Often lost in the indignant protests over the NHS not funding the latest ‘wonder drug’ is that such drugs can be eye-wateringly expensive. The latest furore has been over NICE’s provisional determination on Kadcyla (trastuzumab emtansine) – the view from NICE was that this drug is not cost-effective unless the drug company reduces the price, which they have so far declined to do.

**Kadcyla**

Kadcyla is a combination of the biologic trastuzumab (also known as Herceptin) conjugated with a cytotoxic agent, mertansine. The theory behind this is that trastuzumab links onto cell receptors in certain kinds of breast cancer and delivers the cytotoxic drug to the cell. The drug costs £90 000 for a course of treatment and can potentially extend life by six months compared to another standard second-line treatment in breast cancer.

It is important to recognise when looking at median survival figures that 50 per cent of people in the drug trial did not get this benefit, and 50 per cent got more. Also drug trials present an estimate of clinical efficacy from a selected group of patients that might not wholly translate to clinical practice (clinical effectiveness).

The incremental cost-effectiveness ratio was estimated in the NICE Technology Appraisal for Kadcyla to be £185 600 per quality adjusted life year (QALY) compared to standard treatment.

**The Cancer Drugs Fund**

All this begs a very reasonable question: should the NHS pay for a drug regardless of how much it costs? When the current government came into power in 2010 it set up a £200 million annual Cancer Drugs Fund (CDF) in England to pay for cancer drugs where either value was as yet uncertain or which NICE has deemed not cost-effective. The simple reason for this fund seemed to be that politicians found it too challenging to deny patients expensive cancer treatments claimed to be ‘life saving’ or innovative, even if the price set by drug companies appeared too high. Possibly, they also wanted to keep drug companies ‘sweet’.

It was anticipated that both the CDF and drug prices set by the drug industry under the elderly Pharmaceutical Price Regulation Scheme (PPRS) would be replaced in 2014 by a negotiated system of drug cost reimbursement called value-based pricing (VBP). After considerable debate about how this might work, and how it might not, VBP never happened and was quietly shelved in 2013. Instead, a new PPRS emerged for 2014 and the CDF lives on.

**A new evaluation process**

There remain many questions about how rational or fair the CDF system is. Why should drugs for cancer treatment in people dying of cancer (they are rarely life-saving) get priority over people who need noncancer treatment, for example for hepatitis C? Why shouldn’t the NHS negotiate over value for money? Shouldn’t austerity measures apply to drug prices? What else of greater value could the money be better used for? At present the CDF pays for Kadcyla in England, and it has to be said that the role of NICE in determining cost-effectiveness of cancer drugs for the NHS for England and Wales is undermined.

The intent is that NICE will now develop a scheme that enables a wider assessment of drug value than the QALY-based system used by them for Kadcyla. This is called value-based assessment, presumably to indicate its origins in the concepts of value-based pricing. How this will operate is not yet clear, but alongside the QALY it is likely to consider ‘burden of illness’ to give additional weight for loss of healthy life, and ‘wider societal impact’ looking at the impact of disease on function within society rather than the direct effect on health. If this description seems rather vague, how this will translate into the evaluation process remains woolly. NICE are out for consultation on this new appraisal process until 20 June and hopefully after this clarity will emerge.

**Declaration of interests**

None to declare.

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**Have your say**

What do you think about the cost of new drugs to the NHS? Let us know at: http://bit.ly/1mj26mG.