NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Appraisal consultation document

Sorafenib for treating advanced hepatocellular carcinoma

The Department of Health has asked the National Institute for Health and Care Excellence (NICE) to produce guidance on using sorafenib in the NHS in England. The appraisal committee has considered the evidence submitted by the company and the views of non-company consultees and commentators, clinical experts and patient experts.

This document has been prepared for consultation with the consultees. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the consultees and commentators for this appraisal and the public. This document should be read along with the evidence (see the committee papers).

The appraisal committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

Note that this document is not NICE's final guidance on this technology. The recommendations in section 1 may change after consultation.

After consultation:

- The appraisal committee will meet again to consider the evidence, this appraisal consultation document and comments from the consultees.
- At that meeting, the committee will also consider comments made by people who are not consultees.
- After considering these comments, the committee will prepare the final appraisal determination (FAD).
- Subject to any appeal by consultees, the FAD may be used as the basis for NICE's guidance on using sorafenib in the NHS in England.

For further details, see NICE's guide to the processes of technology appraisal.

The key dates for this appraisal are:

Closing date for comments: 12 September 2016

Second appraisal committee meeting: TBC

Details of membership of the appraisal committee are given in section 6.

1 Recommendations

1.1 Sorafenib is not recommended for treating advanced hepatocellular carcinoma in adults when surgical or locoregional therapies have failed or are not suitable.

1.2 This guidance is not intended to affect the position of patients whose treatment with sorafenib was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop.

2 The technology

Description of the technology	Sorafenib (Nexavar, Bayer) is a multikinase inhibitor that inhibits tumour blood vessel development and tumour cell proliferation. It does this by inhibiting the Raf cascade, and vascular endothelial growth factor (VEGF)/platelet-derived growth factor (PDGF) receptors of tumour cells, vascular endothelial cells and pericytes.
Marketing authorisation	Sorafenib has a marketing authorisation in the UK for treating hepatocellular carcinoma.
Adverse reactions	The summary of product characteristics includes the following conditions that may be associated with sorafenib treatment: dermatological toxicities, hypertension, haemorrhage, cardiac ischaemia and/or infarction, gastrointestinal perforation, hepatic impairment and wound healing complications. For full details of adverse reactions and contraindications, see the summary of product characteristics.
Recommended dose and schedule	Sorafenib is administered orally as 200-mg film-coated tablets. The recommended dosage is 400 mg twice daily (a total daily dose of 800 mg). The dosage may be adjusted to 2×200-mg tablets once daily if adverse drug reactions are suspected. The summary of product characteristics recommends that treatment should be continued as long as clinical benefit is observed or until unacceptable toxicity occurs.
Price	The price for a pack of 200-mg tablets (112 tablets per pack) is £2980.47 (excluding VAT, company's Cancer Drugs Fund reconsideration submission). The company has agreed a nationally available price reduction for sorafenib with the Commercial Medicines Unit. The contract prices agreed through the framework are commercial in confidence.

3 Evidence

3.1 The appraisal committee (section 6) considered evidence submitted by Bayer and a review of this submission by the evidence review group. This appraisal was a Cancer Drugs Fund reconsideration of the published NICE technology appraisal guidance on sorafenib for treating advanced hepatocellular carcinoma. It focused on data from Palmer et al. (2013) and the GIDEON study to validate survival extrapolations from the company's original submission. New cost-effectiveness analyses

were done using a Commercial Medicines Unit price, which provides sorafenib at a reduced cost. The Commercial Medicines Unit price is commercial in confidence, and cannot be presented here.

3.2 The company's original submission presented clinical effectiveness data from the SHARP study. SHARP was a multicentre, double-blind, placebo-controlled randomised trial in patients with advanced hepatocellular carcinoma who had not received previous systemic treatment. The study included 602 patients and assessed the effect of sorafenib plus best supportive care (n=299) compared with placebo plus best supportive care (n=303). The primary outcomes in SHARP were overall survival and time to symptomatic progression.

3.3 Sections 4.1 to 4.17 reflect the committee's consideration of the evidence submitted in the original appraisal (NICE technology appraisal guidance 189). Sections 4.18 to 4.24 reflect the committee's consideration of the additional evidence submitted for the Cancer Drugs Fund reconsideration.

3.4 See the committee papers for full details of the Cancer Drugs Fund reconsideration evidence and the history for full details of the evidence used for NICE's original technology appraisal guidance on sorafenib for treating advanced hepatocellular carcinoma.

4 Committee discussion

4.1 The appraisal committee reviewed the data available on the clinical and cost effectiveness of sorafenib, having considered evidence on the nature of hepatocellular carcinoma and the value placed on the benefits of sorafenib by people with the condition, those who represent them, and clinical experts. It also took into account the effective use of NHS resources.

4.2 The committee considered the UK treatment pathway for patients with hepatocellular carcinoma. The clinical experts described that in UK clinical practice one third of patients with hepatocellular carcinoma would be eligible for procedures such as local resection, radiofrequency ablation or chemoembolisation. They noted that these procedures are not considered effective for approximately 50% of patients, who would progress to further locoregional therapy or systemic treatment. The committee accepted that the scope of this technology appraisal was restricted to these patients. The committee further reviewed the treatment pathway consistent with the Barcelona Clinic Liver Cancer (BCLC) staging classification and treatment schedule as presented by Llovet et al. (2008). The clinical experts agreed that the BCLC staging system is used in UK clinical practice.

4.3 The committee was aware that the licensed indication for sorafenib is hepatocellular carcinoma without specific restrictions. However, the clinical effectiveness evidence from the SHARP study was for patients with advanced hepatocellular carcinoma when surgical or locoregional therapies had failed or were not suitable. This population was consistent with UK clinical practice and clinical guidelines as outlined in the company's decision problem. The committee noted that the company presented evidence from SHARP in which patients had predominantly BCLC stage C (that is, advanced stage) disease (82.4%). They also had predominantly good liver function (that is, Child-Pugh grade A liver function; 96.5%), and good Eastern Cooperative Oncology Group (ECOG) performance status (0–2). The committee considered how the clinical effectiveness evidence from SHARP related to the total UK population with advanced hepatocellular carcinoma, particularly for patients with Child-Pugh grade B liver function. The committee heard from the clinical experts that systemic therapy with sorafenib would be considered for patients with Child-Pugh grade B liver

function although this type of therapy may be less clinically effective than for patients with Child-Pugh grade A liver function. The committee accepted that patients with advanced hepatocellular carcinoma with either Child-Pugh grade A or B liver function may benefit from systemic therapy, although not necessarily to the same degree. The committee accepted that the company's decision problem focused on advanced hepatocellular carcinoma and was in accordance with the scope.

4.4 The committee then discussed possible comparators used in the UK for advanced hepatocellular carcinoma in clinical practice. It noted the evidence review group (ERG) comments that doxorubicin could be a relevant comparator, although the extent of its use was unclear. The clinical experts stated that, before sorafenib was introduced, patients with advanced hepatocellular carcinoma usually received best supportive care. Conventional chemotherapy with systemic agents such as doxorubicin was occasionally used. However, the clinical experts highlighted that there were a number of adverse events associated with doxorubicin therapy (such as hair loss, nausea and vomiting, lower resistance to infection, bruising and bleeding) that limited its use to relatively fit patients. Also, the clinical experts discussed some studies that had shown doxorubicin not to have apparent benefit based on radiological assessment. The committee accepted that in UK clinical practice treatment with conventional chemotherapy (such as doxorubicin) would be recommended only for a minority of patients who are able to tolerate it. The committee noted that usual treatment for patients with intermediate hepatocellular carcinoma (defined as asymptomatic tumours without vascular invasion or hepatic spread) is transarterial chemoembolisation, in line with current clinical guidelines. The committee were aware that this subgroup was outside the decision problem as presented by the company. Therefore best supportive care was accepted as an appropriate

comparator for most patients with advanced hepatocellular carcinoma.

Clinical effectiveness (NICE technology appraisal guidance 189)

4.5 The committee considered the clinical effectiveness data presented by the company. It noted that evidence from the clinical studies of sorafenib plus best supportive care suggested that it increased median survival by more than 2.8 months compared with placebo plus best supportive care. The committee also noted that there was a statistically significant difference in median time to radiological disease progression for patients in the sorafenib group compared with the placebo group. The committee was aware that there was an extension in time to disease progression of 11.7 weeks according to independent assessment or 5.1 weeks according to investigator assessment, compared with placebo. The committee accepted the evidence from SHARP, but was aware that the study was stopped early, potentially underestimating the survival benefit attributable to sorafenib. The committee heard from clinical experts and patient experts that the observed benefits in overall survival and time to radiological disease progression were clinically meaningful. It noted that a statistically significant difference was not seen for time to symptomatic disease progression for sorafenib compared with placebo. However, the committee accepted the company's and ERG's view that the questionnaire used to measure time to symptomatic disease progression (FHSI-8) may not have been able to distinguish between the toxicity of sorafenib, symptoms of the underlying liver disease, and the symptoms of advanced hepatocellular carcinoma.

4.6 The committee heard from a patient expert that severe adverse events (such as diarrhoea and hand-foot skin reaction) had been experienced during 15 months of treatment with sorafenib, and

occasionally it was necessary to stop treatment temporarily. The clinical experts confirmed that similar adverse events have been seen in clinical practice, but no patients in their experience had completely stopped treatment with sorafenib for this reason. The patient experts agreed that although the adverse events experienced were unpredictable and affected health-related quality of life, they could be tolerated because of the benefits in terms of extension to life.

4.7 Based on the clinical effectiveness evidence and the testimony from clinical experts and patient experts, the committee concluded that sorafenib is a clinically effective treatment for advanced hepatocellular carcinoma when surgical or locoregional therapy had failed or was not suitable.

Cost effectiveness (NICE technology appraisal guidance 189)

4.8 The committee discussed the cost effectiveness of sorafenib for patients with advanced hepatocellular carcinoma when surgical or locoregional therapies had failed or were not suitable. The committee noted that the base-case incremental cost-effectiveness ratio (ICER) presented by the company was originally £64,800 per quality-adjusted life year (QALY) gained. When the patient access scheme was included this went down to £51,900 per QALY gained. Both ICERs were substantially higher than those normally considered to be an acceptable use of NHS resources.

4.9 The committee noted that the ICER presented in the company's base case depended on the extrapolation of overall survival beyond the SHARP study timeframe by fitting a log-normal probability distribution. Several alternative probability distributions were considered and fitted the data well, and the committee was aware that although the log-normal curve provided a slightly better fit, particularly for the early trial data, alternatives also fitted the data

well. The main differences were in the shape of the curves at the tail of the distribution where, for example, a Weibull curve with a heavier tail was a good fit. The committee concluded that, although the log-normal curve provided a slightly better fit to the observed data, it could not be accepted as the definitive function to extrapolate beyond the study data. The Weibull distribution, which also provided an acceptable fit, should also be considered in any consideration of uncertainty. The base-case log-normal extrapolation produced an ICER for sorafenib of £51,900 per QALY gained, which was at the lowest end of the range. The Weibull extrapolation of survival data produced an ICER that was substantially higher (commercial in confidence) than the log-normal base case.

4.10 The committee then discussed the ERG's critique of the company's patient access scheme submission. The committee noted concerns about the discrepancies in the dosage of sorafenib and the length of time a pack would last between the patient access scheme as modelled and as described in the summary of product characteristics. It agreed that the description in the summary of product characteristics did not account for dose reductions or stopping treatment temporarily, and that the treatment intensity modelled in the company's submission (based on SHARP) was more appropriate. The committee considered that the cost of post-progression sorafenib treatment was removed from the model but that the benefits were not adjusted. It agreed that, because in clinical practice the benefit from post-progression treatment is likely to be small, retaining the benefits in the model would have a minimal effect on the ICER.

4.11 The committee also noted the inconsistencies in costs associated with treatment duration and agreed that the treatment costs should be based on the actual length of the model cycle. This increased the ICER derived using the log-normal extrapolation from £51,900

to £52,600 per QALY gained. It also increased the corresponding (commercial in confidence) ICER using the Weibull extrapolation of survival data. The committee also noted that the company's model did not take into account the administration costs to the NHS of the patient access scheme but concluded that this would only increase the ICERs marginally.

4.12 The committee was aware of the concerns raised by the ERG about inconsistencies in the utilities used in the company's model. However, it noted that when alternative utility values from a previous renal cell carcinoma assessment report (used to develop NICE's technology appraisal guidance on sunitinib for the first-line treatment of advanced and/or metastatic renal cell carcinoma and bevacizumab [first-line], sorafenib [first- and second-line], sunitinib [second-line] and temsirolimus [first-line] for the treatment of advanced and/or metastatic renal cell carcinoma) were used in a sensitivity analysis, the log-normal base-case ICER was not significantly affected.

4.13 The committee considered the additional work by the ERG on the independent and investigator assessments of time to radiological disease progression. It noted that the ICER presented in the company's base case depended on investigator assessment (rather than independent assessment, which was the primary analysis in SHARP). The committee noted that the ERG's analyses demonstrated that the original log-normal base case increased to £76,000 per QALY gained (not including the patient access scheme) when using the independent assessment of time to radiological disease progression. The corresponding (commercial in confidence) ICER derived using the Weibull extrapolation of survival data would also be substantially higher. Therefore it concluded that sorafenib, as a treatment for advanced hepatocellular carcinoma when surgical or locoregional therapies

had failed or were not suitable, would not be a cost-effective use of NHS resources.

4.14 The committee then considered supplementary advice from NICE that should be taken into account when appraising treatments that may extend the life of patients with a short life expectancy and that are licensed for indications that affect small numbers of people with incurable illnesses. For this advice to be applied, all the following criteria must be met:

- The treatment is indicated for patients with a short life expectancy, normally less than 24 months.
- There is sufficient evidence to indicate that the treatment offers an extension to life, normally of at least an additional 3 months, compared with current NHS treatment.
- The treatment is licensed or otherwise indicated for small patient populations.

In addition, when taking these criteria into account, the committee must be persuaded that the estimates of the extension to life are robust and that the assumptions used in the reference case economic modelling are plausible, objective and robust.

4.15 The committee discussed whether the benefit provided by sorafenib in hepatocellular carcinoma fulfilled the criteria for consideration as a life-extending, end-of-life treatment. It noted from the clinical studies that life expectancy without sorafenib was unlikely to be greater than 24 months and was potentially as low as 7.9 months, although the latter was based on SHARP, which was stopped early. The committee considered that evidence from the clinical studies of sorafenib plus best supportive care suggested that it increased median survival by more than 2.8 months compared with placebo plus best supportive care, and the company's economic model predicted a mean gain in overall survival of 6.1 months, although this depended on the method of extrapolation. Although the committee noted that sorafenib is

licensed for indications other than hepatocellular carcinoma, the committee considered sorafenib to fulfil the small population criterion for an end-of life treatment. In summary, the committee was satisfied that sorafenib for advanced hepatocellular carcinoma met the criteria for an appraisal of a life-extending, end-of-life treatment, and that the evidence presented was supported by robust data.

4.16 The committee then discussed the range of cost-effectiveness estimates for sorafenib (with the lowest being the ICER of £52,600 per QALY gained and the highest being substantially greater), in light of the end-of-life considerations. It considered that the magnitude of additional weight that would need to be assigned to the original QALY benefits in this patient group for the cost effectiveness of the drug to fall within the current threshold range would be too great. Therefore the committee concluded that sorafenib as a treatment for advanced hepatocellular carcinoma when surgical or locoregional therapies had failed or were not suitable would not be a cost-effective use of NHS resources.

4.17 The committee considered whether there were any subgroups for whom sorafenib would be considered a cost-effective use of NHS resources. The committee noted that scoping showed that the prevalence of hepatocellular carcinoma is high in people from black and minority ethnic groups who have recently moved to the UK. These groups may have limited access to the NHS and therefore present with a more advanced stage of the disease, such as Child-Pugh grade B and C stages. However, the committee noted that no specific analysis was presented for this subgroup, and that clinical effectiveness data for people with Child-Pugh grade B and C liver function were limited. The committee was aware that only 3 subgroups presented by the company related specifically to advanced disease (people with BCLC stage C, Child-Pugh grade A liver function or macroscopic vascular invasion). The committee

noted that the analyses for the 3 subgroups resulted in ICERs that were all higher than the base-case ICER (including the patient access scheme). It was aware that the ICERs were substantially higher than those normally considered to be an acceptable use of NHS resources. The committee also noted that the company presented subgroup data that did not specifically relate to advanced hepatocellular carcinoma (for example for BCLC stage B). The ICERs for these subgroups were both higher and lower than the base-case ICER (including the patient access scheme). The committee noted that the subgroups presented by the company were based on a small number of patients, and because the clinical study was not powered to assess differential patient response to treatment, the subgroups were intended to be descriptive only. Also, no adjustments were made for multiple comparisons. The committee was aware that there was limited evidence of clinical effectiveness in these subgroups and that the ICERs would be based on a weak evidence base. Therefore the committee was not satisfied that the estimates of extension to life were robust or that the resulting subgroup ICERs were plausible. It concluded that it would not be appropriate to recommend sorafenib for specific subgroups of patients with advanced hepatocellular carcinoma.

Cancer Drugs Fund reconsideration of NICE technology appraisal guidance 189

4.18 This appraisal was a Cancer Drugs Fund reconsideration of the published NICE technology appraisal guidance on sorafenib for the treatment of advanced hepatocellular carcinoma. The committee considered the company's reconsideration submission that:

- included a Commercial Medicines Unit price that was lower than the price presented during the original appraisal

- presented evidence from 2 observational studies, GIDEON and Palmer et al. (2013), to validate the overall survival extrapolation curve chosen by the company beyond the end of the SHARP study (see section 4.9)
- addressed the committee's preferred assumptions about costs (see section 4.11)
- updated unit cost and resource use estimates.

The committee also considered the ERG's critique of the company's reconsideration submission and the ERG's exploratory analyses.

Validating the extrapolation of overall survival

4.19 The committee understood that the final draft guidance issued during the original appraisal went to an appeal panel. It was aware that the appeal panel agreed with the committee's view that the Weibull distribution should be taken into account in any consideration of uncertainty, and that all appeal points were dismissed. The committee discussed Palmer et al. (2013) and GIDEON. It recognised that Palmer was a retrospective unpublished UK observational study comparing patients with hepatocellular carcinoma who received funding for sorafenib (n=57) with those who did not receive funding (n=76). The committee recognised that patients who did not receive funding did not live as long as patients who did have funding and were also likely to be in poorer health. The committee noted the ERG's comment that the study was not suitable for decision-making. The committee agreed that Palmer was not suitable to validate the extrapolation of overall survival beyond SHARP because the results were likely to be confounded. The committee appreciated that GIDEON was a multinational post-marketing uncontrolled safety study of over 3000 people. It highlighted that the population in SHARP had a higher performance status at baseline than the population in

GIDEON. For liver function, the committee noted that 97% of people in SHARP had Child-Pugh grade A liver function at baseline whereas only 62% in GIDEON did. The committee concluded in the original appraisal that the appropriate population for sorafenib had Child–Pugh grade A liver function and that sorafenib would likely be less effective in people with Child-Pugh grade B liver function (see section 4.3). The committee stated it would have been appropriate for the company to modify the GIDEON population to reflect the characteristics of the population enrolled into SHARP when attempting to use GIDEON to validate SHARP. The committee noted that this would have provided more weight to support the company's choice of a log-normal function to extrapolate overall survival in its reconsideration submission. The committee concluded that the log-normal function used by the company to extrapolate survival beyond the SHARP study fitted the GIDEON data better than the Weibull function, but because the populations between SHARP and GIDEON differed in the company's current analysis of GIDEON, the Weibull function still had some plausibility.

Duration of treatment

4.20 The committee understood that the company and the ERG used various estimates for duration of treatment with sorafenib. It acknowledged the debate in the original appraisal on using either the investigator or the independent assessment of progression as a surrogate for time on treatment. The committee noted that the choice of investigator or independent assessment had little effect on the QALYs estimated in the cost-effectiveness analyses. However, it affected the duration of treatment with sorafenib, and as a result the ICER. The committee understood from the company that this was because it had assumed treatment would continue for most people until disease progression (or death). The committee was aware that in SHARP, median times to progression were approximately 17 weeks and 24 weeks for investigator and

independent assessment respectively. The committee heard from the ERG that the company had stated in its original submission that the median treatment duration in SHARP was around 23 weeks. The committee concluded that it would use the results of the independent assessment of treatment progression for its decision-making, because this matched the median treatment duration proposed by the company in its original submission. The committee also noted that the European public assessment report reported a mean treatment duration of 25 weeks for sorafenib from SHARP. The committee was concerned that this figure came from an assessment in May 2007 of 599 patients who had received at least 1 dose of study medication. Therefore it would underestimate the actual treatment duration for all patients in the study because not everyone had actually stopped treatment (that is, it is a restricted mean). The committee concluded that it was possible and appropriate for the company to estimate the duration of treatment with sorafenib based on the actual patient-level data from SHARP rather than using the proxy measure of progression-free survival.

Cost and resource use estimates

4.21 The committee was aware that the company used updated unit cost data in its reconsideration submission. It was also aware that in clinical practice, the company charges the NHS for a full pack of sorafenib at the start of each treatment cycle. Some patients do not complete their treatment cycle, and therefore the company may have underestimated the cost of treatment in its economic modelling. The committee concluded that it was appropriate for the company to use updated unit cost data and account for any drug wastage because this reflected the price relevant to the NHS.

4.22 It was aware that in the original appraisal the company's estimates for resource use were based on the clinical opinion of 4 clinicians, but the company had provided revised resource use estimates

based on the clinical opinion of 3 different clinicians in this reconsideration submission. The committee noted that the estimates in the revised resource use data varied widely. It concluded that it was appropriate to pool the original and revised estimates of resource use because of the small number of clinicians.

End-of-life considerations

4.23 The committee considered the advice about life-extending treatments in NICE's final Cancer Drugs Fund technology appraisal process and methods. It noted the committee's previous conclusion that the end-of-life criteria had been met (see sections 4.14–4.15) and that the criterion that the treatment is licensed or otherwise indicated for small patient populations is no longer included. The committee concluded that the end-of-life criteria were still met.

Conclusion

4.24 The committee discussed the most plausible ICER for sorafenib compared with best supportive care for treating advanced hepatocellular carcinoma when surgical or locoregional therapies have failed or are not suitable. The committee went on to discuss the range of cost-effectiveness estimates. It highlighted that:

- there remained some uncertainty around validating the extrapolation of overall survival from SHARP; although the log-normal function appeared to fit better than the Weibull function (see section 4.19), the validation population (GIDEON) differed from the SHARP study population
- there was considerable uncertainty around the treatment duration and how this was reflected in the economic modelling (see section 4.20)
- it preferred the company to account for any costs associated with drug wastage and to use updated unit cost and pooled resource use data (see sections 4.21 and 4.22).

The committee considered that the most plausible ICER, including the Commercial Medicines Unit price, would not be lower than £51,200 per QALY gained, and that it could be higher taking into account the uncertainty in extrapolating overall survival and treatment costs. Taking into account all factors including the end-of-life criteria, the committee stated that sorafenib did not have plausible potential to be cost effective at the Commercial Medicines Unit price. Therefore, the committee concluded that sorafenib was not recommended for use within the Cancer Drugs Fund or for routine commissioning in the NHS.

TAXXX	**Appraisal title: Sorafenib for treating advanced hepatocellular carcinoma**	**Section**
Key conclusions: Cancer Drugs Fund reconsideration of TA189		
Sorafenib is not recommended for treating advanced hepatocellular carcinoma in adults when surgical or locoregional therapies have failed or are not suitable. The committee discussed the range of cost-effectiveness estimates. It highlighted that: • there remained some uncertainty around validating the extrapolation of overall survival from SHARP • there was considerable uncertainty around the treatment duration • it preferred the company to account for any costs associated with drug wastage and to use updated unit cost and pooled resource use data. The committee considered that the most plausible incremental cost-effectiveness ratio (ICER), including the Commercial Medicines Unit price, would not be lower than £51,200 per quality-adjusted life year (QALY) gained. Taking into account all factors including the end-of-		1.1 4.24

life criteria, the committee stated that sorafenib did not have plausible potential to be cost effective at the Commercial Medicines Unit price. Therefore, the committee concluded that sorafenib was not recommended for use within the Cancer Drugs Fund or for routine commissioning in the NHS.	

5 Proposed date for review of guidance

5.1 NICE proposes that the guidance on this technology is considered for review by the guidance executive 3 years after publication of the guidance. NICE welcomes comment on this proposed date. The guidance executive will decide whether the technology should be reviewed based on information gathered by NICE, and in consultation with consultees and commentators.

Andrew Stevens and David Barnett
Chairs, TA189 appraisal committee, November 2009

Amanda Adler
Chair, Cancer Drugs Fund reconsideration of TA189 appraisal committee, July 2016

6 Appraisal committee members and NICE project team

Appraisal committee members

The technology appraisal committees are standing advisory committees of NICE. This topic was considered by members of the existing standing committees who have met to reconsider drugs funded by the Cancer Drugs Fund. The names of the members who attended are in the minutes of the appraisal committee meeting, which are posted on the NICE website.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

NICE project team

Each technology appraisal is assigned to a team consisting of an associate director, 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

TA189

Fay McCracken
Technical Lead

Rebecca Trowman
Technical Adviser

Laura Malone
Project Manager

Cancer Drugs Fund reconsideration of TA189

Frances Sutcliffe
Associate Director

Sabine Grimm and Inigo Bermejo
Technical Leads

Martyn Burke
Technical Adviser

Jenna Dilkes
Project Manager

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