

PRESS RELEASE

NICE draft recommendation on the use of drugs for renal cancer

The National Institute for Health and Clinical Excellence (NICE) is currently appraising the use of bevacizumab, sorafenib, sunitinib and temsirolimus for the treatment of advanced and/or metastatic renal cell carcinoma. Following the independent advisory Committee meeting on 14 January 2009 NICE has decided to split this appraisal in two in order to get guidance out to the NHS as quickly as possible.

In the first appraisal **sunitinib is recommended as a first-line treatment** option in advanced and/or metastatic renal cell carcinoma for patients who are suitable for immunotherapy with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.

In the second appraisal bevacizumab, sorafenib and temsirolimus are not recommended as first-line treatment options for advanced and/or metastatic renal cell carcinoma. In addition, the two drugs also licensed for second-line treatment of advanced or metastatic renal cell carcinoma, sorafenib and sunitinib, are not recommended for this indication.

Guidance on bevacizumab, sorafenib and temsirolimus for first-line treatment and sorafenib and sunitinib for the second-line treatment of renal cancer is available for public consultation on the NICE website until 4 March 2009. Comments received during this consultation will be reviewed by the independent appraisal Committee at their meeting on 11 March 2009.

Andrew Dillon, NICE Chief Executive said: "Having decided that one of these treatments should be recommended for use in the NHS, we felt that it was in the interests of patients to get that advice out as quickly as possible. Although this final

recommendation is subject to appeal we very much hope it will form the basis of our guidance to the NHS. The other 3 drugs we are looking at will be the subject of further consultation.”

Ends

For more information call the NICE press office on 0845 003 7782 and out of hours on 07775 583 813.

Notes to editors

About the latest appraisal drafts

1. NICE has always had the difficult task of ensuring that patients receive the best care from the NHS but also to ensure that the NHS gets value for money. We know that people regard the things that the NHS can do to save or extend life as being especially important.

The previous draft of this guidance, although acknowledging that sunitinib is a clinically effective treatment, concluded that it was not a cost effective use of NHS resources. After applying NICE’s new arrangements for taking into account the added value society puts on treatments that extend life at the end of life, as well as the manufacturer’s proposed pricing scheme which provides the first cycle of sunitinib free to the NHS, the NICE independent advisory Committee concluded that sunitinib does represent a cost effective use of NHS resources when used as a first-line treatment for advanced and/or metastatic RCC.

When considering the use of bevacizumab, sorafenib and temsirolimus for first-line treatment of renal cancer with cost per QALYs of £82,700 - £102,000 and sorafenib and sunitinib for second-line treatment with cost per QALYs above £65,900 the NICE independent advisory Committee did not think they represented a cost effective use of NHS money even when taking into account the end of life advice. NICE’s position on all these drugs is now out for comment.

Until NICE issues final guidance on the use of bevacizumab, sorafenib, sunitinib or temsirolimus as treatment options for advanced and/or metastatic renal cell carcinoma, individual cases should be assessed at a local level within the NHS. Once NICE issues its guidance on a technology it replaces local recommendations.

About the appraisal

2. Information on the NICE appraisal of bevacizumab, sorafenib, sunitinib or temsirolimus as treatment options for advanced and/or metastatic renal cell carcinoma and the consultation documents are available at www.nice.org.uk
3. First-line treatment of renal cell carcinoma is initial therapy, second-line treatment is given if this initial therapy has failed.
4. Bevacizumab (Avastin, Roche Products). Over a 6-week cycle, the average total cost of drug acquisition is £5982 per patient for the first cycle and £6117 for subsequent 6-week cycles, approximately £53,000 per patient per year.
5. Sorafenib (Nexavar, Bayer). The price for a pack 200-mg tablets (112 tablets per pack) is £2980.47 (excluding VAT) - this is an increase in the price submitted to NICE for the purpose of this appraisal.. The manufacturer of sorafenib has agreed a patient access scheme with the Department of Health, in which the first pack of sorafenib is free to the NHS.
6. Sunitinib (Sutent, Pfizer). The price for a pack of 50-mg capsules (30 capsules per pack) is £3363.00 (excluding VAT; BNF edition 55). The average daily cost of sunitinib is £74.74, with an average 6-week cycle costing £3139. The manufacturer of sunitinib has agreed a patient access scheme with the Department of Health, in which the first treatment cycle of sunitinib is free to the NHS. The Department of Health considered that

this patient access scheme does not constitute an excessive administrative burden on the NHS.

7. Temsirolimus (Torisel, Wyeth Pharmaceuticals). No price is listed in the BNF.
8. (QALY) Quality Adjusted Life Year. Cost per QALY = the additional cost of one year of healthy life for one person (when comparing a new drug to current standard practice). It is one way of taking into account both the costs and benefits of a health technology. Expressing benefits in cost per QALYs allows decision makers to consider technologies for different diseases in a consistent framework.
9. Sorafenib, sunitinib are not recommended by SMC because their cost-effectiveness has not been demonstrated. Bevacizumab in combination with IFN is not recommended by the SMC because the manufacturer did not make a submission.

About NICE

10. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
11. NICE produces guidance in three areas of health:
 - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
 - **health technologies** – guidance on the use of new and existing medicines, treatments and procedures within the NHS
 - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.