Abiraterone - a case study in the challenges for cancer drug licensing

Posted on Friday 23rd March 2012

March is Prostate Cancer Awareness Month. In a few weeks time NICE will meet to discuss the responses to their draft decision not to recommend abiraterone, a life extending drug for men with incurable prostate cancer.

This British discovery is one of the biggest breakthroughs in the treatment of men with advanced prostate cancer for years. A large scale trial of the drug published in 2011 showed that abiraterone combined with acetateâ€“prednisone extended overall survival by almost four months. (14.8 months vs. 10.9 months in the control group).

Historically, prostate cancer has suffered from a legacy of neglect and in recent years very little progress has been made in the treatment of the advanced stages of the disease. New treatments, like abiraterone are significant because the treatment options in advanced prostate cancer as in bladder and lung cancer are so limited.

Whatever decision NICE makes on abiraterone it highlights a wider problem for the NHS in licensing the increasing number of cancer drugs that are effectively used to extend life in patients with late stage disease.

There are many parallels between this case and the drug sorafenib (Nexavar), which was first licensed for use in renal cancer in 2006. Despite this we estimate that only a third of UK patients had access to the drug between licence in 2006 and 2009 when NICE recommended against NHS funding for the drug.

Our own audit of survival in renal cancer patients attending clinic between 2006–2008 showed that patients given access to sunitinib and sorafenib had substantially better survival than those denied treatment (average survival 22 versus 7 months).

The pace of cancer drug development has brought onto the market an increasing number of cancer drugs that are effective in extending life rather than in inducing remission. In 2009, NICE actually agreed new criteria for appraising drugs which can extend life for people with terminal cancer. This has been used to assess 25 anti-cancer agents, of which 9 resulted in positive recommendations for use in the NHS.

These include the use of sunitinib for the first-line treatment of renal cell carcinoma and, trastuzumab plus cisplatin and capecitabine or 5-fluorouracil for HER2-positive metastatic gastric cancer. Unfortunately abiraterone is not currently being assessed using these criteria although there is a strong clinical case to say it should be.

The issue of licensing for drugs used in advanced cancer treatment will increase as breakthroughs from a wealth of clinical studies are translated into new therapeutic agents. Whilst we rightly celebrate treatments that can send disease into remission, we should not underestimate the power of drugs like abiraterone and serafanib to extend the quality and length of patients lives.

Undoubtedly, in this time of austerity NICE has some hard decisions to make. If it is not licensed the likelihood is that men across England and Wales will face a postcode lottery when they try to access this important treatment.

In many ways the decision on arbitaterone will be interesting. For clinicians because it has been proven to be one of few effective treatments in this group of prostate cancer patients – but also because it poses the question to those making the decision how do we value drugs that offer extensions in survival for patients with late stage disease.

Professor Nicholas James
Professor of Clinical Oncology
Co-Director Research and Development (Cancer) University Hospitals Birmingham NHS FT