

Centralized government value assessments by UK NICE create barriers to patient access, particularly for cancer patients, new research shows

The approach used in the United Kingdom, and other European countries, to make coverage or reimbursement decisions for new tests and treatments based on a centralized value assessment is sometimes pointed to as a model for the U.S. However, new analysis illustrates how the use of a cost-effectiveness standard by the UK's National Institute for Health Care Excellence (NICE) as the basis for coverage decisions often creates barriers to patient access to beneficial new treatment options. While patients with a wide range of diseases and conditions (such as multiple sclerosis, rheumatoid arthritis and diabetes) face access barriers in the U.K, the problem is particularly significant for cancer patients. Policy-makers in the U.S. should pursue alternative approaches that support patient access to the range of appropriate treatment options and provide incentives for continued innovation.

In the last seven years (2007-2013), NICE has become more restrictive over time for cancer products.

- Almost 80% of cancer medicines reviewed in the last seven years have been given some kind of access restriction.
- Cancer medicines were more than 3 times likely to be given non-coverage recommendations than non-oncology medicines.
 - 56% of oncology medicines were given non-coverage recommendations, compared to only 16% of non-oncology products.
- NICE gave non-coverage recommendations for all six cancer medicines that it reviewed in 2013.

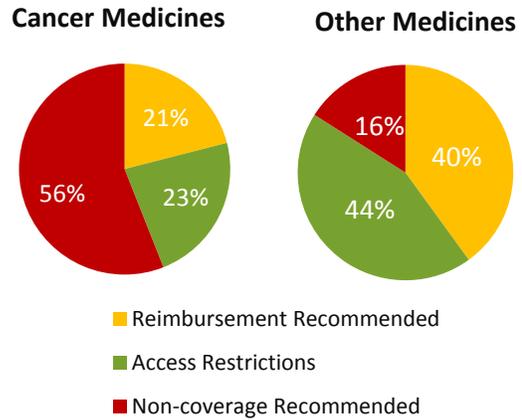
Rejection rate for cancer medicines is more than three times higher than other types of treatments

The UK's NICE uses a cost-effectiveness threshold (cost/quality adjusted life year) to determine whether new tests and treatments should be covered by the National Health System. New analysis from Context Matters reveals that, between 2007 and 2013, 79% of appraisals for cancer medicines recommended some type of access restriction (non-coverage or coverage with restrictions), and 56% of appraisals for non-cancer medicines included some type of access restriction.ⁱ These may include restrictions based on the characteristics of the disease/patient, prior treatment history, or how the medicine is delivered.

NICE has issued negative appraisals (in which NICE recommends non-coverage) 56% of the time for cancer medicines, compared to 16% of the time for non-cancer products.

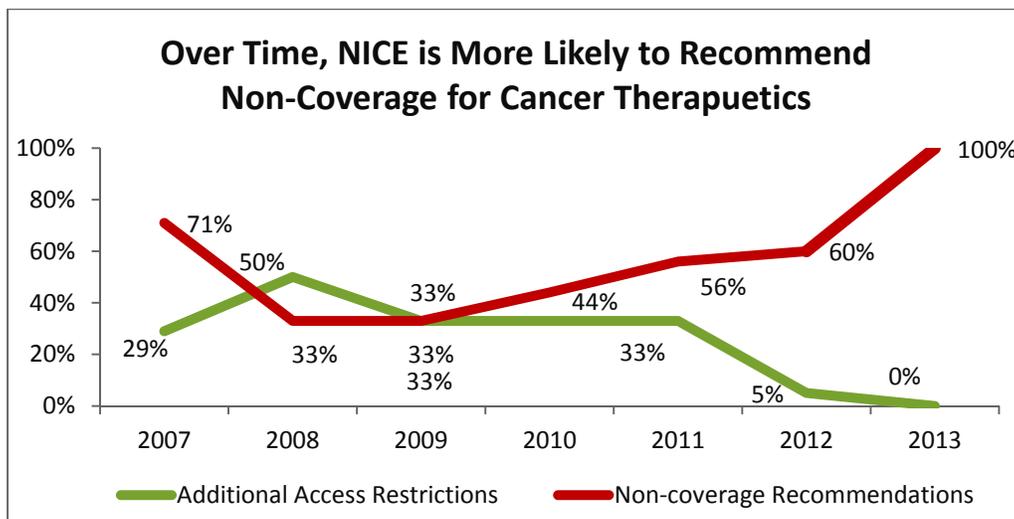
The UK NICE cost-effectiveness standard sets a subjective government value threshold based on patient population averages. This one-size-fits-all standard fails to recognize significant differences in patients' clinical needs, treatment responses and preferences within these broad averages. It also does not reflect the ways that understanding of a treatment's value evolves over time due to changes in clinical practice and the evidence base. As a result, not only cancer patients but those with many other serious and life-threatening diseases can not gain access to beneficial treatment options.

NICE is more likely to issue access restrictions for cancer therapeutics than other medicines



The UK NICE has been more restrictive over the last seven years in its review of cancer treatments

The rate at which NICE rejects cancer medicines appears to be increasing; last year, NICE rejected all six cancer medicines it reviewed. In contrast, in 2008, NICE recommended against coverage in 33% of oncology appraisals and recommended coverage with restrictions in 50% of cases.



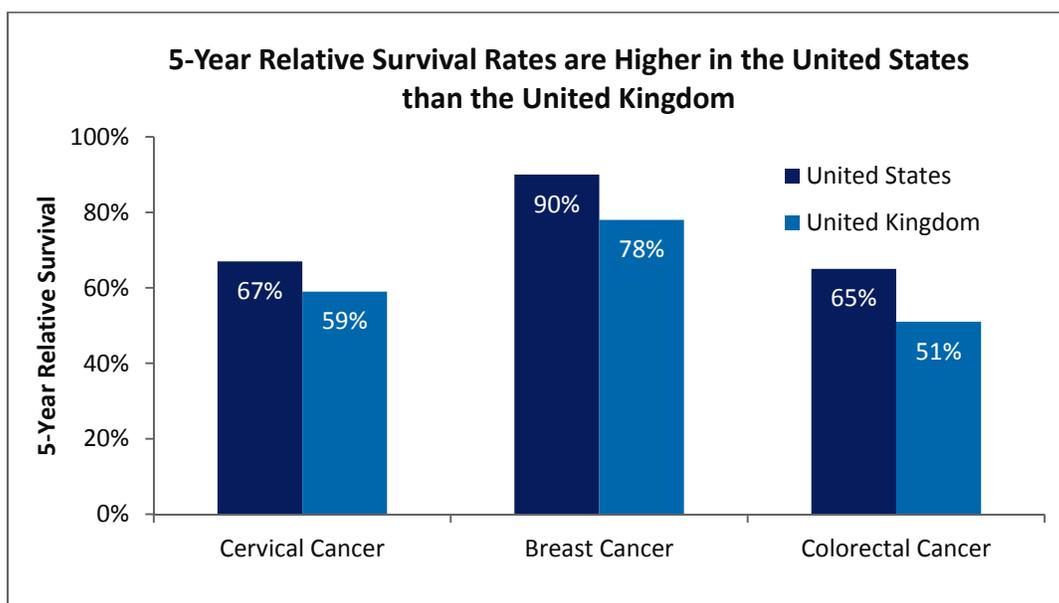
This trend has become particularly evident following the establishment of the Cancer Drugs Fund in the UK, which was established in 2010 as an alternative mechanism for patient access to cancer medicines that were either not yet evaluated by NICE, or had received non-coverage determinations from NICE. Originally created as a 'stop-gap' pending the introduction of a new value-based pricing scheme in the UK, this fund has been renewed past 2014 as this new mechanism has not been established yet.ⁱⁱ The need to establish the fund demonstrates the restrictiveness of NICE decisions, with many patient groups fearful that, if the fund does not continue to receive funding, "access to cancer medicines will revert to being the worst in Europe, with more than 16,000 patients a year denied help."ⁱⁱⁱ

Recent Examples Show How NICE appraisals conflict with patient needs and continued medical progress

In September 2013, NICE rejected coverage of crizotinib, a breakthrough targeted therapy for lung cancer even though clinical trial showed the treatment provided median gain of 5.1 months in progression-free survival compared with docetaxel. A member of Parliament, Priti Patel, responded to the decision, stating, “we once again have to question why NICE has rejected another cancer drug for use in England. Improving the lives of cancer patients should be their key priority. England runs the risk of lagging behind Europe when it comes to research and development in life sciences and the use of pioneering, lifesaving drugs. Reform of NICE so they put the improved access to treatments for patients first is vital so that we end what increasingly looks like a lottery when it comes to access for drugs.”^{iv}

Similarly, a breakthrough personalized medicine for chronic myelogenous leukemia called imatinib experienced a controversial NICE rejection when it was first reviewed. Though the innovative CML treatment received regulatory approval in the US and UK in 2001^{v,vi}, NICE’s preliminary technology appraisal (in May 2002) recommended the treatment only for patients in the accelerated phase of CML, based on “lack of cost-effectiveness”.^{vii} Patient groups and political leaders protested (this recommendation conflicted not only with European and US medical practice but also with the imatinib policy of NICE’s sister agency in Scotland, which called imatinib “the first treatment to offer major improvement in the clinical response to CML.”^{viii}) In September 2002, NICE added eligibility for chronic phase patients unable to tolerate alpha-interferon; and in October 2003, the agency endorsed first-line use for all chronic phase patients.^{ix} Today, CML patients are living close to normal lifespans; the 5-year survival rate for CML patients nearly tripled (from 31% to 89%) since the introduction of imatinib.^x

It is worth noting that the five-year relative survival rates for cervical, breast and colorectal cancer are higher in the U.S. (67%, 90%, and 65% respectively) than they are in the UK (59%, 78%, and 51%, respectively).^{xi} Global differences in cancer burden and outcomes may be due to multiple factors, including differences in population characteristics, disease prevalence, the prevalence of cancer risk factors, and the availability and use of various preventative, screening, and treatment options.^{xii}



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- ⁱ Context Matters analysis, “NICE Limits Reimbursement for Oncology Products beyond EMA Product Labeling,” May 2014.
- ⁱⁱ C. Chamberlain, et al. “Does the cancer drugs fund lead to faster uptake of cost-effective drugs? A time-trend analysis comparing England and Wales,” *British Journal of Cancer* (2014), 1-10.
- ⁱⁱⁱ Hope, J. “Cancer patients in fear at losing their drugs fund lifeline: Fears 16,000 patients a year could be denied help,” *Daily Mail* (<http://www.dailymail.co.uk/health/article-2352096/Cancer-patients-fear-losing-drugs-fund-lifeline-Fears-16-000-patients-year-denied-help.html>), July 2013 (accessed June 2014).
- ^{iv} Chapman, J. “NICE bars cancer drug that's free in Scotland: £4,000-a-month treatment that can halt disease will not be available in England or Wales,” *Daily Mail* (<http://www.dailymail.co.uk/news/article-2449288/NICE-bars-cancer-drug-thats-free-Scotland--4-000-month-treatment-halt-disease-available-England-Wales.html>), October 2013 (accessed June 2014).
- ^v US FDA Press Release, “FDA Approves Important New Leukemia Drug,” <http://www.cancer.gov/newscenter/newsfromnci/2001/gleevecpressrelease> (accessed May 2014)
- ^{vi} EMA EPAR Summary for Public, “Glivec – imatinib”, June 2013, http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Summary_for_the_public/human/000406/WC500022201.pdf (accessed May 2014).
- ^{vii} UK NICE Appraisal Consultation Document: Imatinib for chronic myeloid leukaemia, May 2012, <http://www.nice.org.uk/guidance/index.jsp?action=article&o=32471> (accessed May 2014).
- ^{viii} Scottish Medicines Consortium press release, “The Scottish Medicines Consortium issues advice on imatinib mesylate (Glivec) for chronic myeloid leukaemia,” http://www.scottishmedicines.org.uk/Press_Statements/Imatinib_Glivec_174 (accessed May 2014).
- ^{ix} UK NICE Technology Assessment, “Dasatinib, nilotinib and standard-dose imatinib for the first-line treatment of chronic myeloid leukaemia (part review of technology appraisal guidance 70),” <http://publications.nice.org.uk/dasatinib-nilotinib-and-standard-dose-imatinib-for-the-first-line-treatment-of-chronic-myeloid-ta251> (accessed May 2014).
- ^x HHS, CDC, NCHS. “Health, United States, with Chartbook on Trends in the Health of Americans.” Hyattsville, MD: HHS, 2006. www.cdc.gov/nchs/data/hus/hus06.pdf (accessed December 2012).
- ^{xi} Squires, D. “The U.S. Health System in Perspective: A Comparison of Twelve Industrialized Health Systems,” *The Commonwealth Fund – Issues in International Health Policy*, pub. 1532, Vol. 16, July 2011.
- ^{xii} American Cancer Society, “Global Cancer Facts and Figures: 2nd Edition,” Atlanta: American Cancer Society; 2011. <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-027766.pdf> (Accessed June 2014).