Britain: National Health Service denies kidney cancer drugs to patients

Robert Stevens 14 August 2008

The National Institute for Health and Clinical Excellence (NICE) has ruled that patients with advanced kidney cancer will be denied four treatments on the National Health Service (NHS) in England and Wales. NICE is the government's drugs advisory body. It ruled that the drugs—bevacizumab, sorafenib, sunitinib and temsirolimus—do not offer "value for money."

The drugs are routinely available in the United States and in the rest of Europe. The brand name for the drugs are Avastin (bevacizumab), Nexavar (sorafenib), Sutent (sunitinib) and Torisel (temsirolimus).

More than 7,000 people are diagnosed with kidney cancer annually in the UK, and of these, around 1,700 patients will be diagnosed with advanced cancer. Although the drugs are not able to cure renal cell carcinoma or cancer that has spread from the initial tumour, they are able to extend life by five to six months.

Drugs can be prescribed on the NHS once NICE has given them approval. The body was established by the Labour government in 1999 with a remit to offer "independent" advice on drugs and clinical best practice for the NHS. However, its main criterion for assessing drugs is whether they offer "value for money" and are "cost-effective."

In accepting or rejecting drugs for the NHS, NICE adheres to a formula called the "Quality-adjusted Life Year" (QALY). Within this, a drug is deemed to be cost-effective if it delivers an extra QALY at a cost of roughly £20,000 a year or less. The four kidney cancer drugs were primarily rejected, as their QALY was above £20,000. Extending a patient's life by six months was deemed to be uneconomical.

Some patients in England and Wales are currently using the drugs on a trial basis pending the decision

from NICE. Many of them had to wage a protracted campaign to get treatment.

Jean Murphy, a terminally ill 68-year-old from Manchester, was denied the drug Sutent despite a High Court ruling in her favour.

Murphy said, "I can't see any reason why it can't be funded on the National Health Service if it's a case of living or dying. The only thing that will help me is the Sutent.... It's like manslaughter because if I can't get this I will die."

Murphy was only able to get the drug this month following an anonymous donation of £10,000.

In its assessment of the drugs, NICE admitted that they provided "significant gains" in survival. However, its final ruling on rejecting the use of the drugs was strictly based on financial considerations.

Professor Peter Littlejohns of NICE said, "The decisions NICE has to make are some of the hardest in public life. NHS resources are not limitless and Nice has to decide what treatments represent best value to the patient as well as the NHS. Although these treatments are clinically effective, regrettably, the cost to the NHS is such that they are not a cost-effective use of NHS resources. Bevacizumab, sorafenib, sunitinib or temsirolimus have the potential to extend progression-free survival by five to six months, but at a cost of £20,000-£35,000 per patient per year."

"If these treatments were provided on the NHS," he added, "other patients would lose out on treatments that are both clinically and cost effective."

NHS resources are limited as the result of government policy, determined by the demands of a financial elite that views funds devoted to public health as a drain on profits.

The inevitable result of the NICE policy is that patients who could be offered treatment are being

condemned to death unless they can buy the drugs themselves. The decision prompted an outcry from patients, healthcare campaigners, healthcare professionals and particularly doctors who treat kidney cancer patients.

Kate Spall, an activist on behalf of cancer patients, said of the decision, "We plough billions into cancer research but the benefits of that research—some remarkable drug treatments—are not available to all who need them. Patients are disregarded and given up on because they cannot get the drugs they need."

Professor John Wagstaff, an honorary consultant in medical oncology at the South Wales Cancer Institute in Swansea, told the media: "The possibility that we clinicians may be prevented from offering Sutent to our patients is an outrage and a devastating blow to the kidney cancer community.

"If this draft guidance is not overturned, there will be no point in me accepting referrals of patients with metastatic renal cell cancer as three quarters of patients do not gain any real benefit from interferon, leaving only the option of palliative care.

"This decision will mean that the UK will have the poorest survival figures for metastatic renal cell cancer in Europe. Sutent produces a remarkable effect on survival for patients. It is now no longer ethical or reasonable for patients to have access to treatment with only interferon."

Two years ago, the NICE "citizen's council"—27 members of the public who advise the body—recommended that it should adopt the "rule of rescue" as a general policy. "It is human nature to help in an emergency," one member of the council said.

NICE rejected this principle. "There is a powerful human impulse, known as the 'rule of rescue', to attempt to help an identifiable person whose life is in danger, no matter how much it costs," NICE responded in a document entitled *Social Value Judgments*. "When there are limited resources for healthcare, applying the 'rule of rescue' may mean that other people will not be able to have the care or treatment they need.... The Institute has not therefore adopted an additional 'rule of rescue.'"

NICE also rejects both what it calls the "utilitarian approach" and the "egalitarian approach" in allocating health resources, in favour of its own guidelines based on "procedural justice."

It describes the utilitarian approach as allowing an "efficient distribution of resources, but sometimes at the expense of fairness. It can allow the interests of minorities to be overridden by the majority; and it may not help in eradicating health inequalities."

NICE defines the "egalitarian approach" as the effort to distribute "healthcare resources to allow each individual to have a fair share of the opportunities available, as far as is possible. It allows an adequate, but not necessarily maximum, level of healthcare, but raises questions as to what is 'fair.' But an egalitarian approach cannot be fully applied when there are limits on resources."

According to NICE, the fundamental basis of "procedural justice" is that it provides for "accountability for reasonableness," which is essential because the "NHS is funded from general taxation, and it is right that UK citizens have the opportunity to be involved in the decisions about how the NHS's limited resources should be allocated."

Having rejected the recommendation of the 27-member "citizens' council," NICE cannot legitimately claim that it is responding to the interests of the public. The decision of NICE to deny treatment to patients is in fact a reflection of the interests of a small plutocratic layer who can pay for their own medical treatment and have nothing in common with the majority of the population who rely on the NHS for care.



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