective and appropriate treatment, based on the available evidence and the patient's own wishes and preferences. We believe that:

- Patients should have access to the most effective treatments appropriate to them as individuals;
- Patients should be able to choose – in partnership with their oncologist – the treatment that is likely to suit them best in terms of relative benefits and side-effects;
- The impact of treatments on patient's quality of life, as well as length of life, should be given full consideration by the Appraisal Committee.

We urge the Appraisal Committee to recommend that docetaxel in combination with prednisolone should be available for the treatment of patients with hormone refractory prostate cancer.

Living with hormone refractory prostate cancer

An estimated 24,716 new cases of prostate cancer are diagnosed each year in England and Wales. Prostate cancer risk is strongly related to age: very few cases are registered in men under the age of 50 and 65 percent occur in men over 70 years old.

Prostate cancer is the most common cancer in men in the UK accounting for one in five of all new male cancers diagnosed. Even though there may have been huge increases in incidence in the last 20 years, mortality from prostate cancer has remained fairly stable. The apparent rise in incidence is mainly due to the increased use of prostate specific antigen testing (PSA).

Cancer of the prostate is dependent on the male hormone, testosterone, for its growth. Testosterone is produced by the testicles and by reducing the amount of the hormone in the body it is possible to slow down or stop the growth of prostate cancer.

The level of testosterone in the body can be lowered by removing the part of the testicles that produce testosterone or by using drugs. The drugs can be given as tablets or injections, or a combination of both.

Hormonal therapy is the standard treatment for prostate cancer which has spread or developed secondary cancers or metastases. Often there is very good shrinkage of the cancer and symptoms such as poor urinary flow, bone pain or tiredness are greatly improved.

Unfortunately, most hormonal therapies usually cause distressing side effects including the inability to have an erection and loss of sexual desire. Other side effects include hot flushes and sweating, weight gain, fatigue and breast swelling/tenderness.

Even with hormone treatment, most advanced prostate cancers will eventually begin to progress again. This situation is known as hormone refractory or hormone escaped disease and is thought to occur as prostate cancer cells become increasingly androgen independent.

For a hormone refractory prostate cancer, treatment may include symptom control using radiotherapy, drugs such as steroids and pain relieving medication.

Chemotherapy may also be considered. However, there is no standard treatment. Some of the drugs used are mitoxantrone, epirubicin, docetaxel and estramustine.

Chemotherapy is used as a palliation treatment to try to shrink and control the cancer and relieve symptoms, with the aim of prolonging a good quality of life. It can also reduce PSA levels in patients with hormone refractory prostate cancer and relieves pain. Tolerability is of concern, particularly since most patients are elderly and many have other medical problems. Common side effects of chemotherapy include tiredness, lowered immunity to infections, nausea, vomiting and hair loss.

Docetaxel

Docetaxel is a chemotherapy agent that is given as a treatment for some types of cancer. It is most commonly used to treat breast cancer and non-small cell lung cancer. In the UK it is licenced for use in combination with prednisolone for hormone refractory prostate cancer.

CancerBACUP argues strongly that NICE should recommend that docetaxel in combination with prednisolone is available on the NHS for the treatment of patients with hormone refractory prostate cancer in accordance with its licence for the following reasons:

1. Docetaxel can extend survival for men with hormone refractory prostate cancer

Results from trials of patients with hormone refractory prostate cancer show that when given with prednisolone, treatment with docetaxel given every three weeks can lead to improved survival.¹

Results from a randomised, non blinded, phase 3 study carried out in 24 centres, found that the median survival for patients given docetaxel was 18.9 months compared to 16.5 for patients given mitoxantrone. Among these groups 32 percent and 45 percent respectively had at least a 50 percent decrease in their PSA level

2. Docetaxel significantly improves quality of life

Patients given docetaxel in combination with prednisolone report a significantly higher improvement in quality of life. In a report in the New England Journal of Medicine², the percentage of patients who had an improvement in the quality of life was similarly higher in two groups given docetaxel (22 percent in a group given docetaxel every three weeks and 23 percent in the group given weekly docetaxel) compared to the mitoxantrone group (13 percent).

Adverse effects experienced with docetaxel

Although docetaxel can improve survival and quality of life, trial data suggests that patients receiving docetaxel in combination with prednisolone can experience an increased number of low grade adverse effects. These include fatigue, nausea or vomiting or both, alopecia, diarrhoea, nail changes, sensory neuropathy, anorexia, changes in taste, stomatitis, dyspnoea, peripheral oedema and epistaxis.

However, in trials of mitoxantrone, a higher incidence of cardiac events among patients has been reported.³

Declaration of interest

CancerBACUP has received sponsorship from Sanofi Aventis, the manufacturer of docetaxel, for several publications and projects.

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¹ Ian F Tannock, Ronald de Wit, William R Berry, Jozsef Horti et al. The New England Journal of Medicine. Boston: Oct 7 2004. Vol 351, Iss 15, p 1502-1512 (11pp)

² Ian F Tannock, Ronald de Wit, William R Berry, Jozsef Horti et al. The New England Journal of Medicine. Boston: Oct 7 2004. Vol 351, Iss 15, p 1502-1512 (11pp)

³ ibid