

VALUE BASED PRICING IN SWEDEN: LESSONS FOR DESIGN?

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PRINCIPLES OF VALUE BASED PRICING IN SWEDEN

The Dental and Pharmaceutical Benefits Agency (TLV) is a Swedish health technology assessment (HTA) body (TLV, 2012). For any new outpatient medicine to be eligible for reimbursement in Sweden, the manufacturer must receive approval from the TLV¹. Products may be marketed without TLV review, but will not be eligible for reimbursement throughout Sweden.

The three primary criteria the TLV applies in making decisions are equity, need and solidarity, and cost-effectiveness. The first two criteria are considered fundamental objectives; cost-effectiveness is seen as an aid in decision-making rather than as an objective.

The Swedish reimbursement system based on value based pricing (VBP) was established officially in 2002 with the creation of LFN, which became the TLV in 2008 when dental care was added to its remit.

Three core principles underpin the Swedish VBP approach:

1. Taking a societal perspective in decisions to take account of the economic effects beyond the health sector
2. Applying a threshold value that focuses on individuals' maximum willingness-to-pay for a quality life year (QALY) gained, rather than using QALYs to control the health care budget
3. Assessing the decreasing marginal utility of treatments, recognising that different indications for the same product may provide different health gains

Social and economic perspective

The first, and most important, focus of the Swedish VBP system is the impact of using new treatments on the broader economy and society. Assessments include not only the potential consumption and costs of the medicine being evaluated, but also those of related medicines, out-patient and in-patient care costs, and social services such as home care and rehabilitation. Included in social costs is the value of caregivers, who most often are a relative of the patient. This we calculate by assigning a value to the leisure time and work that the caregiver foregoes to care for the patient.

A human capital approach is used to calculate production losses due to absence or early retirement because of illness. When treatment prolongs life, we consider the costs for life-years gained, which are equal to total consumption less total production during those additional years.

The threshold value

The threshold value is an estimation of individuals' willingness to pay for health gain. Sweden does not use

¹ The remit of TLV also includes reassessing medicines that appeared on the market prior to the introduction of the new system in 2002. It also reviews medical devices and dental procedures. Unlike NICE in the UK, TLV does not publish clinical guidelines (TLV, 2012).

an “official” threshold value; we still are searching for the right number, which may vary by disease or condition. Currently, the TLV can consider the following QALYs as references or benchmarks.

1. From Sweden:
 - a. €90,000 per QALY from the transport sector
 - b. €40,000 per QALY from a pilot study in Sweden
2. From outside Sweden: £30,000 per QALY used by NICE (NICE, 2008)²

In the transport sector, it is estimated that the value of avoiding a fatality is about €2.3 million (2006 prices) and the average number of life-years lost is 34 (Persson, 2004). These figures have been used to calculate the value of a QALY at around €90,000 (see Persson and Hjelmgren, 2003).

A similar methodology was used in a study for the UK, producing estimates in the same range (Mason, Jones-Lee and Donaldson, 2009).

The second figure, €40,000, is the result of a small pilot study in Sweden where an ex-ante valuation of insurance was conducted. A sample of the general population was given the following scenario.

- “Imagine that next year you will face a slight risk of getting a disease and that your quality of life will decrease to a certain extent as a consequence”.
- “You will have to wait for one year to get a treatment; in the meantime, you will suffer from the disease”. (The symptoms of the disease were described.)

The study participants then were asked:

- “Would you buy insurance to bypass the waiting list?”
- “How much would you be willing to pay for such insurance?”

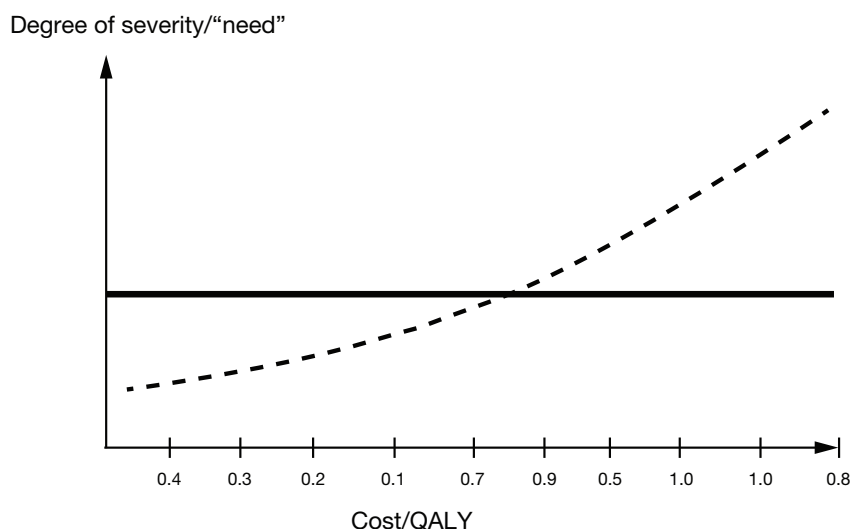
Surveys with the aim of eliciting an individual’s willingness to pay for a QALY also have been conducted in the EuroVaQ study³.

The estimates of the willingness to pay for a QALY are used as a benchmark by TLV in reimbursement decisions. Note that the threshold value used is not related to the health care budget.

The cost-per-QALY threshold also is adjusted to take into account other criteria such as “need”, which is related directly to disease severity. Figure 1 illustrates how the cost per QALY threshold varies with severity.

Severity is assessed based on the expected loss in QALYs if patients are not treated. In practice, if the cost per QALY of a new medicine is high (say, €80,000 per QALY), the manufacturer must provide an estimate of the loss of QALYs that would occur if the treatment was not provided. If the loss in QALYs is at the higher end of the spectrum (high degree of severity/need), the medicine is reimbursed—for example, a treatment for metastatic cancer affecting young people is likely to be reimbursed while a medicine for atopic dermatitis is not. The degree of severity is not based on a strict formula, but is decided by the TLV based on evidence provided by the manufacturer.

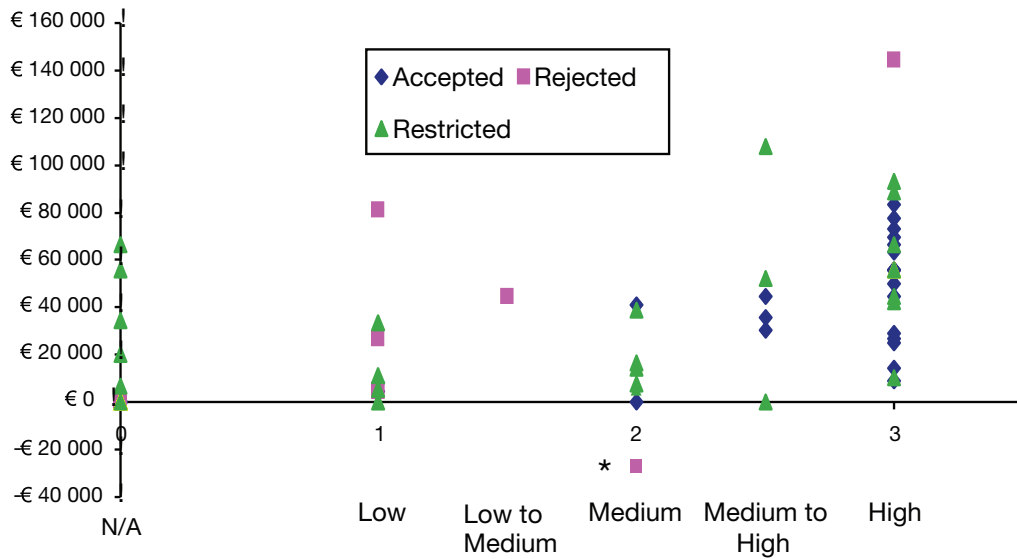
Figure 1: Equity/need-adjusted cost per QALY threshold versus constant threshold



² Sweden takes into account that the UK’s GDP per capita is roughly three times Sweden’s (Eichler et al, 2004).

³ The EuroVaQ study is an international study involving 13 universities intended to estimate the monetary value of a QALY across ten European countries. See Donaldson et al (2010) and Donaldson (2011).

Figure 2: TLV reimbursement decisions, corresponding cost per QALY and severity of disease



* Lower effect and lower cost than the comparator. Thus, a saving per QALY lost.

Source: Hugosson and Engstrom (2008)

Figure 2 shows how the concept of an adjusted threshold has been applied by the TLV in practice. The data confirm that for many medicines for cancer and other severe diseases, the TLV has accepted a relatively high cost-per-QALY estimate. The highest has been for the treatment of advanced cancer and Parkinson disease with Duodopa®, at €90,000 per QALY (Willis et al, 2010a). Other treatments with a similar or lower cost-per-QALY ratio were not reimbursed because the degree of severity was deemed low or uncertainty in clinical or economic evidence was too high. These appear as pink squares on the left in Figure 2.

Diminishing marginal utility of treatments

The third principle is illustrated using the graph in Figure 3. One treatment may have different indications or uses in different patient populations. For example, one drug can target different at-risk patient subgroups, such as patients with a high, medium or low cholesterol level. Based on economic theory, it follows that the health benefits of the first indication are higher than the second or any subsequent indication. In Figure 3, indication 1 generates large improvements in health (B1). As the patient population expands with indication 2 and 3, the extra health benefit decreases ($B_3 < B_2 < B_1$).

Figure 3: Diminishing marginal utility of treatments

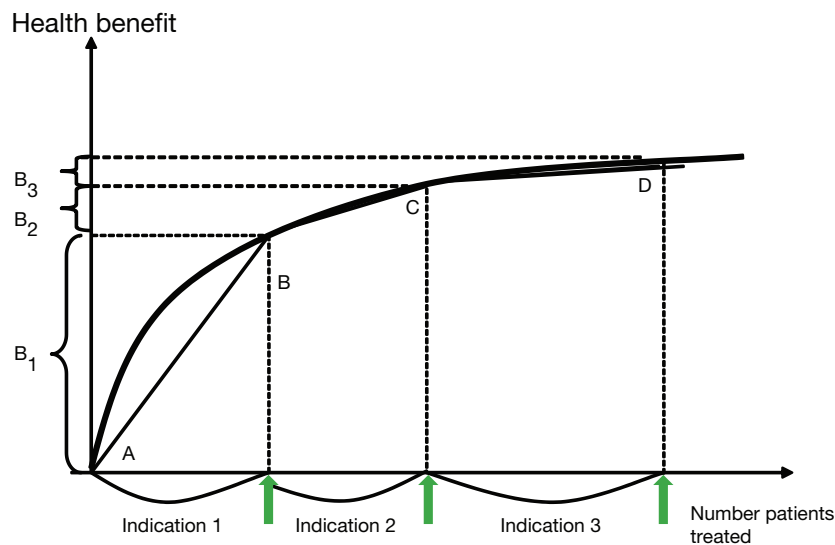
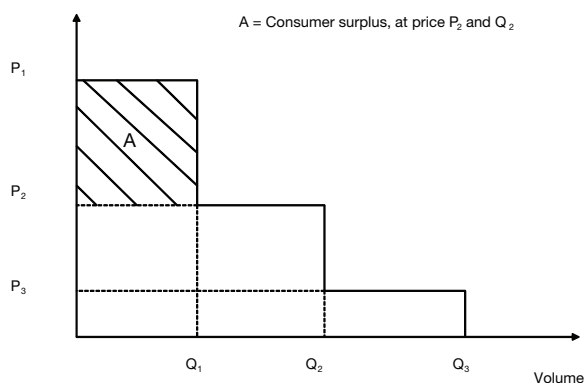


Figure 4: Price, volume and consumer surplus in VBP



As the value of a treatment decreases with the number of additional indications, the price should change accordingly. As shown in Figure 4, if the first indication is very effective, it can be priced at P1. The price should decrease in the second and third indication, depending on their relative effectiveness (value).

What happens in practice is that the manufacturer sets a price and submits its cost effectiveness calculation using that price. Depending on the price set, the treatment will be cost effective for one or more patient subgroups. If we refer to Figure 4, the manufacturer can claim price P2 and ask for the reimbursement of subgroups Q1 and Q2, although the marketing license also covers Q3. If it wants a higher price, say P1, TLV then will limit the reimbursement to Q1. Each brand medicine has a single price; prices cannot vary by indication.

In this system, TLV in effect controls the volume of use of new treatments because most patients will not pay for medicine out of pocket. In a sense, this is a value-based purchasing system where the manufacturer's objective is to maximise the price while TLV's objective is to maximise the number of indications/populations covered.

ARGUMENTS AGAINST VBP

Many arguments have been used against VBP. Three of the more important are as follows.

1. VBP drives costs up when based on individual willingness to pay. This does not happen in other sectors, where budgets determine expenditure.
2. Prices are too high in a VBP system. Because the threshold value is known prior to the negotiation between the manufacturer and payer, prices tend to converge to the maximum price per QALY allowed in the system.

3. Orphan drugs do not fit into a VBP reimbursement system. Given the small patient populations, prices of orphan drugs are high to reward and encourage innovation for rare diseases. Orphan drugs rarely can meet the standard cost-per-QALY threshold and would be excluded using this criterion alone.

Evidence that addresses the criticisms

In Sweden, what we expect to gain from VBP is:

1. Cost-effective use of health care resources
2. Cost containment instruments
3. A sustainable system where access to treatments is combined with incentives for the development of new treatments

How VBP works in practice in Sweden is reviewed below to illustrate these points.

Cost-effective use of resources

Before the advent of VBP, the Swedish medicines bill increased 10% each year, on average. Since TLV's inception in 2002, the annual growth rate for pharmaceutical expenditure has decreased substantially, as shown in Table 1. In 2010, it appears to have remained virtually the same.

Table 1: Increase in pharmaceuticals expenditure per year in Sweden

Year	Annual Increase
1990-1999	10.0%
2002	8.5%
2003	2.1%
2004	2.8%
2005	2.9%
2006	5.1%
2007	6.1%
2008	5.2%
2009	2.6%
2010	0.3%

Source: Apotekens Service AB, various years

Expenditure for pharmaceuticals has increased at a slower pace than the rest of health care, as shown in Figure 5.

How can we explain this trend? Table 2 shows that TLV granted reimbursement to the majority of products (around 60%) without limitations. Reimbursement was denied for 22% and 21% were granted reimbursement only under certain conditions, such as collection of additional data for later review.

The two key cost containment instruments implemented by TLV are *ex-ante* and *ex-post* evaluations. For new products, the evaluation occurs before marketing begins—*ex-ante* evaluation—and decisions are made within three or four months. When a drug is not deemed cost effective and therefore not eligible for

full reimbursement, the manufacturer has the option of marketing the drug without reimbursement by the national pharmaceutical benefit scheme. The county councils, which are responsible for providing health care, may decide to cover the cost of these medicines themselves.

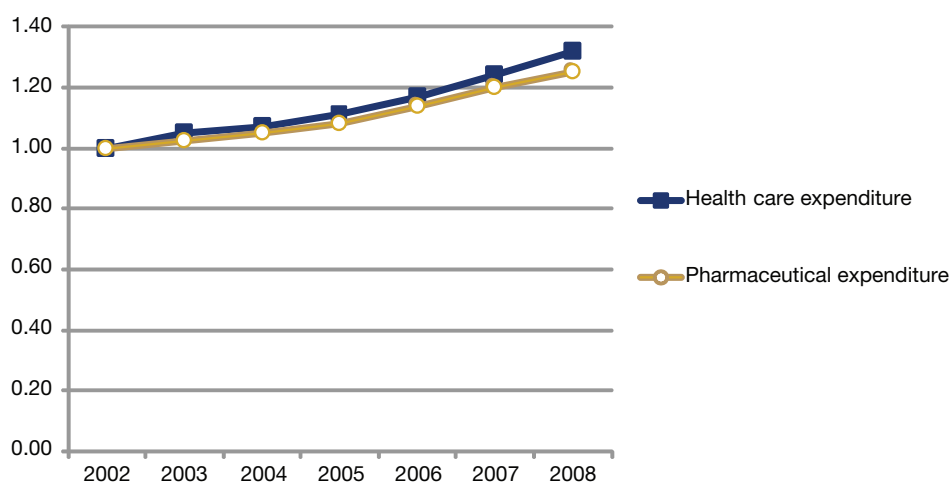
Ex-post evaluation refers to the 2,000 or so medicines that were on the market before the new scheme was initiated in 2002. The review began in 2003 with two pilot groups of medicines—antimigraines and antacids. Ex-post evaluations can take between 12 and 15 months. Antihypertensive drugs provide a good illustration of this process. As a result of the review, 46 antihypertensives are reimbursed fully; 23 are allowed limited reimbursement, including angiotensin ii receptor blockers reimbursed only as second-line treatment; and

Table 2: Reimbursement decisions by TLV over the period 2002- 2010

Year	Reimbursement granted		Reimbursement granted with restriction		Reimbursement denied		Total number of decisions
	Number	Percent	Number	Percent	Number	Percent	
2002 Oct	-	-	-	-	-	-	-
2003	15	55%	4	14%	9	31%	29
2004	56	89%	2	3%	5	8%	63
2005	51	88%	3	5%	4	7%	58
2006	54	73%	7	9%	13	18%	74
2007	41	62%	11	17%	14	21%	66
2008	31	30%	37	36%	36	35%	104
2009	21	36%	22	37%	16	27%	59
2010	29	41%	23	33%	18	26%	70
Total	299	57%	109	21%	115	22%	523

Source: Author's calculations based on TLV data

Figure 5: Index of health care expenditure versus pharmaceutical expenditure, base year 2002



three are not reimbursed at all. TLV calculated that these decisions produced a cost saving of SEK 400 million (€43 million) per year with no negative impact on health. Most of the savings were the result of limiting reimbursement (SEK 250 million, €27 million). Other sources of saving were denials for reimbursement (SEK 30 million, €3 million) and cuts in prices for medicines that could not be proven to be more effective than their competitors (SEK 115 million, €13 million).

Ex-post evaluations enable TLV to take old drugs off the reimbursement system when they are no longer cost-effective. This frees resources for covering new, more cost effective treatments.

Cost containment

Some argue that VBP has led to high pharmaceutical prices in Sweden. Only rarely, however, has Sweden granted reimbursement for treatments with a cost per QALY of up to €90,000 and these were for very severe conditions (see Figure 2). On average, the cost per QALY of drugs approved between October 2002 and October 2007 was €36,000. The TLV has rejected one treatment because the QALY was deemed too high (lapatinib for advanced breast cancer, associated with a cost per QALY of €120,000).

At the same time, TLV has ensured that innovation is rewarded appropriately. The examples below illustrate this.

In diabetes, neutral protamine hagedorn (NPH) insulin was reimbursed at the price of €1.50 per patient per day. The new insulin analogs were expected to produce a similar reduction in the HbA1c in blood sugar, but were more costly—€1.90 per patient per day. However, TLV decided the new insulin analogs deserved a premium

price because they could result in less weight gain and lower risk of low blood sugar (hypoglycaemia).

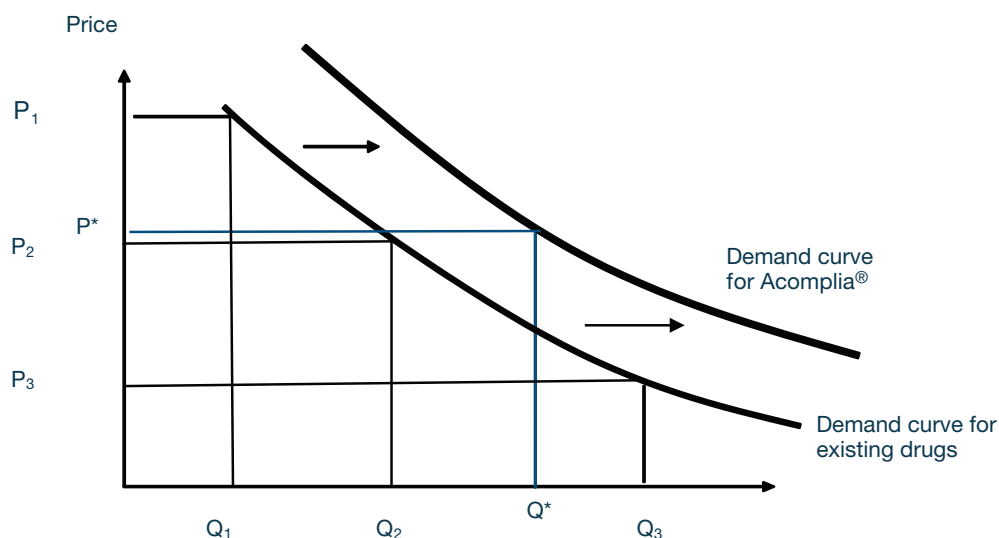
A further innovative treatment for diabetes was developed—GLP-1 agonist—that not only showed a similar reduction in HbA1c and a reduced risk of weight gain, but could also postpone diabetes progression. This treatment received an even higher price premium: €3.2 per patient per day.

A similar situation occurred for oral treatments for type 2 diabetes. Sulphonylurea derivatives were available at only €0.15 per patient per day. TLV set a higher price of €1.60 per patient per day for the new DPP-4 inhibitors—such as sitagliptin, vildagliptin and saxagliptin—because they produce similar HbA1c levels with a lower risk of weight gain and hypoglycaemia.

These are the types of improvement that TLV believes warrant a higher price. They are not necessarily “breakthrough” advances, but they provide extra value compared to existing treatments.

The last example, rimonabant, shows how VBP can affect volume. Rimonabant was licensed in Europe in 2006 for the treatment of obese or overweight patients with associated risk factors such as type 2 diabetes or dyslipidaemia⁴. At the time of TLV evaluation, the manufacturer set the rimonabant price at the same level as its competitors (P^* in Figure 6). Reimbursement for additional indications, beyond those for existing drugs, was requested (Q^* in Figure 6). As the medicine was deemed better than the existing drugs, TLV agreed reimbursement for a broader population that included not only patients with diabetes and weight issues, but also patients with bulimia and high cholesterol.

Figure 6: VBP and consumer surplus for marginal subgroups: the example of rimonabant (Acomplia®)



Source: Persson, Willis and Ödegaard (2010)

Coverage with evidence development

Another dimension of VBP that can help control pharmaceutical expenditure is coverage with evidence development. This can allow a new treatment to be reimbursed earlier in its life cycle on the condition that additional effectiveness data will be collected in real world settings. For example, risperidone is an oral treatment for schizophrenia. It was developed to address some of the issues related to the treatment of the disease, including poor adherence because of side effects such as weight gain. Risperidone, a new formulation of an existing schizophrenia drug, could improve adherence and therefore reduce hospitalisations.

At the time of launch, however, the manufacturer did not provide compelling evidence showing this improvement, as it is difficult to obtain such evidence from an RCT. TLV agreed to grant reimbursement on the condition of receiving additional evidence from a follow-up study conducted over a period of three years. As Table 3 shows, the manufacturer proved that the use of risperidone was associated with a decrease in hospitalisation and hospital costs.

In summary, TLV values innovation when it translates into cost offsets from a societal perspective and positive consequences for the health of patients. The price premium that an innovative product can receive is proportional to the degree of health gain it can generate as compared to existing treatment. It is important to note that what is valuable from TLV's perspective is patients' health, not the extent of innovation of a new medicine. In addition, incremental health benefits must be proven, based on robust evidence collected in real world settings that can be used to populate an economic model.

VBP also means that the manufacturer has an incentive to target R&D towards therapeutic areas where the established price is higher. This is because the overall

price of a new product is likely to be low if the price of the alternative treatment (the comparator) is low; the latter will be used as a benchmark to calculate any price premium.

Sustainability and innovation

To what extent can VBP lead to a sustainable system ensuring access to new treatments and encouraging innovation? With respect to access, Sweden's record is good overall. For example, the relatively high uptake of TFN-inhibitors for rheumatoid arthritis is similar to uptake in the US. One reason in this case might be that patient registries were established at an early stage (Jönsson et al, 2008).

The issue of rewarding and encouraging innovation under VBP is particularly pronounced for orphan drugs. Because their high cost-per-QALY ratios usually exceed the accepted threshold value, orphan drugs face problems in obtaining reimbursement. From June 2003 to April 2010, TLV received requests for reimbursement for 30 orphan drugs. It awarded reimbursement to 29, six of which were reimbursed with limitations⁵. Only one drug was denied reimbursement⁶. Overall, TLV has accepted a lower level of evidence for orphan drugs compared to non-orphan drugs and has approved reimbursement for many more than in some other countries—Scotland, for example (Denis et al, 2009).

One of the reasons why TLV has said “yes” to so many orphan drugs may be that it has allowed so-called “coverage with evidence development” schemes whereby reimbursement is granted in return for the collection of additional data by the manufacturer. An example is levodopa/carbidopa for the treatment of advanced idiopathic Parkinson's disease. Sweden has only 60 patients with this condition. When the manufacturer first approached TLV, it asked for full reimbursement

Table 3: Risperidone (Risperdal®Consta®) follow-up study to test model assumptions

Per patient	Before switch	After switch	Difference
Hospital days per year	39	22	-17
Hospitalisations per year	0.86	0.63	0.23
LOS, days	51	35	-16
Annual hospital costs, SEK	157,000	105,000	-52,000
Annual drug costs, SEK	9,000	15,000	+6,000
Annual costs for Risperdal Consta, SEK	-	34,000	+34,000
Total annual costs, SEK	166,000	154,000	-12,000

Source: Willis et al (2010b)

4 The drug was suspended in 2008 due to safety issues.

5 For more details on TLV decisions, see TLV (2012).

6 This was sapropterin dihydrochloride (Kuvan®) for hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4)- responsive phenylketonuria (PKU).

based on orphan status and provided no economic data. TLV did not agree and requested that some evidence be submitted. Three resubmissions followed.

1. The first included data from a randomised clinical trial and a very high cost-per-QALY estimate. TLV granted reimbursement under the condition that additional data be collected based on actual use.
2. In the second resubmission, the manufacturer provided more evidence, but the cost per QALY still was relatively high. TLV then disallowed reimbursement for new patients.
3. The third resubmission reported the results of an observational study that included data on caregivers. The estimated cost per QALY was much lower and TLV awarded full reimbursement for the drug.

As shown in Figure 7, during this five-year period, the cost effectiveness ratio for levodopa/carbidopa and the associated uncertainty changed substantially.

TENSIONS BETWEEN THE NATIONAL REIMBURSEMENT SYSTEM AND REGIONAL PROVIDERS

Although a VBP system works well at the national level, issues may appear in implementing reimbursement decisions at the local level. Regional health care providers—the county councils in Sweden—have budget responsibility and thus take decisions based primarily on implications for the budget (price times quantity) rather than value. In addition, it can be difficult for county councils to recognise the value offered by new treatments because they lack the

expertise to understand the complex cost effectiveness models that TLV uses to make most decisions.

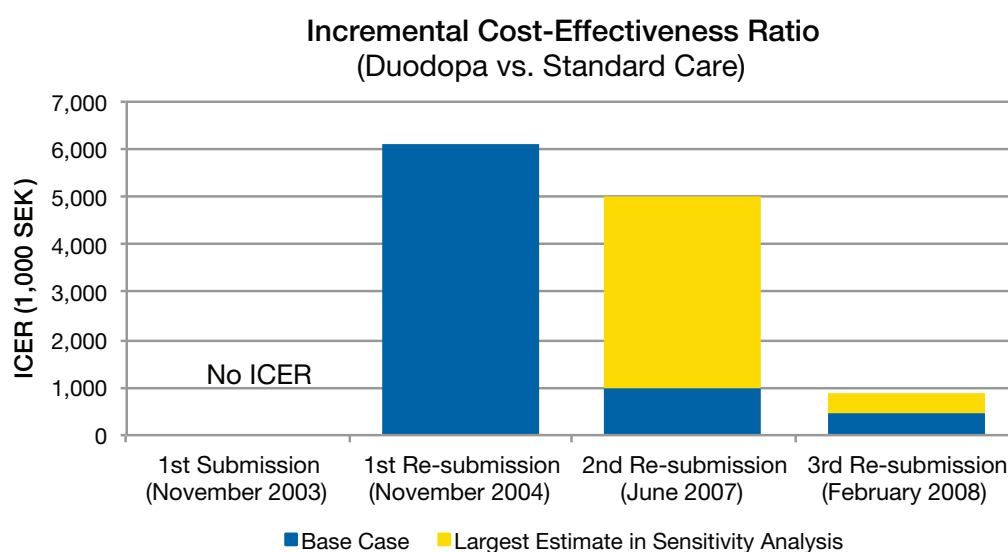
These differences have created substantial regional variation in access to innovative products. For example, lapatinib (associated with a cost per QALY of €120,000) and bevacizumab were not awarded reimbursement by TLV, but they were covered by some regional health care providers. Moreover, although local providers must follow TLV reimbursement decisions, they may limit usage in practice by influencing prescribing behaviour. It is also important to note that the TLV sets the retail price of outpatient medicines; by law, county councils cannot obtain discounts. Discounts are available for hospital medicines, however, and the county councils tend to purchase the least expensive product in a therapeutic class regardless of product profile or the evaluation by the TLV. The TLV mandate has recently been extended to in-patient medicines, which likely will create further issues in the implementation of VBP decisions at the local level.

SUMMARY AND REFLECTIONS ON THE FUTURE OF VBP

The Swedish experience proves that:

- Under VBP, pharmaceutical costs do not increase more rapidly than expenditure for other health care resources
- VBP does not result in high pharmaceutical prices when society's willingness to pay is known
- VBP does encourage improvements in medical technologies when these are deemed valuable

Figure 7: Cost effectiveness of levodopa/carbidopa (Duodopa®) at each stage of the reimbursement process



Source: Persson, Willis and Ödegaard (2010)

Figure 8: National versus regional/local decision-making in Sweden

National	Regional/local
Value based pricing	Politicians responsible for resource allocation
Price & reimbursement decision	Media influence
“Arm’s length” approach	Silo perspective
Broad societal perspective	Cost containment
Individuals’ WTP for QALY gain	Budget responsibility

However, manufacturers of orphan drugs may find it difficult to obtain reimbursement under VBP. This echoes the broader issue about whether and how much the threshold should vary depending on the condition or the type of treatment.

In a small country such as Sweden, TLV must balance three goals:

1. Maintaining cost containment
2. Cost effectively implementing the VBP reimbursement system
3. Ensuring a sustainable system that offers effective tools for encouraging innovation

A number of policy changes are possible, including:

- Expanding the TLV mandate to include in-patient drugs. This took effect recently. It will be interesting to see how VBP and price discounting will work together. However, as long as the country councils, not the TLV, have budget responsibility, VBP for hospital drugs probably will not be effective.
- Expanding the TLV mandate to include medical devices. This would involve using the same metrics as for pharmaceuticals, i.e. cost per QALY.
- Dealing with the conflicts between VBP and procurement. It is possible that Sweden may move from a VBP system to a price comparison system where value would have no role in reimbursement decisions.
- Improving implementation of TLV decisions. One approach might be to include more representatives from county councils on the TLV board. This might help local decision-makers better understand the VBP process and, as a result, increase compliance with TLV decisions.

When TLV’s predecessor, LFN, initiated its work in October 2002, what emphasis each of the principles should receive was uncertain. For example, it was not clear what role cost-effectiveness should play in relation to other criteria such as need and solidarity. Also undecided was whether the interpretation of cost-effectiveness should include cost containment and minimisation of health care costs, which can conflict with rational and cost-effective treatment approaches. Over time, practice has shown a preference for cost-effectiveness over cost containment. This may not have been the strategy if other reforms that produced substantial cost containment had not been introduced in the Swedish medicines market—effective generic substitution reform, in particular, and parallel trade. This allowed LFN to emphasize cost-effectiveness and strive to maximize health at a reasonable cost. LFN otherwise might have chosen to interpret the principles for the new reimbursement system differently.

Space in the overall health care budget in Sweden has been created by the effective cost containment achieved through generic substitution. An important consequence is greater opportunity for reimbursing new, more effective medicines. That this has happened is illustrated by widespread use of the new TNF-alpha inhibitors, Enbrel® (etanercept), Humira® (adalimumab) and Remicade® (infliximab) for rheumatoid arthritis, Crohns disease and psoriasis (Jönsson, Kobelt and Smolen, 2008).

The Swedish experience, then, suggests that a national VBP system for medicines can work relatively well in practice (Persson, Willis and Ödegaard, 2010). However, it also shows that decisions taken at the national level are not always implemented at the regional/local level. This may hamper the effect of VBP and create variations in access for patients across health care decision-making units.

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