

RISK-SHARING SCHEMES ONCOLOGY: FUTURE



Johnson & Johnson's risk-sharing strategy for Velcade worked in the United Kingdom, but experts say such success is unlikely in the United States.

The year was 2006 and Johnson & Johnson had just received word that the National Institute of Health & Clinical Excellence (NICE) had rejected its multiple myeloma agent, Velcade [bortezomib], for reimbursement by the United Kingdom's National Health Service (NHS). Velcade was not considered a fiscally sound treatment option, as it cost nearly £33,000 (\$51,803.27) per quality-adjusted life year (QALY) for treatment of first relapse and had the potential to reach as high as £107,000 (\$167,968.17) for subsequent relapses, far surpassing the NICE threshold of £30,000 (\$47,093.88) per QALY.

Rejection by NICE typically sounds the death knell for a novel chemotherapeutic in the U.K., but Johnson & Johnson remained undaunted; and in 2007 offered up the Velcade Response Scheme, a groundbreaking proposal that set the oncology world astir. The refund scheme stated that if a patient achieved a complete or partial response ($\geq 50\%$ reduction in serum M-protein) within the first 4 cycles of treatment, the NHS would pay the

full cost of therapy. Conversely, if a patient had a reduction of $\leq 50\%$ or proved non-responsive, Johnson & Johnson would reimburse the NHS the entire cost of treatment.

Other manufacturers quickly followed suit with similarly themed—albeit less aggressive—rebate programs. Merck Serono reimbursed primary-care trusts the cost of any vials of its metastatic colorectal cancer drug Erbitux [cetuximab] used by patients who failed to respond to therapy at 6 weeks. Pfizer gained approval for its kidney cancer drug Sutent [sunitinib malate], in part, by agreeing to offer the first cycle of treatment to NHS patients for free. And, Celgene entered into an agreement with the NHS regarding its multiple myeloma drug Revlimid [lenalidomide], in which the company agreed to pay all costs for patients who stay on the drug after 2 years.

These latest programs work more through rebates and discounts than risk sharing. As such, NICE and the NHS now use the umbrella term “patient-access schemes” when referring to them.

“The patient schemes, generally, allow NHS patients access to expensive new products with established effectiveness for the claimed indications, which would otherwise be cost ineffective,” said Sir Michael Rawlins, MD, Chairman of NICE.



Sir Michael Rawlins, MD,
chairman of NICE

According to Rawlins, ease of use and the ability to clearly prove economic feasibility are key to ensuring a patient-access scheme will be accepted by NICE.

“They must be simple and straightforward for the hospital’s management to administer,” he said. “If they include a response measure [like Velcade], it must be simple and reliable. And they must ensure that the net acquisition cost results in an incremental cost effectiveness ratio that is considered to be cost-effective by the appraisal committee.

EMES IN OR FAD?



By Paul Watson

A NICE Compromise

“The Velcade agreement gave cancer patients in the U.K. access to potentially life-saving treatments at reduced costs and Johnson & Johnson access to the formulary. Perhaps most importantly to Johnson & Johnson, however, was the fact that this could be achieved without compromising their position in other countries.

“The Velcade Response Scheme enabled Johnson & Johnson to essentially lower the price of Velcade without changing the global price,” said Sean Sullivan, PhD, a professor in the Schools of Pharmacy and Public Health/Community Medicine and the director of the Pharmaceutical Outcomes Research and Policy Program (PORPP), at the University of Washington in Seattle. “If Johnson & Johnson had lowered the price of Velcade to gain access to the U.K., they would essentially be setting



Sean Sullivan, PhD,
University of Washington

a benchmark price for Velcade across Western and Eastern Europe, Canada and Australia. And, Johnson & Johnson did not want to have that ripple effect.”

Although a considerable buzz is building about risk-sharing schemes and the attendant benefits they bring to both manufacturers and payers in the U.K., they are not without their problems.

“These are administratively burdensome schemes, which is why they will never be widespread in every country,” said Sullivan. “They will most likely be reserved for high-cost drugs where the uncertainties are high, the tests are reliable, and the administrative complexities can be reduced by making the schemes very simple.”

“These schemes do create additional reporting problems and verification burdens as well,” added Canada Research Chair Greg Zaric, PhD, an associate professor in health care management science at the Richard Ivey School of Business, University of Western Ontario. “Somebody has to be measuring success or failure outcomes and it has to be done in a way that is transparent and verifiable to both sides.”

According to Rawlins, NICE looks for response outcomes that can be performed easily and with limited risk of subjectivity. “An outcome relying on, say, an MRI scan for tumor progression would be much more difficult to interpret,” he said.

Can It Work in the United States?

According to those interviewed, even the most successful patient-access schemes may have only limited potential in the United States.



Lee Newcomer, SVP,
United Healthcare

“In the U.S., federal regulations require us to cover an FDA-approved drug for its indication,” said Lee Newcomer, Senior Vice President of Oncology at United Healthcare. “In the U.K., NICE can question if there is value for the money in a given treatment. So the incentive for J&J to come to the table in the U.K. and actually guarantee their drug is much stronger.

Another considerable obstacle is presented by the Medicaid Best Price Law, a provision requiring that manufacturers who participate in the Medicaid Drug Rebate Program provide the federal government with the lowest possible price for a drug. This makes entering into a risk-sharing scheme with a private insurer a fraught proposition.

If the Medicaid Best Price for Velcade is 30% off the Average Manufacturer Price, and Johnson & Johnson enters into a risk-sharing scheme with Anthem Blue Cross Blue Shield that resulted in a 50% discount at year’s end, then Johnson & Johnson would be mandated by law to reimburse the Centers for Medicare and Medicaid Services (CMS) the 20% difference.

“These schemes are limited in the U.S. by the federal floor price,” said Sullivan. “You have to do a lot of plan-

cont. on pg 18 >>



ning up front to make sure you don't bust through that floor."

Despite these complications, there is a track record of success in implementing risk-sharing schemes in the United States. Surprisingly, the best example of this is not found with an established drug, but instead with a diagnostic test that was something of an unknown commodity at the time.

The Oncotype DX® Example

Developed by Genomic Health, Oncotype DX is a genomic assay that determines the likelihood of disease recurrence in women with early-stage invasive breast cancer who are estrogen-receptor positive (ER+) and whose lymph nodes are negative. At a total cost of \$3,978 per test, payers were hesitant to reimburse physicians using something that had yet to be approved by the U.S. Food and Drug Administration.

"At the time of launch, there wasn't a lot of evidence on how well the diagnostic information would actually be used in the healthcare setting in terms of decision making," said Sullivan. "Genomic Health had actually done significant studies to validate the test, but they were making a claim that the test had actually changed medical practice."

According to Newcomer, who spearheaded the risk-sharing scheme for the assay, the lack of a conclusive endorsement from the FDA did not make for a compelling case in Genomic Health's favor.

Only one CMS agency in California, the National Heritage Insurance Company, agreed to cover the costs of the assay in eligible patients. The rest of

the country failed to follow suit, giving United Healthcare considerable leverage over Genomic Health.

Genomic Health based the price of Oncotype DX on the belief that oncologists would be less likely to administer expensive chemotherapy if the test results deemed it unnecessary. However, if an oncologist went ahead and administered treatment despite a negative result, United Healthcare would be on the hook for both the cost of the diagnostic test and the chemotherapy.

...many believe that comparative effectiveness research will be the more likely alternative.

"Our concern was that the test was being used improperly," said Newcomer. "If a patient had a low-risk score and the doctor still went ahead and treated, there was no reason to do the test."

To ensure that the test was being used appropriately, United Healthcare entered into a risk-sharing scheme with Genomic Health, agreeing to reimburse for the test for 18 months. During that period, the two parties would monitor the results. If an excessive number of women with low-risk scores were still receiving chemotherapy, then United Healthcare would re-open the contract and negotiate a lower price.

"After the first round we found that 16 percent of doctors were using the tests incorrectly," said Newcomer. "That number has since gone down dramatically, so we have not had to re-open the contract and re-price it."

New Strategies

Although the scheme used for Oncotype DX has been successful for both United Healthcare and Genomic Health, it is important to note that none of the experts interviewed for this article believed that risk-sharing schemes would become a fixture on the U.S. healthcare circuit. Nor, for that matter, did they believe that such schemes would remain widespread in the U.K., owing to their administratively burdensome nature. Rather, many believe that comparative effectiveness research will be the more likely alternative.

"At United Healthcare—and I know that other insurers are doing this as well—we have inserted language into our upcoming contracts that say if we have two equally effective treatments we will only pay for the lesser expensive one," explained Newcomer.

As the national healthcare debate continues to drag on, it will be interesting to see how insurers and drug companies successfully pay for and price novel oncology agents in the months to come. **PW**

>>OBR DAILY NEWS FLASHES

U.S. regulators have asked for additional data on Spectrum Pharmaceutical's experimental drug for advanced metastatic colorectal cancer, Fusilev®, whose sNDA was denied approval last October. (*Reuters*, 1/25/10)

Physicians who want to prescribe Amgen's anti-anemia drugs, Epogen®, Aranesp® and Procrit®, for cancer patients will have to register and undergo special training under a risk-management plan unveiled recently by the FDA. (*Los Angeles Times*, 2/17/10)