Utilization and Cost of Sildenafil in a Large Managed Care Organization With a Quantity Limit on Sildenafil

CATHERINE E. COOKE, PharmD, BCPS; WINSTON WONG, PharmD, MBA; and HELEN LEE, PharmD, MBA

ABSTRACT

OBJECTIVE: Erectile dysfunction (ED) affects approximately 30 million men in the United States. The objectives of this study were to (1) assess the cost and utilization of sildenafil citrate (Viagra), an oral therapeutic agent for ED, in a large managed care organization (MCO) with a quantity limit of 6 units per 30-day supply and (2) describe the incidence of comorbid conditions and the severity of cardiovascular disease in adult male users of sildenafil.

METHODS: Pharmacy claims for sildenafil were identified from an administrative database of claims with dates of service in calendar year 2001 for male members aged 18 years or older. Medical claims for MCO members who had sildenafil claims were used to identify comorbid diseases and categorize patients by degree of cardiovascular risk. High risk was defined as having at least 1 medical claim with a diagnosis of diabetes mellitus, ischemic heart disease, abdominal aortic aneurysm, or peripheral arterial disease, and medium risk was defined as not having any diagnosis in the high-risk category but at least 1 cardiovascular risk factor that included smoking, hypertension, hypercholesterolemia, family history of premature coronary heart disease, or being aged 45 years or older.

RESULTS: There were 67,914 pharmacy claims for sildenafil during 2001 for 20,281 MCO members, an average of 3.3 pharmacy claims per patient. The prevalence of sildenafil use was 54.1 per 1,000 male MCO members aged 18 years or older. The total allowed charges for sildenafil pharmacy claims in 2001 were $3.56 million, of which patients paid 26.6% in average cost-share, and the net MCO cost per member per month (PMPM) was $0.18. A total of 1,681 patients (8.3%) exceeded their quantity restrictions for sildenafil tablets in 2001, of which 1,362 (81.0%) paid cash and 319 (19.0%, or 1.6% of all sildenafil users) appealed (8.3%) exceeded their quantity restrictions for sildenafil tablets in 2001, of which 1,362 (81.0%) paid cash and 319 (19.0%, or 1.6% of all sildenafil users) appealed

CONCLUSIONS: A quantity limit of 6 tablets of sildenafil per 30-day period was associated with a drug cost to users and the MCO of $0.25 PMPM. Sildenafil users paid an average cost-share of 26.6%, resulting in a net drug cost of $0.18 PMPM to the MCO.

KEYWORDS: Erectile dysfunction, Sildenafil citrate, Viagra, Quantity restriction, PMPM cost

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Authors

CATHERINE E. COOKE, PharmD, BCPS, is a clinical education consultant, Pfizer Inc., New York, New York, and a clinical assistant professor, University of Maryland School of Pharmacy, Baltimore; WINSTON WONG, PharmD, MBA, is director of pharmacy, and HELEN LEE, PharmD, MBA, is a clinical pharmacist, CareFirst BlueCross BlueShield, Baltimore, Maryland. (Lee was a managed care resident at the University of Maryland School of Pharmacy at the time of this study.)

AUTHOR CORRESPONDENCE: Catherine E. Cooke, PharmD, BCPS, Clinical Education Consultant, Pfizer Inc., 5106 Bonnie Branch Rd., Ellicott City, MD 21043. Tel: (410) 480-5012, Fax: (410) 480-5296; E-mail: catherine.cooke@pfizer.com

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According to a National Institutes of Health consensus panel, erectile dysfunction (ED) is defined as the inability to attain and/or maintain penile erection sufficient for satisfactory sexual performance.1 This consensus panel estimated that 30 million men in the United States have ED of some degree.7 The Massachusetts Male Aging Study (MMAS) described an ED prevalence of 52% for men aged 40 to 70 years, with the incidence of complete ED tripling from 5% to 15% from youngest to oldest patients in the study.8 The incidence of ED also varies with other social factors such as race and ethnicity, socioeconomic level, smoking and alcohol intake, diet, and comorbidities such as diabetes mellitus, prostate cancer and its treatments, depression, and cardiovascular diseases.1,3-5 In a study assessing sexual dysfunction in the United States, men with a self-reported health status of fair or poor were nearly 2.8 times (95% confidence interval [CI], 1.26-6.63) more likely to report experiencing ED than those in the healthy reference group.7 The MMAS found that men with self-reported diabetes were 1.83 times (95% CI, 1.23-2.73) more likely than men without diabetes to have ED. In addition, men undergoing treatment for heart disease (1.96; 95% CI, 1.32-2.91) and high blood pressure (1.52; 95% CI, 1.11-2.07) had a greater risk of ED compared with men without these conditions.7 ED commonly occurs in men with cardiovascular disease as a result of shared risk factors that impair circulation in both the penis and cardiac blood vessels.6

Erectile Dysfunction: Treatment, Costs, and Interventions

Treatment of Erectile Dysfunction

Erectile dysfunction can be characterized as organic, psychogenic, or mixed in origin, with treatment ranging from psychological to medical to hormonal, or a combination of these. The American Association of Clinical Endocrinologists (AACE) recommends trying to identify the cause of sexual dysfunction first, with a thorough evaluation that should include some or all of the following: medical evaluation, blood tests, vascular assessment, sensory studies, and nocturnal penile tumescence and rigidity testing.7 When the cause of ED is organic, the AACE recommends identifying the medical risk factors and correcting them. For example, determining whether medications for other comorbid conditions may be the source of or a contributing factor to the patient’s ED is a primary step.

The first oral medical treatment for ED, sildenafil citrate (Viagra), was approved by the U.S. Food and Drug Administration on March 27, 1998.6 Sildenafil selectively inhibits phosphodiesterase type 5, which is found in vascular smooth
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The introduction of sildenafil for ED and the growing public awareness of ED resulted in an 84% increase in the number of U.S. men seeking and using treatments for ED from 1998 through 2002. Within 2 years of the introduction of sildenafil, the number of patients visits for the chief complaint of ED increased in Mexico (279%), the United States (250%), the United Kingdom (103%), Spain (90%), and Germany (55%). Wilson et al. attributed the rising cost of managing ED in the United Kingdom to a 3-fold increase in the number of men visiting their general practitioners for ED, many of whom are referred to specialists. Health plans have been concerned about the impact sildenafil will have on their pharmacy budgets because of the nature of the disease it treats, namely, that ED is a self-reported condition, and, for this reason, potentially large numbers of men could seek to obtain sildenafil for self-reported ED.

Several studies, however, have shown that sildenafil has not had the adverse economic effect initially anticipated. For example, Smith et al. found the cost-effectiveness of sildenafil treatment to be comparable to accepted therapies for other medical conditions, such as cholesterol-lowering medications, coronary artery bypass grafting, and renal dialysis. Smith et al. suggested that sildenafil is in the same category as other treatments for non–life-threatening illnesses that affect only quality of life and are covered by insurance, such as migraine headaches.

Although there are no articles published on evaluation of the costs associated with adding sildenafil coverage in a managed care drug benefit plan, 3 studies, in abstract form, found only lower than expected pharmacy benefit costs. Lehman and Duttagupta discovered that the drug costs per member per month (PMPM) of adding sildenafil coverage to 4 health plans with 93,000 to 15 million members ranged from $0.04 to $0.21, much less than the predicted estimate of $1.00. In a study evaluating PMPM drug costs of sildenafil in managed care organizations (MCOs) that did not restrict the quantity of tablets dispensed, Cherayil and Duttagupta found that actual PMPM costs ($0.03 to $0.24) were also significantly lower than the projections. When MCOs did impose restrictions on the number of sildenafil tablets allowed per prescription, but without requirement for prior authorization for sildenafil, drug costs were also lower than expected, at $0.07 to $0.18 PMPM.

Managed Care Interventions

Among the methods employed by MCOs to control pharmacy costs is exclusion from coverage, imposition of quantity limits, or higher copayments. In a study examining which factors MCOs use to make drug coverage decisions, Titlow et al. concluded that value judgments, rather than cost, seemed to play a central, though largely unspoken, role in drug coverage decisions. For sildenafil in particular, Titlow et al. discovered, among 53 organizations surveyed, that the most common method of controlling sildenafil cost was by limiting the quantity of medication covered or the duration of its use. Sixty-four percent of MCOs placed limits on sildenafil coverage, 23% did not cover treatment for sexual dysfunction at all, 21% required prior authorization, and only 2% of MCOs covered sildenafil without any restrictions. Other research has found the quantity limit for sildenafil to range from 4 to 12 tablets per month.

The present study analyzes sildenafil utilization and cost associated with a quantity limit of 6 units per 30-day supply and describes the incidence of comorbid conditions and the severity of cardiovascular disease in sildenafil users in a large MCO with 1.2 million pharmacy lives.

Methods

Pharmacy claims data for sildenafil for calendar year 2001 were obtained from the pharmacy benefit management company of a large MCO with 1.2 million pharmacy lives located in the mid-Atlantic states. Medicare beneficiaries, who comprised 2.5% of the MCO population, were eligible for a senior pharmacy benefit drug program, which had an annual benefit maximum of $1,000. At the time of this study, sildenafil was on the second tier of the drug formulary and was restricted to a maximum of 6 tablets per month (or up to 18 tablets for a 3-month supply). There was a gender edit that permitted only male members to receive sildenafil. The refill-too-soon edit was 75%, meaning that a covered member could not obtain a refill of sildenafil until at least 75% of the days in the period had transpired, 23 days for a 30-day pharmacy claim or 68 days for a 90-day pharmacy claim for sildenafil. Physicians could appeal sildenafil claim denials, and decisions were made on a case-by-case basis since there were no specific criteria for medical exception. The study cohort was composed of men aged 18 years or older with...
continuous pharmacy benefits for calendar year 2001 and with at least 1 pharmacy claim for sildenafil during the calendar year.

In the pharmacy claims database, there were both positive and negative (reversed) claims. Pharmacists generate a positive claim when tablets are dispensed by the pharmacy, and a negative claim occurs when the filled prescription is reversed. Reasons for negative claims include an error in the submission of the electronic claim or if the member does not pick up the prescription. All positive and negative matched claim pairs were deleted to ensure that only prescriptions received by members were included in the data used in this study.

The data set contained the following fields: unique generator member identification, which was different from the member’s actual identification to protect member confidentiality; age as of January 1, 2001; amount paid by the MCO; amount of member copayment; drug name; dispense date; dose; number of tablets dispensed; and the days supply (number of drug therapy days submitted by the pharmacist on the pharmacy claim).

Members who received sildenafil were grouped into high-, medium-, and low-cardiovascular-risk categories based on an adaptation of classification criteria in the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) guideline. The high-risk category consisted of patients with at least 1 of the following diagnoses: diabetes mellitus, ischemic heart disease, abdominal aortic aneurysm, or peripheral arterial disease. Patients in the medium-risk category were those who did not have any diagnoses from the high-risk category but had at least 1 of the following cardiovascular risk factors: smoking, hypertension, hypercholesterolemia, family history of premature coronary heart disease, or were aged 45 years or older. The remaining patients were placed into the low-risk category.

### Results

A total of 67,914 prescription claims for sildenafil occurring during calendar year 2001 for 20,281 patients were available for analysis. The prevalence of sildenafil use was 54.1 per 1,000 male MCO members aged 18 years or older. The mean ± standard deviation (SD) age of patients in the cohort was 53.1 ± 10.4 (median 53) years. Most of the patients in the cohort were between age 50 and 59 years (38.5%) (Table 1). There were 2,559 sildenafil patients (12.6%) enrolled in a senior pharmacy benefit program for Medicare beneficiaries with a $1,000 annual benefit maximum.

The number of sildenafil prescriptions filled per utilizing member for this MCO cohort during 2001 was 3.3 ± 2.7 (mean ± SD; median = 2), with a range of 1 to 29 prescriptions (Table 2). Most prescriptions (85%) were for 6 tablets at a time (6.3 ± 2.4; median = 6), with a range of 1 to 100 tablets. Some (9.3%) prescriptions were for fewer than 6 tablets, and some were for 7 or more tablets (3.4% for 7 to 11 tablets and 2.5% for 12 or more tablets).

Median annual sildenafil utilization for calendar year 2001, extrapolated from partial-year use, was 29.4 tablets per utilizing member, which includes both cash and MCO-paid pharmacy claims. There were 933 pharmacy claims (1.4%) for 6,127 tablets of the 25 mg dose of sildenafil, whereas the remainder of the prescriptions was evenly split between 33,208 pharmacy claims (207,994 tablets) for the 50 mg dose (48.9%) and 33,773 pharmacy claims (213,471 tablets) for the 100 mg dose (49.7%). A total of 1,681 members (8.3%) exceeded their quantity restrictions for sildenafil tablets in 2001, of which 1,362 (81.0%) paid cash for the additional tablets, and 319 (19.0%) appealed and received approval from the MCO for additional sildenafil tablets beyond the limit of 6 tablets per month. Total pharmacy benefit expenditures in 2001 were $516 million for this MCO with 1.2 million members or about $36 PMPM in MCO costs after subtraction of member cost-share but before the effect of manufacturer rebates. The MCO spent $2.6 million on sildenafil prescriptions in 2001, approximately $0.18 PMPM, or about 0.5% of the annual

### Table 1

<table>
<thead>
<tr>
<th>Age Category*</th>
<th>No. of Members</th>
<th>Rx†</th>
<th>Units</th>
<th>Units/Rx</th>
<th>Dollars ($)‡</th>
<th>% of Total $</th>
<th>Rxs/Patient</th>
<th>Units/Patient</th>
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</thead>
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<td>18-29</td>
<td>328</td>
<td>764</td>
<td>5,206</td>
<td>6.8</td>
<td>43,270</td>
<td>1.2</td>
<td>2.3</td>
<td>15.9</td>
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<td>30-39</td>
<td>1,689</td>
<td>4,903</td>
<td>30,689</td>
<td>6.3</td>
<td>255,935</td>
<td>7.2</td>
<td>2.9</td>
<td>18.2</td>
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<td>5,000</td>
<td>16,808</td>
<td>104,175</td>
<td>6.2</td>
<td>868,730</td>
<td>24.4</td>
<td>3.4</td>
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<td>27,022</td>
<td>169,974</td>
<td>6.3</td>
<td>1,414,673</td>
<td>39.8</td>
<td>3.5</td>
<td>21.8</td>
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<td>60-69</td>
<td>4,386</td>
<td>14,987</td>
<td>95,651</td>
<td>6.4</td>
<td>792,859</td>
<td>22.3</td>
<td>3.4</td>
<td>21.8</td>
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<tr>
<td>70+</td>
<td>1,076</td>
<td>3,430</td>
<td>21,897</td>
<td>6.4</td>
<td>180,289</td>
<td>5.1</td>
<td>3.2</td>
<td>20.4</td>
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<td>Total</td>
<td>20,281</td>
<td>67,914</td>
<td>427,592</td>
<td>6.3</td>
<td>3,555,756</td>
<td>100</td>
<td>3.3</td>
<td>21.1</td>
</tr>
</tbody>
</table>

* Medicare-eligible members participated in a senior prescription drug program benefit that had an annual benefit maximum of $1,000.
† Includes community pharmacy and mail-service claims.
‡ Total allowed charges (managed care organization cost plus member cost-share).
Rx = prescription.
pharmacy budget. Costs for the MCO were divided nearly equally between the 50 mg ($1.2 million) and 100 mg ($1.3 million) doses of sildenafil, with the 25 mg dose accounting for $36,726 of the pharmacy budget in 2001.

The total allowed charges for sildenafil pharmacy claims in 2001 were $3.56 million, of which members paid 26.6% ($0.944 million) in average cost-share and the MCO net cost was $2.61 million. Members of the MCO had varying levels of copayments and total out-of-pocket costs for sildenafil. The average copayment per sildenafil pharmacy claim in 2001 was $13.90 ± $8.67 (mean ± SD; median = $15), with a range of $0 to $240. The average member copayment in 2001 for any sildenafil claim was $14.70 ± $8.82 (median = $15), with a range of $0 to $240. The total out-of-pocket cost for sildenafil per member for the year was $46.55 ± $45.01 (median = $30), with a range of $0 to $623.

More than half of the 18,899 members had their first sildenafil prescription for the year filled in the first quarter of 2001 (9,722 members, 51.4%). Successively lower numbers of members filled their first prescription in the second (3,620 members, 19.1%), third (2,925 members, 15.5%), and fourth quarters (2,632 members, 13.9%), respectively.

Medical Claims Data and Member Comorbidity
Among the 20,281 patients who had sildenafil claims in 2001, there were 15,644 patients (77.1%) who had at least 1 medical claim for a comorbid disorder. The mean ± SD age of members in this group was 53.4 ± 9.9 (median 54) years. A total of 135,298 medical claims (average 8.65 per patient) were included in the evaluation. About 81% of these sildenafil users were classified as either high risk or medium risk for cardiovascular events based on an adaptation of the risk factor classification outlined by the NCEP ATP III guideline.28 Hypertension (37%), dyslipidemia (36%), and diabetes mellitus (18%) were the most common comorbid conditions. (Table 3)

| TABLE 2 | Frequency Distribution of Sildenafil Claims Among Users in 2001 |
|----------|------------------|------------------|------------------|
| No. of Claims | No. of Patients | % of Total |
| 1 | 6,925 | 34.1 |
| 2 | 3,693 | 18.2 |
| 3 | 2,465 | 12.2 |
| 4 | 1,805 | 8.9 |
| 5 | 1,373 | 6.8 |
| 6 | 1,065 | 5.3 |
| 7+ | 2,955 | 14.6 |
| Total | 20,281 | 100.1* |

* Total is greater than 100 due to rounding.

Discussion
Our study found that most (85%) members from the MCO filling sildenafil prescriptions were between the ages of 40 and 69 years, with 10% of members younger than 40 years and 5% of members 70 years or older. These results are consistent with other published research describing the characteristics of sildenafil users.29

In a study evaluating sildenafil prescribing practices immediately after its approval, Harrold et al. found that patients prescribed sildenafil tended to remain on the initial dose they were prescribed, with little reported dose titration.29 The majority (59%) of patients were initially prescribed the 50 mg dose, with 35% prescribed an initial dose of 25 mg and 7% prescribed an initial dose of 100 mg. In the present study, only 1.4% of pharmacy claims were for the 25 mg dose of sildenafil, and about one half (48.9%) of all sildenafil pharmacy claims were for the 50 mg dose and one half (49.7%) were for the 100 mg dose.

Our median annual sildenafil utilization for calendar year 2001 was 29.4 tablets per year, or 2.5 tablets per month, which corresponds to results from a study by Delate et al.,17 who found that the mean tablets dispensed over a 9-month period ranged from 21.0 to 23.5 (2.3 to 2.6 tablets per month) over the 5 years of pharmacy claims included in their analysis. For their study year 2001, corresponding to the data from our cohort, the mean

| TABLE 3 | Cardiovascular Risk and Comorbid Conditions in Patients With Sildenafil Utilization |
|------------------|------------------|------------------|
| Cardiovascular Risk* | No. of Patients | % |
| High risk | 4,186 | 26.8 |
| Medium risk | 8,534 | 54.6 |
| Low risk | 2,924 | 18.7 |
| Total† | 15,644 | 100 |
| Comorbid Conditions‡ |
| Hypertension | 5,777 | 37 |
| Dyslipidemia | 5,570 | 36 |
| Diabetes mellitus | 2,784 | 18 |
| Hypertrophy of prostate | 2,589 | 17 |
| Chest pain, unspecified | 2,057 | 13 |
| Ischemic heart disease | 1,656 | 11 |

* High risk was defined as having at least 1 of the following diagnoses: diabetes mellitus, ischemic heart disease, abdominal aortic aneurysm, or peripheral arterial disease.

Medium risk was defined as not having any diagnosis in the high-risk category and at least 1 of the following cardiovascular risk factors: smoking, hypertension, hypercholesterolemia, family history of premature coronary heart disease, or being age 45 years or older.

Low risk was defined as all "other."

† Medical claims were available for 15,644 (77.1%) of sildenafil users.
‡ A given sildenafil user may have more than 1 comorbid condition.
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prostatectomy. In the present study, 81% of members in whom 16% had ischemic heart disease, and 5% had a history of radical antipsychotic agents, and others, 25% had diabetes mellitus, as a possible side effect (such as beta-blockers, diuretics, digoxin, lipidemia, 33% were receiving a medication associated with ED who received sildenafil also had hypertension, 42% had hyperlipidemia, 33% were receiving a medication associated with ED as a possible side effect (such as beta-blockers, diuretics, digoxin, antipsychotic agents, and others), 25% had diabetes mellitus, 16% had ischemic heart disease, and 5% had a history of radical prostatectomy. In the present study, 81% of members in whom comorbid health conditions could be determined, were classified as either high risk or medium risk for cardiovascular conditions. Previous studies have shown a strong link between ED and many of the conditions for which members in our cohort accessed medical care. In fact, Johannes et al. observed that the age-adjusted risk for ED was higher for men with diabetes, heart disease, and hypertension, which supports our data obtained from the medical claims.

Scope of drug coverage and the amount of member cost-share are important factors in member satisfaction with the pharmacy benefit plan. Motheral and Heinle concluded that about 75% of respondents felt that their out-of-pocket copayment was the most important feature of their prescription benefit plan, with an additional 20% of respondents listing copayment as the second most important factor. Other factors considered included the list of drugs covered by the plan, having a mail-order option, which pharmacies accepted the plan, and getting help with questions or problems with drug coverage. In a survey evaluating member satisfaction with their pharmacy benefit plans, Desselle found that total out-of-pocket cost was the second most important factor out of 9 total factors rated by respondents. The only factor that ranked higher for plan satisfaction was the list of drugs on the formulary. The amount of medication (days supply) the plan allows for each pharmacy visit was ranked the third most important factor.

Limitations

The data from the pharmacy benefit manager did not provide an indication or diagnosis for the use of sildenafil, which could affect interpretation of utilization patterns, such as the off-label use of sildenafil for primary pulmonary hypertension, and we did not assess the medical claims to determine diagnosis information for this purpose. Second, as with any analysis of pharmacy claims data, there was no way to determine whether the patient used the medication, only that the prescription was filled and the tablets were received by the patient.

Third, we could not determine from the database if cash payment for sildenafil prescriptions was due to exhaustion of benefits for those Medicare beneficiaries with an annual benefit maximum or by sildenafil users in excess of the quantity limit of 6 tablets per month. Of the 1,362 patients who paid cash for sildenafil, 136 (10.0%) were patients aged 65 years or older. We estimated but could not verify that 53 of these seniors exceeded their $1,000 annual benefit maximum, accounting for 3.9% of the patients who paid cash for sildenafil prescriptions. Conversely, approximately 96% of the cash prescriptions for sildenafil were assumed to be from patients who had exceeded the limit of 6 tablets per 30-day period.

We also could not determine how often members simply purchased sildenafil prescriptions outside of the pharmacy claims system due to the use of sildenafil in excess of the quantity limit. Our data may further underreport the actual use of sildenafil since we could not account for samples provided by physicians to patients during medical encounters.

Because the data collection period was limited to 2001, it was not possible to determine duration of sildenafil use or to categorize patients as new or established sildenafil users. Drug use patterns may differ between new and established sildenafil users, and sildenafil had been available for about 3 years at the time of the study. The population for this MCO probably included both members initiating and continuing therapy with sildenafil, as might be expected for other MCO populations.

Our attempt to determine comorbid conditions in the study population was limited since medical claims were not found in 2001 for all sildenafil users; for example, a sildenafil user could have had a medical encounter prior to the 2001 study period. The medical record information was also limited by the maximum of 3 diagnosis codes per medical claim and may therefore be
Incomplete. Other reasons for inaccurate or incomplete coding were possible, including accidental or intentional miscoding.

Lastly, at the time of our study, sildenafil was the only phosphodiesterase type 5 inhibitor on the market, and it may not be reasonable to extrapolate our findings to the current environment in which other ED therapies are now available. A recent clinical monograph on ED therapies was published in the Journal of Managed Care Pharmacy.36

CONCLUSIONS

Our study found that the majority of members who used sildenafil were between the ages of 40 and 69 years and had a medium to high risk for a cardiovascular event based on an adaptation of the classification system in the NCEP ATP III guideline for treatment of dyslipidemia. A quantity limit of 6 tablets of sildenafil per 30-day period was associated with a drug cost to users and the MCO of $0.25 PMPM. Sildenafil users paid an average cost-share of 26.6%, resulting in a net drug cost of $0.18 PMPM to the MCO. The impact of sildenafil on the MCO’s pharmacy budget was 0.5%, and 91.7% of members did not exceed their sildenafil quantity restriction.

DISCLOSURES

The authors disclose that no outside funding supported this study. Author Catherine E. Cooke is employed by Pfizer Inc., the manufacturer of sildenafil. Author Winston Wong discloses that he has received honoraria from and served on the advisory board of Pfizer Inc.; author Helen Lee discloses no potential bias or conflict of interest relating to this article. Cooke served as principal author of the study. Study concept and design were contributed primarily by Cooke and Wong. Analysis and interpretation of data were contributed by all authors. Drafting of the manuscript was primarily the work of Cooke and Lee, and its critical revision was the work of all authors. Statistical expertise was contributed by Cooke.

REFERENCES


