

Covered in this issue:

A Broader Look at End of Life

Exploring the Concept of Pharmaceutical Value in BRIC Markets

A Broader Look at End of Life

Viewed worldwide as a leader in health economics, the UK has begun broadening its approach to evaluating high-value pharmaceuticals, bringing more flexibility into the assessment. Earlier this year, the National Institute of Health and Clinical Excellence (NICE) announced that it would give special consideration to products that are used in the treatment of people with very short life expectancies. The End of Life Guidance, which is now part of NICE methodology, provides flexibility to the unofficial £30,000 per QALY threshold, suggesting that products targeting these areas deliver greater value than those in other areas. Meanwhile, on 23 March 2009, the Department of Health (DoH) released its "Guidance on NHS Patients Who Wish to Pay for Additional Private Care," which includes the authorisation of top-up payments for pharmaceuticals not reimbursed by the NHS. Previously, patients who opted to pay privately for non-reimbursed drugs were then forced to pay for all of their medical services. Cancer groups and patients considered this a victory for their very public campaign to allow personal financial contributions for biopharmaceuticals without risking free access to NHS services.

These developments give credence to arguments that, at least for certain disease areas, rigid measurements and assessments of value can leave identifiable gaps in patient care. Given these new potentials for additional funding, many are hoping that patients will have more treatment options. However, a closer examination of what these new policies mean for patient access reveals that while the UK has made some steps forward in addressing these gaps, more flexibility is still needed.

End of Life

NICE has the difficult task of making rationing decisions in terms of what treatment options are available to UK patients. While utility measurements and everything else that goes into health economic analysis are viewed by UK payers as efficient and equitable means to make these decisions, many have questioned this methodology, especially as it overlooks patients with special needs. Recognising this potential gap in care, and perhaps because of political pressure to improve the UK's low ranking in country comparisons measuring cancer care, NICE released new guidance on therapies used to treat patients who have limited treatment options and a short life expectancy. This guidance leaves little room for loose interpretation, requiring that:

- The treatment is indicated for patients with a short life expectancy, normally less than 24 months;
- There is sufficient evidence to indicate that the treatment offers an extension to life, normally of at least an additional 3 months, compared to current NHS treatment;
- No alternative treatment with comparable benefits is available through the NHS;
- The treatment is licensed or otherwise indicated for small patient populations.

Many predicted that this would reverse NICE's preliminary August 2008 negative decision on metastatic renal cell carcinoma (mRCC) treatments and open the door to other oncology agents that extend the last, and often most valued, months of life.

More Flexibility Is Still Needed

While the End of Life Guidance was heralded by patient groups and physicians, it still falls short if applied to products previously evaluated by NICE. James Raftery, a leading academic in health economics, undertook a review that found that only a very small number of decisions would likely have been made differently using the new End of Life Guidance. Two examples include Sutent for mRCC and Tyverb for breast cancer. However, for these products to qualify, it requires a stretch in the definition of a "lack of any alternative treatment." Raftery's analysis suggests that the End of Life Guidance is not sufficient to meet the growing demand for new therapeutic options.

The 4 February 2009 appraisal of four mRCC treatments (Avastin, Nexavar, Sutent and Torisel) may serve as a more legitimate litmus test for how helpful the new “End of Life Guidance” will be in expanding access to new drugs. Out of the four, only Sutent was found by NICE to be cost effective as a first line treatment. It is important to note that this decision took into consideration a “risk-sharing” offer by Pfizer which provides the first cycle of treatment for free. All interested parties were eager to see if this decision would create a new threshold for drugs that fit the criteria for end of life. QALYs published for Sutent in the NICE appraisal include:

- £105,000 (Assessment Group’s estimation for the ITT population without the first cycle of treatment being free)
- £54,366 including the first cycle being free
- “Less than” £50,000 for the no post-study treatment group

As NICE has not clearly stated which QALY was used for the basis of their decision, it suggests that NICE was not eager to clearly define what this new end of life threshold will be.

Despite NICE’s recognition that the assessment of QALYs should not be wholly standardised, there is still a need to consider a wider scope of variables when assessing the value of a biopharmaceutical product. One method of adding this “flexibility” is to turn to patients and ask them how they value those products not currently funded in the UK.

Individual QALYS: Top-Up Payments

After great public scrutiny (notably The Sunday Times’ “Right to Pay Campaign” against the DoH’s policy of top-up payments for cancer treatments), the UK Secretary of Health announced on 4 November 2008 that patients would no longer be penalised for dipping into their savings accounts to obtain treatments they want. Whilst portraying a relatively warm reception to this diversification in healthcare funding, the DoH is not wholly embracing the concept. In a recent PriceSpective roundtable discussion with UK clinical leaders and payers, one physician commented that the new guidance would make it too bureaucratic to actually help provide access to treatments that face budgetary hurdles.

Unfortunately, the Government’s 23 March 2009 clarification about top-up payments does little to alleviate concerns about bureaucracy. The DoH guidance stipulates that patients can consider paying privately only if all public funding options are exhausted. Time spent to ensure that no other funding alternatives exist will be excruciating for patients with severe or life-threatening diseases. Once this option has been made available, a series of stipulations exist, including:

- It should always be clear whether an individual procedure or treatment is privately funded or NHS funded;
- Private and NHS care should be kept as clearly separated as possible;
- Private care should be carried out at a different time to the NHS care that a patient is receiving;
- Private care should be carried out in a different place to NHS care, as separate from other NHS patients as possible.

These guidelines illustrate the UK’s difficulty with evolving a public health care system based on equity to a more flexible and diversely funded system. But this “modernisation” of the NHS is a change asked for by the people it was created to serve, and it reflects new ways of adapting health services to the broadening range of treatment options available.

With this new guidance, it is likely that patient advocacy groups will be instrumental in educating patients about navigating approval for treatments not recommended by NICE or where primary care trusts decline funding. This will lead to an interesting development in the UK where, previously, patients were not considered “payers” in the same way US patients are, and it may create new disparities in access to care. However, UK patients’ decision-making role in their treatment plans will increase, and, with that, will help inform other UK decision-makers as to which drugs provide value.

Advances in healthcare, and in society’s valuing of health, will continue to demand more flexibility. This is warranted not only for emotive disease areas like cancer, but also for other conditions where quality of life is severely impacted, such as Alzheimer’s disease and dementia. Working with payers to identify the true value of therapeutic options will help spur an evolution of healthcare systems that recognises and rewards innovation. Likewise, this evolution will positively influence industry pipelines and research commitments.

Exploring the Concept of Pharmaceutical Value in BRIC Markets

Despite noticeable differences in healthcare expenditure between established and emerging markets, industry interest in BRIC markets is increasing due to their size (40% of the world’s population) and contribution to recent growth in the pharmaceutical market (BRIC, referring to Brazil, Russia, India and China, is a term coined at Goldman Sachs in 2001 to cluster these rapidly growing economies). While stagnation, cost containment and patent expiries restrain

opportunity in established markets, government prioritisation of healthcare investment, growing middle classes and increased healthcare awareness are driving demand in BRIC markets.

Even given the current turmoil that has affected BRIC economies to varying degrees, this growth may eventually pave the way for better access to healthcare and improved health benefits. However, a careful review of how these markets are making their healthcare purchasing decisions and their willingness to recognize and reward innovation is a necessary first step to determine whether there will be viable opportunities for branded pharmaceuticals in these markets.

In Brazil, value recognition is almost completely driven by that achieved in other global markets. Price controls for innovative products are based entirely on external reference pricing, taking no account of value relative to local standards of care. For 'non-innovative' drugs, price cannot exceed that of existing presentations in the same therapeutic class. Within the current scheme, a refined value story uniquely tailored to the Brazilian market is unlikely to be rewarded.

Russia is moving towards a federal public healthcare system in which valuation of pharmaceutical innovation may align more closely with established markets. The Supplementary Medicines Program (DLO in Russian) provides full drug coverage for eligible patients and has been the major driver of pharmaceutical market growth in the last 4 years. The Essential Drugs List (EDL) is an additional means for reimbursement through hospital formularies and regional programs. DLO and EDL drugs are price controlled and subject to informal cross-country referencing. While pharmacoeconomic analyses are theoretically required, in practice they are not rigorously employed. A value story for new products in Russia is likely to become of greater benefit and importance as reimbursement systems are expanded.

The highly genericized market in India has strict price regulations with little credit given to innovation. Limited funding and a dearth of health insurance result in patients paying out of pocket for healthcare. With no national payer, P&R success in India is driven primarily by consumers via brand loyalty and actual cost differentials between list prices of medicines. Although programs are in place to improve healthcare provision and develop the intellectual property environment, without substantial changes the concept of and reward for pharmaceutical innovation will be unlikely to spread far beyond the wealthiest classes in India.

Pricing restrictions exist for reimbursable drugs in China, but pricing policies appear to encourage innovation and

recognize value. Prices of prescription drugs are not fixed unless they are listed in national or provincial reimbursement catalogues, which currently include around 20% of drugs available in China. Prices are set based on production costs as well as the level of innovation according to a fixed set of criteria. Of the four BRIC markets, China's policies are the most transparently directed at rewarding innovation and a well-developed value story is recommended.

While it is clear that the concept of pharmaceutical value varies among BRIC markets, as healthcare systems continue to evolve it will be important for the industry to take emerging markets into greater account – especially China and Russia. Pricing policies in China recognize innovation and, as such, this market warrants consideration when building value stories to support global launch strategies. Additionally, government initiatives to increase federal healthcare funding in Russia may provide a substantial opportunity for the industry, and this market is worth examining when thinking strategically about global launches including emerging markets. However, the absence of reward for innovation in Brazil and the lack of federal funding in India limit the opportunity for these markets to contribute substantially to the return on investment for developing innovative pharmaceuticals, although this has to be balanced in the context of providing appropriate access to important drugs that address clinical need. As these markets continue to evolve, it will be critical for the industry to build strategic value stories for products entering BRIC markets that appropriately recognize and reward the value of innovation, and to be cognisant of evolving healthcare trends that may increase the opportunity in other emerging markets.

PriceSpective produces this quarterly bulletin to assess current issues with relevance to value strategy in the biopharmaceutical industry. We accept suggestions for coverage as well as articles from external parties. Should you be interested in participating in an upcoming PriceSpective Bulletin, or if you have questions or comments about current articles, please contact:

Editors:

Keiron Sparrowhawk, PriceSpective Ltd, U.K.
+44 (0) 207 832 1086
ksparrowhawk@pricespective.com
Ted Sweeney, PriceSpective LLC U.S.A.
+1 917 446 2473
tsweeney@pricespective.com
www.pricespective.com