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### **Comments from the Health Economics Committee**

#### **Health Economics Perspective on Clinical Practice Guidelines for Hepatocellular Carcinoma, 2013 Edition**

##### **– Regarding CQ43 in Particular –**

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Systemic chemotherapy with sorafenib is recommended for unresectable hepatocellular carcinoma (HCC), and the drug expenses for sorafenib monotherapy are approximately 540,000 yen per month. When better and more effective medical care is available, it should be implemented. However, countries where drug expenses are covered by the public health care system are evaluating the cost-effectiveness of treatment.

In the United Kingdom, the National Institute for Health and Care Excellence (NICE) evaluates the cost-effectiveness of new medical technologies and pharmaceutical products and provides counselling on whether its use should be recommended to the public health care system, the National Health Service (NHS). Sorafenib therapy was not recommended for unresectable HCC

in the “Technology Appraisal Guidance 189” published in May 2010. The NICE uses the Quality Adjusted Life Year (QALY) as an outcome indicator for evaluating cost-effectiveness. The QALY is a weighted indicator that is based on the number of life years and health-related quality of life (QOL). The health-related QOL uses a scale of 0 = death and 1 = complete health.

Cost-effectiveness is analyzed on the basis of the cost per increase in 1 QALY, and because the NICE has determined that this cost (of sorafenib) is high, its use has not been recommended to the NHS. Nevertheless, it should be examined in order to provide therapy to patients who have no other treatment options. The Cancer Drugs Fund was established for this reason; even anticancer drugs that were not recommended in the NICE assessments can occasionally be covered with public funds on an individual basis if requested by a specialist. These determinations are made locally, and applications are judged on an individual basis. For example, cancer drug funds in London may be applied toward sorafenib therapy for advanced liver cancer.

Similar to the UK, Australia requests cost-effectiveness assessments for new drug benefits, and an assessment was performed in July 2008 for the use of sorafenib as a treatment for advanced liver cancer. Although sorafenib does not always exhibit superior cost-effectiveness, its clinical utility is high for patients who have no other treatment options, and its efficacy has been demonstrated in clinical studies. It is therefore recommended only for patients with Child–Pugh class A disease with a WHO performance status of 2 or lower.

Assessments of cost-effectiveness performed outside Japan should not be applied directly to Japan without further consideration. Costs are particularly different between Japan and other countries, as are health care systems and medical fees. Even in Japan, since 2012, there have been ongoing discussions at the Central Social Insurance Medical Council (Chu-I-Kyo) concerning cost-effectiveness assessments and applications of medical technologies. Further cost-effectiveness studies will be necessary in the future.

#### ▪ **References**

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