

APRIL 2011

Guide to Cancer Drugs



Sponsored by:



Roche has had no editorial input to this supplement apart from the article written by Steve Bojakowski. Roche has checked the supplement for factual inaccuracies. The printing and distribution of the supplement has been sponsored by Roche.

EXPERT INSIGHT INTO KEY AREAS OF THE HEALTH INSURANCE INDUSTRY

Guide to cancer drugs

Contents



4-7

Cancer drugs – an introduction



8-11

How much do cancer drugs cost?



12-15

How does the NHS manage access to cancer drugs?



16-19

How do insurers manage access to cancer drugs?



20-23

Treatment authorisation processes – time for change?

Health Insurance
Informa UK Limited
 Telephone House, 69-77 Paul Street,
 London EC2A 4LQ
 fax: 020-7017 4194
 tel: 020-7017
 + extensions as below

Editor

David Sawers • ext.4154
 david.sawers@informa.com

Deputy editor

Madeleine Davies • ext.5581
 madeleine.davies@informa.com

Sales director

Matthew Brookes • ext.6779
 matthew.brookes@informa.com

Deputy advertising manager

Annalisa Russell De Clifford • ext.4124
 annalisa.declifford@informa.com

Designer

Paul Pancham

Marketing manager

Louise Canfield • ext.4088
 louise.canfield@informa.com

Customer services department

subscriptions@informa.com



Member of the Audit Bureau of Circulation
 Average net circulation for the period 1 July 2009 to
 30 June 2010 – 10,525 • ISSN: 1477-9781

Health Insurance is published by Informa Business
 Information a trading division of Informa UK Limited

Annual subscription: £305/€375/US\$550

For **subscription queries** and enquiries, or back issues, please contact Customer Services Department, Informa UK Limited, Sheepen Place, Colchester, CO3 3LP, UK

Tel: 020 7017 7860 • Fax: 020 7017 4781
 Email: subscriptions@informa.com

© Informa UK Limited, all rights reserved; no part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electrical, mechanical, photocopying, recording or otherwise without the prior written permission of the publisher.

Printer: ESP Colour
 www.hi-mag.com

Cancer drugs

Giving the best advice



At the end of last year employee benefits consultancy Mercer revealed that it was advising companies not to review the cancer cover in their private medical insurance (PMI) policies until the Government provided more clarity about what the NHS will and will not fund.

Several changes are set to take place during the course of the current parliament. The Government has pledged to introduce value-based pricing in a

bid to ensure that it secures value for money from expenditure on drugs and has also pledged to recast the role of the National Institute for Health and Clinical Excellence (NICE), an organisation widely blamed in the press when cancer drugs are unavailable on the NHS. This month a £200m cancer drugs fund will be launched in order to provide a short-term solution to public outcry about limits on access to drugs on the NHS.

The impact of these reforms will take years to materialise and while Mercer was right to highlight the challenge of designing a policy around a shifting national offering, *Health Insurance* readers need to be able to give their clients the best possible advice today. As recent consumer research from the Association of British Insurers shows, cancer remains a key expectation of cover.

The importance of independent advice was highlighted earlier this year when Lord Crisp launched a fierce public attack on the insurance industry for an alleged lack of transparency with regard to cancer cover. The funding of cancer drugs remains a highly emotive subject.

Against this backdrop, we are pleased to publish this guide to cancer drugs. Perhaps the real take-home message is that cancer treatment is as individual as each cancer patient. While clarity about cover is important, we should also recognise that by reviewing claims for cancer drugs on a case by case basis insurers can sometimes act more compassionately and generously than they would by complying strictly with a policy's terms and conditions. Clarity is important, but so is flexibility.

Madeleine Davies

Deputy Editor, *Health Insurance*

Cancer drugs – an introduction

Cancer is complex. There are over 200 different types of the disease and each patient affected by it will be given an individual treatment plan. For some patients, surgery will be the only treatment required. Others will undergo surgery, chemotherapy, radiotherapy and biological therapy over the course of months or even years. The treatment will depend on many factors; not only the type of cancer, but the stage at which it is diagnosed, specific characteristics such as its sensitivity to certain hormones and, importantly, the patient's preferences.

While a lot of media attention is focused on cancer drugs, it is important to remember that surgery cures more people of cancer than any other intervention. Radiotherapy, a treatment first used 100 years ago, helps to cure four in ten patients, more than conventional chemotherapy. Yet a recent survey conducted by the College of Radiographers found that only one in ten people thought it was a modern cancer treatment, compared to 47% who believed this of targeted cancer drugs. Nevertheless, cancer drugs do play an important role in treating cancer and have delivered important improvements for patients in recent years, from reducing the risk of cancer recurring to improving their quality of life.

Q: WHAT DRUGS ARE USED TO TREAT CANCER?

A: Cancer drugs fall into three main categories: biological therapies, chemotherapy and hormone therapy. (See table opposite).

Q. WHEN ARE CANCER DRUGS PRESCRIBED?

A. Cancer drugs have many different uses and can be deployed at several points in the patient's treatment pathway. For example, they may be used to cure the cancer, to prevent the cancer from recurring or to keep a patient with a terminal cancer alive for longer.

Many of the drugs licensed in the UK in recent years are targeted at advanced cancer or cancer that has spread and are designed to stop the cancer from growing further, enabling the patient to live longer and enjoy a better quality of life.

Q. DO CANCER DRUGS CURE CANCER?

A. Cancer drugs can play a curative role, destroying cancer cells or reducing the risk of cancer recurring for example. However, many of the new drugs licensed in the UK will not cure cancer but can delay it from progressing to a more advanced stage and possibly extend the patient's life.

They may be developed for cancers which are difficult to treat, such as certain forms of leukaemia or advanced cancers which have progressed beyond the point of cure.

For example, the National Institute for Health and Clinical Excellence (NICE) has recommended pazopanib for advanced kidney cancer, which can delay progression of the cancer for about eight months, compared with a placebo.



They may be developed as an alternative to existing treatments which are not suitable for all patients, perhaps because of their side effects.

For example, NICE has recommended a chemotherapy called bendamustine for patients with chronic lymphocytic leukaemia if the existing chemotherapy (fludarabine combination chemotherapy) is not appropriate for them. It can slow the growth and spread of the cancer by over 13 months more than the only other drug alternative to fludarabine.

It is important to remember that many biological therapies are only effective for a sub-set of patients, for example those whose tumour has particular characteristics that can be targeted by the drug. This is good news because it means that only those most likely to benefit from the drug receive it, but it also highlights the complexity of modern cancer treatment, which is highly targeted rather than universal in its approach.

For example, stomach cancer affects about 7,700 people in the UK every year, but only 350 would be suitable for treatment with Herceptin®.

TYPES OF CANCER DRUGS		
Type of drug	Example	How it works
BIOLOGICAL THERAPIES (also known as biological response modifiers) use substances that occur naturally in the body to destroy cancer cells. These include interferons, monoclonal antibodies, cancer growth inhibitors, vaccines and gene therapy.	Trastuzumab (Herceptin®)	Some cancers have too much of a protein called HER2 on their cell surface which helps them to grow. Herceptin® is a monoclonal antibody that attaches to the HER2 protein, blocking the signal that promotes their growth. This stops the cells from dividing and growing. It also works by attracting the body's own immune cells to help destroy the cancer cells.
CHEMOTHERAPY destroys cancer cells.	Docetaxel	Chemotherapy drugs can stop cancer cells dividing and reproducing. Carried in the blood, the drugs can reach cancer cells anywhere in the body. Healthy cells can repair the damage caused by chemotherapy, but cancer cells can't and eventually die.
HORMONE THERAPY alters the production or activity of particular hormones in the body	Anastrozole (Arimidex®)	This drug is used to treat breast cancer in post-menopausal women whose cancer is sensitive to the hormone oestrogen. It reduces the amount of oestrogen in the body – the hormone that causes the cancer to grow.

Type of cancer	Treatment overview	Recent drug developments
Lung cancer (non-small-cell)	This cancer is sometimes removed by surgery, depending on the stage at which it is diagnosed. Radiotherapy can also be used. Chemotherapy is sometimes used after surgery to reduce the risk of the cancer coming back and can be used before surgery. In advanced forms of the disease chemotherapy may be given to shrink the cancer, prolong survival and improve the patient's well-being.	Patients may be prescribed erlotinib (Tarceva®) or gefitinib (Iressa®). These are biological therapies known as cancer growth inhibitors. Erlotinib is prescribed if the cancer has come back after initial treatment or has not responded to at least one course of chemotherapy. Gefitinib is prescribed if the cancer has spread.
Colon cancer	Surgery is the most common treatment. For more advanced cancers, chemotherapy may also be used. Radiotherapy may be used to shrink a cancer that is causing pain.	Biological therapies such as the monoclonal antibodies bevacizumab (Avastin®) and cetuximab (Erbix®) may be used to control advanced colon cancer for a time.
Breast cancer	Most breast cancers are treated by surgery. Sometimes chemotherapy or hormonal therapy may be given to shrink a cancer before surgery. After surgery radiotherapy is used to destroy any remaining cancer cells. Patients may have further treatment with hormonal therapies or chemotherapy.	Biological therapies may be prescribed such as Herceptin® which can prevent the cancer from recurring.

Q. DO ALL CANCER PATIENTS WANT TO BE TREATED WITH DRUGS?

A. Patients always have a choice when it comes to treatment and it is important to weigh up the pros and cons of receiving cancer drugs.

For example, trials show that about 5% more people survive for five years if chemotherapy is given after an operation to remove lung cancer. This could be explained to patients by saying that of 20 patients treated, one more of them will be "cured". Or the doctor could explain that on average, patients live another few months. Depending on how this is explained to patients and their individual priorities and preferences, patients with the same condition

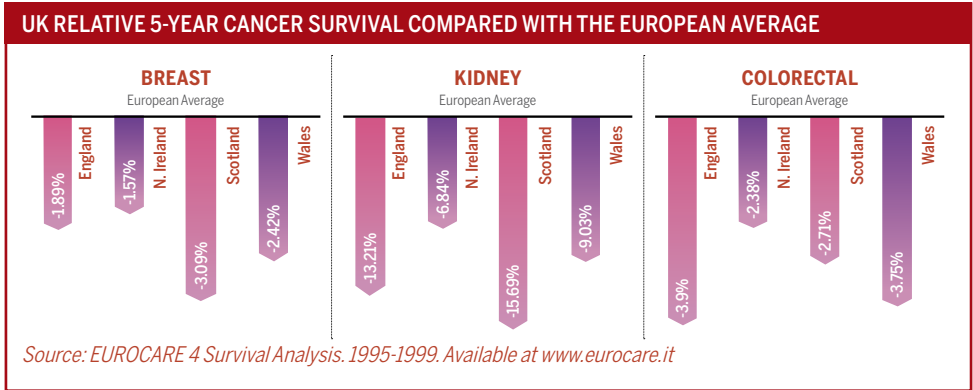
may make very different decisions. They will need to weigh up the possible benefits of treatment with the risks, including side effects.

Source: National Confidential Enquiry into Patient Outcome and Death

Q. HOW DOES THE USE OF CANCER DRUGS IN THE UK COMPARE INTERNATIONALLY?

A. UK spending on cancer medicines is about 60% of that recorded in other advanced European countries (source: Wilking, N, Comparator Report on Patient Access to Cancer Drugs in Europe, 2009).

A report by the national cancer director Professor Mike Richards (Extent and causes of international



variations in drug usage, July 2010 – see table opposite) found that the UK ranked below many other countries in the use of cancer drugs, particularly those launched within the last five years. For this last category, usage is less than 50% of the average across all the 14 countries included in the study.

Variation is not necessarily caused by different amounts of funding, but is the result of a range of factors. This includes the way that drugs are assessed in different countries. For example, the study found that when NICE recommends that a drug should not be routinely used in the UK (see chapter 3), uptake tends to be low “and will mainly be restricted to patients in the private sector.”

Another factor is the attitudes of doctors in different countries. Some experts who contributed to the report suggested that clinicians in the UK are more “toxicity averse”, which may mean that they take a different view of whether the benefits of a drug sufficiently outweigh the risks associated with its use in a particular patient.

While survival rates in the UK are poorer than in many other countries (see graph above), it has not been proven that this is as a result of access to cancer drugs. It is believed that the late stage of diagnosis is a key cause.

Usage	Cancer drugs launched in last 5 years	Cancer drugs launched in last 6-10 years	Cancer drugs launched more than 10 years ago
1	France	France	France
2	Austria	Denmark	Italy
3	USA	Switzerland	Spain
4	Germany	Austria	Germany
5	Spain	Spain	Switzerland
6	Switzerland	Italy	Austria
7	Denmark	Germany	Denmark
8	Sweden	USA	USA
9	Italy	UK	Sweden
10	Norway	Australia	UK
11	Australia	Sweden	Canada
12	UK	Canada	Norway
13	Canada	Norway	Australia
14	New Zealand	New Zealand	New Zealand

How much do cancer drugs cost?

Much of the recent media coverage of cancer drugs has focused on the high cost of new cancer drugs and the challenges of putting a price on the benefit that they deliver to patients. It is important to remember that drugs are not the biggest cost to the NHS cancer budget (see table below). More than half of the costs are generated by admitting patients to hospital and many savings could be made by reducing the average length of stay, which varies significantly across the country. However, there is no denying that many new cancer drugs are expensive, posing challenges for both for the NHS and the private sector.

NHS spending on cancer care	% of total NHS cost*	Estimated cost in 2008-09 (£m) **
Inpatient costs	27	1,386
Surgery	22	1,129
Drugs	19	924
Outpatients	8	410
Screening	5	256
Radiotherapy	5	256
Specialist palliative care	5	256
Other	10	513
Total		5,134

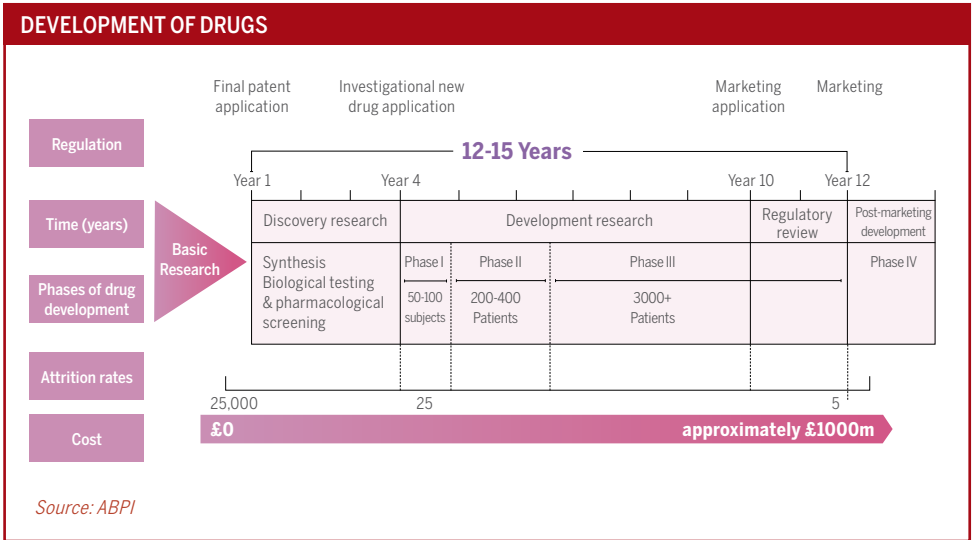
*Cancer Reform Strategy 2007 ** Policy Exchange calculations from NHS data

Source: *The cost of cancer, Policy Exchange, 2010*

Q. WHAT LIES BEHIND THE PRICE OF CANCER DRUGS?

A. According to the Association of the British Pharmaceutical Industry (ABPI), the development of a new drug takes between 12 and 15 years. Just 25 out of 25,000 compounds tested in a laboratory

will go on to be tested in clinical trials (where drugs are tested on patients) and of these just five will be sold, of which just one will enable the company to recoup its investment. By this point £1000m will have been invested in the drug. When pricing drugs, the manufacturer has to take into account the



considerable costs of research and development (the industry invests more in research and development than any other industry in the UK – 36.3% of sales) and the losses sustained as a result of the many that do not reach the licensing stage.

Q. WHO DECIDES HOW MUCH THEY COST?

A. Since 1957 the pharmaceutical industry has entered into a series of voluntary agreements with the Government, which regulate the profits that companies are allowed to make on sales of drugs to the NHS. The current Pharmaceutical Price Regulation Scheme (PPRS) expires at the end of 2013. It applies to all branded, licensed NHS medicines in the UK (which account for 80% of the NHS drugs bill). Although this is not a formal contract, both sides have a stake in making sure that drugs are available on the NHS. In exchange for accepting “reasonable limits” on the profits to be made from selling to the NHS (a target of 21%), the industry is free to pursue research and development with a minimum of government interference.

The current PPRS made provision for two price cuts (a price cut of 3.9% in February 2009 and a further price cut of 1.9% in January 2010) and the introduction of generic substitution in the NHS (whereby more expensive, branded medicines are replaced with generic ones). It is expected that these two measures will reduce NHS expenditure on branded medicines by an average of 5% a year until 2013. However, price increases will be made in each year from 2011 to make up for the losses to the industry caused by the generic substitution.

Cancer drugs vary in price. For example, Herceptin® for stomach cancer patients is estimated to cost about £10,185 per patient on average but sorafenib (Nexavar®) for liver patients would cost £27,000 per patient on average. It is also important to remember that not all cancer drugs are expensive. For example, the drug tamoxifen costs just £200-400 for five years per patient, and is highly effective, reducing the risk of death over the course of 10 years by at least a quarter for premenopausal women with hormone-sensitive breast cancer.

Q. WHAT IS THE PHARMACEUTICAL INDUSTRY DOING TO MAKE DRUGS AFFORDABLE?

A. Pharmaceutical companies sometimes develop patient access schemes in order to increase the likelihood of patients being able to receive a drug on the NHS. The schemes usually involve a discount or rebate to reduce the cost of the drug to the NHS and may be taken into account by NICE when it decides whether or not to recommend the drug (see chapter 3). These schemes have enabled NICE to recommend sunitinib (Sutent®) for the treatment of kidney cancer and bortezomib (Velcade®) for multiple myeloma.

According to the ABPI, the UK has the lowest prices for medicines compared with other European countries.

Q. HOW WILL THE PRICING OF CANCER DRUGS CHANGE IN FUTURE?

A. The Government has pledged to introduce a new approach to pricing drugs called value-based pricing. A consultation on this, which ended on 17th March 2011, states: "Too often the NHS has been in the position of either having to pay high prices that are not always justified by the benefits of a new medicine, or having to restrict access." The Government wants to create "a much closer link between the price the NHS pays and the value that a medicine delivers".

Exactly how this might work is yet to be finalised, but the consultation makes it clear that the aim is to develop a system which would:

- Improve outcomes for patients through better access to effective medicines
- Stimulate innovation and the development of high value treatments
- Improve the process for assessing new medicines, ensuring transparent, predictable and timely decision-making

- Include a wide assessment, alongside clinical effectiveness, of the range of factors through which medicines deliver benefit for patients and society
- Ensure value for money and best use of NHS resources

Currently, it looks like the system will involve the following key elements:

- The Government will set a range of thresholds or maximum prices reflecting the different values that medicines offer
- There will be a basic threshold: this will be based on the benefits the drug offers compared with the benefits that could be gained if funds required were used to help patients elsewhere in the NHS
- There will be higher thresholds for medicines that tackle diseases where there is greater "burden of illness" (for example, they serve an unmet need or are targeted at patients with particularly severe illnesses)
- There will be higher thresholds for medicines that can demonstrate greater therapeutic innovation and improvements compared with other products
- There will be higher thresholds for medicines that can demonstrate wider societal benefits (like reducing the burden on carers)

"Value-based pricing will lead to lower drug prices, and I think this will lead to some improvement in widening access, but I don't think price is the only issue to be considered," says Francesca Bruce, senior reporter at *Scrip*, a sister publication of *Health Insurance* focused on the global pharmaceutical industry. "Other factors have an impact too, including the nature of the healthcare system and clinical culture. For example, doctors in one country are more inclined to prescribe new drugs as soon as they become available, whereas in other countries, doctors have a more conservative approach."



Q. WHAT COSTS ARE ASSOCIATED WITH CANCER DRUGS?

A. In addition to the cost of a cancer drug, there are often many associated costs, including the cost of paying for healthcare professionals to administer it, the cost of the healthcare setting where it is administered, the costs of tests required to check that it is safe to administer the drug and potentially, the costs of dealing with side effects caused by the drug.

Some of these costs can be reduced. For example:

- Breast cancer patients can receive the drug Herceptin® at home, saving on the cost of delivering it in a hospital setting
- Chemotherapy drugs that can be taken orally are less expensive than those given by a drip

Q. HOW ARE DRUGS LICENSED?

A. Drugs cannot be marketed in the UK until they are licensed.

Drugs can be licensed for use in the UK either through the European Medicines Evaluation Agency (EMA) or the Medicines and Healthcare products Regulatory Agency (MHRA). Even after securing a licence from the EMA, drug manufacturers must apply to the MHRA for

marketing authorisation. The drug will be licensed for a very specific use – for example, to treat a specific form of cancer.

Doctors can prescribe unlicensed medicines but must comply with certain guidelines set by the General Medical Council (GMC), such as being satisfied that the medicine is safe and effective. They can also prescribe medicines for purposes for which they are not licensed. For example, a drug may be licensed to treat one type of cancer but a doctor may decide to prescribe it to treat another type of cancer, based on evidence or experience of its effectiveness. This is called using a drug “off-label”. Again, doctors should follow GMC guidelines when doing so.

A report by the charity Rarer Cancers Forum (Off Limits, 2009) highlighted the fact that licensed drugs are often not available for patients with more rare forms of the disease. This is because the small numbers of patients affected by rare cancers is a barrier to pharmaceutical companies carrying out trials of treatments or pursuing a license for the use of drugs to treat their particular cancer.

Patients seeking funding for unlicensed drugs can face particular challenges. The next chapter looks in more detail at how drugs are funded on the NHS.

How does the NHS manage access to cancer drugs?

Access to new cancer drugs on the NHS has generated huge amounts of media coverage in recent years, with much of it focusing on the decisions made by the National Institute for Health and Clinical Excellence (NICE).

Similar bodies set up to make recommendations on the use of drugs in the NHS exist in Scotland (Scottish Medicines Consortium) and Wales (All Wales Medicines Strategy Group).

Although most cancer drugs are available on the NHS, the high cost of new biological therapies and the limited financial resources of the NHS mean that access is low by international standards and varied across the country.

Below we look at how decisions about funding are made and the Government's proposal to widen access to drugs in future.

Q. WHAT IS NICE?

A. The National Institute for Health and Clinical Excellence (NICE) was set up by the Government in 1999. It decides which drugs and treatments are available on the NHS in England and Wales.

The government developed NICE to get rid of 'the postcode lottery' – where some drugs and treatments were available in some parts of the country, but not in others. NICE aims to give independent advice about which treatments should be available on the NHS in England and Wales and to make sure that people have the same access to treatment and care wherever they live.

Source: Cancer Research UK

Q. CAN NICE BAN DRUGS?

A. Doctors can prescribe medicines that they believe to be effective and safe. However, the NHS

does not have to fund drugs, unless they have been recommended by the NICE.

NICE cannot ban drugs on the NHS, but if it does not recommend them then it will be down to local NHS decisions makers to determine whether or not they should be funded on the NHS. Currently these decisions are made by primary care trusts (PCTs).

Q. HOW DOES NICE MAKE ITS DECISIONS?

A. In appraising drugs, NICE looks at all available clinical evidence, including data submitted by the pharmaceutical company that manufactured it. This is called a technology appraisal.

NICE will not only consider the clinical effectiveness of the drug – the benefits it delivers to patients – but the cost effectiveness – whether it represents value for money for the NHS. The evidence for the drug is reviewed by an independent



advisory committee made up of clinical experts, industry representatives and lay people, and at least one round of public consultation. NICE then publishes its guidance on how a drug can best be used in the NHS to deliver benefit to patients and make best use of limited NHS resources.

According to Cancer Research UK, it can take 18 months or more for NICE to decide if a drug or treatment should be available. Once NICE has issued guidance recommending a drug, the NHS has to make funding available for it within three months.

WHAT IS A QALY?

When making a decision about whether a drug represents value for money NICE will determine how much money the NHS would need to spend in order to give the patient receiving it one quality-of-life adjusted year (QALY). One QALY is equal to one year of life in perfect health.

QALYS are calculated by estimating the years of life remaining for a patient following a particular treatment and weighting each year with a quality of life score. It is often measured in terms of the person's ability to perform the activities of daily life, freedom from pain and mental disturbance.

Source: NICE

Q. ARE MOST CANCER DRUGS AVAILABLE ON THE NHS?

A. Yes, most cancer drugs are available on the NHS. To date, 72% of NICE's cancer drug recommendations have supported use of the drug.

However, not all licensed cancer drugs are routinely available on the NHS. This is particularly the case for new biological therapies.

Q. DOES NICE APPRAISE EVERY CANCER DRUG?

A. NICE does not appraise every cancer drug or every possible use of every cancer drug. In the absence of a recommendation from NICE, it will be the decision of the local NHS whether or not to prescribe and fund the drug.

Q. WHAT HAPPENS IF THERE IS NO NICE RECOMMENDATION OR IF NICE DOES NOT RECOMMEND A DRUG?

A. Primary care trusts (PCTs) make decisions about whether, in the absence of NICE guidance, drugs are funded on the NHS. For drugs that are not routinely funded by the PCT it is possible to make an "individual funding request". If this is turned down, patients and their doctors can make an appeal for "exceptional funding" to their PCT. The proportion of those that are granted varies significantly across the country.

An investigation carried out by *Health Insurance* last year found that the proportion of funding requests approved by PCTs ranged from 0% to 100%. Of the 122 PCTs who responded, a third approved 50% or less of the requests they received in 2009 while 18 approved every single one. The number of requests received by each PCT varied from none to 112.

Q. HOW WILL THE ROLE OF NICE CHANGE?

A. The Government believes that once value-based pricing is in place in 2014 (see chapter 2), the NHS will no longer need a judgement from NICE on whether or not drugs are worth their price.

Although it will continue to assess the benefits of drugs, NICE will focus on advising clinicians on the best way to use treatments and on the development of quality standards. NICE will still be a source of advice on the cost-effectiveness of new medicines but other factors will be taken into consideration.

Q. WHAT WILL THE ROLE OF GPs BE?

A. Under reforms proposed by the Government, 80% of the NHS budget is to be controlled by new commissioning groups led by GPs. These GP consortia are set to come into place by 2013 with the current commissioning groups – PCTs – abolished. The Government has said that they will be “expected to fund services and interventions which are clinically and cost effective” and believes that value-based pricing will enable this. Kirsty Jagielko of insurer CIGNA HealthCare believes that the shift to GP commissioning will lead to a return of the postcode lottery, giving private medical insurers “an opportunity to provide clear and equitable access to different levels of cancer cover in the longer term” (see chapter 4).

Q. WHAT IS THE CANCER DRUGS FUND?

A. In order to bridge the gap until value-based pricing comes into effect in 2014, the Government

DRUG IN THE SPOTLIGHT: AVASTIN FOR METASTATIC COLORECTAL CANCER

NICE does not currently recommend bevacizumab (Avastin®) in combination with chemotherapy for treating metastatic colorectal cancer. The evidence shows that patients receiving this combination may on average live six weeks longer than patients receiving standard chemotherapy and a placebo. This is a median figure, so half the patients in the study received less than six extra weeks of life.

However, the drug would cost the NHS around £20,800 per patient and it is estimated that about 6,500 people per year might be eligible for it, at a cost to the NHS of up to £135m per year.

Although the manufacturer offered a patient access scheme (free after 12 months of cumulative treatment and the cost of chemotherapy reimbursed plus an additional upfront payment to the NHS for each person starting treatment), NICE judged that the cost per QALY would be around £70,000.

NICE concluded: “There were simply too many uncertainties in the economic analysis to be able to recommend the drug for use in the NHS.”

launched a Cancer Drugs Fund in April 2011. In each of the three years in this interim period, £200m will be made available to enable clinicians to prescribe drugs not routinely funded on the NHS.

The Government has proposed that this will be managed on a regional basis, with clinicians coming together to make decisions about how the fund is used.

Whether £200m a year will be sufficient is yet to become clear. The figure was calculated based on analysis of a report into international variations in drug usage by the national cancer director Professor Mike Richards. This analysis suggested that if England

were to provide newer cancer drugs (less than five years old) in line with European average levels, this would cost a maximum of £200m a year. The fund only covers the cost of the actual drug, not associated costs such as dealing with the side effects of using it. Patients will have to have exhausted all other routes (notably making an individual funding request to their PCT) before getting access to the fund.

“The signs are that the interim drugs fund – which was put in place before the big £200m a year fund comes into effect – has improved access and a number of drugs that NICE has not recommended have been made available,” says Francesca Bruce, senior reporter at *Scip*, a sister publication of *Health Insurance* focused on the global pharmaceutical industry. “But access is not uniform and different drugs have been available through different Strategic Health Authorities. If this is not dealt with properly, this could be a real issue with the bigger fund. Added to this, there is no such fund in Scotland, and there has been some concern that this will further increase inequalities in access across the UK.”

DRUG IN THE SPOTLIGHT: HERCEPTIN FOR METASTATIC STOMACH CANCER

NICE recommends trastuzumab (Herceptin®) for patients with metastatic stomach cancer who have high levels of HER2. Research suggests that the drug can enable patients to live for an average of 5.6 months longer.

Stomach cancer affects about 7,700 people in the UK every year, of whom about 350 would be suitable for treatment with the drug.

The cost per patient is £10,185. NICE estimates that the cost per QALY would be between £63,100 and £71,500. Because patients receiving it cannot be cured of their cancer (average life expectancy is less than 24 months), a more generous measure of cost effectiveness is applied by NICE.

GLOSSARY:

The glossary below explains some of the terms often used in NICE communications.

- **First-line treatment:** This is the first course of treatment you have when diagnosed with cancer. Or the first course of treatment after the cancer has come back (recurred).
- **Progression-free survival (median):** The time point in a clinical trial at which 50% of patients experienced disease progression, usually measured in months.
- **Advanced:** Advanced cancer usually means a cancer that has spread from where it started to another part of the body. ‘Locally advanced’ cancer usually means the cancer has grown

outside the organ that it started in and into surrounding body tissues.

- **Metastatic:** Metastatic cancer is cancer that has spread from where it started to other parts of the body.
- **Relapse:** A relapse is when an illness that has seemed to be getting better, or to have been cured, comes back or gets worse again.
- **Overall survival value (median):** The time point in the clinical trial at which 50% of patients had died).
- **Maintenance treatment:** Treatment used to stop a cancer from returning following initial chemotherapy.

How do insurers manage access to cancer drugs?

When it comes to buying private medical insurance (PMI), cancer cover is undoubtedly a priority for both consumers and corporate purchasers.

The latest study of consumer understanding of PMI carried out by the Association of British Insurers (ABI) showed that people tend to assume that they are covered for cancer by their insurer. However, it also highlighted that they remain uncertain about the actual extent of cover. None of the respondents could recall the details of their cancer cover, including whether specific drugs were funded. Even after reading the policy literature provided by their insurer, respondents' understanding remained "limited".

Insurers have expended considerable efforts in recent years to provide greater clarity about cancer cover and it is important to stress that it remains the buyer's responsibility to get to grips with terms and conditions. Below we look at some frequently asked questions.

Q. WHAT DO INSURERS ROUTINELY FUND?

A. All PMI policies differ with regard to cancer cover. As a rule of thumb, most policies cover diagnostic procedures and treatment, including drugs prescribed to cure the cancer.

Insurers may use the phrase "active treatment" as an umbrella term for the treatment they will fund and they should define exactly what this means. The charity Cancerbackup (now Macmillan Cancer Support) defines this as: "Treatment intended to affect the growth of the cancer by shrinking the cancer, stabilising it or slowing the spread of disease, and not given solely to relieve symptoms."

Q. WHAT DO INSURERS NOT FUND?

A. The challenge for insurers, intermediaries and consumers is that cancer does not easily fit into the

usual categories used by insurers to define conditions: acute or chronic. Increasingly, cancer is a condition that is not cured but controlled, often for many years. Many new drugs are aimed at slowing the progression of the disease rather than curing it. Different policies offer different approaches to funding these drugs.

"Biological therapies used to shrink the tumour to the point at which curative surgery is possible would definitely be covered," says Dr Doug Wright, head of clinical services at insurer Aviva UK Health. "But we would usually not cover indefinite use of a drug aimed at slowing the growth of the tumour. The standard limit would be 12 months with options to downgrade or upgrade this."

The ABI statement of best practice on the selling of PMI makes it clear that insurers must have a distinct section in their policy literature for consumers,

defining their approach to covering cancer. This should set out any limits to cover in place. For examples of limits see table below.

It is important to remember that many policies do not cover palliative treatment for cancer – aimed purely at relieving the symptoms of the disease. However, it is possible to buy more comprehensive plans that will cover all stages of the disease, including plans from Bupa and Exeter Family Friendly and PruHealth’s Full Cancer Cover.

Q. DO CUSTOMERS WANT TO PUT LIMITS IN PLACE?

A. Insurers are divided over the wisdom of offering customers the option to place limits on cancer cover. “The last thing we want to do is add a cap or caveats to cover which mean that our customers run out of cover when they really do need it most, during a

cancer claim,” says Mike O’Brien, head of intermediary sales at Exeter Family Friendly.

Although Bupa introduced financial limits as an option for large corporate customers in 2009, managing director of Bupa Health & Wellbeing Dr Natalie-Jane Macdonald says the company is “increasingly uncomfortable” about this and is looking at alternative ways of controlling costs while maintaining full cover. Groupama Healthcare, which provides PMI to employers, is also unwilling to put limits in place. However, CIGNA HealthCare reports that the number of corporate clients that select its enhanced cancer cover (which pays for the first-line treatment of metastatic cancer) makes up a smaller percentage of its portfolio than those who choose its standard option (which only pays for cancer that has not spread). AXA PPP healthcare reports that most

Limit on cover	For example
Time limit	Aviva will typically only fund biological therapies for up to 12 months
	AXA PPP healthcare customers can choose a time limit, from one year, to three years to no limits
Maximum number of cycles of treatments	CIGNA’s Premier Plan will pay for the first course of “active and evidence-base treatment” for metastatic cancer. Its standard plan only covers the treatment of primary cancer.
Maximum payments	Some corporate PMI plans will include a maximum amount (for example £100,000) that will be spent on cancer treatment
Circumstances in which cover would not be provided	Many policies including PruHealth’s “Core” cancer cover will not cover palliative care – care designed purely to relieve the symptoms of cancer.
	WPA will not fund biological therapies if they are readily available on the NHS. It provides a regularly-updated list of therapies covered on its website
	Exeter Family Friendly uses NICE’s judgement on drugs’ clinical effectiveness as a benchmark for decisions on funding.

customers choose one-year cover for cancer drugs with fewer opting for limitless cover.

Brian Walters, of intermediary Regency Health, believes that individual clients will often prioritise cancer cover when it is brought to their attention that provision differs between insurers.

"Brokers should always draw their clients' attention to any limitations on cancer cover, but insurers could do more to impose clarity on this issue," he says. "In particular, such limitations are conspicuous by their absence on most insurers' policy summaries, relegated instead to the full policy wording."

"Most corporate clients still want comprehensive cover," reports Larry Bulmer, chief executive of intermediary AVO Group. "It's the most emotive of illnesses and at the point of treatment patients will desire anything is they feel it could be advantageous. If you commence treatment within a PMI plan it should be comprehensive as changing to the NHS mid-treatment can be distressing."

Bulmer adds, however, that the impact of a claim on future premiums can make limits "more palatable" to employers.

"The introduction of time-limited cover, for example, stopping benefit after one year, or by stage of disease or financial threshold, are crude attempts to control cancer costs. While they may be simple to describe and can be sold by advisers to business customers, they are dubious ethically for affected employees."

Dr Natalie-Jane Macdonald, Bupa

Q. ARE THERE OTHER QUESTIONS I SHOULD ASK ABOUT CANCER DRUGS?

A. It is common for insurers to place limits on the funding of cancer drugs. "If PMI were to provide blanket cover for treatment with all cytotoxic drugs,

the cost would be prohibitive in many cases and affordable for the vast majority," according to John Hall, consultant surgeon and medical director at insurer General & Medical Healthcare.

A common approach is to limit the use of biological therapies to 12 months. Dr Gary Bolger, chief medical officer at AXA PPP healthcare, says that this timeframe is sufficient for a lot of patients but not for others. For example, some drugs are administered for as long as the patient survives, which can exceed a year.

Q. HOW ARE CANCER CLAIMS MANAGED BY INSURERS?

A. A positive development among insurers in recent years is that many now employ dedicated claims staff to manage cancer claims. These trained members of staff will liaise between the patient, oncologist and insurer to ensure that claims are paid fairly and quickly. AXA PPP healthcare now offers each cancer claimant a dedicated nurse who will provide support to them and their family, liaise with their specialist and answer questions about their treatment and cover.

Q. HOW CLEAR ARE INSURERS WHEN IT COMES TO DESCRIBING CANCER COVER?

A. It is important to weigh up the importance of providing clarity with policyholders' desire for flexibility.

"It is necessary to recognise that cancer medicine is advancing very quickly and what is accepted practice one day, may not have been a few days earlier," says Alistair Sclare, healthcare director at insurer Groupama Healthcare. "It is not reasonable to expect a degree of insurance certainty that outweighs the certainty the medical profession has in the treatment that is being provided. The only way to do this would be to base cover on all known treatments at the time a policy is taken out or renewed. This would operate against the interests of the policyholder, restrict the levels of

cover provided and surely be a retrograde step. It is time it was recognised that the grey areas that are causing concern do so because cover is extended to encompass as much as possible, they are not as a result of cover restrictions.”

Given the fact that claims for cancer drugs, particularly those prescribed off-label, may be reviewed on a case by case basis, intermediaries may want to ask insurers about their processes for managing this process. Bupa reports that its internal approval process takes no more than 48 hours.

Q. HOW EASY IS IT TO TRANSFER TO CARE IN THE NHS?

A. Many PMI policyholders will receive treatment in both the NHS and a private setting and insurers are accustomed to managing this. For example, through its Care Coordination Programme CIGNA HealthCare offers customers that opt for NHS treatment a range of benefits including covering childcare costs.

Customers may find they have to transfer to the NHS for treatments not funded by their policy, for example palliative care at the end of life. Guidance from the Department of Health makes it clear that patients do not lose their entitlement to NHS care if they opt to pay privately for some element of their treatment (for example, a drug not funded on the NHS). Charlie MacEwan of insurer WPA, which pioneered insurance aimed solely at funding cancer drugs not available on the NHS (now available in the ‘mycancerdrugs’ option of its NHS Top-Up Plan) believes that pressures on NHS funding will mean that “top-up” provision will become the norm.

It is important to remember that NHS cancer care is highly rated by patients. The findings of the Cancer Patient Experience Survey 2010 show that 84% of patients had confidence and trust in all of their doctors and 82% said they were always treated with dignity and respect.

OTHER LIMITS TO BEAR IN MIND INCLUDE:

Licensing and evidence

Insurers will often only fund drugs that are licensed by the EMA or the MRHA.

This approach can be an issue if a doctor wishes to use a drug “off label”, particularly to treat a rare cancer (see chapter 2). However, most insurers say that they will take a flexible approach to making decisions about off-label prescribing.

“This is decided on a case by case basis as it may be a very rare tumour which can only respond to a certain drug,” says Dr Doug Wright of Aviva UK Health. “In this case, our clinical team will research the options fully and may well recommend cover outside of the licensing.”

When making decisions about unlicensed drugs, insurers will look at the evidence base

for their effectiveness. They may have different criteria in place for judging the validity of evidence, seeking advice from a variety of authorities. In general, an insurer’s chief medical officer will be involved in reviewing the evidence.

Outpatient drugs

Intermediaries may want to check whether hormonal drugs (such as Arimidex® which is designed to block oestrogen in women with oestrogen-sensitive cancers) and bisphosphonates (drugs used to protect bones against some of the effects of cancer) are covered. There are often time limits or full exclusions on these drugs, which may be prescribed by a doctor for several years. However, they are usually available on the NHS.

Treatment authorisation processes

– time for a change?

By Steve Bojakowski, Roche Products Limited

For people living with cancer, every day can bring a new struggle, including, for some, getting access to the most appropriate treatment option for their individual disease. In recent years, lack of NHS funding for innovative new treatments has meant that patients have needed to explore other avenues. The recent introduction of the Government's £50m interim cancer drugs fund (CDF) has helped to alleviate the situation, but already large variations in approach to the administration of the fund and approval status for some drugs and indications across strategic health authorities, have been observedⁱ. Therefore, private medical insurance (PMI) could continue to be the only option for fast access to these treatments for many patients.

But, while PMI provides an alternative option to access some of the newer cancer treatments, a recent audit carried out on behalf of Roche suggests that there are large discrepancies in the cover that PMI companies offer, as well as inconsistent pre-authorisation processes used by these companiesⁱⁱ. Both factors are likely to have an impact on the treatment patients are receiving as well as the outcomes. The purpose of this article is to investigate PMI processes and the impact reapplying for treatment has on patient care.

AUDIT FINDINGS

The audit, conducted between May and September 2010 and before the introduction of the CDF, examined the treatment authorised for 70 colorectal and breast cancer patients (50 colorectal and 20 breast). These patients were treated in nine hospitals throughout the UK between 2008 and 2010 and all were treated with a drug not currently approved for use on the NHS by NICEⁱⁱⁱ.

The patients treated were covered by PMI policies provided by a range of large, medium and small PMI companiesⁱⁱ. The audit provided

some interesting findings, the results of which are summarised in the table opposite.

EXTENDING TREATMENT COVER – AN UNNECESSARY BURDEN?

Currently, one of the main incentives for purchasing PMI is the access it provides to cancer treatment and care not readily available on the NHS, and insurers have been using this benefit in an attempt to differentiate themselves from competitors. A survey by the charity Beating Bowel Cancer in 2007 showed that 91% of those questioned felt cancer cover was



Results ^{ii, iii}	Colorectal (CRC)	Breast (BC) ⁱ
Number of patients	50	20
Percentage pre-authorized for a set number of months	52%	60%
Percentage authorised for less than 12 months	20%	25%
Percentage authorised for 12 months or more	32%	35%
Percentage pre-authorized for a set number of cycles	26%	15%
Percentage authorised for less than 12 cycles	16%	10%
Percentage authorised for 12 cycles or more	10%	5%
Percentage pre-authorized for treatment until disease progression	18%	25%
Percentage of patients who sought to extend their treatment	44%	35%
Percentage of patients who were successful in their application to extend their treatment	82%	57%

ⁱThe drug used in the audit is indicated to be used until disease progression.

the most important disease to be included in their policy^{iv}. However, with insurers setting restrictions on the length of treatment or number of cycles permitted as part of the pre-authorisation process, patients living with cancer are often required to re-apply for an extension to their cover.

The good news from the audit was that 54% of patients were pre-authorised for more than 12 months and just over half (52% of CRC and 60% BC) of patients were pre-authorised for treatment with the drug for a set amount of months^{iv}. Of those, one fifth of colorectal patients and a quarter of breast cancer patients were authorised for less than 12 months of treatment. This means that patients may be treated for a shorter period, and miss out on the potential beneficial effects, when the clinician may have preferred to be treated for longer in accordance with the drug's licence – which is for as long as the patient is responding and deemed in good healthⁱⁱⁱ.

With insurers setting restrictions on the length of treatment or number of cycles permitted as part of the pre-authorisation process, patients living with cancer are often required to re-apply for an extension to their cover

The less positive news from the audit was that due to restrictions set at pre-authorisation stage, nearly half of colorectal cancer patients and over a third of breast cancer patients in the audit had to reapply to extend their treatment. Of these, well over half, (82% CRC and 57% BC) were successful with their applicationⁱⁱ. This begs the question, if a second phase of treatment is so frequently authorised by insurers, is it really necessary to make patients already experiencing significant

challenges in their life to endure the added burden of reapplying for an extension to their treatment with all the added emotional stress this brings?

In some cases, patients featured in the audit were required to apply for an extension to their cover three times during their treatment, when the likelihood was that they had assumed that the cost of their premium would cover them throughout the duration of their treatmentⁱⁱ.

THE FORGOTTEN PATIENTS

An important observation from the audit was the high number of patients who did not extend their cover following the first authorisation – 56% of colorectal patients and 65% of breast patientsⁱⁱ. The audit does not reveal why these patients did not reapply but it is possible to speculate that one reason could be that the patient may not have been aware that an extension to their cover was available. Therefore, they could have missed out on treatment unnecessarily. Another possibility is that the cover was limited to a fixed number of cycles or months of treatment, with no option for an extension available.

A VIEW FROM THE PATIENT GROUP

Ian Beaumont from Bowel Cancer UK says: “We believe that medical insurance providers should work together to offer a more streamlined approach to pre-authorising treatments for cancer patients. Currently, too many patients are having to re-apply for medical cover mid-way through their treatment – at what is already a very difficult time of their lives. The process of applying and claiming for treatments needs to be made much easier for patients, if they are going to ensure they get the best possible outcomes.”

The need for insurers to control cost is well understood. However, an unintended consequence

of this approach is that some patients may be receiving sub-optimal care, by reducing the clinical benefit that could be gained from treatment. The audit shows that less than a quarter of patients (18% colorectal cancer and 25% breast cancer) were pre-authorised to receive treatment to disease progression, as recommended in the medicines prescribing informationⁱⁱⁱ; most were restricted to a defined treatment duration or number of cycles.

TAKING A NEW APPROACH TO AUTHORISING TREATMENT

The findings from the audit suggest there may be an opportunity to streamline the pre-authorisation process, reducing both the administrative burden on insurers and the emotional, time-consuming burden for the patient. A process that routinely pre-authorises 12 months of treatment would reduce the need to reapply and reassess the need to continue treatment.

A process that has a default approval of treatment up to 12 months will also remove ambiguities in the authorisation process, which may result in a prolonged wait for the patient, thus delaying treatment, increasing processing and administration for the insurer, the patient, and care providers. Putting such measures in place would remove the burden of reapplying from the patient and clinician.

In conclusion, this audit suggests that an overhaul of the approval process for cancer treatments funded through PMI may be long overdue and a re-engineering of the pre-authorisation process could yield benefits for both the patient and the PMI provider.



Sources:

ⁱRarer Cancers Foundation. RCF responds to consultation on the cancer drugs fund. http://www.rarercancers.org.uk/news/current/rarer_cancers_foundation_response_to_the_consultation_on_the_cancer_drugs_fund. Last accessed 16.02.11.

ⁱⁱRoche Data on File IS001.

ⁱⁱⁱAvastin Summary of Product Characteristics. <http://www.medicines.org.uk/EMC/medicine/15748/SPC/Avastin+25mg+ml+concentrate+for+solution+for+infusion/> Last accessed 02.03.11.

^{iv}Beating Bowel Cancer. PMI packages uncovered 2006

^vRoche Data on File IS002.



Steve Bojakowski is the Independent Sector Strategy Lead for Roche Products Limited. Before joining Roche, he worked for the NHS for over ten years,

during which time he developed an interest in healthcare policy. He holds an MBA and an MA degree in social and political philosophy and is the author of a number of peer reviewed papers.

