

## HEALTH POLICY REPORT

## Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs

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Fifteen years ago, the only commonly used cancer drug on the market that cost more than \$2,500 per month was paclitaxel (Taxol, Bristol-Myers Squibb), which Chabner and Roberts labeled the first cancer “blockbuster.”<sup>1</sup> Today, cancer drugs that come on the market routinely cost many times that amount (Fig. 1). Several established cancer drugs have recently seen price increases, which has added to the general upward trend in prices. Nitrogen mustard, a drug that has been used to treat cancer since 1949, saw its price for a course of treatment increase by a factor of 13 between the beginning and the end of 2006 (from \$33 to \$420).<sup>2</sup>

In part because of rising prices, and in part because of increased rates of use, spending on cancer drugs has risen faster than spending in many other areas of health care. For Medicare, spending on Part B drugs — a category dominated by drugs used to treat cancer — rose from \$3 billion in 1997 to \$11 billion in 2004 (an increase of 267%), as compared with a rise in overall Medicare spending from \$210 billion to \$309 billion (an increase of 47%) during the same period.<sup>3,4</sup> The strong upward rise in cancer-drug prices and spending has provoked concern on several fronts.<sup>5,6</sup>

Patients who face life-threatening illnesses are also facing out-of-pocket costs for cancer therapies that can threaten their family's financial security.<sup>7</sup> Their physicians, trained to manage the former set of challenges, are poorly equipped to help with the latter.<sup>8,9</sup> Health economists are concerned, too, both by the rising expenditures for cancer care and because the prices of cancer drugs appear to be rising faster than the health benefits associated with them, at least in some cases. Both Schrag<sup>6</sup> and Meropol and Schulman<sup>10</sup> note such a pattern of diminishing returns in the treatment of metastatic colorectal cancer. With each advance in treatment, the magnitude of the increase in the

cost of treatment exceeded the magnitude of improvement in efficacy, thus making each treatment advance less cost-effective than the one that preceded it.

Given these concerns, it is worth assessing why cancer-drug prices and spending have risen so quickly. I believe the growth can be attributed primarily to a unique legislative and regulatory framework that shields cancer drugs (as well as a few other specialty drugs) from the strategies that health care payers such as Medicare typically use to hold down the price and utilization of drugs and other health care goods.

In this article, I illustrate this point, focusing on the Medicare program. I first review the major strategies that Medicare uses to rein in spending on health care goods such as drugs and delineate those strategies into three general categories: those that reduce utilization, those that reduce prices, and those that have both effects (Table 1). For each of the strategies, Medicare requires a particular type of administrative flexibility, which I outline. I then review the laws and regulations that specifically limit these flexibilities when it comes to cancer drugs.

### MEDICARE'S STRATEGIES FOR KEEPING DOWN COSTS

#### CONTROL OF UTILIZATION

The primary strategy Medicare uses to hold down utilization of a drug (or another health care good or service) is to limit coverage of payment for it. The program does so by actively determining in which settings the drug is or is not “reasonable and necessary” through either a single national or one or more local coverage decisions. When these coverage decisions result in restricted guidelines for the use of the drug, the result is decreased utilization. For instance, in 2007, Medicare narrowed the coverage of erythropoiesis-stimulating

agents (ESAs) for cancer treatment. Medicare limited not only the types of patients who could receive ESAs but also the clinical scenarios in which they could be used.<sup>11</sup> Amgen reported to their investors in August 2007 that changes in coverage for ESAs by the Centers for Medicare and Medicaid Services (CMS) would reduce annual sales of the company's ESA, Aranesp, from approximately \$1 billion to \$200 million among Medicare patients.

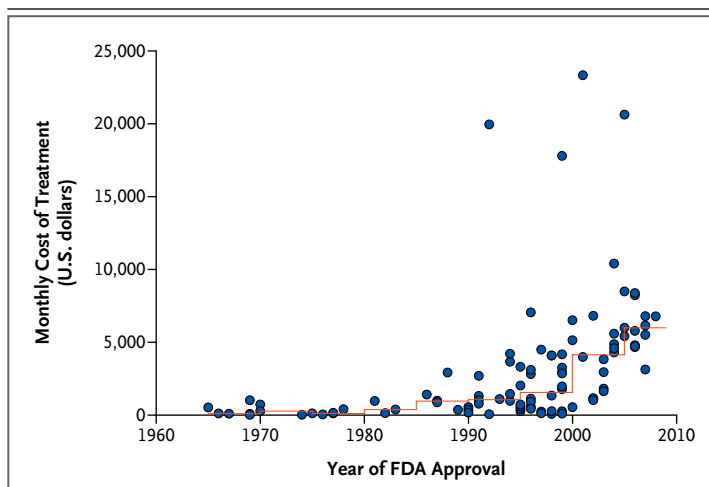
#### CONTROL OF PRICES

Medicare uses other strategies when trying to hold down the prices of drugs. All rely on the program's ability to conclude that several drugs are clinically interchangeable. Once concluded, Medicare can either encourage price competition among the manufacturers of interchangeable drugs or engage third-party intermediaries to negotiate directly with manufacturers to obtain lower prices.

Blended reimbursement is an example of the application of a reimbursement formula to groups of interchangeable drugs in order to obtain lower prices. Under this approach, Medicare reimburses for the use of a particular drug on the basis of a weighted average of prices for that drug and other similar drugs, with the weighting linked to the sales volume of each drug.

Under this approach, lower-priced drugs garner market share because their price is below the blended-reimbursement rate. As the sales of the lower-priced drugs increase and sales of the higher-priced drugs decrease, the blended-reimbursement rate declines. In July 2007, Medicare implemented blended-price reimbursement for two nebulized beta-agonist drugs that were not identical but that Medicare, through one of its contractors, deemed were clinically equivalent and thus interchangeable. Generic albuterol and branded levalbuterol (Xopenex, Sepracor) were the two drugs.

At the time the policy was implemented, the reimbursement rate for levalbuterol was higher than the rate for albuterol by a factor of 19 (\$0.20 per unit of albuterol and \$3.84 per unit of levalbuterol), whereas the blended rate was \$0.525 per unit (1 mg of albuterol or 0.5 mg of the twice-as-potent levalbuterol).<sup>12</sup> Because the reimbursement rate was higher than the purchase price of albuterol and lower than that of levalbuterol, the market shifted to albuterol. From July through September 2007 (the first quarter under blended reimbursement for the two drugs), the shift in sales lowered the blended rate by 16% (to \$0.442



**Figure 1. Monthly and Median Costs of Cancer Drugs at the Time of Approval by the Food and Drug Administration (FDA), from 1965 through 2008.**

Shown are costs for 1 month of cancer treatment for a person who weighs 70 kg or has a body-surface area of 1.7 m<sup>2</sup>. The red line indicates median prices during a 5-year period. Prices have been adjusted to 2007 dollars and reflect the total price for the drug at the time of approval, including both the amount of Medicare reimbursement and the amount paid by the patient or by a secondary payer. (For details about the costs of individual drugs, see the Supplementary Appendix, available with the full text of this article at NEJM.org.)

per unit), thus reducing Medicare's costs by the same amount. Reimbursement for the two compounds was later "unblended," so it is hard to know how much further prices would have fallen ultimately.

Similar to the strategy of blended reimbursement is that of least-costly-alternative (LCA) reimbursement. With this strategy, Medicare reimburses at the price of the least costly drug among all those that are interchangeable, no matter which drug is actually used. Manufacturers respond to LCA reimbursement by lowering prices so that their prices are not higher than the amount of reimbursement a provider can receive after administering the drug. Many of the local contractors to the Medicare program have instituted LCA reimbursement for the clinically interchangeable prostate-cancer drugs leuprolide acetate (Lupron, Abbott) and goserelin acetate (Zoladex, AstraZeneca). The Office of the Inspector General estimated that in 2002, full use of LCA reimbursement for the two drugs would have saved Medicare \$40 million, because the reimbursement rate for the least costly drug (goserelin acetate) was 27% lower than the alternative drug (leuprolide acetate).<sup>13</sup>



An interactive version of this figure is available at NEJM.org

**Table 1. Strategies Used by Medicare and Other Payers to Control Drug Prices and Spending.**

Strategy	How It Works	Example
Control of utilization through determination of coverage		
Coverage limitations or noncoverage for drug payment	By restricting coverage, the types of patients who receive the drug and the types of clinical situations in which the drug is used are both limited, thereby reducing utilization.	Restricted coverage of erythropoiesis-stimulating agents
Control of prices through determination of drug interchangeability		
Blended-price reimbursement	Because the purchasing intermediary will prefer drugs whose cost is below the blended average, the market will shift toward cheaper drugs, thus lowering the blended-reimbursement rate and the cost to the payer.	Nebulized beta-agonist drugs (albuterol, levalbuterol)
Least-costly-alternative reimbursement	The payer needs to pay only the lowest prevailing price for the least costly version of available interchangeable drugs.	Luteinizing hormone-releasing hormone drugs (leuprolide, goserelin acetate)
Competitive bidding	Manufacturers of interchangeable products lower their prices to be chosen as the supplier, thus lowering the cost to the payer.	Durable medical equipment
Control of both prices and utilization through third parties		
Prospective payment	By creating a purchasing intermediary (such as a hospital) that has a financial interest in negotiating for cheaper goods and using fewer of them, the payer's costs fall over time as the reported costs for the hospital decline through implementation of cost-containment strategies.	Inpatient hospital stays
Formulary flexibility	By creating a purchasing intermediary that has an incentive to reduce spending for drugs and the flexibility to include only certain drugs, the formulary manager can bargain with different drug manufacturers to obtain lower prices.	Part D plans

Today, it is unclear whether Medicare has the authority to establish LCA reimbursement at the national level, and its authority to do so at the local level has been thrown into doubt by a recent court decision.<sup>14</sup> In that decision, the court ruled that Medicare was required to reimburse for the combination brand-name inhaled drug Duoneb (Dey) on the basis of the price the company charged for the drug, rather than on the basis of the cost of the drug's two components, albuterol and ipratropium, which are both available as generics.

Medicare can also engage a third-party intermediary to obtain competitive bids when clinically

interchangeable drugs are available. Under competitive bidding, Medicare puts out an offer to various intermediaries to bid to supply health care goods for clinical care. These intermediaries negotiate with various competing manufacturers, using their purchasing leverage and the intrinsic competition among the manufacturers to obtain low prices. They then present to Medicare bids that reflect the cost savings they have achieved. Medicare recently completed a pilot program of competitive bidding for durable medical equipment and other supplies (such as home hospital beds, wheelchairs, and home oxygen-delivery ma-

chines). Through the bidding process, the Government Accountability Office estimated that Medicare saw a 26% reduction in prices.<sup>15</sup> A recent law (the Medicare Improvements for Patients and Providers Act of 2008) stopped Medicare from implementing competitive bidding for these goods at the national level.

#### CONTROL OF BOTH UTILIZATION AND PRICES

In general, Medicare's strategies for simultaneously holding down utilization and prices involve third-party purchasers. The prospective payment system that is used to pay for inpatient care in most hospitals is a prominent example. Under prospective payment, hospitals receive a single payment that encompasses the costs of an entire hospitalization episode for a patient. With few exceptions, the drugs, devices, hardware, and disposables that are used to care for the patient during hospitalization are paid for by the hospital with the funds included in that single payment. As such, hospitals have an incentive to obtain needed goods at lower prices and actively manage their utilization.

The prospective payment system is credited with slowing hospital expenditures for both Medicare and private payers.<sup>16</sup> Russell and Manning estimated that the savings in the first and second decade after the system was instituted were on the order of \$12 billion and \$18 billion, respectively.<sup>17</sup> A number of organizations are developing methods by which prospective payment could be instituted over an extended period of outpatient care, but there are few examples of the approach being used currently.<sup>18</sup> Some other terms that are used to describe this approach are "episode-based" payment, "case-rate" payment, and "bundled" payment.

Medicare's Part D (prescription-drug) program employs a third party to obtain drugs at low prices and manage their utilization. Under Part D, drug plans are given significant negotiating leverage when trying to obtain low prices from drug manufacturers, because their formularies need contain only a few drugs from each class of interchangeable drugs, rather than all drugs in that class.<sup>19</sup> The plans may also attach different copayment amounts to different drugs within a category, thus holding down utilization of costly drugs and steering market share toward lower-priced drugs when they are available.<sup>19,20</sup> Along with varying copayments (in which bene-

ficiaries pay a set amount for each prescription), a recent trend is to introduce coinsurance (in which beneficiaries pay a percentage of the total drug cost, rather than a set amount) for very expensive drugs.<sup>7</sup> The RAND Health Insurance Experiment and other studies have shown that increased cost sharing reduces utilization.<sup>21,22</sup>

There is general agreement that the negotiating leverage and the use of tiered copayments and coinsurance are to be credited for the fact that the Part D program is less expensive than was originally projected. For instance, plan bids for 2009 came in 37% lower than had been projected at the time the program was created.<sup>23</sup> Still, policy analysts disagree about the relative strengths and weaknesses of the program as it is currently constituted.

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#### LAWS AND REGULATIONS INHIBITING MEDICARE'S FLEXIBILITY

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##### DRUG COVERAGE

Several provisions of the law address Medicare's coverage of cancer drugs, and Medicare has traditionally interpreted these as mandates that it provide coverage, thus undoing the use of coverage restrictions to limit utilization. For cancer drugs that are covered under Part B, which are generally drugs that are administered in a physician's office, the law requires Medicare to cover any drug used in an "anticancer chemotherapeutic regimen," as long as the use is "for a medically accepted indication" (Table 2). The law defines "medically accepted indication" broadly as uses approved by the Food and Drug Administration (FDA), uses listed in one of several drug compendia, and uses supported in the peer-reviewed medical literature.

For Part D drugs, which are generally oral drugs that a patient obtains from a pharmacy, the private plans that contract with Medicare to implement the program are required to include on their formularies virtually all cancer drugs that were available at the time the program was implemented in 2006.<sup>19,24</sup> In 2008, Congress addressed the inclusion on formularies of oral cancer drugs that came on the market after 2006, amending the law to mandate that as of 2010, Part D plans must include all drugs in certain categories in which the treated condition is "major" or "life-threatening." The prototypical example listed in the law is "drugs used in the treatment

**Table 2. Laws, Regulations, and Court Rulings That Prevent Medicare from Using Strategies to Control the Prices or Utilization of Cancer Drugs.\***

Strategy	Text of Law, Regulation, or Court Ruling	Implication
Coverage limitations or non-coverage	"[Appears to require coverage of] any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication." [§1861(t)(2)(A)]	Limits national or local coverage discretion for Part B (physician-administered) cancer drugs
Blended reimbursement	"[M]ultiple source drug means . . . a drug for which there are two or more drug products which [are] rated as therapeutically equivalent under the Food and Drug Administration's [categorization] [and] pharmaceutically equivalent [and] bioequivalent." [§1847A(c)(6)(C)(i)] "[D]rug products are pharmaceutically equivalent if [they] contain identical amounts of the same active drug ingredient. . . . [They are] bioequivalent if they do not present a known or potential bioequivalence problem." [§1847A(c)(6)(F)] CMS guidance reads: For a "biological product . . . or a single source drug . . . a unique HCPCS [Healthcare Common Procedure Coding System] code will be assigned to facilitate separate payment." (Applies only to drugs coming on the market after October 1, 2003.)	Limits Medicare from combining clinically equivalent drugs into the same billing code by narrowly defining "multiple source drugs" and from combining drugs into the same code as those that are "multiple source"
Least-costly-alternative reimbursement	"[T]he Secretary [of Health and Human Services] lacks authority under §1862(a)(1)(A) to apply the least costly alternative to DuoNeb." <sup>14</sup>	Suggests that Medicare may not have the legal authority to implement least-costly-alternative reimbursement or reference pricing at the national level
Competitive bidding	"[T]he Secretary shall conduct such competition among entities for the acquisition of at least one competitively biddable drug and biological within each billing and payment code within each category." [§1847B(b)(1)]	Requires that competitive bidding for Part B drugs include effectively all new physician-administered drugs and biologics, thus limiting the negotiating leverage the bidders could hold over the drug manufacturers
Formulary flexibility	Pertaining to Part D plans at inception (2006), CMS guidance reads: "CMS will check to see that beneficiaries who are being treated with these classes of medications have uninterrupted access to all drugs in that class." [(Listed classes include "antineoplastic" drugs and five other drug classes.)] Pertaining to Part D plans as of 2010: "PDP [prescription-drug plan] sponsors offering prescription drugs shall be required [by 2010] to include all covered Part D drugs . . . where restricted access would have major or life threatening clinical consequences . . . such as drugs used in the treatment of cancer." [§1860D-4(b)(3)(G)(ii)]	Requires Part D plans to include essentially all cancer drugs on their formularies, which limits their negotiating leverage. Formulary managers can obtain lower prices only when they have the ability to forgo some drugs and include or preferentially treat others in the same clinically equivalent category.

\* The listed quotations are from Title 18 of the Social Security Act, unless otherwise indicated.

of cancer." In the case of Part D plans, both the initial regulations and the 2008 legislation carved out protections for other categories of drugs, too. Initially, Part D plans were required to include all agents within a few other treatment classes, such as antipsychotics and drugs used to treat human immunodeficiency virus infection.<sup>19</sup> In the more recent legislation, it is safe to assume that the language related to Part D drugs also extends to

treatments of a number of other "major" or "life-threatening" conditions, although the full effect has not yet been defined.

#### DRUG INTERCHANGEABILITY

A complex set of laws and regulations prevents Medicare from deeming that related cancer drugs are interchangeable, thus undoing strategies that depend on this designation (Table 2). This occurs

because the laws have two related effects. First, they classify nearly all newer cancer drugs as “sole-source” drugs. Second, they require that Medicare give each sole-source drug its own unique payment rate, which effectively requires Medicare to give each new drug its own unique billing code. These twin outcomes are the result of the legal definition of sole-source drugs versus multiple-source drugs and of the legal requirements with respect to payment and coding for the two respective drug categories (Table 2).

The law states that drugs qualify as multiple-source only if there are multiple compounds that are pharmaceutically, therapeutically, and biologically equivalent, as classified in the FDA’s Orange Book of approved drugs. This standard is strict enough to ensure that no new cancer compound will be sufficiently similar to an existing compound to be classified as a multiple-source drug. On the issue of payment and coding, the law simply states that sole-source drugs must be given their own payment rate. As a result, blended reimbursement for cancer drugs is nonexistent in Medicare, and as noted above, LCA reimbursement may be on shaky legal footing.

A related law undid a previous attempt at competitive bidding for Part B drugs. The law required that all bids contain all sole-source drugs and thus stripped the bidders of any real negotiating leverage that could have come from an ability to

designate related clinical compounds as interchangeable.

Medicare has not tried to implement prospective payment for cancer care that stretches over the course of an episode of illness. If it were to do so, it might consider providing to a treating oncologist a lump-sum payment that would cover all the costs of doctor visits, chemotherapy treatments, and the chemotherapy itself over a period of care (e.g., a lump-sum payment for a course of adjuvant chemotherapy). My interpretation of the laws governing the reimbursement of cancer drugs is that they would not allow Medicare to implement such a payment change, because the program is required to reimburse separately for the costs of each drug when it is used.

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#### PRIVATE PAYERS AND CANCER DRUGS

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Although the focus of this article is the Medicare program, it is worth noting that some state laws limit the ability of private payers to curb the utilization of cancer drugs. These laws mandate coverage of cancer drugs in many cases (Table 3).

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#### DISCUSSION

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College economics courses clarify why drug manufacturers seek both to charge high prices for their products and to encourage utilization: for-profit

**Table 3. State Legislation Affecting the Coverage of Off-Label Uses of Cancer Drugs by Private Payers.\***

Requirement	States Affected	Total Population of States Affected	Percentage of the U.S. Population Affected
Mandated coverage if use is listed in either recognized compendia or peer-reviewed medical literature	AL, AZ, AK, CA, FL, GA, IL, IN, KS, LA, ME, MD, MA, MN, MS, NE, NV, NJ, NY, OH, OR, RI, SC, SD, TN, VT	174,621,577	62
Mandated coverage if use is listed in recognized compendia only	CT, NC, OK, VA	21,984,047	8
Mandated coverage if use is supported in medical literature only	MI	9,938,444	4
Mandated coverage if use is “medically necessary” (but no other requirements)†	NH	1,235,786	<1
Total mandated coverage		207,779,854	74

\* Data are from the National Cancer Institute’s State Cancer Legislative Database Program. Population estimates are from the 2000 U.S. Census. The total U.S. population was 281,421,906 in 2000.

† A number of states include “medical necessity” as an additional standard for coverage beyond the compendia or medical-literature standards, including AL, AZ, AR, CA, FL, IL, LA, ME, MD, MA, MN, NE, NV, NJ, OH, OK, OR, RI, SD, TN, VT, and VA.

corporations have a fiduciary responsibility to their shareholders to maximize their profitability. Medicare has several strategies that counterbalance this profit-seeking behavior. But for cancer drugs and some other high-priced specialty drugs, these strategies have been disabled by laws and regulations that specifically constrain Medicare from making use of flexibilities that it has in other settings.

Policymakers are now in a quandary. To be sure, they are worried both by the increased total costs of cancer care and by the fact that high prices are leading to higher out-of-pocket expenses for patients. Yet, it is difficult for them to discount the progress that has been made overall in the treatment of cancer and to wholly disassociate that from the high prices that innovative cancer treatments are able to capture. Progress that has been made in the treatment of patients with chronic myelogenous leukemia and renal-cell carcinoma, for example, has come as a result of the discovery of new therapies that garner high prices.<sup>25,26</sup> Similarly, the doubling of the median survival time among patients with metastatic colon cancer can be attributed in large part to new treatments, which are substantially more expensive than the older treatments they displaced.<sup>6</sup> Some health economists argue for a causal link between high prices and the pace of innovation, which would suggest that efforts to reduce spending on cancer drugs would retard the pace of innovation.<sup>27-29</sup>

Thus, policymakers must decide whether they want to see lower prices and reduced spending on cancer drugs by Medicare, and if they do, they must determine how to achieve these ends without stifling beneficial innovation. One possible approach is to judiciously amend or reverse the laws that limit Medicare's flexibility with respect to cancer drugs, while moving rapidly toward the creation of a center for comparative effectiveness that could guide Medicare's actions.<sup>30</sup> Such a center could help Medicare ensure that cancer drugs are covered when their use is reasonable and necessary but are not covered when it is not. This center could also create a robust framework for classifying cancer drugs and other specialty drugs as interchangeable when they are, basing the judgment on clinical rather than pharmacologic criteria. This would achieve two ends. Manufacturers would seek to prove through clinical research that their products are not interchangeable with other

compounds on the market but, rather, are superior to their competitors. Meanwhile, Medicare and other payers could apply formulas for reimbursement that would encourage lower prices when products are in fact clinically interchangeable.

Giving Medicare the authority (or the mandate) to pursue small demonstration projects of prospective payment in cancer care could lead to an eventual alignment of incentives for both payers and providers. In part, this would help to undo some of the problematic incentives that physicians face because of the "buy and bill" system of reimbursement. Under this system, oncologists profit when they can buy a drug from a manufacturer for less than the reimbursement amount they obtain by billing for the drug after it is administered.<sup>31,32</sup> Such demonstration projects would have to include mechanisms and measurements ensuring that patients are not undertreated, an evaluation that could be achieved by monitoring whether oncologists follow practice guidelines.<sup>33</sup>

Medicare could use a number of other strategies for containing costs and utilization. For instance, UnitedHealthcare instituted prior authorization for physicians ordering trastuzumab (Herceptin, Genentech). Their chief oncology officer reported that the program would probably reduce utilization by about 15 to 20%.<sup>34</sup> "Reference pricing" is a version of LCA reimbursement in which the payer covers only the cost of the lowest-priced alternative, and patients pay the difference if they want a higher-priced item.<sup>35,36</sup> "Payment for results" is a somewhat new idea that involves reimbursement for a drug by the payer only when it "works." One prominent example: under a preliminary agreement, Britain's National Health Service (NHS) will reimburse for doses of bortezomib (Velcade, Johnson & Johnson) when it has a therapeutic effect but not reimburse for the drug when it does not.<sup>37</sup> The NHS has also experimented with limiting coverage only to drugs that are "cost-effective." The National Institute for Clinical Effectiveness in the United Kingdom is the entity charged with making such determinations.<sup>38</sup>

So, if policymakers seek to slow the upward rise in cancer-drug prices and spending, they could enable Medicare to use its existing approaches or provide legislation that would empower the program to experiment with new ones. Medicare's previous successes in several related areas suggest that the potential reductions in spending on

cancer drugs could be meaningful. Determining whether innovation is hampered or helped by such actions should be an important part of the review process.

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**CORRECTION**

**Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs**

Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs . In Figure 1, some of the data points for drug approvals occurring after the year 2003 were incorrect, and they affected the data in the interactive graphic and the supplementary appendix. The article and the interactive graphic have been corrected and the supplementary appendix has been replaced at NEJM.org.