Evaluation of the Costs to Medicare of Covering Therapeutic Shoes for Diabetic Patients

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OBJECTIVE — A three-year demonstration was fielded in three states to evaluate the cost to Medicare of a therapeutic shoes benefit for Medicare Part B beneficiaries with severe diabetic foot disease.

RESEARCH DESIGN AND METHODS — Eligible Medicare beneficiaries who applied were randomly assigned to either a treatment group that received the extra therapeutic shoe coverage or a control group that received only standard Medicare coverage. This study analyzes the Medicare payments and service use of 3,428 demonstration participants in California, Florida, and New York for whom data on a 12-month follow-up period were available. These results are comparable to those for the entire sample over a variable length follow-up period that averaged 20 months but ranged from 3 months to 3 years.

RESULTS — Differences between groups are not statistically significant. However, Medicare payments for all services among the treatment group were $451 (3.8%) higher than those for all services among the control group. Similarly, Medicare payments for foot-care services were $318 (14.6%) higher among beneficiaries in the treatment group, which considerably exceeded the cost of the shoe benefit ($118).

CONCLUSIONS — The demonstration produced no definitive evidence that expanding Medicare Part B to cover therapeutic shoes for beneficiaries with severe diabetic foot disease would increase total Medicare costs. However, our findings indicate that the demonstration was successful at increasing therapeutic shoe ownership and was instrumental in increasing beneficiaries' use of the shoes when walking outdoors.

People with diabetes are at high risk of developing foot problems that may lead to amputation, an experience with high personal, medical, and social costs. People with diabetes can develop ulcers and infections as a result of painless trauma from wearing ill-fitting shoes and socks, stepping on sharp objects, or stubbing their toes. Untreated, these ulcers and infections can become gangrenous, and amputation of part or all of a foot or leg may become necessary. Clinicians who treat diabetic foot problems advise their patients to practice careful foot hygiene and to wear shoes to protect their feet from trauma. For patients with foot deformities or previous ulcerations, clinicians often prescribe special shoes.

A demonstration of a Medicare Part B therapeutic shoe benefit for diabetic Medicare beneficiaries was mandated by Congress in 1987 (1). The legislation specified the beneficiary eligibility requirements, the types of shoes covered and the prices Medicare would pay: $316 for custom-molded shoes and $158 for depth-inlay shoes (including customized inlays), and the types of physicians and suppliers who could participate in the demonstration. Congress mandated that Medicare Part B coverage for therapeutic shoes would become permanent if it could not be demonstrated that the benefit was not cost-effective. With this criterion, Congress sought to introduce a benefit that might save money (or provide better outcomes for beneficiaries at no increase in cost), as long as there was not clear evidence to the contrary. Accordingly, we designed the evaluation of the demonstration to estimate the effects of the extra shoe coverage on Medicare costs but not to estimate the clinical effectiveness of the therapeutic shoes.

Medicare costs for diabetic foot care are high because diabetes is widespread among all three groups of individuals who have coverage for Medicare Part B services (which primarily includes physician care). Nationwide, we estimate there were 3.5 million Medicare beneficiaries with diabetes in 1990 (10% of the aged, 21% of the disabled, and 33% of the end-stage renal disease program beneficiaries). Using findings from one study of adult-onset diabetes in Wisconsin, we es-

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HCFA, Health Care Financing Administration; OLS, ordinary least-squares.

timated that about one of every six Medicare beneficiaries with diabetes and Part B coverage have foot disease, measured by ever having had a foot ulcer (2).

Estimates of lower-extremity amputations among aged diabetic Medicare beneficiaries nationally range from 12,400 in 1984 to 38,000 in 1987 (4; personal communication from ADA). Mortality rates for individuals who have had lower-extremity amputations are high. Reported mortality rates 5 years after amputation range from 41 to 70% (2,5,6).

If therapeutic shoes are clinically effective (for which there is limited evidence), they may prevent ulcers and help to avert costly hospital stays for ulcer treatment and amputation (7). Recent estimates put the average charge per hospital stay for diabetic diseases of the lower-extremity arteries (including skin ulcers and gangrene) at $12,730 (8) and the average Medicare payments for lower-extremity amputations at $12,230 (9).

The therapeutic shoe demonstration was implemented largely according to the legislative specifications and operated from 1 August 1989 to 31 October 1992, in California, Florida, and New York (10). The benefit was limited during the demonstration to beneficiaries who resided in the three demonstration states, were not enrolled in a Medicare health maintenance organization, and were assigned to receive the extra therapeutic shoe coverage. Our design called for 27,500 eligible beneficiaries to apply for the shoe benefit (about one-fifth of the estimated number of eligible beneficiaries in the three states), but only 4,373 actually applied. Publicity about the benefit focused on both physicians and potentially eligible beneficiaries. Two campaigns were mounted, one before and one during the demonstration. The campaigns made use of direct mailings, inserts in newsletters, and conference handouts, and included mailings to physicians by their professional associations.

To provide the most precise estimate of the impact of the benefit on Medicare costs, the demonstration used an experimental design to assign eligible applicants randomly in equal numbers to either the treatment group, which received the extra therapeutic shoe coverage, or the control group, which received only standard Medicare coverage. Control group members could still purchase the shoes with their own money. Limitations of this study were the short follow-up period over which costs could be measured and the limited information on the clinical health status of the beneficiaries at randomization.

Given the congressional mandate, we focused on cost neutrality from the perspective of Medicare payments rather than adopting a comprehensive cost-effectiveness analysis. Our formal hypothesis test was whether we could reject the null hypothesis that, under the demonstration, costs were lower than or equal to what they would have been without the intervention. The benefit would not be cost-neutral if the net cost to Medicare of providing the therapeutic shoes significantly exceeded zero, that is, if the gross cost of covering the shoes exceeded any savings from a reduction in the use of other Medicare services (such as hospital stays) that would arise if the therapeutic shoes help prevent new foot problems.

The costs of the therapeutic shoe demonstration include the costs of the shoes, any physician costs that would not otherwise have been incurred (such as a special visit to ask a physician to prescribe or fit the shoes), and any costs of care received under a comprehensive plan of care for diabetes that exceeded those that would have been incurred in the absence of the demonstration. The monetary benefits expected from the therapeutic shoe demonstration were a reduction in foot-care costs (from a reduction in the number of infections and amputations). The purpose of the evaluation was not to determine whether therapeutic shoes are clinically effective, although the shoe benefit would probably not reduce costs or be cost-neutral if the shoes were not clinically effective.

RESEARCH DESIGN AND METHODS

Study sample

The 4,373 applicants were enrolled in the demonstration for an average of 20 months. We analyzed the Medicare payments and service use of the full sample and three subsamples, providing a different length of follow-up for each sample. Because the results were consistent across samples, we present results from the sample providing a 12-month follow-up period. This sampling period permitted us to study the experience of 3,428 beneficiaries (1,711 in the treatment group and 1,717 in the control group) who applied by 25 August 1991 and were randomized by 30 September 1991, during the 12-month period after they applied for the benefit.

Outcomes evaluated

We studied the differences in the total Medicare payments (including Part A and Part B covered services) between the treatment and control groups for 12 months after they had applied for the therapeutic shoe benefit. We also compared the total, Part A, and Part B foot-care payments between the treatment and control groups.

Because hospital admission is the highest-cost service, we also looked at hospital admissions and number of days in the hospital for the two groups for all reasons and for foot care. Therapeutic shoes are expected to prevent lower-extremity amputations, and so we also compared the lower-extremity amputation rate between the two groups. Finally, because mortality rates are high among persons who have had a lower-extremity amputation, we studied the proportion of individuals in each group who died.

Data sources

The Health Care Financing Administration's (HCFA) Medicare Automated Data Retrieval System file and National Claims History file were the sources of data on payments, hospital use, and amputations

for Part A and Part B covered services for beneficiaries enrolled in the demonstration. These data are a complete record of Medicare payments for beneficiaries not enrolled in health maintainance organizations. We allowed a minimum lag of 4 months in claims submission and payments, which would result in >90% of claims being available for analysis. However, foot-care payments were not complete, as we were unable to identify payments for foot-care provided as part of physician office visits. HCFA's Health Insurance Skeleton Eligibility Write-Off file provided data on certain demographic and Medicare-entitlement characteristics at the time of randomization: age and sex, the original reason for Medicare entitlement, and dual entitlement to both Medicare and Medicaid. This file also provides reasonably complete information on dates of death (11).

The demonstration's enrollment form asked for identifying and demographic information on the beneficiary, a description of the patient's foot conditions (on the basis of which the physician certified the eligibility of the individual for the demonstration benefit), the estimated duration of diabetes (a series of categories), previous prescriptions or recommendations for therapeutic shoes, the types of shoes currently owned, and the specialty of the prescriber. The demonstration's therapeutic shoes claims file contains the date of purchase, type of shoe supplier, and the claim amount, as well as the amount actually paid by Medicare by type of shoes, number of inserts, and types of modifications.

Finally, a telephone survey of beneficiaries was administered in May and June 1992 to 80% of all surviving Medicare beneficiaries who enrolled between 1 August 1989 and 30 June 1991. The survey asked whether respondents had special shoes, under what circumstances the shoes were worn, what other types of footwear they owned, foot problems they had experienced since acquiring the shoes, and whether and the extent to which beneficiaries adhered to the clinical management of diabetes.

Statistical analysis

Although the random assignment process yielded comparable treatment and control groups (reported elsewhere [10]), we used regression analysis to increase the precision of our estimates by reducing error variance. We used a one-tailed test of statistical significance to assess the null hypothesis that Medicare payments for the treatment group were less than or equal to payments for the control group. The direction of this test was mandated by Congress. We also used a one-tailed test to assess the null hypothesis that the service use and amputation rates for the treatment group were greater than or equal to the rates for the control group. The direction of the latter test was based on our intention to disprove the hypothesis that the shoe benefit would result in beneficiaries using Medicare services more frequently than did beneficiaries in the control group. The rejection of this hypothesis would lead us to believe that the shoe benefit reduces service use, which, clinicians suggest, is the effect of the shoes.

We conducted a subgroup analysis using F tests to assess *1*) whether the difference between the treatment group and the control group was constant across subgroups for a specific characteristic; and 2) whether the difference in Medicare payments between the two groups was equal to zero within each of the subgroups for a specific characteristic. In this instance, we used a two-tailed test because we had no directional hypothesis.

We used ordinary least-squares (OLS) to estimate the coefficients of an analysis of covariance of Medicare payments for all types of services and for foot-related procedures, controlling for confounding factors. We also used OLS to estimate impacts on other outcome variables, such as the number of hospital days, and used logistic regression models to estimate effects on the probability of experiencing a lower-extremity amputation and the probability of death during the follow-up period (12). Finally, we used Poisson regression to measure the impact of the demonstration on the number of hospital admissions (13).

Because we were interested in the effects of being in the treatment group, we estimated the differences between the two groups in the adjusted means of the outcome variables, where the adjusted outcomes are standardized means (or probabilities) calculated from the model in which the study group status was varied but other factors were held constant (e.g., duration of diabetes). Tests of the statistical significance of program effects reported are actually tests of the statistical significance of the coefficients on the treatment status variable, regardless of the type of model used (OLS, logit, or Poisson regression).

Model of selected outcomes

Our regression model included a set of sociodemographic characteristics and eligibility indicators (age, sex, race/ethnicity, state of residence, original reasons for entitlement to Medicare, and whether the individual had dual Medicare and Medicaid eligibility). The specification also included the duration of diabetes at the onset of the demonstration (a categorical variable reflecting the way the measure was collected) because foot problems increase with duration of diabetes (4). We also included a categorical measurement of clinical impairment at enrollment (that is, individuals are classified in the category that indicates the most severe foot condition present, in the following order: prior amputation, prior ulceration, and other problems, such as poor circulation, callus formation, or foot deformity with potential for ulceration) because it provided the only measure of the health status of the beneficiary at randomization. Finally, the model included the total Medicare payment for the beneficiary in the year before randomization (expressed in categorical form) because, as an indicator of recent use of health services (and indirectly a measure of recent health sta-

Table 1—*Service use during the first 12 months after shoes were prescribed for beneficiaries who enrolled between 1 August 1989 and 30 September 1991*

Outcome measure	Treatment group (n = 1,711)	Control group (n = 1,717)	Difference	P value
Average number of hospital admissions				
Total	0.86	0.89	−0.03	0.227
Foot care	0.22	0.20	0.02	0.887
Percentage of beneficiaries with a hospital admission				
Total	44.78	44.67	0.11	0.526
Foot care	15.09	14.21	0.88	0.537
Average number of hospital days				
Total	9.67	10.06	−0.39	0.287
Foot care	3.06	2.98	0.06	0.594
Percentage of beneficiaries who had a lower-extremity amputation	2.57	1.80	0.77*	0.935
Percentage of beneficiaries who died	9.13	8.03	1.10	0.884

Treatment and control group means or probabilities were calculated from OLS, Poisson, or logit regression model varying study group but keeping the following factors constant: age at randomization, sex, race, state of residence, original reason for entitlement, dual entitlement, duration of diabetes, clinical impairment at enrollment, and Medicare reimbursement in the year before randomization. P value is for a one-tailed test to assess the null hypothesis that service use for the treatment was greater than or equal to the service use for the control group. * Regression-adjusted only by age at randomization.

tus), it was also a good predictor of payments and use in the postenrollment period.

RESULTS

Beneficiary characteristics at enrollment

During the year before they enrolled in the demonstration, beneficiaries had average Medicare costs of nearly $11,000 (four times the average cost for Medicare beneficiaries nationwide). This cost is consistent with but not fully explained by the high proportion of disabled beneficiaries (30%) and end-stage renal disease program beneficiaries (nearly 4%) in the sample. The average age was 70 years.

One-quarter of the beneficiaries had previously experienced a lower-extremity amputation, and 59% had previously had a foot ulcer. Three-quarters had deformed feet with potential for ulceration.

Shoe ownership and use

The survey results indicate that the Medicare coverage for therapeutic shoes increased the ownership of these shoes among participating beneficiaries, especially the more expensive custom-molded shoes. When they entered the demonstration, 32% of both the treatment group and the control group owned therapeutic shoes. By the time of the follow-up survey, almost 3 years after the demonstration began, 85% of the treatment-group members reported owning therapeutic (either custom-molded or depth-inlay) shoes, compared with 55% of control-group members. This difference is significant (with a P value of essentially zero) and can be attributed confidently to the effect of the demonstration.

Although the therapeutic shoe benefit provided the economic resources necessary to enable Medicare beneficiaries to purchase the shoes, any cost impact of the demonstration benefit depended on whether the beneficiaries wore the shoes. To identify whether the demonstration had the intended effect of increasing therapeutic shoe use, we asked beneficiaries when and where they wore the prescribed shoes.

In assessing therapeutic shoe use, we first examined how much the beneficiaries in the demonstration walked outdoors. Survey data indicate that ~6% in each group could not walk at all and that another 10% in both groups reported walking only indoors. Thus, ~16% of all beneficiaries in the sample did not walk outdoors at all and, hence, had less need to wear therapeutic shoes than those who did walk outdoors.

Among the 83% of the sample members who did walk outdoors, a striking (and statistically significant) difference in shoe use was found. (No information was available for about 1% of the sample on whether they walked.) Treatment-group members were almost 70% more likely to use therapeutic shoes when walking outdoors than were control-group members (61% of the treatment group reported wearing therapeutic shoes when they walked outside the house, compared with 37% of the control group). This difference in shoe use appears to be largely because of the effect of the demonstration on increased ownership of therapeutic shoes. Participation in the demonstration did not increase shoe use independently of its effect on shoe ownership. (Shoe-use rates were comparable among shoe owners in the treatment and control groups.)

Differences in hospital admissions, amputations, and mortality

About 45% of both groups were admitted to a hospital at least once during their first year in the demonstration, and about one-third of those (14–15% of the whole) received Medicare-reimbursed foot-care services (Table 1). Beneficiaries were admitted an average of just less than one time (0.9) during their first year in the demonstration to a hospital and about 0.2 times for foot care.

Both groups of beneficiaries spent

Table 2—*Medicare payments during the first 12 months after shoes were prescribed for beneficiaries who enrolled between 1 August 1989 and 30 September 1991*

Outcome measure	Treatment group (n = 1,711)	Control group (n = 1,717)	Difference	P value
Average Medicare payment ($)				
Part A	7,184.46	6,957.32	227.14	0.293
Part B	5,055.61	4,949.62	105.99	0.280
Shoe benefit	117.75	—	—	—
All services	12,358.06	11,906.70	451.36	0.199
Average Medicare foot-care payment ($)				
Part A	1,968.92	1,818.71	150.21	0.222
Part B	409.30	359.66	49.64	0.147
Shoe benefit	117.75	—	—	—
All services	2,496.21	2,178.13	318.08	0.085

All services include all Part A and Part B services, including the therapeutic shoe benefit. The sum of payments for Part A and Part B services may not add up to the payment for all services due to rounding. No foot-care services could be identified from Part B records for physician office visit records and other services provided in the office. Treatment and control group means were calculated as described in Table 1. P value is for a one-tailed test of the null hypothesis that Medicare payments for the treatment were less than or equal to payments for the control group.

~10 days in the hospital on average over the 12-month follow-up period, with the average number of days for those with one or more admissions being ~23 days. For foot-care admissions, the results were comparable: 3 days in a hospital on average among both groups of beneficiaries, but close to 21 days for beneficiaries who were admitted one or more times during their first year in the demonstration. The differences between treatment and control groups are not statistically significant in any instance.

Of treatment group beneficiaries, ~2.6% had at least one lower-extremity amputation within the first 12 months after randomization, compared to 1.8% of control group members, a difference that is not statistically significant at the 5% level using a one-tailed test. Approximately 8–9% of all beneficiaries died within a year after the date of randomization. A higher proportion of beneficiaries in the treatment group than in the control group died during the study period. However, the differences are small and not significantly different statistically from zero at conventional levels.

Differences in Medicare payments

Consistent with their high hospital use and high amputation rates, participating beneficiaries' Medicare payments were ~$13,000 per year, which is about five times the payment for the average Medicare beneficiary in the national population in 1989 (14). Differences between the treatment group and the control group reveal no consistent evidence of program effects on either total Medicare payments or foot-care payments. For the first year of the demonstration, Medicare payments for all services among the treatment group were $451 (3.8%) higher than those for all services among the control group, as shown in Table 2. Medicare payments for both Part A services and Part B services were higher among the treatment group. Similarly, payments for all foot-care services were $318 (14.6%) higher among beneficiaries in the treatment group, considerably exceeding the cost of the shoe benefit ($118). In none of these comparisons is the difference statistically significant at the 5% level. Part A services comprise the largest component of payments for all services and for foot-care services (~80%).

Differences across subgroups

To assess whether the therapeutic shoe benefit is more effective for more precisely targeted subgroups of Medicare beneficiaries than for others, we reviewed differences in Medicare payments for all services and for foot-care services among subgroups of treatment and control group beneficiaries. The subgroups were defined by beneficiary age at enrollment, states of residence, the specialties of the physicians who certified eligibility, the duration of diabetes, three clinical conditions of the foot at the time of the benefit application (including prior amputation), and the reason for original entitlement to Medicare.

We found variation across subgroups in 12-month Medicare total payments and Medicare foot-care payments that correspond with expectations. Beneficiaries with end-stage renal disease had total payments more than twice as high as other beneficiaries. Beneficiaries had higher foot-care payments the longer they had diabetes, and beneficiaries who had previously had an amputation had higher foot-care (and total) payments than those with previous ulceration only. Yet, in only one set of subgroups, the original reason for Medicare entitlement, was there a statistically significant difference between treatment and control group members in Medicare payments. Of participants that originally enrolled in Medicare because of end-stage renal disease (4% of the demonstration sample), the treatment group

had significantly lower total Medicare payments over the 1-year follow-up period than did the control group. However, this difference ($7,575) was 27 times the difference in the Medicare foot-care payments for this subgroup, which suggests that the difference is not attributable to the shoe benefit, but probably is a result of variation in this very small group.

CONCLUSIONS— The demonstration was designed to test whether adding a Medicare therapeutic shoe benefit would be cost-neutral to the Medicare program. Four prerequisites for the shoe coverage to be cost-neutral were that the demonstration was implemented as planned, that beneficiaries received the shoes, that they wore the shoes after acquiring them, and that the shoes were clinically effective. Elsewhere, we showed that the demonstration was implemented largely as legislated, although participation among beneficiaries was lower than planned (10). Here, we showed that the benefit prompted a significantly larger proportion of the treatment group to acquire therapeutic shoes and to wear them outdoors, presumably because Medicare paid 80% of the price (less the annual deductible). We did not collect systematic evidence on clinical effectiveness, although there was a suggestion (inconclusive) that foot problems may have been reduced among those who wore therapeutic shoes. On balance, if the benefit is cost-neutral, the demonstration created the conditions for this effect. Although a more orderly approach would have been to determine the conditions for clinical effectiveness of the therapeutic shoes before assessing their effects on Medicare costs, the former analysis was outside the scope of our mandate.

The results of the demonstration left us with substantial uncertainty. The findings did not permit us to state confidently either that the Medicare therapeutic shoe benefit increases Medicare payments or that the benefit reduces Medicare payments. Our data suggest that the therapeutic shoe benefit did not have a significant effect on Medicare payments for foot-care services or all services, despite a preponderance of positive differences between the treatment group and the control group on several cost measures. Essentially, we found that there was a reasonable chance that the benefit was cost-neutral and that the observed estimates arose from chance differences between the treatment and control groups. Given the congressional mandate that, in the absence of clear findings showing increased Medicare costs, therapeutic shoes would become a covered benefit, therapeutic shoes were added to the Medicare Part B program on 1 May 1993.

The uncertainty of this demonstration resulted in part from the small sample available to us. Despite our goal of enrolling 27,500 eligible beneficiaries, we enrolled only 4,373 over 3 years. The reasons for this shortfall seem to lie with lack of knowledge about the role of therapeutic shoes among both beneficiaries and physicians, despite extensive publicity. As a result, the sample size was not large enough to make likely the detection of a true effect equal to the cost of the shoes. For example, if the effect of the shoe benefit were an increase in Medicare costs by the observed difference between treatment and control groups, the available sample of beneficiaries and the difference observed would provide only a 7% chance (about 1 in 14) of correctly detecting that the benefit increases Medicare payments.

Conclusions about the effect of the shoe benefit on Medicare costs depend on the type of error policy-makers prefer to avoid. The therapeutic shoe benefit was implemented because, as Congress mandated, we found no strong evidence that it increases Medicare costs. However, if Congress had mandated that the benefit would be implemented only if we found it did not increase Medicare costs, we would have tested whether beneficiaries eligible for the shoe-coverage benefit would have higher average Medicare payments than beneficiaries not eligible for the shoe-coverage benefit. The evidence presented here would not have permitted us to reject this hypothesis. We would not have been able to reject confidently the possibility that the shoe benefit did not increase costs. As a consequence, we would have failed to show that the demonstration was cost-effective and, accordingly, the benefit would not have become covered by Medicare Part B.

Nevertheless, the evaluation of this demonstration provided the first estimates of the rates of ownership of therapeutic shoes by a diabetic population that knows about the importance of the shoes, indicated that reducing the cost of the shoes through a Medicare benefit would substantially increase ownership and use of therapeutic shoes, and provided estimates of the effect of shoe coverage on Medicare costs.

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