

## Access to Innovative Treatment of Erectile Dysfunction: Clinical, Economic, and Quality-of-Life Considerations

Based on a presentation by A. Mark Fendrick, MD

### **Presentation Summary**

While effective therapies exist for health conditions that diminish the quality of life, there remain hurdles in healthcare delivery that may limit access to such therapies for individuals who would benefit from them. Limited company resources coupled with double-digit increases in pharmaceutical costs—frequently designated as the “culprit” behind recent increases in medical expenditures—may not allow health plans to cover every effective drug in every clinical circumstance for every affected individual. Managed care companies currently employ several mechanisms to counter runaway

pharmaceutical costs, such as excluding some drugs from coverage, imposing significant limitations, or requiring higher copayments through tiered pharmaceutical coverage structures. The trend toward greater patient contribution for indicated agents could well invoke cries of bias, in that a tiered copayment system may discriminate based on income and ability to pay. The practical inability within the healthcare community to compare healthcare interventions such as treatments for erectile dysfunction with those for asthma, hypertension, or other conditions prevents the optimal allocation of healthcare services.

In 1999, annual healthcare expenditures within the United States topped the trillion-dollar mark, compared with just \$200 billion 20 years ago (Figure 1).<sup>1</sup> In recent years, pharmaceutical costs have been viewed as a key driver of this worrisome trend. In 1960, prescription drugs accounted for 1% of total national health expenditures (\$2.7 billion); by 1997, that increased to 7.2% (\$78.9 billion).<sup>2</sup> Although the portion of the healthcare dollar spent on pharmacy costs is relatively low (estimated 8.25% of total healthcare spending in 1999, or \$100.6 billion out of \$1.22 trillion,<sup>3</sup> concern sur-

rounds the fact that the average annual growth rate of expenditures on prescription drugs was in the double digits—far higher than other major healthcare sectors (Figure 2).<sup>2</sup> There appears to be no end in sight. The Health Care Financing Administration (HCFA) estimates prescription drug spending will increase 11.2% annually between 1999 and 2001.<sup>1</sup>

While innovative, more effective, and more expensive drugs contribute to the rise in pharmaceutical costs, other factors also come into play. Older drugs often experience incremental price hikes after becoming well established and accepted among

providers and patients. Additional indications for use as well as longer duration of therapy also contribute to increased drug spending. Another significant cost driver has been the introduction of so-called "lifestyle" drugs, which are quality-of-life enhancing but not lifesaving. These drugs are used to treat a variety of maladies—male pattern baldness, seasonal allergies, and toenail fungus (a well-known public health menace). Clearly, therapies for erectile dysfunction (ED) fall square in the middle of the lifestyle genre. While some may argue that ED is not a direct cause of death, an affected individual knows the great impact this condition has on his well-being.

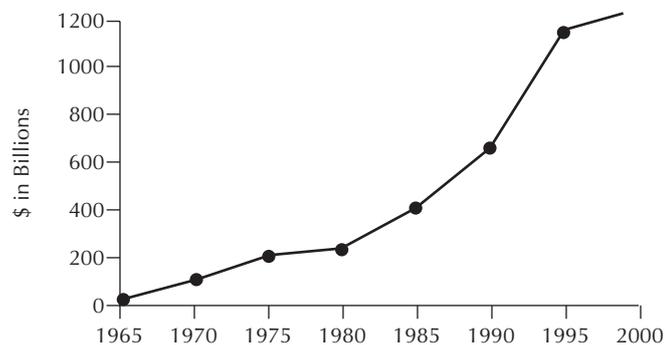
Lifestyle drugs for conditions such as ED have given rise to philosophical discussions as to whether insurers should differentiate coverage policies between drugs that enhance quality of life and drugs that demonstrably decrease mortality. Such benefit decisions are founded on a delicate interplay among considerations such as health plan priorities, enrollee preferences, and cost. While consumers generally would prefer access to any intervention that improves quality of life, the underlying question remains, "Who should pay?" The importance of an explicit valuation of these lifestyle drugs was highlighted in a recently published cost effectiveness study of sildenafil, an oral treatment for erectile dysfunction. Using a Markov decision model with conservative assumptions on the increase in quality of life, the investigators found that the cost effectiveness of treatment with sildenafil compared favorably with that of accepted therapies for other commonly recommended interventions such as dialysis and cholesterol reduction.<sup>4</sup>

**Managed Care Considerations**

Options for dealing with this problem include increasing insurance pre-

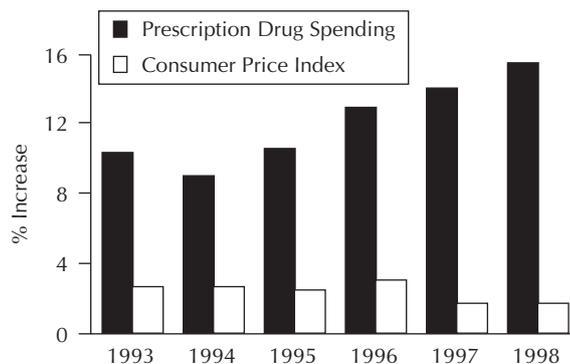
miums to pass the spiraling cost of new drugs on to employers. Another is to shift the expense to the point of demand in the form of significant copayment requirements. Another is simply to exclude coverage altogether; if the consumer wants the drug, then the consumer must pay for it in full. As evidenced by the multibillion-dollar alternative-care market, many consumers are willing to pay for new therapies.

**Figure 1.** Total US Health Expenditures: 1965 to 1995



Source: Reference 2.

**Figure 2.** US Prescription Drug Expenditures



The introduction of effective, more acceptable therapies for the treatment of ED has brought the debate surrounding lifestyle coverage issues to full force. Sildenafil, for example, has enjoyed widespread popularity since its initial marketing in early 1998. Ongoing treatment with sildenafil, however, is potentially costly (approximately \$9 per pill average wholesale price, according to the *Drug Topic Redbook*). Citing the cost of the drug and its “life-enhancing” value versus its medical necessity, only 80% of large insurers and health plans cover the therapy. On the other side of the debate are those who challenge the traditional notion of what constitutes a medical problem, citing the secondary impact on overall well-being that could result from sexual problems.

Managed care plans follow a business model and must balance revenues with costs, much like every other industry. Challenged by employers who demand affordable premiums and at the same time by rising medical costs, many health plans today are struggling not for large financial gains but simply for viability. Some of the largest and highest-quality health plans have found themselves teetering on the brink of collapse.

Given this business reality, the critical consideration in drug cover-

age decisions from the managed care perspective is obviously cost. However, because of the scarcity of resources, tough choices must be made about resource allocation. While in the “golden age” of health-care all therapies approved by the Food and Drug Administration as safe and efficacious were automatically offered as a covered benefit, today cost concerns make such generous coverage impossible.

A number of strategic questions must be addressed by managed care organizations when evaluating access to emergent treatments for ED (or other lifestyle conditions):

- Can ED be clearly defined as an important disease to my enrollees?
- Can employer/payer data be used to identify the incidence of the disease?
- Can the cost of treatment of ED be viewed as an investment? Are there measurable productivity issues in addition to health and quality-of-life improvements?
- How does ED compare with other diseases that compete for resources?
- Does successful treatment of ED prevent other healthcare expenditures?
- In the “age of consumerism,” will ED be a disease that is amenable to good public education? How will ED costs be influenced by direct-to-consumer advertising?
- Have experts developed a disease management program with which the medical community agrees?

**Table 1.** Which Agent When? Access to Innovative Therapy

■ Coverage denial
■ Guidelines/step therapy
■ Prior authorization
■ Formulary management
■ Physician capitation for drugs
■ Tiered copayments

### Estimating the Cost of ED

To determine the actual cost to health plans associated with various ED therapies, researchers in 1 study examined the economic cost of ED by using a prevalence-based, cost-of-illness approach to estimate the direct medical cost for ED treatment.<sup>5</sup> The investigators developed a treatment plan algorithm for a hypothetical

managed care organization to model the initial treatment selection of 100,000 enrolled members and their therapy outcomes during a 3-year period. The prevalence was based on US epidemiology data showing the prevalence of ED to be 5% in men, making it an underreported public health problem affecting an estimated 10 to 20 million men in the United States and a total of 30 million with ED of mild to moderate severity.<sup>6</sup> Researchers found the total cost of ED for a hypothetical managed care plan with 100,000 members would be \$3,204,792, or about \$855 per patient over a 3-year period, including the physician/specialist consultation visit and diagnostic services, cost of treatment including initial treatment and subsequent switches of therapy, and follow-up care. The researchers concluded in light of costs associated with therapy switches related to successive treatment failures, providers should focus on achieving long-term patient satisfaction in the interest of cost. They recommended oral agents and vacuum erectile devices be considered as first-line management strategies.

It is important to realize providers are taking care of people with symptoms, and nonfinancial considerations are an extremely important part of the picture. Other factors taken into consideration include improving quality of life for patients and reducing the psychological stigma and all its ramifications, which may be ameliorated by therapy. When considering these factors, there are clear benefits of therapy unique to the condition under question. This reality makes decisions regarding access to a variety of quality-of-life enhancing drugs even more challenging. Given this variety of considerations, our inability to compare healthcare interventions such as treatments for ED with treatments for asthma or hypertension complicates the optimal allocation of healthcare services.

### Coverage Decisions

While effective therapies exist for conditions that diminish the quality of life, systemic hurdles may still deter access to them. Barriers to access may include outright denial of coverage, coverage restricted to a limited quantity, or significant patient copayments (Table 1). A growing trend is the implementation of tiered formulas that require members to pay more for different classes of drugs, with the lifestyle drugs being the most costly. The number of managed care organizations offering 3-tiered copayments increased from 52% to 67% during 1999 (Table 2). However, refusing coverage or requiring very high copays may invoke cries of socioeconomic bias. Tiered copay systems, although increasingly popular, may be viewed as discriminating based on a member's ability to pay and not a patient's likelihood of benefiting from therapy.

When deciding whether to cover a particular treatment, in addition to cost considerations the managed care industry generally applies 3 criteria: efficacy, medical necessity, and appropriateness. Yet 1 study of 53 managed care plans (including self-insured employers) suggests that value judgments, rather than cost, seem to play a central although largely unspoken role in drug coverage decisions.<sup>6</sup> Researchers asked the managed care organizations about

**Table 2.** Access to New Pharmaceuticals: Tiered Formularies

<ul style="list-style-type: none"> <li>■ MCOs offering 3-tiered copays increased from 52% to 67% during 1999</li> <li>■ Average copay                     <ul style="list-style-type: none"> <li>Tier 1—\$6.63</li> <li>Tier 2—\$13.94</li> <li>Tier 3—\$28.32</li> </ul> </li> </ul>
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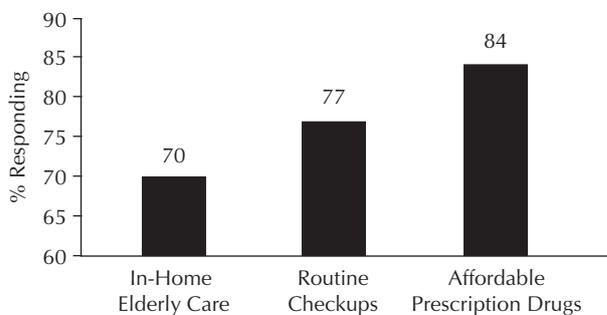
coverage policies for 4 new drugs: sildenafil citrate for treatment of organic impotence, bupropion hydrochloride to aid smoking cessation, etanercept for treatment of rheumatoid arthritis, and celecoxib for relief of symptoms of osteoarthritis and rheumatoid arthritis. These drugs were chosen in part because of their high cost relative to other options and controversy surrounding their coverage. Researchers found that etanercept and celecoxib were much more likely to be covered than sildenafil and bupropion hydrochloride. Coverage of etanercept and celecoxib was limited through strategies such as prior authorization, whereas coverage of sildenafil and bupropion hydrochloride was limited through generalized exclusion or through restrictions on quantity or duration of use. Neither differences in information used for coverage decisions nor drug efficacies could account for these differences. The investigators surmise that a distinction was made between those therapies that offered clear medical benefits and those that offered lifestyle benefits. "While it may appear that there is a clear distinction between diseases and lifestyle, such distinctions tend to be value-laden and controversial," the investigators concluded. "Are lung

cancer and type-II diabetes diseases or the result of 'bad' lifestyles? These distinctions and the values they embody may need to be examined as pharmacy coverage decisions evolve," said the investigators.<sup>5</sup>

Of the plans studied, only 1 included a consumer representative on its pharmaceutical decision-making committee. In a recent *Newsweek* (Cowley G, Turque B, Hager M, King P. Critical condition: From the capital to kitchen tables, and from frustration with HMOs to worries about cost, healthcare is topic A. And the patients are ready to rumble. A special report. *Newsweek*, November 1999) survey, consumers indicated that the most important component of their managed care coverage is in fact affordable prescription drugs (Figure 3). According to the poll, 61% of consumers are "frustrated and angry" about the state of the healthcare system. More than half believe "fundamental changes" are needed—and 7 in 10 favor some kind of action by the federal government. Because affordable prescription drugs seem to be key to consumer happiness within managed care delivery systems, clearly health plans need to rethink criteria used for pharmacy benefit decisions. The current debate in Washington, DC, about Medicare prescription drug benefits is bringing the politically charged issue of pharmacy benefits to the center of public attention.

It is becoming increasingly apparent that there exists a significant gap between consumers' and health plans' views of what constitutes a positive outcome when it comes to evaluating pharmaceuticals. While the medical community continues to focus on surrogate endpoints such as cholesterol levels, endoscopic findings, or coronary angiography results, consumer satisfaction largely depends on the presence or absence of symptoms that affect the quality of day-to-day life. While health plans may question the clinical value of coverage for ED

**Figure 3.** Managed Care—What's Important?



drugs, consumers place a high value on them in terms of quality of life and overall satisfaction with their health plans.<sup>7</sup> In the end, it appears that after issues of safety are addressed, decisions regarding access to lifestyle drugs are simply based on money.

As healthcare delivery becomes increasingly politicized and a staple of virtually every campaign platform, increasingly consumers' votes are the prevailing force behind coverage decisions. A vote may depend on giving consumers the full range of coverage and services they want.

A *USA Today* Gallup poll survey (Lynn G. Most favor expanding Medicare drug coverage: USA Today CNN Gallup Poll. *USA Today* May 23, 2000:A19.) of 1000 adults agreed with this view as it pertains to Medicare coverage, with 57% favoring the inclusion of prescription benefits to Medicare, and 26% saying such benefits should be federally subsidized. However, consumer satisfaction with pharmacy benefits will undoubtedly come at a price consumers and their employers must be willing to pay.

**Table 3.** Abridged International Index of Erectile Function\*

Over the past 6 months:	Very low	Low	Moderate	High	Very High
1. How do you rate your <b>confidence</b> that you could get and keep an erection	1	2	3	4	5
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration?	Almost never/never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always/always
	1	2	3	4	5
3. During sexual intercourse, <b>how often</b> were you able to maintain your erection after you had penetrated (entered) your partner?	Almost never/never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always/always
	1	2	3	4	5
4. During sexual intercourse, <b>how difficult</b> was it to maintain your erection to completion of intercourse?	Extremely difficult	Very difficult	Difficult	Slightly difficult	Not difficult
	1	2	3	4	5
5. When you attempted sexual intercourse, how often was it satisfactory for you?	Almost never/never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always/always
	1	2	3	4	5

\*The IIEF-5 score is the sum of the ordinal responses to the 5 items; thus, the score can range from 5 to 25.

Source: Rosen RC, Riley A, Wagner G, et al. The International Index of Erectile Dysfunction (IIEF): A multidimensional scale for assessment of erectile dysfunction. *Urology* 1997;49:822-830. Reprinted with permission of the Nature Publishing Group.

### The Role of the Primary Care Physician

It is important for primary care physicians to take a proactive stance in securing information about sexual performance from their patients. In 1 recent study presented at the May 2000 meeting of the American Urological Association, investigators evaluated the rate of ED in men older than 50 years who were visiting their urologist for other urological problems.<sup>8</sup> They asked 500 men whether they were having problems with potency. When patients answered yes, they were asked to complete a questionnaire giving their reasons for not mentioning the problem and indicating whether they had discussed the problem with their primary care physician. Researchers found that 218 of 500 men (44%) experienced some degree of ED. Only 48 (22%) men with ED had discussed the problem with their primary care physician. One hundred forty (82%) of the 170 men who did not have such discussions would have liked their primary care physician to initiate a discussion of impotence during their routine visits. The results of this study show that a significant percentage of men who see a urologist for a problem unrelated to impotence also have some degree of ED, which remains undiagnosed unless the patient is specifically questioned. Patient embarrassment is the most common reason for underreporting. However, the researchers suggest that men seem to be comfortable and willing to discuss potency with their primary care physicians. One short and easy-to-use survey tool is a shortened version of the International Index of Erectile Function, a multidimensional scale for assessment of ED (Table 3).<sup>9</sup>

These findings suggest that primary care physicians need to discuss ED with their patients in a systematic and thorough way with appropriate survey instruments designed by leaders in the field of ED.

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