

Patient access schemes: making them work in practice

Imagine that your local supermarket is having a sale. Let's say, for the sake of argument, that it's a '3 for 2' offer on tinned tomatoes. However, on investigation it becomes clear that this offer is only available if you can provide evidence that the product has been used when making spaghetti bolognese (and not, for example, when making chilli). Furthermore, in order to benefit from this generous offer, you are required to register your interest with the company by faxing off a form and then later complete another form providing evidence that you have used the tomatoes to make the qualifying dish. Not only would you consider this absurd but you would probably not even get around to taking them up on it.

If all this sounds strange then consider this. In August 2009 the National Institute of Health and Clinical Excellence approved the use of cetuximab for the treatment of locally advanced colorectal cancer but one of the qualifying conditions is that cetuximab be used in conjunction with a patient access scheme. The patient access scheme in this particular case was an arrangement whereby the cost of cetuximab was reduced by 16% only when used in combination with oxaliplatin for patients with potentially resectable liver metastases (National Institute for Health and Clinical Excellence, 2009). To obtain the refund, the provider trust is required to register the patient with the manufacturer (using a coded system to maintain anonymity) and then to request a refund several months down the line.

Patient access schemes: the theory

Under the 2009 Pharmaceutical Price Regulation Scheme (Department of Health, 2009), manufacturers were given the opportunity to submit proposals for innovative pricing structures to the Department of Health. Patient access schemes were one such option described in the agreement.

At first glance, this seemed like a win-win situation for the pharmaceutical industry and the NHS. Clinicians gain access to a new product and the company can adjust the cost of the drug to the NHS without altering the list price. Similar examples of patient access schemes were already available and many came soon after. Broadly speaking they consisted of two types: financially-based schemes and outcome-based schemes.

Financially-based schemes involve the company offering discounts or rebates that may be linked to the numbers of people treated or to the types of patient treated (as seen in the cetuximab example above). The single patient access scheme organized by AstraZeneca for the supply of gefitinib (Iressa) in non-small-cell lung cancer is another type of financially-based scheme whereby the provider obtains the first 2 months' supply free of charge then a fee is paid at month 3 to cover the full cost of the course of treatment, regardless of how long the treatment should continue (National Institute for Health and Clinical Excellence, 2010).

Outcome-based schemes are usually 'risk share' arrangements where outcomes are measured and a rebate is applied to the provider based on that outcome. One example of this is the Velcade Response Scheme endorsed by National Institute for Health and Clinical Excellence TA 129 in October 2007 (National Institute for Health and Clinical Excellence, 2007). In this scheme for patients with relapsed multiple myeloma, the patient receives four cycles of treatment and if there is an insufficient response (defined as a 50% reduction in myeloma protein) the provider can apply for a rebate equal to the cost of those four cycles.

Schemes such as these were considered by the National Institute for Health and Clinical Excellence and the Department of Health to generate no administrative burden and that the cost of administering the patient access scheme would be out-

weighed by the financial benefit derived from them (National Institute for Health and Clinical Excellence, 2007).

The reality of patient access schemes

In practice, however, these risk share arrangements were forced upon an already administratively burdened NHS that had no facilities to deal with them. They created havoc with pharmacy systems – most pharmacy software has a tendency to calculate the average price of a drug over a period of time (in order to cope with fluctuations in generic drug prices) and this makes it difficult to pass on the saving to the commissioner. Additionally, there were early reports that few hospitals had the capability to track patients in sufficient detail to allow the schemes to be administered (Wynd, 2008; Williamson and Thomson, 2009).

As experience was showing that patient access schemes were not working as effectively as expected, Steve Williamson, network pharmacist for the then Northern Cancer Network, based in Newcastle, conducted a survey of hospital pharmacists to determine the extent of the uptake of patient access scheme and their feelings towards them. The results, discussed in *The Lancet Oncology*, were striking, showing that around half of patient access schemes were not being administered correctly and that savings were not being passed to commissioners (Williamson, 2010). In other words, the NHS was not getting the value for money that the National Institute for Health and Clinical Excellence suggested it would.

The Patient Access Schemes Liaison Unit

Following this, and with concerns being expressed across the NHS that patient access scheme schemes were being applied without due consideration, the National Institute for Health and Clinical Excellence formed the Patient Access Schemes Liaison

Unit. This is a group which works with the pharmaceutical industry to assess the potential burden and benefit of any patient access scheme. The principles of the Patient Access Schemes Liaison Unit are that any scheme should be clinically plausible, that the burden should be proportional to the benefit and that it should match normal NHS financial flows (National Institute for Health and Care Excellence, 2013).

The Patient Access Schemes Liaison Unit applied a stringent process to their reviews and the result was that few risk share schemes passed the assessment. To the relief of many NHS staff, the most successful type of patient access scheme at the Patient Access Schemes Liaison Unit was the 'simple discount' scheme where the price is discounted at the purchase point without any further information being required of the purchaser.

Interestingly, most of the patient access schemes approved by Patient Access Schemes Liaison Unit have been for cancer drugs. Whether this reflects the high proportion of cancer drugs being reviewed by the National Institute for Health and Clinical Excellence, the high cost of cancer drugs or the willingness of the industry to work with the NHS in this disease group merits further investigation.

The future

The Pharmaceutical Price Regulation Scheme will expire in January 2014, to be replaced with a system known as value-based pricing where drugs are priced on their value to the NHS (Department of Health, 2010). It is still not known exactly how this system will function but it is likely that there will be an element of data

collection involved and that patient access schemes will play a part by allowing the price to be adjusted according to the demonstrated value. Hopefully, lessons will have been learnt from the last 6 years and we will see sensible schemes in place which the NHS can support. **BJHM**

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KEY POINTS

- n Patient access schemes are a feature of the Pharmaceutical Price Regulation Scheme 2009.
- n They can take the form of an 'outcome-based' scheme or a financial scheme.
- n Outcome-based schemes are usually risk share arrangements that require the provider to report a specific event or outcome of treatment (either success or failure) in order to obtain a discount or rebate.
- n Schemes are often difficult to implement because of issues with accurate pricing, administration of rebate to the payer, and identification and tracking of specific patients.
- n 'Simple discount' patient access schemes are preferred.
- n Patient access schemes may become an important feature of value-based pricing.
- n Examples of patient access schemes include gefitinib in non-small-cell lung cancer, bortezomib in multiple myeloma and certolizumab pegol for arthritis.

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