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TECHWATCH

How Medicare's Payment Cuts For Cancer Chemotherapy Drugs Changed Patterns Of Treatment

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ABSTRACT **The Medicare Prescription Drug, Improvement, and Modernization Act, enacted in 2003, substantially reduced payment rates for chemotherapy drugs administered on an outpatient basis starting in January 2005. We assessed how these reductions affected the likelihood and setting of chemotherapy treatment for Medicare beneficiaries with newly diagnosed lung cancer, as well as the types of agents they received. Contrary to concerns about access, we found that the changes actually increased the likelihood that lung cancer patients received chemotherapy. The type of chemotherapy agents administered also changed. Physicians switched from dispensing the drugs that experienced the largest cuts in profitability, carboplatin and paclitaxel, to other high-margin drugs, like docetaxel. We do not know what the effect was on cancer patients, but these changes may have offset some of the savings projected from passage of the legislation. The ultimate message is that payment reforms have real consequences and should be undertaken with caution.**

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 substantially reduced reimbursements for outpatient chemotherapy drugs. Prior to the act's passage, Medicare reimbursed such drugs at the lesser of the charge billed for the drugs, or 95 percent of the average wholesale price (AWP) of the drugs.[1] Many drugs were widely available to physicians at costs averaging 13–34 percent below the average wholesale price, and some agents were priced significantly lower.[2] (At the same time, Medicare paid what many oncologists viewed as a below-cost fee for them to administer the drugs.) The net effect was that physicians and outpatient clinics administering the drugs were able to "buy" them on the open market at one price and "sell" them to Medicare patients at a higher price.

The large discrepancy between payment rates and acquisition costs for these drugs was identified as early as 1997.[3] The then-named General Accounting Office, now the Government Accountability Office, reported widely available discounts of about 20 percent below average wholesale price for two drugs, carboplatin and paclitaxel, in 2001.[4] A later analysis calculated that reimbursement for paclitaxel in 2004 was six times higher than actual cost.[2] These reports documented that these chemotherapy purchase prices were well below Medicare reimbursement rates.[3,4] As a result, the Medicare reform law aimed to lower Medicare spending by reducing reimbursements for specific drugs. It also aimed to reduce the incentive to prescribe certain drugs that afforded particularly higher margins for the doctors and clinics but did not offer any clear clinical advantage for patients.

Under the law, starting 1 January 2004, Medicare first lowered reimbursements on the drugs from 95 percent to 85 percent of average wholesale price as of 1 April 2003. Then, on 1 January 2005, Medicare instituted a new payment system based on a so-called average sales price. Under

this system, Medicare reimburses chemotherapy agents based on manufacturers' average national sales prices over the previous two quarters plus 6 percent to ensure adequate reimbursement to providers facing above-average drug costs. Medicare also began paying physicians an increased fee for administering the drugs, to better approximate physicians' and clinics' actual costs.

The new payment system set chemotherapy reimbursements at 1.06 times the average costs of the drugs. This rate represented a notable decline from the 2004 weighted average payment-to-cost ratio of 1.22.[2] Comprehensive estimates of what this ratio was prior to 2004 are unavailable, but it was likely higher since reimbursement as a percentage of average wholesale price was higher.

The implicit reduction in margins for oncology drugs raised important concerns about cancer treatment.[5] Many feared that the legislation's reimbursement change would reduce access to cancer chemotherapy for Medicare beneficiaries. Community oncologists worried that the law would make it too unprofitable to treat cancer patients, forcing them to shift some beneficiaries from their offices to hospitals, where the patients might face treatment delays.[6]

Previously published studies have found no evidence that cancer patients on Medicare experienced delays in chemotherapy treatment.[7,8] To date, however, no work has formally assessed whether the likelihood of receiving chemotherapy in the first place has changed, or whether the administered agents have changed. Our study was designed to determine the answers.

Study Data And Methods

DATA SOURCE We used Medicare claims data for beneficiaries with newly diagnosed lung cancer to analyze changes in treatment before and after the January 2005 implementation of the new payment system. We focused on lung cancer because it is the leading cause of death from cancer in the United States;[9] because patients are relatively homogenous from a clinical standpoint; and because chemotherapy itself is a standard treatment option for these patients, particularly for those with advanced disease.[10]

We studied five drugs in common use singly or jointly for lung cancer: carboplatin, paclitaxel, etoposide, docetaxel, and gemcitabine HCl. We did not assess the effect of the more modest January 2004 change from 95 percent to 85 percent of average wholesale price.

STUDY POPULATION We started with a cohort of all beneficiaries having at least one claim with a lung cancer diagnosis (*International Classification of Diseases*, Ninth Revision, or ICD-9, codes 162.0–162.9) in Medicare's Outpatient or Carrier Files between 2003 and 2005. To confirm lung cancer, we restricted our sample to two types of beneficiaries. One was those who experienced either more than one noninstitutional claim with a lung cancer diagnosis from a carrier, for durable medical equipment, or for an outpatient charge, separated by at least 28 days but no more than 365 days. The other was beneficiaries having at least one institutional claim with a lung cancer diagnosis, such as from a hospice. We imposed these restrictions to exclude patients with incorrectly entered ICD-9 codes or who were undergoing evaluation for lung abnormalities that were subsequently deemed benign.[11] The final cohort included 222,478 beneficiaries with a confirmed diagnosis between 2003 and 2005 (see Technical Appendix for details).[12]

STATISTICAL ANALYSIS We first analyzed monthly utilization patterns to discern whether the January 2005 switch to average sales price–based reimbursement generated discontinuities in treatment. We studied patients diagnosed up to twenty-four months before and ten months after January 2005. We excluded cases diagnosed between November and December 2005 because of incomplete claims data.

We plotted, by month of diagnosis, regression-adjusted average changes in the likelihood that a newly diagnosed lung cancer patient received any chemotherapy treatment, chemotherapy treatment in a physician's office, and treatment with specific agents conditional on receiving any chemotherapy, all within thirty days of diagnosis. To compare utilization changes more directly to the payment change for a given agent, we analyzed drugs separately, even though most are given in combination. As described in the Technical Appendix,[12] the regression adjusted for a host of patient demographics such as age, race, and sex. We used the month as a unit of observation for ease of visual interpretation.

To estimate the magnitude of treatment changes more precisely, we used a similar regression with the week as the unit of observation (see Technical Appendix).[12] To increase confidence that our estimates were causally related to the Medicare Modernization Act and not to preexisting trends, we estimated models using progressively smaller windows around average sales price implementation. These included twenty-four months before and ten months after, twelve months before and ten months after, and nine months before and ten months after implementation.

A complication is that carboplatin went off patent in October 2004, the quarter before average sales price implementation. Because of the lag in average sales price determination—

1.06 times

Average Cost Of Drugs

The Medicare reform law set chemotherapy reimbursements at 1.06 times the average sales price of each drug in the previous two quarters. In 2004 the average weighted payment-to-cost ratio had been 1.22.

quarterly reimbursements are based on wholesale prices in the previous two quarters—it is likely that carboplatin maintained a margin above the 6 percent mandated by the legislation for some months after January 2005. As a sensitivity check, we therefore also examined chemotherapy use with regimens not containing carboplatin.

We also tested the stability of patient characteristics around the payment change. As in a randomized controlled trial, patient characteristics and the number of new diagnoses should look similar just before and after average sales price implementation.

Study Results

SUMMARY CHARACTERISITCS Exhibit 1 provides characteristics of our analytic sample and monthly reimbursement rates for chemotherapy agents commonly used for lung cancer (see Technical Appendix for rate calculations).[12]

Median age at diagnosis was seventy-four years old. Just over half of patients were male, and about 88 percent were white. Although some changes in characteristics after average sales price implementation are statistically distinguishable from zero, none is meaningful in magnitude.

Payment rates for carboplatin, paclitaxel, and etoposide declined dramatically after average sales price implementation. However, payment rates were relatively flat for docetaxel, a high-price drug at about $2,500 per standardized monthly dose, and gemcitabine HCl, at $1,300 per monthly dose.

Changes were most striking for carboplatin and paclitaxel. Reimbursement rates for a standard monthly dose declined from $1,845 to $930 for carboplatin and from more than $2,270 to $225 for paclitaxel.

Exhibit 2 shows the time pattern of payment changes, confirming that the changes for carboplatin and paclitaxel occurred around the time of the new payment system's introduction. Carboplatin's patent expiration in October 2004 may account for some of its change, particularly the sharp decline between the first quarter (time 0) and the second quarter of 2005, when average sale price was based on two quarters of off-patent

EXHIBIT 1

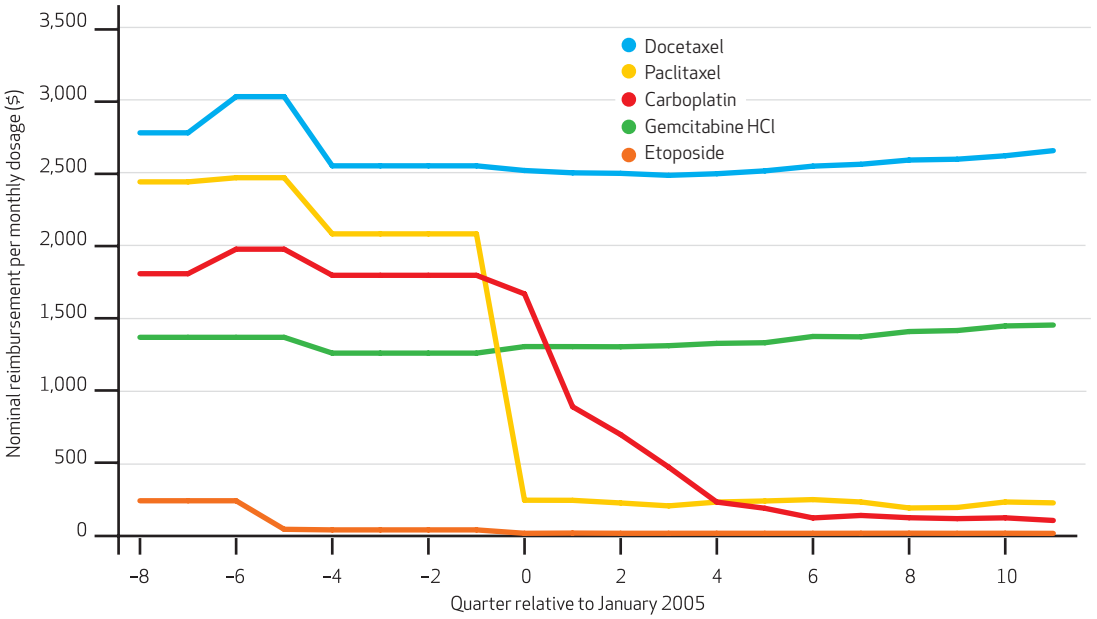
Characteristics Of The Study Sample Overall And Relative To The January 2005 Payment Change

Characteristic	Overall	Before payment change	After payment change
Age at diagnosis (years)	74.1 (8.29)	74.1 (8.26)	74.0 (8.37)
Percent male	51.6	51.9	51.1
Percent white	87.8	87.8	87.8
Percent African American	8.9	9.0	8.8
Percent Asian	1.1	1.0	1.1
Percent Hispanic	1.0	1.0	1.0
Deyo-Charlson score	1.05	1.03	1.08
Percent with metastasis within 1 month	28.6	28.7	28.5
REIMBURSEMENT RATES PER STANDARD MONTHLY DOSE ($)			
Carboplatin	1,540 (153)	1,845 (29)	930 (261)
Paclitaxel	1,590 (294)	2,272 (70.9)	225 (9.28)
Docetaxel	2,657 (58.4)	2,732 (74.8)	2,506 (6.87)
Etoposide	77.6 (27.8)	111 (36.8)	11.4 (0.369)
Gemcitabine HCl	1,311 (13.5)	1,313 (20.6)	1,305 (1.71)
PERCENT RECEIVING CHEMOTHERAPY WITHIN 1 MONTH			
Any treatment	17.3	16.5	18.9
Any treatment excluding carboplatin	7.8	7.3	8.8
Treatment in a physician's office	13.7	13.0	15.3
AMONG PATIENTS TREATED WITH CHEMOTHERAPY WITHIN 1 MONTH, PERCENT RECEIVING			
Receiving carboplatin	55.1	55.9	53.7
Receiving paclitaxel	28.7	30.0	26.2
Receiving docetaxel	9.4	9.2	9.7
Receiving etoposide	21.0	21.3	20.5
Receiving gemcitabine HCl	9.6	10.3	08.4

SOURCES Claims data from the Centers for Medicare and Medicaid Services. **NOTES** The sample includes Medicare beneficiaries with a confirmed lung cancer diagnosis between January 2003 and October 2005. Associated claims data are available for 2002–2006. The "after" period is January–October 2005. Standard deviations are in parentheses. "Any treatment excluding carboplatin" means that a patient was treated with chemotherapy and the patient received no carboplatin. The Deyo-Charlson score is a comorbidity index, which we measure in the year prior to a cancer diagnosis. Standard deviations are in parentheses.

EXHIBIT 2

Change In Nominal Quarterly Chemotherapy Reimbursement Rates Relative To The January 2005 Payment Change



SOURCE Centers for Medicare and Medicaid Services Average Sales Price Drug Pricing Files.

prices. The gradual decline in carboplatin's payment rates, which may also capture continued switching to generics, suggests that it maintained a margin above 6 percent of the average sales price for longer than paclitaxel did.

CHANGES IN TREATMENT The raw data show that prior to January 2005, 16.5 percent of patients received chemotherapy within one month of diagnosis. After implementation of the new payment system, chemotherapy treatment within one month increased 2.4 percentage points ($p < 0.001$) to 18.9 percent (Exhibit 1). Nearly two-thirds of this increase (1.5 percentage points) was among patients receiving regimens without carboplatin. Moreover, this increase came almost entirely from treatment in physicians' offices. Although 13 percent of patients received chemotherapy in a physician's office within one month of diagnosis prior to January 2005, 15.3 percent did so afterward.

Among those treated with chemotherapy, the percentage receiving carboplatin declined from almost 56 percent to 54 percent, and the percentage receiving paclitaxel declined from 30 percent to 26 percent, consistent with the large decline in payment rates for these agents. In other words, physicians were prescribing these drugs to a smaller share of chemotherapy-treated patients than before because there was far less financial inducement to use them. Because carboplatin and paclitaxel are often given in combination, and because carboplatin probably retained a margin above 6 percent of average sales price for a few quarters because of the lag in prices used to determine average sales price, some of carboplatin's decline may have been driven by the sharp reduction in paclitaxel's profitability. By contrast, trends in use of docetaxel and etoposide were comparatively flat.

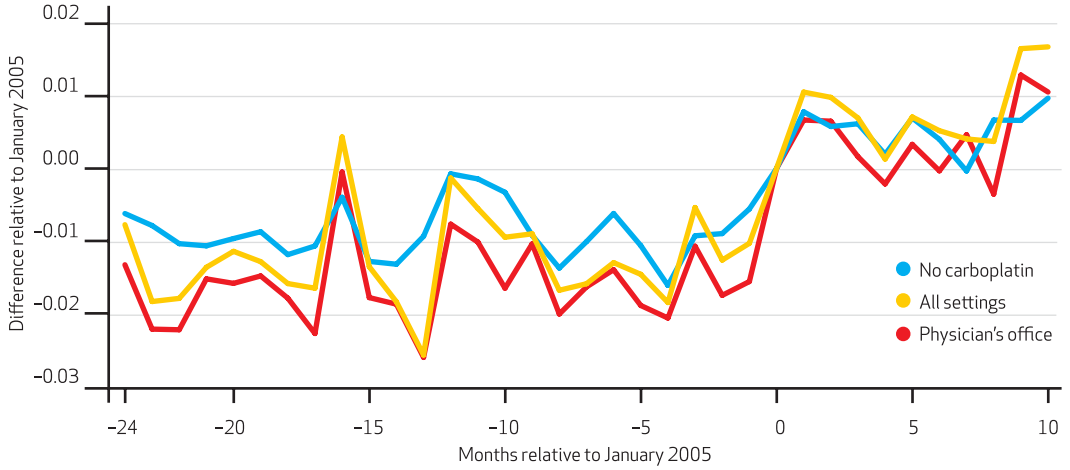
Exhibit 3 graphically illustrates regression-adjusted mean changes in the likelihood that patients received any chemotherapy at all, any chemotherapy regimen excluding carboplatin, and chemotherapy in a physician's office, by month of diagnosis relative to January 2005. (See the Technical Appendix for separate graphs by outcome and with 95 percent confidence intervals around the estimates).[12] As evident in the jumps at time 0, the likelihood of chemotherapy treatment increased after January 2005.

The timing of the increase strongly suggests that the switch to the average sales price system drove the change. The similarity across outcomes confirms that the increase in treatment is not driven by the sustained margin on carboplatin and that most of the increase in chemotherapy treatment occurred in physicians' offices.

Exhibits 4 and 5 show regression-adjusted changes in the probability that chemotherapy-treated patients received carboplatin, paclitaxel, docetaxel, etoposide, and gemcitabine HCl, which are the most commonly prescribed agents in our sample. (See the Technical Appendix for

EXHIBIT 3

Change In The Share Of Beneficiaries Given Chemotherapy, By Month Of Diagnosis Relative To The January 2005 Payment Change



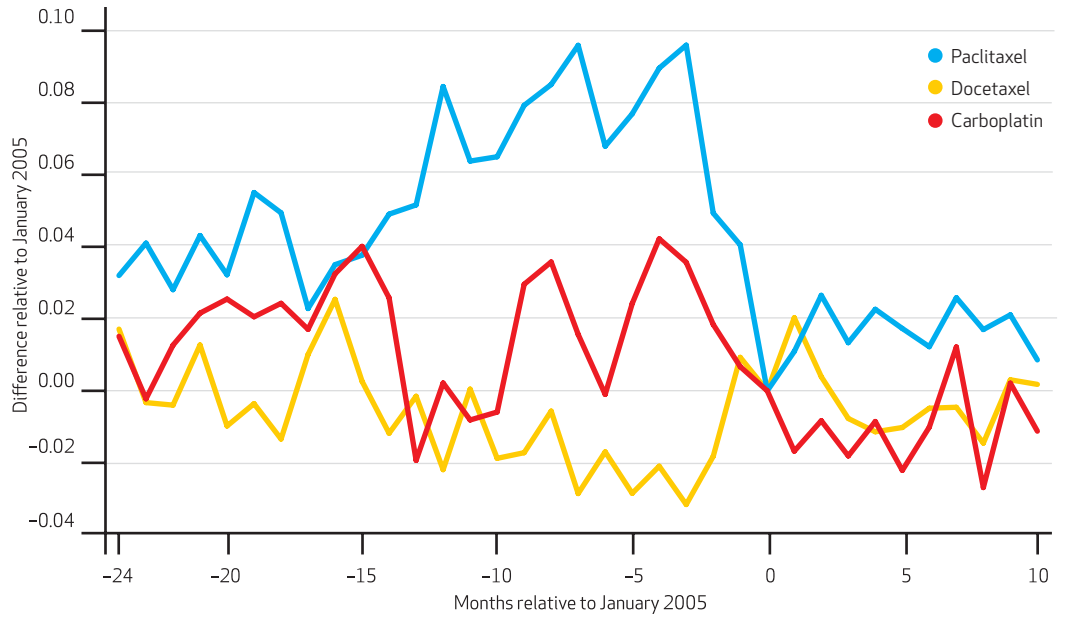
SOURCES Centers for Medicare and Medicaid Services Average Sales Price Drug Pricing Files; and Medicare claims data for beneficiaries with newly diagnosed lung cancer.

separate graphs by agent and with the estimated 95 percent confidence intervals).[12] Although more patients received chemotherapy after the new payment system was implemented, treated patients were less likely to receive a mix of agents that included carboplatin or paclitaxel than other agents.

The timing of the sustained decline in use of these agents preceded the introduction of the average sales price payment system by a few months. The Medicare Modernization Act was passed more than a year before the implementation of the average sales price system. Presumably physicians knew that the reduction in

EXHIBIT 4

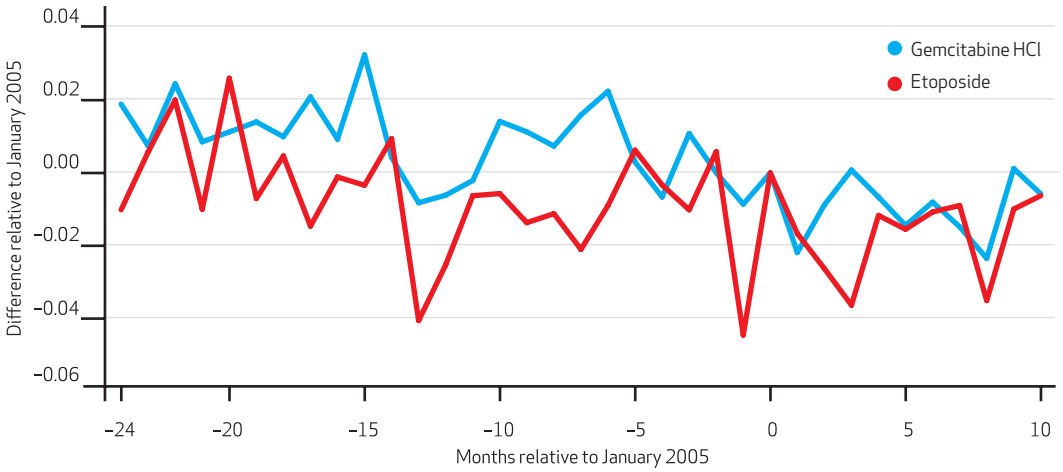
Change In The Use Of Paclitaxel, Docetaxel, And Carboplatin, By Month Of Diagnosis Relative To The January 2005 Payment Change



SOURCE Centers for Medicare and Medicaid Services, Medicare claims data for beneficiaries with newly diagnosed lung cancer.

EXHIBIT 5

Change In The Use Of Gemcitabine HCl And Etoposide, By Month Of Diagnosis Relative To The January 2005 Payment Change



SOURCE Centers for Medicare and Medicaid Services, Medicare claims data for beneficiaries with newly diagnosed lung cancer.

payment rates for these drugs would be large and were reducing their reliance on them in advance. Failure to do so could have meant a considerable loss of income.

In contrast, the probability of receiving docetaxel, a relatively expensive agent implicitly favored by the 6 percent margin on all drugs, increased modestly for patients receiving chemotherapy treatment. The increase preceded the change in reimbursement by about a month, further suggesting that physicians were rearranging their stock of agents in anticipation of the average sales price system. The likelihood of receiving etoposide or gemcitabine HCl and other less commonly used agents did not change systematically.

Exhibit 6 quantifies the changes illustrated in Exhibits 3–5, using weekly data and controlling for patient characteristics and cyclical patterns in treatment. When we used 104 weeks (24 months) of data from before implementation of the new payment rules, the likelihood of receiving chemotherapy within a month of diagnosis increased 1.9 percentage points (column 2) after the change. This represents an increase of more than 10 percent of newly diagnosed lung cancer patients. Narrowing the study window to nine months before and ten months after January 2005 reduced the estimated increase to 1.6 percentage points. This increase was concentrated in regimens without carboplatin (row 3) and in regimens administered in a physician's office (row 4).

Rows 5–9 show adjusted changes in the agents administered to patients receiving chemotherapy treatment. As a share of all agents, physicians were less likely to give patients carboplatin or paclitaxel after average sales price implementation. The probability that chemotherapy-treated patients received carboplatin declined about three percentage points. The estimates were stable across all of the time frames of our sample.

The decline in the probability of receiving paclitaxel was more dramatic. Over the whole sample period, it declined 4.3 percentage points, or about 14 percent overall. This estimate increased as the time frame narrowed. Some physicians switched patients to docetaxel; the likelihood that patients received docetaxel increased 1.2–1.8 percentage points. Although the absolute change was small, off a base of only 9.2 percent of patients receiving docetaxel prior to January 2005, this represents a large, 13–20 percent, relative increase in use. Estimates for etoposide and gemcitabine HCl are listed as well, but the exhibits suggest that these declines were driven by preexisting trends.

Discussion

Despite initial concerns, we found no evidence that the Medicare Modernization Act's reduction in reimbursement rates reduced beneficiaries' access to chemotherapy treatment. This finding is consistent with prior work analyzing a 5 percent sample of Medicare claims that found no significant change in travel distance or wait times for those receiving chemotherapy after the implementation of the average sales price system.[7]

It is also consistent with a study of a sample

13–20%

Increase In Docetaxel Use

The share of chemotherapy-treated patients receiving docetaxel, a high-price drug, rose 13–20 percent from levels before January 2005, when the payment change took effect.

EXHIBIT 6

Estimated Changes In Chemotherapy Treatment After the January 2005 Payment Change

	Mean, before January 2005	Estimated change across different windows (percentage points)		
		Jan 03–Oct 05	Jan 04–Oct 05	Apr 04–Oct 05
Number of observations (weeks)	104	155	100	76
SHARE OF PATIENTS RECEIVING CHEMOTHERAPY TREATMENT				
Within 1 month of diagnosis	16.5%	1.9 (0.2)	01.8 (0.2)	1.6 (0.2)
Excluding carboplatin	7.3	1.8 (0.2)	1.6 (0.1)	1.3 (0.1)
In a physician's office	13.0	1.8 (0.1)	1.7 (0.1)	1.5 (0.1)
SHARE OF CHEMOTHERAPY-TREATED PATIENTS RECEIVING				
Carboplatin	55.8%	−3.1 (0.5)	−3.2 (0.7)	−3.6 (0.5)
Paclitaxel	30.0	−4.3 (1.0)	−5.8 (0.3)	−7.0 (0.4)
Docetaxel	9.2	0.5 (0.7)	1.2 (0.3)	1.8 (0.1)
Etoposide	21.3	−1.2 (0.4)	−0.8 (0.2)	−1.3 (0.4)
Gemcitabine HCl	10.3	−2.2 (0.4)	−1.8 (0.4)	−1.2 (0.3)

SOURCE Claims data from the Centers for Medicare and Medicaid Services. **NOTES** Means in column 1 are for the dependent variable for the period before average sales price implementation, January 2003 to December 2004. All cells in columns 2–4 present estimates from separate time-series regressions. Estimates are the coefficients on an indicator for the period that the average sales price payment scheme was in effect. Regressions control for mean patient characteristics (see Exhibit 1) and calendar month fixed effects. Newey-West standard errors allowing for autocorrelation up to fifty-two-week lags are in parentheses.

of chemotherapy-treated cancer patients that found no change in median wait times to first administration or in the setting of administration of chemotherapy.[8] These studies, however, did not assess whether the Medicare Modernization Act affected the likelihood of chemotherapy treatment.

We found that chemotherapy treatment rates increased among lung cancer patients in response to the new payment system. This finding was foreshadowed by two Medicare Payment Advisory Commission reports indicating that oncologists increased the volume of chemotherapy administered in their offices after the implementation of average sales price reimbursements.[5,13]

COMPARED TO PRIOR FINDINGS Our findings are consistent with a large health economics literature. The literature theorizes, and finds, that when fees that affect a large share of physicians' incomes decline, utilization increases (a "negative" relationship between utilization and fee changes). However, the literature also theorizes and finds that when fees that affect a small share of physicians' incomes decline, utilization falls (a "positive" relationship.).[14–20]

Because Medicare-reimbursed chemotherapy is a large share of oncologists' income,[21] this theory predicts that the Medicare Modernization Act's fee reduction would generate an increase in use, as we observed. Fee changes for any specific agent, however, affect a smaller share of income. The decline in reliance on paclitaxel is consistent with the large reduction in its profitability.[22] The shift to docetaxel is also consistent with the incentive from a 6 percent margin over average sales price, since docetaxel is among the highest-price agents.

STRENGTHS OF THE STUDY This study is the first to assess whether the Medicare Modernization Act changed the likelihood that beneficiaries received chemotherapy treatment. The strength of our study is its access to all Medicare claims, thus generating a reliable picture of changes in treatment by month of diagnosis before and after average sales price implementation.

STUDY LIMITATIONS At the same time, our study has several limitations. Claims data may contain inaccuracies. They do not capture beneficiaries enrolled in Medicare managed care, although this limitation excluded only 5 percent of the beneficiaries in our original sample. Moreover, they lack clinical detail such as whether chemotherapy is given before (neoadjuvant) or after (adjuvant) a primary treatment such as surgery.

Our study has other limitations. Results may not generalize to cancer types other than lung cancer. We did not observe chemotherapy acquisition costs and, thus, don't know the size of the margins physicians earned on the drugs. The average sales price–based payment rate is based on average drug acquisition costs, but with a two-quarter lag. For most agents, payment rates have been stable since January 2005, which suggests that margins quickly converged to 6 percent above average transaction prices. Margins for carboplatin, which went generic in October 2004, remained higher for at least one quarter. Nonetheless, carboplatin accounted for little of the observed increase in treatment.

Chemotherapy treatment rates increased among lung cancer patients in response to the new payment system.

Because of the before-after design, we could not control for unobserved, time-varying factors affecting treatment. For example, Medicare began to cover bevacizumab (Avastin), a breakthrough drug,[23] in January 2005, just as average sales price payments took effect. However, its use cannot account for the increase in chemotherapy treatment. Beginning January 2005, less than 0.25 percent of patients in our sample received Avastin within thirty days of diagnosis, possibly because it was approved for metastatic colorectal cancer and only received a labeling extension for lung cancer at the end of 2006.[24]

Similarly, research showing no survival difference across several chemotherapy regimens could have prompted some physicians to switch from paclitaxel to docetaxel. However, any adjustment due to these findings should have preceded average sales price implementation by several years.[25]

Even after consulting with academic oncologists who treat lung cancer, we could identify no major, coincident changes in practice patterns that plausibly explain our results. The switch to average sales price payments marked such a monumental shift in how Medicare reimbursed for chemotherapy drugs that its effect on physician prescribing undoubtedly swamped other simultaneous influences. Moreover, the timing of the observed changes in chemotherapy treatment corresponded so closely to the average sales price implementation period that these trends were almost certainly related.

CONCLUSION In sum, far from limiting access, the Medicare Modernization Act actually increased the likelihood that lung cancer patients received chemotherapy. The legislation's reduction in payment rates was also associated with relative shifts in the agents administered. These changes may have offset some of the savings projected from passage of the bill.

The increase in utilization may have important implications for the well-being of Medicare beneficiaries with cancer. Unfortunately, we cannot infer the appropriateness of treatment or health outcomes from these data. Among patients receiving chemotherapy treatment, some work suggests that the switch away from paclitaxel to docetaxel should have limited effects on outcomes, although at a considerable increase in cost.[26] Future work should determine the implications of these findings for Medicare spending and the health of Medicare beneficiaries. More generally, our work urges caution for health care payment reform. Any redesign requires an understanding of both the value of services and the impact of changing reimbursements on the use of those services. ■

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NOTES

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