

## Consequences of Prior Authorization Programs— A Case Example: DDAVP in Pediatric Nocturnal Enuresis

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One attempt to contain spiraling healthcare costs has been to reduce pharmaceutical expenditures through the use of prior authorization programs. Prior authorization (PA) is a prospective utilization appraisal process that allows payers to establish a need for specific drugs before making payment. Recently, it has been reported that PA is now the primary method by which Medicaid programs control expenditures for drugs. However, whether PA reduces expenditures for specific drugs without causing the unwanted substitution of other drugs or medical services has been largely unstudied.<sup>1</sup> Furthermore, it is evident that some drugs have been placed on PA programs without clinical and economic justification.

### Prior Authorization Programs

Medications selected for a PA process are chosen because they are presumed to have potential for misuse and/or abuse, extensive cost, limited place in therapy, or a narrow therapeutic index. Table 1 offers a list of drugs typically subjected to a PA program. Criteria for drugs selected for PA are usually made by clinical pharmacists based upon a review of medical and pharmaceutical literature, manufacturer product information, and consultation with medical and financial professionals. Criteria are designed to reflect the interpretation of the most appropriate use(s) of the medication and outline limitations for use.

New therapies or changes in practice patterns often identify a need for PA status. Most contracted PA programs establish recommended policies and criteria for selected prescription medications. These recommendations are designed to help their clients provide safe, appropriate, and cost-effective utilization of prescription medications in compliance with the prescription benefit.

*Prior Authorization Process.* A typical PA program follows the process depicted in the figure. The degree that the steps of the process are automated is increasing as technology penetrates the environment. Briefly, when a prescription is received for a drug covered under the PA program, the consumer or pharmacist is provided the option for the prescribing physician to submit requests by telephone, fax, or in writing. Physician requests are submitted and reviewed for compliance with the PA criteria. If the approval criteria are met, the PA is approved; otherwise, it is denied. If the physician has not completely addressed the criteria or completed the PA request form, this information must be provided to obtain approval.

### Effectiveness of Prior Authorization Programs

Until there is evidence that PA is capable of promoting cost-effective healthcare, it will be open to evaluation. Recently, it was reported that the PA program for Tennessee Medicaid was cost-effective in controlling NSAID expenditures.<sup>2</sup> At the same time, these investigators stated that their findings were not applicable to other drugs or classes. Several other reports challenge the benefits of PA and similar programs.<sup>3-5</sup>

A review of the various drugs currently under PA programs through contracted services such as PBMs and Medicaid yielded some interesting findings (Table 1). The case of desmopressin (DDAVP) is a prime example. DDAVP is indicated for the treatment of pediatric nocturnal enuresis (PNE) and diabetes insipidus. Reasons most often stated for its PA status are its potential for overuse and high cost when used for the treatment of PNE.

The management of PNE starts with education, counseling and motivation of the child and the family. Subsequently, behavioral modification and pharmacological therapy are considered. Behavior modification techniques include the use of bed-wetting alarms and pads. The two pharmacologic agents approved for the treatment of PNE are imipramine and DDAVP.

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**Table 1.** Medications Commonly Subject to Prior Authorization

• Atovaquone (Mepron)
• Clozapine (Clozaril)
• Colony Stimulating Factors (Neupogen, Prokine, Leukine)
• Desmopressin (DDAVP)
• Dextroamphetamine (Dexedrine)
• Didanosine (ddl, Videx)
• Erythropoietin (Epogen, Procrit)
• Fluconazole (Diflucan)
• Growth Hormone (Protopin, Humatrope)
• Itraconazole (Sporanox)
• Menotropine (Pergonal)
• Methamphetamine (Desoxyn)
• Nafarelin (Synarel)
• Nimodipine (Nimotop)
• Pentamidine (Nebupent)
• Rifabutin (Mycobutin)
• Sumatriptan (Imitrex)
• Ticlopidine (Ticlid)
• Vancomycin capsules (Vancocin)
• Zidovudine (AZT, Retrovir)
• Zalcitabine (ddC, di deoxycytidine, Hivid)

Imipramine is indicated for the adjunctive therapy of PNE. The mechanism of action of imipramine in PNE is not exactly known. Imipramine does possess antidepressant properties, and can produce an alteration in arousal and sleep patterns, an anticholinergic/antispasmodic effect, and an increased antidiuretic

hormone (ADH) release. Adverse effects of imipramine include personality changes, insomnia, anxiety, nervousness, dry mouth, dry eyes, and a disturbance in sleep patterns and sleep architecture.

There is the potential of clinically significant drug interactions between imipramine and antihistamines, sedative/hypnotics (increased central nervous system (CNS) depression and anticholinergic effects), anti-convulsants (increased CNS depression and decreased seizure threshold), methylphenidate (increased imipramine levels), and sympathomimetics/decongestants (increased cardiovascular and proarrhythmic effects).

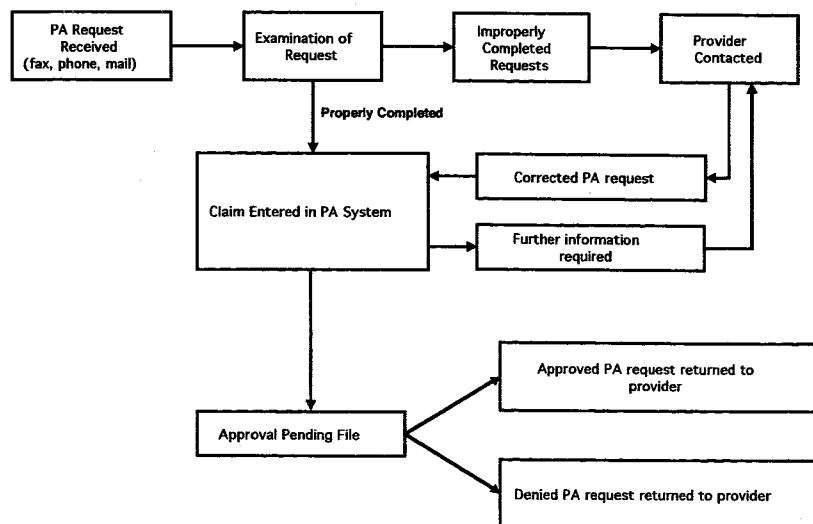
DDAVP may be used alone or in combination with behavioral modification and is effective in the short-term symptomatic treatment of PNE. DDAVP's pharmacologic mechanism includes the ability to concentrate urine due to increased water reabsorption by the kidney secondary to an increased ADH response and detrusor relaxation during sleep. Adverse effects associated with DDAVP are infrequent and mild. The most commonly reported side effects of DDAVP are headache, nasal congestion, rhinitis, and epistaxis.

Treatment patterns and the prevalence of PNE are shown in Table 2. In a theoretical 100,000-member HMO, there are approximately 104 PNE patients seeking pharmacologic therapy. Of those seeking pharmacologic therapy, 61 would most likely be on DDAVP, 32 would receive imipramine, and 11 would be on other pharmacologic therapy according to nationwide practice patterns.

PA programs restricting the use of DDAVP for PNE may be decreasing the quality of patient care. It appears the motivation for including DDAVP in a PA program is its relative cost difference versus imipramine. A representative average wholesale price (AWP) to an HMO for imipramine therapy is \$2.12/month compared to DDAVP's \$100-105/month.

What is often forgotten, however, is the cost to the HMO for the provision of the PA services. When examining the cost

**Figure 1.** Schematic of Prior Authorization Process



of including DDAVP in a PA program, we used a fee structure of \$0.05 PMPM for 10 drugs. This equates to an annual cost of \$6,000 to cover DDAVP participation in a 100,000 member HMO. The fee structure used was based upon interviews with contracted PA providers. Since it would be expected that there be variances in this fee, we considered a range of \$3,000 to \$9,000 per year. This equates to an average charge of \$57.69 per PNE patient (range \$28.85–\$86.54) assuming that there are 104 PNE patients seeking pharmacologic therapy in the HMO. In addition, since it is likely that at least one-third of these patients won't be prescribed DDAVP, the cost when spread over the remaining PNE patient population rises further. Additional costs are also likely to occur as a result of the criteria established by the PA program that need to be met in order to obtain DDAVP (additional office visits, physician time, pharmacist time, etc.).

When all this is examined, it appears to make little economic sense to require prior authorization for DDAVP when used for PNE. At the same time, perhaps that greatest cost to the HMO would be decreased member satisfaction.

### Consumer Awareness and Reactions

What happens to consumer expectations when an industry such as healthcare is faced with rapid change? How do the expectation and satisfaction levels of consumers affect their choice of healthcare provider? Clearly, managed care has resulted in a more discriminating healthcare consumer. Unlike their predecessors, the consumers of today are more likely to evaluate their healthcare providers. The information processing theory in consumer behavior suggests that the consumer is an intelligent, rational problem-solver who seeks and analyzes information to evaluate the various alternatives or choices.<sup>6</sup> As consumers learn, they develop expectations of their chosen services. The confirmation of these expectations can be described as satisfaction while a failure to meet them can lead to dissatisfaction.

### Implications for Healthcare Provider Strategies

Healthcare providers must maintain an awareness of how members view their services if strategic decisions are to keep pace with changing expectations. It is widely recognized that an HMO's survival is determined by its ability to enroll and retain members.<sup>7</sup>

**Table 2.** Treatment Patterns of PNE Patients\*

Total Population	259,547,300	100%
Total 6–18 year olds	46,468,486	18
# of PNE patients	2,141,838	5
Seeking Treatment	1,349,358	63
Actually Treated	674,679	50
Nonpharmacological	404,807	60
Pharmacological	269,872	40
· DDAVP	159,224	59
· Imipramine	83,660	31
· Other therapy	26,987	9

\*Data from Rhone-Poulenc Rorer.

Consumers assess healthcare plans according to two major categories of characteristics. The first category includes the characteristics of the plan, such as the benefit package, the premium cost to the enrollee, and the cost-sharing provisions such as deductibles and copayments. The second category is the delivery system and includes such aspects as access, continuity, comprehensiveness, clinical quality, and social quality.<sup>7</sup>

The first category is rather straightforward and relates to the consumer's perceptions of health and financial risk. The second category is often "learned" through experience and encounters with the healthcare plan. On the basis of the information that we have presented, the prior authorization of agents like DDAVP can negatively affect both categories. The economic benefits touted by PA programs may not actually be present. At the same time, the delivery system characteristics are also not likely to satisfy the member's expectations if there is any hesitation in the availability of an agent commonly accepted as the drug of choice (ie, DDAVP for PNE).

Therefore, we strongly recommend that all healthcare plans re-examine critically their process of prior authorization. In particular, a movement away from solely comparing the costs of pharmacologic alternatives towards an assessment of total healthcare costs and member satisfaction is encouraged.

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