

DRUG COST MANAGEMENT REPORT

Developing a Reference-Based Pricing Strategy for Your Formulary

The following is excerpted from an upcoming book from AIS entitled PBM Formulary Strategies by Tim Watson, PharmD, MBA.

One of the concepts dominating the global discussion for how to manage increasing prescription drug costs has been reference pricing. Though reference pricing has received much discussion abroad, it is only beginning to gain some attention in the U.S.

Whereas governments control most of the reference pricing programs established abroad, the efforts under way in the U.S. will likely rely on private-sector solutions. Several PBMs and some major health plans have announced plans to create and market reference-based formularies.

What Is Reference Pricing?

Reference pricing is a reimbursement mechanism in which payers set a ceiling price for medications that exhibit similar therapeutic benefits. Reference pricing does not regulate pharmaceutical pricing directly; rather, it attempts to constrain overall reimbursement from a payer's perspective by setting a reimbursement threshold for individual drug classes.

In constructing reference pricing reimbursement mechanisms, payers must:

- ◆ Develop groupings of products that exhibit similar therapeutic effects (proton pump inhibitors are profiled in this example).
- ◆ Determine a "reference price" or maximum reimbursement amount for specific therapeutic classes. The reference price is based on some point (lowest cost in defined class, midpoint, etc.) Patients may still receive any medication. However, if they choose a medication that is priced higher than the reference drug, the member must pay the difference in price.
- ◆ Develop a communication platform to inform patients and providers of the new system, including education about the relative effectiveness of products within therapeutic classes.
- ◆ Design a process for medical exception.

Prevalence of Reference Pricing

In a seminal work on reference pricing abroad, Patricia M. Danzon of the Wharton School at the University of Pennsylvania provides the following timeline for adoption of reference pricing:

Though it seems unlikely that the government will develop reference pricing models in the U.S., many insurers and other payers are considering various versions of

| Country | Reference Pricing Introduced |
|------------------|------------------------------|
| Germany | 1989 |
| The Netherlands | 1991 |
| Sweden | 1993 |
| Denmark | 1993 |
| New Zealand | 1993 |
| British Columbia | 1995 |
| Australia | 1996 |
| Italy | 1996 |
| Spain | 2000 |

Source: Danzon PM. Reference Pricing: Theory and Evidence. May 22, 2001, page 1.

reference pricing models in an effort to restrain escalating prescription drug costs.

Defining Equivalent Therapeutic Groups

A critical component in developing a reference pricing approach is a thorough and clinically sound process for establishing "therapeutic equivalence" within specific therapeutic classes. Two different approaches to developing treatment groups are discussed below.

Overall treatment of selected diseases:

One approach to defining therapeutic equivalence is to group all agents that are effective in treating a disease into the same disease treatment group. In this case, let's consider an example of agents used to treat depression. In recent years, newer antidepressants called SSRIs have dominated the treatment of depression due to their efficacy and improved side-effect profile over older antidepressants. However, if a plan wanted to aggressively lower the overall prescription cost of treating depression, it could develop its "depression treatment group" inclusive of older and newer agents.

Though this approach would result in cost minimization of drugs, medical expenses could increase, since an increase in utilization of older antidepressant medications would likely increase side effects dramatically. The author believes that this aggressive approach to defining treatment groups will not become the standard practice. Rather, a second approach that defines treatment groups according to similar mechanisms of action seems likely, as described below.

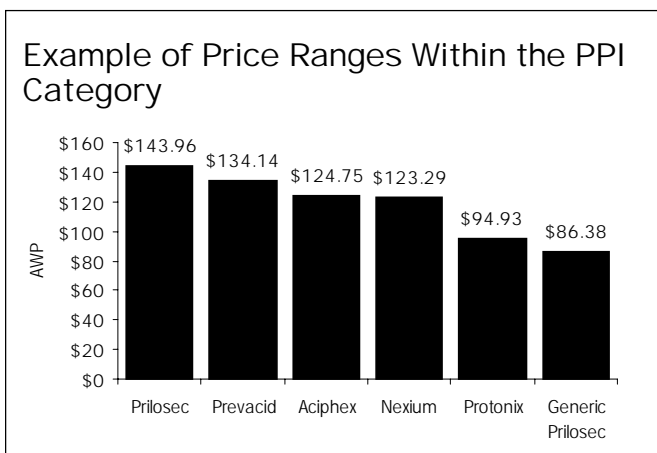
Agents with similar therapeutic mechanisms of action.

The author believes that the most common form of disease treatment groupings for market-based reference pricing systems will be to group medications into treatment categories based on similar therapeutic mechanisms of action. This general approach is used by many PBMs today to define their preferred drug lists.

For example, there are a number of medications used to treat ulcers and other intestinal disorders that work via a similar mechanism of action. These medications are generally defined as proton pump inhibitors (PPIs). Though there are some differences in dosing frequency, pharmacokinetic profiles, etc., many clinicians consider the agents to be similarly safe and effective. Therefore, all medications within the PPI category could be grouped into a disease treatment grouping for reference-pricing purposes. Then, the reference price could be set at some point within the PPI category.

Some additional examples of commonly defined therapeutic classes include:

- ◆ ACE Inhibitors (e.g., Accupril)
- ◆ ARBs (e.g., Diovan)
- ◆ Cox-2 Inhibitors (e.g., Celebrex)
- ◆ HMG-CoA Inhibitors (e.g., Lipitor)
- ◆ Non-sedating Antihistamines (e.g., Allegra)
- ◆ SSRIs (e.g., Zoloft), etc.



Setting the Ceiling Price and Modeling the Economic Impact

Once the disease treatment grouping has been established, the process for establishing a reference price may begin. The following chart provides an example of the potential impact of reference pricing in the PPI category. Note that the prices, plan data and market-share information provided are illustrative only. These concepts could be used to construct a more specific forecasting model based on a plan's actual costs, utilization levels, etc.

Based on the theory that the medications in this class exhibit similar safety and efficacy, a plan might set the ceiling price at the least expensive product in the category (generic Prilosec in this example). Alternatively, a plan could set the maximum price at the cost of the least expensive branded agent available (Protonix in this case).

What follows is a discussion of the financial impact of a various management approaches that could be pursued to control medication costs within this important therapeutic class.

Assume the baseline cost and utilization for the plan is as follows:

| | Market Share | Total Rxs | Avg Price/ Rx | Total Cost |
|----------|--------------|-----------|---------------|-------------|
| Aciphex | 5% | 1,500 | \$124.75 | \$187,125 |
| Protonix | 1% | 300 | \$94.93 | \$28,479 |
| Prevacid | 36% | 10,800 | \$134.14 | \$1,448,712 |
| Nexium | 5% | 1,500 | \$123.29 | \$184,935 |
| Prilosec | 53% | 15,900 | \$143.96 | \$2,288,964 |
| | 100% | 30,000 | | \$4,138,215 |

| | Market Share | Total Rxs | Avg Price / Rx | Total Cost |
|------------|--------------|-----------|----------------|-------------|
| Aciphex | 5% | 1,500 | \$124.75 | \$187,125 |
| Protonix | 1% | 300 | \$94.93 | \$28,479 |
| Prevacid | 36% | 10,800 | \$134.14 | \$1,448,712 |
| Nexium | 5% | 1,500 | \$123.29 | \$184,935 |
| Prilosec | 27% | 7,950 | \$143.96 | \$1,144,482 |
| Omeprazole | 27% | 7,950 | \$86.38 | \$686,721 |
| Total | 100% | | | \$3,680,454 |

| | Market Share | Total Rxs | Avg Price / Rx | Total Cost |
|------------|--------------|-----------|----------------|----------------|
| Aciphex | 5% | 1,500 | \$124.75 | \$187,125 |
| Protonix | 10% | 3,000 | \$94.93 | \$284,790 |
| Prevacid | 5% | 1,500 | \$134.14 | \$201,210 |
| Nexium | 0% | — | — | — |
| Prilosec | 40% | 12,000 | \$143.96 | \$1,727,520 |
| Omeprazole | 40% | 12,000 | \$86.38 | \$1,036,560 |
| Total | 100% | 30,000 | | \$3,437,205.00 |

| | Market Share | Total Rxs | Avg Price / Rx | Total Cost |
|------------|--------------|-----------|----------------|-------------|
| Aciphex | 5% | 1,500 | \$94.93 | \$142,395 |
| Protonix | 1% | 300 | \$94.93 | \$28,479 |
| Prevacid | 36% | 10,800 | \$94.93 | \$1,025,244 |
| Nexium | 5% | 1,500 | \$94.93 | \$142,395 |
| Prilosec | 27% | 7,950 | \$94.93 | \$754,693 |
| Omeprazole | 27% | 7,950 | \$94.93 | \$754,693 |
| Total | 100% | 30,000 | | \$2,847,900 |

| Scenario 4-Impact of Reference Price Set at Least Expensive Product (Generic) | | | | |
|---|--------------|-----------|----------------|-------------|
| | Market Share | Total Rxs | Avg Price / Rx | Total Cost |
| Aciphex | 5% | 1,500 | \$86.38 | \$129,570 |
| Protonix | 1% | 300 | \$86.38 | \$25,914 |
| Prevacid | 36% | 10,800 | \$86.38 | \$932,904 |
| Nexium | 5% | 1,500 | \$86.38 | \$129,570 |
| Prilosec | 27% | 7,950 | \$86.38 | \$686,721 |
| Omeprazole | 27% | 7,950 | \$86.38 | \$686,721 |
| Total | 100% | 30,000 | | \$2,591,400 |

At baseline, members in this plan utilized 30,000 prescriptions for a PPI, for a total plan cost of \$4.1M.

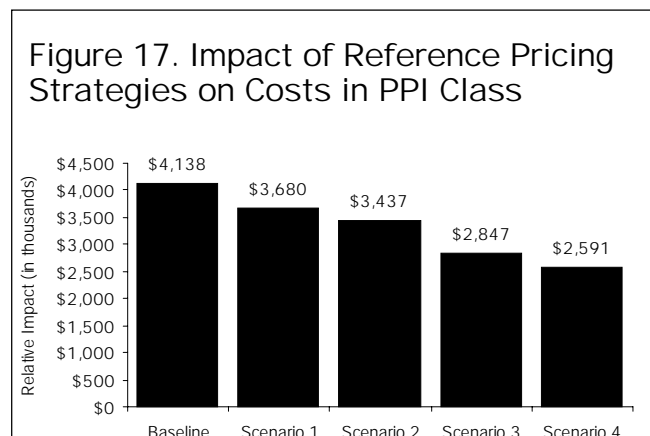
In scenario 1, as the generic version of Prilosec becomes available, the plan's utilization could change. This scenario assumes the market share of all products will remain the same. However, it assumes that 50% of brand Prilosec prescriptions will be converted to generic Prilosec.

In scenario 2, the client sets a goal to shift overall utilization in the category to 80% Prilosec (40% for brand/40% for generic).

In scenario 3, the plan determines to set a reference price for the category at the cost of the least expensive branded product (Protonix). This model assumes market share will be equivalent to the original share, except for overall utilization of omeprazole split equally between the brand and generic forms of the drug.

In scenario 4, the plan sets the ceiling price for the category at the cost of the least expensive product in the category (generic Prilosec). This model assumes market share will be equivalent to the original share, except of overall utilization of omeprazole split equally between the brand and generic forms of the drug.

Each of the scenarios presented above would reduce the plan's overall cost of medications within this class. However the reference pricing approaches would deliver the greatest amount of savings, as summarized below:



Communicating the Relative Value of Medications to Providers and Patients

A key part of effectively implementing a referencing pricing system is ensuring that patients and providers have access to robust information sources about the program. More specifically, patients and providers need information regarding the relative outcomes of individual medications (including incidence of side effects), as well as comparative cost information.

In the absence of clinical outcomes data, critics will argue that reference pricing is a means of rationing care at worst, or cost shifting to patients at best. However, with robust clinical data to support the definition of treatment groups, and by providing patients with access to information that demonstrates the clinical similarity of the product upon which the reference price is based, much of this criticism can be addressed.

In addition to developing basic communication platforms to support the introduction of reference pricing, a process for establishing medical exception should be developed and communicated to plan members. Though the concept of therapeutic equivalence is clinically sound, some patients may have an inadequate response or adverse reaction to the reference medication. In those cases, the patient and provider should have the ability to petition for payment of the necessary medication, based on medical justification of its use.

As payers struggle with developing alternatives to managing their prescription drug programs, some will consider innovative reimbursement mechanisms such as reference-based pricing. Though these programs are new to the U.S., they have been developed and implemented abroad. The concepts outlined in this article provide interested parties with a starting point for considering how reference pricing could minimize the expense of treating certain diseases in defined therapeutic classes.

Each plan must develop a comprehensive, clinically sound approach to developing treatment groups upon which to form the "reference" medication. In addition, aggressive communication plans about the overall program, including how to petition for medical exception, should help overcome initial objections to the idea.

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