



Chair: Allyson Kaye MBE | CEO: Jane Lyons
Board: David Ryner, Helen Jameson, Clara Mackay, Helen Morement, Kathy Oliver, Rebecca Porta, John Solly, John Symons

VBA: NICE do it their way

Cancer52 Briefing on NICE and Value Based Assessment (VBA) February 2014

Background

Cancer52 has been closely monitoring the development of Value Based Pricing (VBP) in the UK. VBP was proposed by Government in 2010 as a key way to deliver improved access to medicines. Over time VBP has changed and now there is more focus on Value Based Assessment (VBA) – in essence allowing NICE to take a wider perspective of the value that new medicines can bring by considering 2 new factors:

- Burden of Illness (BoI)
- Wider Societal Benefits (WSBs)

NICE does not have total freedom on VBA

The Department of Health set out the Terms of Reference for VBA to be undertaken by the National Institute for Health and Care Excellence (NICE) in the summer of 2013. Since then the 2014 Pharmaceutical Price Regulation Scheme (PPRS)¹ has been published. Both of these set out the framework that NICE must work within. NICE must:

- **consult** on how it will implement the wider assessment of value
- **take account of end of life provisions** – this is where NICE may recommend a new medicine even when it might be less cost effective than they usually accept, because it treats small numbers of patients very near to the end of their life
- **keep the basic cost effectiveness threshold** – the cost per Quality Adjusted Life Year (QALY) which is usually between £20,000 to £30,000

The end of life provisions are particularly important for those with less common cancers as many people diagnosed will sadly be near the end of their life.

NICE proposals on VBA focus on QALYs

NICE's Board discussed their proposals for VBA in their January 2014 Board Meeting. VBA will be implemented by changing the methods for Technology Appraisals (TAs). NICE proposes to:

- Define BoI as the total amount of future health (in QALYs) lost for people with the condition – which requires an understanding of what their QALYs would have been without the condition. Options for this include absolute or proportional shortfall.

¹ This is the voluntary agreement between the UK Government and the pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI), on pricing of branded medicines.

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- *Absolute shortfall* = total QALYs without the condition – QALYs you'd expect for people with the same age and gender distribution with the condition. This gives greater weight to diseases that cause very early death, such as childhood cancer versus chronic heart failure
- *Proportionate shortfall* = absolute shortfall divided by the total QALYs without the condition. This gives greater weight to conditions that result in imminent death.
- Instead of the production and consumption approach of the Department of Health (expressed as WSB), NICE would use a measure of Wider Societal Impact (WSI). This would use the absolute shortfall in QALYs as a proxy for the impact of the condition on the person's ability to interact in and contribute to society.
- Use BoI and WSI as additional 'modifiers' – basically NICE Appraisal Committees will consider them in their deliberations.

NICE is proposing changes in the methods guide that will remove the end of life provisions. Instead, NICE thinks that they will work through the absolute shortfall discussed above. They are also thinking about limiting the impact of these modifiers – they won't be able to increase the QALYs gained by more than 2.5 times. This would result in a cost per QALY threshold of £50,000 if we take the £20,000 per QALY that is proposed in the Methods guide.

NICE could be missing opportunities to improve their approach

It's still too early to fully assess the proposals but Cancer52 are concerned that:

- **NICE is missing the opportunity to more fully explore the burden of illness.** QALYs are too crude and together with early mortality, these are not enough to capture the real burden of disease. The experience of disease goes much further and includes the missed opportunities in life of those diagnosed, and the worry and concern of loved ones
- **NICE risks not placing enough weight on treatments that offer precious months at the end of life** – these can be highly valued by patients. The current criteria for end of life are much clearer than the concept of either absolute or proportionate shortfall that NICE is proposing

Next steps for NICE and VBA

NICE is due to consult on their proposals although the exact dates aren't set yet. NICE plans to make consultation accessible to the widest possible audience – we believe that this is crucial as we need to fully understand the proposals and their impact before we can view this as an opportunity to improve the current methods for assessing a medicine's value. NICE will also be reviewing their templates for submissions, including patient templates.

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VBA across the UK

The proposals for VBA are just for England and NICE. We don't know what changes might happen in Scotland, Wales and Northern Ireland.

Cancer52 is asking for:

- **NICE to 'road test' their approach working with patients and carers** - setting out how patients and carers will be able to contribute to ensure a fuller understanding of the burden of illness and the wider societal benefits of new medicines
- **NICE should also set out how these proposals would have changed previous recommendations** so that we can all understand whether these are changes in reality, or just theoretical concepts adding to what can feel like the 'black box' of economic analysis undertaken to inform recommendations
- **Full and open approach to evaluations of VBP/VBA changes.** This should include how far VBP has changed research priorities, including the focus on research to treat those with rare and less common cancers. Cancer52 is willing to work with all stakeholders to build on the opportunities of reform and to improve access to medicines in the UK.

Contact

Jane Lyons

jane.lyons@cancer52.org.uk

info@cancer52.org.uk | www.cancer52.org.uk

Cancer52 a company limited by guarantee and registered in England and Wales
Company no 7994413. Registered office c/o Teenage Cancer Trust, Third Floor, 93 Newman Street, London W1T 3EZ