

CHAPTER

5

**Medicare Part B drug
and oncology payment
policy issues**

R E C O M M E N D A T I O N

- 5** The Secretary should reduce the Medicare Part B dispensing and supplying fees to rates similar to other payers.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

Medicare Part B drug and oncology payment policy issues

Chapter summary

Medicare Part B covers drugs that are administered by infusion or injection in physician offices and hospital outpatient departments (HOPDs). It also covers certain drugs furnished by suppliers. Medicare pays for most Part B–covered drugs based on the average sales price plus 6 percent (ASP + 6 percent). In 2014, Medicare and its beneficiaries paid nearly \$21 billion dollars for Part B–covered drugs paid under this method.

This chapter focuses on two broad issues: potential modifications of the way Medicare Part B pays for drugs, in general, and approaches to improve the quality and efficiency of oncology care, in particular, because more than half of Medicare Part B drug spending is associated with anticancer drugs.

Medicare’s payment methodology for Part B drugs

Our work focuses on three aspects of Medicare’s payment methodology for Part B drugs. First, we explore whether there is a better way to structure the add-on payment to ASP. Second, we examine whether there are payment policies that could be considered to promote more price competition among Part B drugs and put downward pressure on ASP. Third, the Commission recommends reducing the dispensing and supplying fees for certain Part B drugs furnished by inhalation drug suppliers and pharmacies to levels similar to those paid by other payers.

In this chapter

- Background on Part B drug payment
- Option for restructuring the ASP add-on
- Other payment policy approaches
- Part B drugs furnished by suppliers
- Improving the efficiency of oncology care in fee-for-service Medicare
- Conclusions

The 6 percent add-on to ASP has garnered attention because of concern that it may create incentives for use of higher priced drugs when lower priced alternatives exist. Since 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selection of the higher priced drug may generate more profit, depending on the provider's acquisition costs for the two drugs. It is difficult to know whether the percentage add-on to ASP is influencing drug prescribing patterns because few studies have looked at this issue.

We model a policy option that converts part of the 6 percent add-on to a flat fee: 103.5 percent of ASP + \$5 per drug administered per day. Compared with current policy, this option would increase add-on payments for drugs with an ASP per administration of less than \$200 and reduce add-on payments for higher priced drugs. This policy option is estimated to save about 1.3 percent of the \$21 billion in Part B drug spending (assuming no utilization changes). It might also increase the likelihood that a provider would choose a lower cost drug in situations where differently priced therapeutic alternatives exist, potentially generating additional savings for Medicare and its beneficiaries.

In considering a change to the ASP add-on, it is important to consider the effect of the policy on providers' ability to purchase drugs within the Medicare payment amount. Analysis of proprietary data on invoice prices for 34 high-expenditure Part B drugs suggests that for two-thirds of the drugs in our analysis, at least 75 percent of the volume was sold to clinics (e.g., physicians and outpatient hospitals) at an invoice price below 102 percent of ASP. This finding suggests that, in general, there likely is room for a reduction to the add-on portion of the payment rates for Part B drugs. However, small providers might have difficulty purchasing drugs at the Medicare payment rate, although the likelihood of this occurrence would depend on how drug manufacturers respond to the payment changes. If some oncology practices had difficulty purchasing drugs at the Medicare payment rate, this circumstance might contribute to the ongoing trend toward more hospital-based oncology care.

In addition to concerns over financial incentives associated with the 6 percent add-on, there are also concerns about the overall level of prices Medicare Part B pays for drugs. The largest component of Medicare's payments for Part B drugs is the ASP; the 6 percent add-on is a relatively small share of total payments. If policymakers wish to influence Part B drug payments to a larger degree than possible through add-on payments, they could consider Medicare payment policies that create more incentives for price competition among drugs or that put downward pressure on ASP. We examine three such policies:

- **ASP inflation limit**—Medicare’s ASP + 6 percent payment rates are driven by manufacturers’ pricing decisions. In theory, there is no limit on how much Medicare’s ASP + 6 percent payment rate for a drug can increase over time. We examine the idea of placing a limit on how much Medicare’s ASP-based payment for a drug can grow as a way to protect against the potential for a dramatic price increase and to generate savings for drugs undergoing rapid ASP growth.
- **Consolidated billing codes**—The structure of the ASP payment system—with single-source drugs and biologics each being paid their own ASP rate under separate billing codes—does not promote price competition among drugs with similar health effects. We explore the idea of using consolidated billing codes for Part B drugs with similar health effects, including biosimilars, to spur price competition among these Part B drugs.
- **Restructuring the Part B–drug competitive acquisition program**—From mid-2006 through 2008, Medicare operated a competitive acquisition program (CAP) in which physicians who enrolled in the CAP obtained Part B drugs from a Medicare-selected vendor instead of buying the drug directly and billing Medicare for the product. Medicare’s CAP faced challenges due to low physician enrollment in the program and the vendor’s limited leverage to negotiate discounts. We explore ways to restructure a CAP to encourage physician enrollment by offering shared savings to physicians, reducing or eliminating the ASP add-on payment in the traditional buy-and-bill system, and giving physicians more options for how they obtain drugs under the program. To enhance the vendor’s negotiating leverage, we consider the possibility of permitting the vendor to have a formulary.

Medicare Part B pays substantially higher dispensing fees for inhalation drugs and supplying fees for oral anticancer, oral antiemetic, and immunosuppressive drugs than the rates paid by Medicare Part D plans and Medicaid. The Medicare Part B rates have been in effect since 2006 and were set by CMS based on limited data. Under these circumstances, the Commission recommends reducing the Part B dispensing and supplying fees to rates similar to other payers.

Improving the efficiency of oncology care in fee-for-service Medicare

In 2014, Medicare spending for anticancer drugs accounted for about 55 percent of the nearly \$21 billion spent on Part B drugs paid under the ASP methodology to providers in physician office and HOPD settings and to suppliers. In the Commission’s June 2015 report to the Congress, we began to examine bundled approaches as a mechanism to make providers more sensitive than under current Medicare payment to the cost of Part B drugs associated with a cancer care

treatment regimen. With the availability of a large evidence base and regularly updated clinical guidelines, oncology is a clinical area amenable to bundling.

We continue to examine approaches that seek to improve the efficiency of oncology services while improving care quality. With Medicare’s coverage and payment policies for Part B anticancer drugs and their administration in mind, we examined factors that can influence clinicians’ prescribing of anticancer drugs. In addition, we examined four examples of narrower versus broader approaches designed to improve the efficiency of oncology care in Medicare and non-Medicare populations. The two narrower approaches—risk sharing and clinical pathways—attempt to improve the value of drug spending:

- Risk-sharing agreements made between product manufacturers and payers link payment for a drug to patient outcomes, such as a clinical measure (e.g., laboratory value) or an event (e.g., inpatient hospital admission). Product manufacturers and commercial payers have implemented these agreements in the United States and internationally.
- Oncology clinical pathways consist of treatment protocols adopted by commercial payers and providers (hospitals and clinicians) to standardize drug treatment, reduce unnecessary variation, improve quality of care, and reduce costs. Some payers and providers have implemented various approaches that link compliance with clinical pathways to financial incentives.

By contrast, the two broader approaches—medical homes and bundled payments—take a more holistic view of cancer care, seeking to improve care management and coordination:

- The oncology medical home is built on the concept of patient-centered care; the expectation is that enhanced services, such as team-based care, will expand patient access and education and that clinical practices will improve health outcomes and reduce cost. The Center for Medicare & Medicaid Innovation funded an oncology medical home under a three-year grant, which ended in 2015. Commercial payers have also implemented oncology medical homes.
- Bundling Part B oncology drugs with non-oncology services holds providers accountable for the total cost of services across an episode of care. UnitedHealthcare implemented such an approach under which practices were paid ASP for chemotherapy drugs (instead of ASP plus a negotiated add-on amount), an episode fee (based on the contracted drug add-on amount to ASP), and fee-for-service for most other services. Practices were eligible for shared savings if quality improved or total costs decreased. ■

Background on Part B drug payment

Medicare Part B covers infusible and injectable drugs administered in physician offices and hospital outpatient departments (HOPDs). Specifically, Medicare Part B covers these drugs that are administered by infusion or injection in clinicians' offices and HOPDs if they (1) meet the statutory definition of a drug or a biological,¹ (2) are usually not self-administered, (3) are incident to a clinician's service, (4) are reasonable and necessary for the diagnosis or treatment of an illness or injury, and (5) have not been determined by the Food and Drug Administration (FDA) to be less than effective. Medicare Part B also covers certain other drugs provided by pharmacies and suppliers (e.g., inhalation drugs and certain oral anticancer, oral antiemetics, and immunosuppressive drugs).

In accord with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare pays physicians and suppliers for most Part B-covered drugs based on the average sales price plus 6 percent (ASP + 6 percent).^{2,3} Medicare payment for separately payable Part B drugs reimbursed through the hospital outpatient prospective payment system (OPPS) is generally under the discretion of CMS, which established a rate of ASP + 6 percent. Low-cost drugs and certain other drugs are packaged into payment for other services under the OPPS instead of being paid separately.⁴ Like other Medicare services, Part B-covered drugs are subject to the budget sequester effective April, 1, 2013, through 2024.⁵ In this chapter, we use the term *drug* to refer to drugs and biologics (unless otherwise noted).⁶

In addition to a payment of ASP + 6 percent for a Part B-covered drug, Medicare makes a separate payment for administration of the drug under the fee schedule for physicians and other health professionals (also referred to as the physician fee schedule, or PFS) or OPPS.⁷ Medicare also pays a dispensing or supplying fee to pharmacies that dispense (to beneficiaries) inhalation drugs and oral anticancer, oral antiemetic, and immunosuppressive drugs and pays a furnishing fee to providers of clotting factor. The data presented in this section reflect only the ASP + 6 percent payments and do not include the drug administration payments or the supplying, dispensing, or furnishing fees (unless specifically noted).

In 2014, Medicare spending (program payments and beneficiary cost sharing) for Part B-covered drugs paid ASP + 6 percent amounted to nearly \$21 billion dollars

(nearly \$17 billion in program payments and more than \$4 billion in beneficiary cost sharing). Of that spending, physician offices accounted for over \$12 billion; HOPDs, over \$7 billion; and suppliers, over \$1 billion.

To get a sense of the drivers of Medicare Part B spending growth in recent years, we analyzed the change in spending between 2009 and 2013 and examined how changes in utilization and drug prices contributed to this change. This analysis is complicated by two types of policy changes that took place between 2009 and 2013. First, some drugs that were separately payable in 2009 became bundled or packaged by 2013. To remove the effect of these changes from our trend analysis, we excluded these drugs (i.e., drugs furnished by dialysis facilities and drugs that became packaged under the OPPS). Second, Medicare payment rates for Part B drugs changed over this period (some HOPD drugs were paid ASP + 4 percent in 2009, and all drugs were subject to the sequester beginning April 2013). To get the clearest picture of how growth in utilization and drug prices affects spending growth, we standardized the 2009 and 2013 payment rates to equal ASP + 6 percent. Under these assumptions, we estimate that Medicare payments for Part B drugs would have grown at an average annual rate of 10.1 percent between 2009 and 2013 (Table 5-1, p. 122).⁸ About one-third of this spending growth was due to an increase in the number of beneficiaries using Part B drugs (which increased at an average annual rate of 3.6 percent). Roughly two-thirds of the spending growth was due to an increase in the average payment per Part B drug user (which increased at an average annual rate of 6.3 percent). Growth in the average payment per Part B drug user was partly due to an increase in the number of drugs per user, a number that grew at an average rate of 1.5 percent per year. Most of the growth in the average payment per Part B drug user reflects growth in the average payment per drug, which increased 4.8 percent per year on average during this period. This growth in the average payment per drug likely reflects a combination of price increases among existing products and shifts toward a more expensive mix of drugs, including adoption of new drugs.

In recent years, total Medicare Part B drug spending has grown more rapidly for HOPDs than for physician offices and suppliers (average annual growth of about 18 percent and 6 percent, respectively, for the period between 2009 and 2013, data not shown). Of Medicare Part B drug spending in outpatient hospitals in 2014, over half was attributable to hospitals that participate in the 340B Drug Pricing Program. Nonprofit hospitals that qualify for the

**TABLE
5-1****Change in Medicare spending and utilization
for separately payable Part B drugs, 2009–2013**

	2009	2013	Average annual growth 2009–2013
Total payments (in billions)	\$13.1	\$19.3	10.1%
Number of beneficiaries using a Part B drug (in millions)	15.1	17.4	3.6
Average total payments per beneficiary who used Part B drugs	\$869	\$1,111	6.3
Average number of drugs per beneficiary	1.26	1.33	1.5
Average payment per drug	\$691	\$834	4.8

Note: This analysis includes all Part B drugs paid average sales price plus 6 percent (ASP + 6 percent) as well as the small group of Part B drugs that are paid based on the average wholesale price or that are contractor priced. Excluded from the analysis were any Part B drugs that became bundled or packaged between 2009 and 2013 (e.g., drugs that became packaged under the outpatient prospective payment system, regardless of the setting where they were furnished, and drugs furnished by dialysis facilities) and data for critical access hospitals (which are paid 101 percent of cost). We eliminated the effect of payment formula changes between 2009 and 2013 by standardizing the payment rates in the two years to be ASP + 6 percent (i.e., adjusting the payment rate for certain hospital outpatient department drugs in 2009 from ASP + 4 percent to ASP + 6 percent and by removing the effect of the sequester on Part B drug spending in 2013). The average annual growth rates displayed in the table may differ slightly from the average annual growth rates calculated using the 2009 and 2013 values displayed in the table due to rounding.

Source: MedPAC analysis of Medicare claims data for physicians, outpatient hospitals, and suppliers.

340B Drug Pricing Program receive substantial discounts on Part B drugs.⁹ In March 2016, the Commission recommended that Medicare payments for Part B drugs to 340B hospitals be reduced by 10 percent of ASP and the resulting program savings be directed to fund the Medicare uncompensated care pool for hospitals (Medicare Payment Advisory Commission 2016).

Medicare Part B covers drugs for a wide range of indications, although a small number of products and conditions account for a large share of spending. The top 10 drugs that account for the most Part B spending fall into three general areas: cancer, rheumatoid arthritis, and macular degeneration (Table 5-2). Nine of the 10 highest expenditure products are biologics. The 10 highest expenditure products accounted for 47 percent of Medicare spending on Part B drugs paid under the ASP + 6 percent methodology in 2014. Payments for these 10 products on a per administration and annual per beneficiary basis are substantial, ranging from \$1,100 to \$5,400 per administration and \$2,500 to \$30,000 per beneficiary per year in 2014 (Table 5-2). Beyond these high-expenditure drugs are additional Part B drugs used by small numbers of beneficiaries with higher per administration and per beneficiary payment amounts.

Part B also pays for many inexpensive drugs under the ASP payment system. For about 45 percent of Part B–covered

drug administrations, Medicare’s ASP + 6 percent payment per drug administered was less than \$10 (Table 5-3). For an additional 15 percent of drug administrations, the ASP + 6 percent payment per drug administered ranged from \$10 to \$49. Examples of very commonly used, inexpensive Part B–covered drugs include corticosteroids, drugs used during imaging, vitamin B12, and saline. The average ASP + 6 percent payment per administration for these products was generally less than \$15, and for some products, less than \$5.

Medicare’s Part B drug payment rates are updated quarterly. There is a two-quarter lag in the data used to set the ASP + 6 percent payment rate. That means, for example, the ASP + 6 percent payment rate for the third quarter of a year is based on ASP data from the first quarter of the year.¹⁰

In theory, the two-quarter lag in the ASP + 6 percent payment rates may provide a disincentive for manufacturers to institute large, rapid price increases because they may cause providers’ acquisition costs to exceed the Medicare payment rate and potentially affect providers’ willingness to purchase the product.

Payment rates for single-source drugs and biologics, multiple-source drugs, and biosimilars are set differently.

**TABLE
5-2**

Top 10 Part B-covered drugs by total expenditures, 2014

HCPCS code	Short description	Common indication or type of drug	Total Medicare payments (in billions)	Number of beneficiaries who used drug (in thousands)	Average ASP + 6 percent payment	
					Per administration	Per beneficiary
J9310	Rituximab	Cancer, RA	\$1.5	68	\$5,400	\$21,900
J2778	Ranibizumab	Macular degeneration	1.3	142	2,000	9,300
J0178	Aflibercept	Macular degeneration	1.3	132	2,100	9,700
J2505	Pegfilgrastim	Cancer supportive	1.2	98	3,300	11,700
J1745	Infliximab	RA	1.2	59	3,400	19,600
J9035	Bevacizumab	Cancer, macular degeneration	1.1	215	1,100	3,800
J0897	Denosumab	Osteoporosis, cancer supportive	0.8	293	1,200	2,500
J9305	Trastuzumab	Cancer	0.6	18	2,900	30,000
J9355	Pemetrexed	Cancer	0.6	23	5,400	24,200
J9041	Bortezomib	Cancer	0.5	20	1,500	23,200

Note: HCPCS (Healthcare Common Procedure Coding System), ASP (average sales price), RA (rheumatoid arthritis). Nine of these top 10 high-expenditure products are biologics; pemetrexed is the only nonbiologic drug in the top 10. Total Medicare payments include the effect of the sequester. Average ASP + 6 percent payment amount per administration and per beneficiary are calculated at the drug billing code level and do not include the effect of the sequester. These averages are calculated after removing extreme values from the data (i.e., values that are less than the 1st percentile and greater than the 99th percentile for the HCPCS code). Critical access hospitals and Maryland hospitals are excluded from the analysis. Data for beneficiaries with Medicare as a secondary payer are excluded from the analysis.

Source: MedPAC analysis of Medicare claims data.

Each single-source drug and biologic (except biosimilars) is paid based on 106 percent of its own ASP. For multiple-source drugs, both the brand-name and generic versions of the drug are paid under the same billing code and receive the same ASP + 6 percent payment rate based on the weighted average of ASPs for all brand-name and generic products. Biosimilars are paid 100 percent of their ASP, plus 6 percent of the ASP for the reference biologic. In the 2016 PFS final rule, CMS finalized a policy that all biosimilar products associated with the same reference product will be grouped together in one billing code and paid the same rate. The reference biologic, however, will retain its own billing code and be paid 106 percent of its own ASP.

Is the 6 percent add-on the provider’s margin?

The margin an individual provider realizes on a specific Part B drug could be more or less than 6 percent (with negative margins also possible) because, for several reasons, the price an individual provider pays for a drug may differ from the ASP used to establish the Medicare payment rate.¹¹

Since ASP is an average across all purchasers, net of rebates, discounts, and price concessions, some purchasers

**TABLE
5-3**

Low-priced drugs accounted for most Part B drug administrations, while high-priced drugs accounted for most Part B drug expenditures, 2014

Medicare ASP + 6 percent payment per drug administered per day	Percent of:	
	Drug administrations	Medicare Part B drug payments
Less than \$10	45%	0.3%
\$10-49	15	0.6
\$50-199	12	3
\$200-399	9	6
\$400-999	6	9
\$1,000-1,999	7	26
\$2,000-4,999	5	34
\$5,000 or more	1	21

Note: ASP (average sales price). Analysis includes Part B-covered drugs that are paid ASP + 6 percent and furnished by physicians, hospital outpatient departments, and suppliers. Drugs billed under not-otherwise-classified billing codes are excluded from the analysis. For drugs furnished by suppliers, the data reflect each prescription rather than each day the drug was administered. Critical access hospitals and Maryland hospitals are excluded from the analysis. Data for beneficiaries with Medicare as a secondary payer are excluded from the analysis. Numbers may not sum to 100 percent due to rounding.

Source: MedPAC analysis of Medicare claims data.

will pay more and some will pay less than the average (unless the manufacturer has uniform pricing). For example, if manufacturers offer discounts or rebates based on volume, small purchasers may pay higher prices than large purchasers. To the extent that prices vary by type of purchasers, ASP may not reflect the average price paid by each purchaser type. For example, the average price paid by physicians and outpatient hospitals for a product could be less than ASP if other types of purchasers (e.g., pharmacies) pay higher prices.

Price changes can also affect the margin a provider realizes on a Part B drug. With the two-quarter lag in the ASP + 6 percent payment rate, a price increase lowers a provider's margin and a price reduction increases that margin temporarily until ASP catches up.¹² For example, when a generic version of a drug first enters the market, the lag in ASP results in a large profit margin for providers because their payment for the generic drug is based on the brand-name price for at least two quarters (Office of Inspector General 2012, Office of Inspector General 2011a). For single-source drugs and biologics, the pricing dynamics may be different, depending on whether the drug or biologic faces competition from therapeutic alternatives. That is, the manufacturer of a single-source drug may increase prices with less concern about the effect it will have on providers' margins (and potentially the manufacturer's sales volume) if therapeutic alternatives do not exist for its drug. In contrast, if a single-source drug faces competition from other, therapeutically similar drugs, a manufacturer may take into account how a price increase would affect providers' margins on its drug compared with competitor products.

Certain additional factors, such as prompt-pay discounts and wholesaler markups, can create a gap between manufacturers' reported ASP and the average purchase price across providers. For example, manufacturers may offer prompt-pay discounts to drug wholesalers who pay manufacturers quickly. Prompt-pay discounts, which are reported by industry stakeholders to be in the range of 1 percent to 2 percent, lower ASP. These discounts are reported to be an important source of revenue for wholesalers that are largely not passed on to final purchasers (e.g., physicians and hospitals). When these discounts are not passed on from wholesalers to providers, the average price paid by providers for a drug could end up higher than the manufacturer's reported ASP. Another factor that can affect a provider's margin on a drug is wholesaler markup. That markup is not included in ASP (since it does not affect the revenue

earned by manufacturers), but it can increase the price paid by physicians and hospitals. For some drugs, the average price paid by providers for a drug could be higher than ASP due to wholesaler markup. To the extent that wholesaler markup reflects fixed fees like shipping and handling, its effect may be most significant on provider margins for very inexpensive drugs (Medicare Payment Advisory Commission 2007).

To get a sense of how providers' acquisition costs compare with Medicare's payment amount, we obtained proprietary data from IMS Health Incorporated (IMS) on invoice prices for Part B drugs.¹³ These data provide information on the distribution of invoice prices by drug and by channel (i.e., type of purchaser). We examined data for the clinic channel, which includes physician offices, HOPDs, dialysis clinics, nonhospital surgical centers, and public health service clinics. The data are available for the clinic channel as a whole; they are not reported for finer categories of purchasers. The IMS data for the clinic channel include discounted sales to 340B entities. To avoid reflecting 340B prices in our estimates, we did not use data on the average invoice price. Instead, we focus on invoice prices for the top half of the price distribution (i.e., the 50th, 75th, and 90th percentiles). The prices in the IMS data reflect all on-invoice discounts and rebates but not off-invoice rebates. As a result, in some cases the IMS data overstate the actual end-price paid by the purchaser. We do not report any prices for specific drugs due to the terms of our contract with IMS.

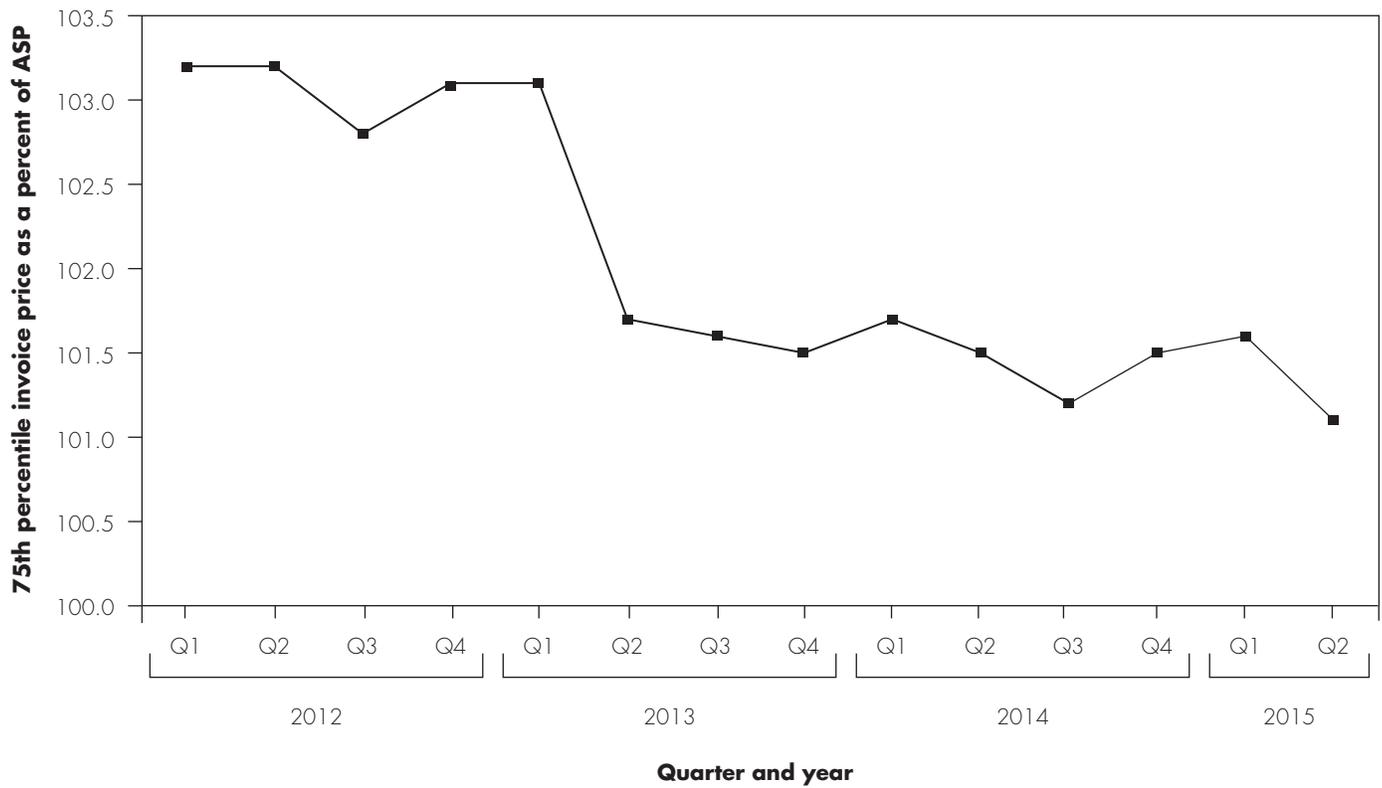
Our analysis of invoice prices focuses on 34 high-expenditure Part B drugs for which we have quarterly invoice price data for the entire period from the first quarter of 2012 to the second quarter of 2015. Overall, these 34 drugs accounted for about two-thirds of Medicare spending on Part B drugs in 2014. Because we do not report invoice prices per our contract with IMS, we divide the invoice price of each drug by 100 percent of the ASP that was in effect for payment purposes in that quarter to create a ratio of the invoice price to ASP.¹⁴ We summarize the results across the group of 34 drugs in our analysis.

We conducted two analyses using these data. First, we examined the trend in the ratio of the 75th percentile invoice price to ASP over time. Then, we observed the distribution of the invoice-price-to-ASP ratios across the 34 drugs in the first quarter of 2015.

Figure 5-1 shows the trend in invoice prices in the clinic channel as a percentage of ASP between the first quarter

FIGURE 5-1

Trend in the median of 75th percentile invoice price as a percent of ASP for clinics across 34 Part B drugs



Note: ASP (average sales price). The data are for the clinic channel of sales, which includes physician offices, hospital outpatient departments, dialysis centers, nonhospital surgical centers, and public health service clinics. Figures reflect invoice prices as a percentage of the ASP that was in effect for Medicare payment purposes that quarter. Figures reflect invoice price data for 34 drugs that have high total expenditures and for which invoice price data were available for every quarter during the period from the first quarter of 2012 to the second quarter of 2015. For drugs with multiple national drug codes (NDCs), the data for the highest volume NDC was used. Data come from a sample of wholesalers and do not include direct sales by manufacturers. The percentile distribution of the ratio of invoice prices to ASP is at the drug unit level. Invoice prices reflect on-invoice discounts and rebate, but do not reflect off-invoice rebates.

Source: This information is a MedPAC estimate derived from the use of information under license from the following IMS Health Incorporated information service: Pricetrak for the period of the first quarter of 2012 through the second quarter of 2015.

of 2012 and the second quarter of 2015. Specifically, the chart shows the median 75th percentile invoice price as a percentage of ASP across the 34 drugs over this time period.¹⁵ For example, if the median 75th percentile invoice price was 103 percent of ASP, that would mean that for half of the drugs (17 of 34), at least 75 percent of the volume was sold to clinics at an invoice price of 103 percent of ASP or less.

We used information on the trend in invoice prices as a percentage of ASP over time to examine how providers' margin on Part B drugs was affected by the sequester. Beginning in the second quarter of 2013, the sequester reduced the total Medicare payment providers received

for Part B drugs from 106 percent of ASP to 104.3 percent of ASP. As shown in Figure 5-1, across the 34 drugs, the median 75th percentile invoice price as a percentage of ASP declined markedly in the quarter that the sequester went into effect. Between the first quarter of 2012 and the first quarter of 2013, the median 75th percentile invoice price oscillated around 103 percent of ASP. Beginning in the second quarter of 2013 and continuing through the second quarter of 2015, the median 75th percentile invoice price oscillated around 101.5 percent of ASP. These data suggest that some manufacturers may have responded to the sequester by changing their pricing patterns in a way that mitigated the effect of the sequester on some providers. There are several ways the ratio of the 75th

**TABLE
5-4**

Distribution of invoice prices for 34 Part B drugs, 1st quarter 2015

	Invoice price as a percent of ASP		
	50th percentile	75th percentile	90th percentile
Percent of 34 drugs with invoice price as percent of ASP:			
Less than 100%	59%	35%	18%
100% to 101.9%	21	29	6
102% to 103.9%	6	12	26
104% to 105.9%	6	12	21
106% or greater	9	12	29
Median 75th percentile invoice price as percent of ASP across the 34 drugs	99.7% ASP	101.6 % ASP	104.0% ASP

Note: ASP (average sales price). The data are for the clinic channel of sales, which includes physician offices, hospital outpatient departments, dialysis centers, nonhospital surgical centers, and public health services clinics. Figures reflect invoice price data for 34 drugs that have high total expenditures. For drugs with multiple national drug codes (NDCs), the data for the highest volume NDC was used. Data come from a sample of wholesalers and do not include direct sales by manufacturers. The percentile distribution of invoice prices is at the drug unit level. Prices reflect on-invoice discounts and rebates but not off-invoice rebates. Invoice prices are for the first quarter of 2015 and are displayed as a percentage of the ASP that was in effect for payment purposes in the first quarter of 2015. Numbers may not sum to 100 percent due to rounding.

Source: This information is a MedPAC estimate derived from the use of information under license from the following IMS Health Incorporated information service: Pricetrak for the first quarter of 2015.

percentile invoice price to ASP for the clinic channel could decline. For example, the ratio could decline if invoice prices in the clinic channel grew more slowly than ASP (which could occur if prices in the clinic channel declined or grew more slowly than other channels). A decline in this ratio could also occur if price variation across purchasers narrowed. These types of pricing dynamics likely vary across drugs.

Table 5-4 provides a more detailed look at the distribution of invoice prices as a percentage of ASP across the 34 drugs in the first quarter of 2015.¹⁶ (These 34 drugs accounted for about two-thirds of Medicare Part B spending in 2014.) Thirty-five percent of the drugs had a 75th percentile invoice price that was less than 100 percent of ASP, and another 29 percent of the drugs had a 75th percentile invoice price that was between 100 percent of ASP and 101.9 percent of ASP. In other words, for about two-thirds of the drugs (22 out of 34 drugs) at least 75 percent of the volume was sold at an invoice price that was less than 102 percent of ASP. The remainder of the drugs had a 75th percentile invoice price that for 12 percent of drugs ranged from 102 percent to 103.9 percent of ASP; for another 12 percent of drugs, from 104 percent to 105.9 percent of ASP; and for another 12 percent of drugs, 106 percent or more of ASP.

For a few drugs, the invoice price in the clinic channel was lower than 100 percent of ASP for the vast majority of units sold. Because ASP is an average across all types of purchasers (with some exceptions), if a manufacturer charged lower prices to clinics than to other purchasers, the clinics could have acquired the drug for less than ASP.

For a few drugs, invoice prices were greater than 106 percent of ASP, which may be the result of a combination of factors. The data do not include off-invoice rebates. Actual prices would be lower than the invoice price in situations where off-invoice rebates were available (which might occur for products with therapeutic alternatives if, for example, the manufacturer offered off-invoice rebates based on the volume of product purchased over a specified time period). It might also reflect small purchasers not getting the same discount as other purchasers in some cases.

Another source of information on acquisition costs is a report from the Office of Inspector General (OIG) examining acquisition costs for two drugs for wet age-related macular degeneration (AMD) and certain other eye conditions (Office of Inspector General 2011b). OIG surveyed ophthalmologists to obtain data on

their acquisition costs in the first quarter of 2010 for ranibizumab (Lucentis) and bevacizumab (Avastin). Ranibizumab is a biologic with a label indication for wet AMD for which Medicare paid just over \$2,000 per dose in 2010. Bevacizumab is a biologic that is used off label for wet AMD at a significantly lower cost; Medicare paid roughly \$50 per dose on average in 2010.¹⁷ OIG found that, on average, ophthalmologists reported acquiring ranibizumab for 5 percent below the Medicare ASP + 6 percent payment amount in the first quarter of 2010. Since that time, another biologic called aflibercept (Eylea) with the same label indications as ranibizumab has come on the market with a Medicare payment rate per administration similar to ranibizumab. In 2014, ranibizumab and aflibercept together accounted for about \$2.7 billion in Medicare program and beneficiary spending.

What was the purpose of the 6 percent?

When a provider administers a Part B–covered drug, Medicare pays 106 percent of ASP for the drug and makes a separate payment to the provider under the PFS or OPFS for administering the drug. There is no consensus on the original intent of the 6 percent add-on to ASP. A number of rationales have been suggested by various stakeholders. Some suggest that the 6 percent was intended to cover drug storage and handling costs.¹⁸ Others contend that the 6 percent was intended to maintain access to drugs for smaller practices and other purchasers who may pay above-average prices for the drugs. Others suggest that the 6 percent was intended to compensate for the financing costs associated with maintaining an inventory of drugs. Another view is that the add-on to ASP was intended to cover factors that may create a gap between the manufacturers' reported ASP and the average purchase price across providers (e.g., prompt-pay discounts). Another rationale is that the percentage add-on was intended to provide protection for providers when price increases occur and the payment rate has not yet caught up.

Does the percentage add-on to ASP influence use of high-cost drugs?

Providers' prescribing decisions may depend on a variety of factors. A number of clinical considerations may influence a provider's choice among therapeutic alternatives. For example, drugs may vary in terms of their effectiveness in treating patients with certain conditions or comorbidities, and they may differ in terms of side effects. In addition, providers may take into account whether a

drug is on label or off label for a patient's condition or whether a drug is compounded.

Financial considerations may also play a role in providers' choice of drugs. Concern has been expressed by some researchers and stakeholders that the 6 percent add-on to ASP creates an incentive to use higher priced drugs when cheaper therapeutic alternatives are available (Hutton et al. 2014, Sanghavi et al. 2014). Since 6 percent of a higher priced drug generates more revenue for the provider than 6 percent of a lower priced drug, selection of the higher priced drug has the potential to generate more profit, depending on the provider's acquisition costs for the two drugs. At the same time, other financial considerations might create an incentive to use lower priced drugs in some situations. For example, some have argued that when selecting a drug, a provider may take into account the cost sharing associated with each drug and the patient's ability to pay, which might lead to choosing a lower priced drug for some patients. Also, the capital cost associated with acquiring and keeping an inventory of a high-priced drug may be a disincentive for some providers to furnish expensive drugs. With respect to oncology specifically (which accounts for roughly 55 percent of Part B drug spending), clinical pathways are used by some payers and providers to guide clinicians' choice of a patient's most appropriate drug regimen. Publicly available information is lacking on how much of the time the clinician has the opportunity within oncology pathways to choose among differently priced drugs that are equally appropriate for a given patient.

Few studies exist examining whether Medicare's 6 percent add-on influences providers' choice of drugs. One study by Jacobson and colleagues of oncologists' prescribing patterns for lung cancer suggests that drug choice may to some degree be influenced by the higher add-on (Jacobson et al. 2010). Looking at five chemotherapy drugs for lung cancer, Jacobson and colleagues found a modest increase in use of the most expensive cancer drug after Medicare began paying for Part B drugs based on ASP + 6 percent in January 2005 (9.2 percent of beneficiaries used the most expensive drug in the 10 months before the payment change, whereas 11.0 percent of beneficiaries used that drug in the 10 months after). A study by OIG reported some movement toward higher priced drugs among a group of therapeutically similar prostate cancer drugs. When the least costly alternative policy for certain prostate cancer drugs was removed in 2010 and the products began to be paid based on 106 percent of their own ASPs, OIG found that utilization shifted away from the lowest priced

prostate cancer drug toward higher priced competitor products (Office of Inspector General 2012).

Option for restructuring the ASP add-on

Building on our work in the June 2015 report that explored budget-neutral options to restructure the ASP add-on, we explored an option to restructure the ASP add-on percentage that would generate savings.¹⁹ The policy option we modeled is 103.5 percent of ASP + \$5 per drug per administration day.²⁰ In developing this option, we sought to balance the desire to reduce the percentage add-on by a substantial amount with the desire to retain some percentage add-on to accommodate price variation or other factors that might lead to some purchasers acquiring drugs at a price greater than ASP. In developing this option, we also sought to keep the flat fee at a modest level, to lessen any incentives a flat fee might create for overuse of inexpensive drugs. This option is illustrative; other percentage add-ons and flat fees could be explored. Also, other approaches could be explored, such as reducing the percentage add-on without establishing a flat fee (e.g., to 105 percent of ASP) or paying the lesser of two payment formulas (e.g., the lesser of 103.5 percent of ASP + \$5 per drug per day or 106 percent of ASP).

In modeling the policy option, we assume that it applies to all Part B drugs currently paid ASP + 6 percent, including those furnished by physicians, HOPDs, and suppliers.²¹ Our analysis is focused on the pre-sequester payment rates. The sequester would reduce the payment amount under this option to 101.8 percent of ASP + \$4.92 per drug per day.

This policy option would have the effect of increasing payments for low-priced drugs and decreasing payments for higher priced drugs. Add-on payments would increase for drugs with an ASP per administration of less than \$200 and decrease for drugs with an ASP per administration higher than \$200.²² Overall, we estimate that this policy option would save about 1.3 percent over current policy (based on 2014 claims data and assuming no changes in utilization). If these rates had been paid in 2014, the Medicare program would have saved about \$215 million and Medicare beneficiaries about \$55 million.

The revenue effects of the policy option by provider type are shown in Table 5-5. The option would reduce Part B drug revenues overall for physicians and HOPDs. HOPDs

and physicians that use expensive Part B drugs—such as oncologists, rheumatologists, and ophthalmologists—would see the largest reduction in Part B drug revenues (by between 1.5 percent and 2.1 percent).^{23, 24} As a share of these providers' total Medicare revenues, the effect would be smaller—a 0.1 percent reduction for hospitals and a reduction of 0.9 percent to 1.3 percent for the three physician specialties. The option would result in a small increase in payments to primary care physicians and certain specialists (e.g., orthopedic surgeons, cardiologists, and infectious disease specialists) who tend to use lower cost drugs and who would benefit from the flat-fee add-on. The policy option would also lead to a very slight decrease in payments for supplier-furnished drugs.

This policy option—designed to mitigate the current payment system's potential to incentivize use of higher priced drugs—would reduce the difference in the add-on payment between a higher priced and lower priced drug by roughly 40 percent. Table 5-6 (p. 130) provides an illustration of how this policy might play out for differently priced drugs that are therapeutic alternatives. Research by Schrag and colleagues identified two products that can be added to two regimens (FOLFOX and FOLFIRI) for treatment of metastatic colon cancer with similar survival and quality of life, but with different prices (Schrag et al. 2015). Table 5-6 (p. 130) models Medicare payments for these two products for an eight-week treatment cycle under current policy and the policy option. Under current policy of ASP + 6 percent, the add-on payment for cetuximab is about \$540 more per treatment cycle than bevacizumab. With the policy option of 103.5 percent of ASP plus \$5 per drug per day, the difference in add-on payments between the two products is reduced by about 40 percent to \$315.²⁵

The changes in payment rates under this policy option could have a number of effects. As discussed previously, the policy option would reduce, but not eliminate, the difference in the add-on payments among differently priced drugs. In situations where different Part B drugs exist to treat a patient's condition effectively, this policy option might increase the likelihood that a provider would choose the least expensive drug. To the extent that this type of substitution occurred and changed utilization patterns, the policy option might generate additional savings (beyond those described above) for both the Medicare program and beneficiaries.

It is also possible that the flat-fee portion of the add-on could lead to increased spending for some products,

**TABLE
5-5**

Impact of the policy option on Part B drug revenues by type of provider

	Medicare payments in 2014 (in billions)		Option: 103.5% ASP + \$5 per drug per day	
	Part B drugs	All types of services	Percent change in Part B drug revenues	Percent change in Medicare payments for all services
Physicians	\$12.0	\$55.0	-1.0%	-0.2%
Oncology	5.5	7.9	-1.5	-1.1
Ophthalmology	2.6	5.5	-2.0	-0.9
Rheumatology	1.2	1.7	-1.8	-1.3
Primary care	0.7	11.0	1.5	0.1
Urology	0.3	2.0	-1.2	-0.2
Neurology	0.2	1.0	-1.7	-0.4
Orthopedic surgery	0.2	3.3	4.5	0.3
Cardiology	0.1	4.2	1.6	0.0
Infectious disease	0.1	0.3	1.1	0.2
Other specialties	1.0	18.0	2.4	0.1
Outpatient hospitals	7.2	164.2	-2.1	-0.1
Urban	6.4	147.3	-2.1	-0.1
Rural	0.8	15.7	-2.0	-0.1
Nonprofit	5.5	116.7	-2.1	-0.1
For profit	0.4	23.7	-2.0	0.0
Government	1.3	22.6	-2.1	-0.1
Major teaching	2.4	40.2	-2.1	-0.1
Minor teaching	2.4	57.3	-2.0	-0.1
Nonteaching	2.4	65.3	-2.0	-0.1
≤100 beds	0.9	15.7	-2.0	-0.1
101–250 beds	1.8	46.5	-2.0	-0.1
251–500 beds	2.3	56.6	-2.0	-0.1
501+ beds	2.3	44.2	-2.1	-0.1
Suppliers	1.6	3.0	-0.4	-0.2

Note: ASP (average sales price). The policy option is modeled to apply to all Part B-covered drugs that are currently paid ASP + 6 percent, excluding drugs billed through not-otherwise-classified Healthcare Common Procedure Coding System codes. Estimates of Medicare payments for all types of services by type of provider exclude providers who did not bill for at least one Part B-covered drug. Medicare payments include Medicare program payments and beneficiary cost sharing and include the effect of the sequester. Critical access hospitals and Maryland hospitals are excluded from the analysis. Data for beneficiaries with Medicare as a secondary payer are excluded from the analysis. Spending figures by category may not sum to total due to missing data on provider characteristics for a small number of providers.

Source: MedPAC analysis of Medicare claims data for physicians, outpatient hospitals, and suppliers.

although we have sought to reduce the likelihood of that outcome through the use of a modest flat-fee add-on (\$5 per drug per day). As noted in our June 2015 report, a flat add-on might create incentives for use of some drugs in smaller, more frequent doses, which could lead to increased add-on payments (Medicare Payment Advisory Commission 2015). It is also possible that a flat add-on

might create incentives for overuse of inexpensive drugs because the add-on would represent a substantial increase in these drugs' payment rate. Manufacturers of very inexpensive drugs might also respond to the flat fee by increasing their prices. The flat fee we model in this policy option is modest, so the risk of the flat fee leading to these effects is likely to be low.

**TABLE
5-6**

Illustration of the effect of the policy option on Medicare payments for two therapeutic alternatives used in chemotherapy regimens for metastatic colon cancer

	106% ASP per 10 mg	Number of 10-mg units per 8-week cycle	Total payment for an 8-week regimen		Add-on portion of the payment for an 8-week regimen	
			Current: 106% ASP	Option: 103.5% ASP + \$5 per drug per day	Current: 6% ASP	Option: 3.5% ASP + \$5 per drug per day
Bevacizumab	\$70.842	160	\$11,335	\$11,087	\$642	\$394
Cetuximab	\$53.809	388	\$20,878	\$20,405	\$1,182	\$709
Difference					\$540	\$315

Note: ASP (average sales price). The example of two therapeutic alternatives is identified in research by Schrag and colleagues (2015). Both bevacizumab and cetuximab are products that can be added to the FOLFOX and FOLFIRI regimens with similar survival rates and quality of life, according to their research. Calculations of payments are the Commission's estimates based on ASP + 6 percent and assumptions about dosing. Bevacizumab estimates assume a dose of 5 mg/kg every 2 weeks, and cetuximab estimates assume a dose of 500 mg/m² every 2 weeks. Estimates assume a patient with a weight of 80 kg and a body surface area of 1.94 m². Estimates are for an eight-week treatment cycle.

Source: MedPAC estimates based on ASP + 6 percent payment rates for the first quarter of 2016 from CMS.

In considering a change to the ASP add-on, it would be important to consider the effect on providers' ability to purchase drugs within the Medicare payment amount. Our analysis of proprietary data on the ratio of invoice prices to ASP for 34 Part B drugs suggests that, in general, there likely is room for a reduction to the ASP add-on. Nonetheless, small providers might have difficulty purchasing expensive drugs at the Medicare payment rate, but this would depend on how drug manufacturers respond to the payment changes. When Medicare began paying 106 percent of ASP in 2005, manufacturers responded by reducing price variation across purchasers (Medicare Payment Advisory Commission 2006). Our analysis of proprietary data on the ratio of invoice prices to ASP for 34 Part B drugs also suggests that some manufacturers responded to the sequester in ways that mitigated the effect of that payment change on some providers. If the ASP add-on were restructured, it is possible that manufacturers would respond in a way that maintained small purchasers' ability to obtain expensive drugs at the Medicare payment rate. Alternatively, it is possible that price variation across purchasers would persist and that smaller oncology practices, for example, might decide to send patients to the larger oncology practices or HOPDs for certain expensive drugs.

Some stakeholders raise concerns that changing the ASP add-on could accelerate a trend toward hospitals buying community oncology practices. Several reasons have been

cited for hospitals' acquisition of these practices (e.g., availability of 340B discounts at some hospitals, general reimbursement pressures, a movement toward integrated care models, and interest among some physicians in employment rather than running a practice). If a change to the ASP add-on resulted in some practices having difficulty purchasing drugs at the Medicare payment rate, this circumstance might contribute to the trend toward more hospital-based oncology care. However, it is in drug manufacturers' interest to support community oncology practices since acquisition of practices by hospitals, some of which participate in the 340B program, would potentially subject more manufacturer sales to 340B discounts.

Other payment policy approaches

In addition to concerns about financial incentives under Medicare's 6 percent add-on payment, there are also concerns about the prices overall that Medicare Part B pays for drugs. The largest component of Medicare's payment is the ASP; the 6 percent add-on is a relatively small share of total payments. If policymakers wish to influence Part B drug payments to a larger degree than possible through add-on payments, they could consider Medicare payment policies that create more incentives for price competition among drugs or that put downward

**TABLE
5-7**

Growth in ASP for the top 20 highest expenditure drugs, January 2005–2016

HCPCS code	Short description	Total Medicare payments in 2014 (in billions)	Average annual ASP growth, from January to January of each year				Earliest year of ASP data if not 2005
			2005–2016	2005–2010	2010–2015	2015–2016	
J9310	Rituximab	\$1.5	5.2%	5.0%	5.2%	6.0%	
J2778	Ranibizumab	1.3	-0.6*	-0.2*	-0.4	-2.1	2008
J0178	Aflibercept	1.3	0.0*	N/A	0.0*	0.0	2013
J2505	Pegfilgrastim	1.2	4.8	0.8	8.1	9.5	
J1745	Infliximab	1.2	3.8	2.0	4.8	7.8	
J9035	Bevacizumab	1.1	2.0	0.1	3.4	4.3	
J0897	Denosumab	0.8	1.8*	N/A	0.6*	5.5	2012
J9355	Trastuzumab	0.6	4.9	4.1	5.4	6.0	
J9305	Pemetrexed	0.6	3.9	4.5	3.7	1.8	
J9041	Bortezomib	0.5	4.6	6.1	4.0	0.4	
J0129	Abatacept	0.3	8.6*	1.4*	11.2	19.0	2007
J2353	Octreotide depot	0.3	5.8	4.9	5.8	10.7	
J9033	Bendamustine	0.3	4.1*	-0.6*	4.2	8.2	2009
J0885	Epoetin alfa	0.3	1.4	-2.1	4.5	3.7	
J0881	Darbepoetin alfa	0.3	1.4	-4.4	6.6	6.4	
J9264	Paclitaxel protein bound	0.3	1.9*	3.0*	0.7	3.6	2006
J8521	Capecitabine	0.3	4.0	13.7	5.2	-36.8	
J9228	Ipilimumab	0.3	2.7*	N/A	2.2*	4.2	2012
J9055	Cetuximab	0.3	0.7	0.0	1.6	0.1	
J2323	Natalizumab	0.3	10.8*	4.7*	13.5	9.9	2008
Median average annual ASP growth across top 20 drugs			3.8	2.0	4.4	4.9	
Consumer price index for urban consumers			2.0	2.6	1.5	1.4	

Note: ASP (average sales price), HCPCS (Healthcare Common Procedure Coding System), N/A (not applicable). Medicare payments include Medicare program payments and beneficiary cost sharing and include the effect of the sequester.
 *Indicates that ASP payment rates were not available for the full time period listed, and the average annual growth rate was calculated based on the earliest year for which data were available.

Source: MedPAC analysis of ASP + 6 percent payment rates and Medicare claims data from CMS.

pressure on ASP. We explore three potential policies: (1) a limit on ASP growth over time, (2) consolidated billing codes for Part B drugs, and (3) restructuring the competitive acquisition program for Part B drugs.

Limit on ASP growth

Under Medicare’s ASP payment system, growth in Medicare’s ASP + 6 percent payment rates for individual drugs is driven by manufacturer pricing policies. In theory, there is no limit on how much Medicare’s ASP + 6 percent payment rate for an individual drug can increase over time.

Table 5-7 shows how ASP has grown over time for the 20 highest expenditure Part B drugs (as of 2014). Between January 2005 and January 2016, the median average annual growth rate of ASP across these drugs was 3.8 percent. Underneath this aggregate figure there are trends that vary by time period. For these drugs, the median average annual growth rates of ASP from 2005 to 2010, 2010 to 2015, and 2015 to 2016 were 2.0 percent, 4.4 percent, and 4.9 percent, respectively. Across these drugs, ASP growth at the median was slower than inflation (as measured by the consumer price index for all

urban consumers (CPI-U)) in the early years of the ASP payment system, but has exceeded inflation since 2010.

Some drugs experienced higher ASP growth than others. For example, over the course of the ASP payment system (from 2005 to 2016), several drugs had average annual ASP growth of roughly 5 percent or more (i.e., natalizumab, abatacept, octreotide depot, rituximab, trastuzumab, and pegfilgrastim). In the last year, more of these drugs have experienced ASP growth of at least 5 percent. Between January 2015 and January 2016, 10 of the top 20 high-expenditure drugs had ASP growth of 5 percent or more, with 4 of these drugs having ASP growth of roughly 10 percent or more. Capecitabine, a drug that first experienced generic entry in September 2013, provides an example of how a drug's ASP can grow rapidly over a number of years before generic entry and then drop substantially after generics become available. From January 2005 to January 2014, capecitabine's ASP grew at an average rate of 13 percent per year; after generic entry between January 2014 and January 2016, the ASP decreased at an average rate of roughly 30 percent per year (data for these time periods not shown in chart).

One policy option that could be considered is limiting the amount that Medicare's ASP + 6 percent payment for a product can grow over time. Such a limit could provide the Medicare program and beneficiaries with protection from the possibility that a manufacturer could institute a dramatic price increase. It could also potentially generate savings for existing drugs that have experienced ASP growth higher than inflation. It would not, however, address the issue of high launch prices for new products, and it might spur some manufacturers to set a higher launch price. Some may argue that such an administrative constraint on price growth is contrary to having market conditions and competitive forces drive payments for Part B drugs; however, in some instances, a competitive market might not exist (e.g., if there are no competitors for a given drug or if payment systems are not structured to facilitate competition among products with similar health effects).²⁶

A limit on ASP growth could be implemented in different ways. One way could be through a rebate mechanism. Another approach would be to limit growth in Medicare's payments to physicians and hospitals made at the ASP + 6 percent rate.

Manufacturers could be required to pay Medicare a rebate if ASP grows faster than a specified threshold, similar to the inflation portion of the Medicaid rebate. The Medicaid rebate has two components: (1) a specified rebate amount

based on a percentage of the average manufacturer price (AMP) or the difference between AMP and best price and (2) an additional rebate if a drug's AMP has grown faster than the rate of inflation (as measured by CPI-U since a base year).²⁷ The inflation portion of the rebate is equal to the difference between the actual AMP and what AMP would have been if it had grown at the rate of inflation. This inflation rebate ensures that the inflation-adjusted prices paid by the Medicaid program for drugs do not increase over time. Under a Medicare inflation rebate modeled after the Medicaid inflation rebate, manufacturers would be required to pay Medicare a rebate when ASP grew faster than inflation.²⁸

Alternatively, a limit could be placed on the amount that the ASP + 6 percent payment rates to physicians and HOPDs can increase over time. Each quarter when CMS establishes the ASP + 6 percent payment amounts, CMS could pay the lesser of (1) the actual ASP + 6 percent for the quarter or (2) an inflation-adjusted ASP + 6 percent. The inflation-adjusted ASP + 6 percent would be calculated by taking the ASP + 6 percent from a base year and increasing it by a measure of inflation that occurred between the base year and the quarter for which payment is being established.

These two approaches to an ASP inflation limit—a Medicare rebate or a limit on Medicare's payments to physicians and hospitals—have different implications for various stakeholders. The options differ in terms of which entity bears the financial risk. Drug manufacturers bear the financial risk under a rebate approach. If the ASP grows faster than the inflation benchmark, manufacturers would pay Medicare the difference through a rebate. Under a limit on the ASP + 6 percent payment rates, physicians and hospitals would bear the financial risk. These providers could lose money if a limit on Medicare's ASP + 6 percent payment rates over time meant that the payment rates for some drugs did not keep up with providers' acquisition costs.

The approaches also could have different implications for beneficiaries in terms of who saves and how much. An inflation limit on the ASP + 6 percent payment rates to providers would lead to savings for beneficiaries in two ways: (1) Medicare program savings would translate into a lower Part B premium for all beneficiaries, and (2) beneficiaries who use Part B drugs would save by paying 20 percent of a lower price. An ASP inflation rebate would lead to the first type of savings for beneficiaries (lower Part B premiums) and could lead to the second type of savings (lower beneficiary cost sharing), depending on

how it was structured. Under the simplest approach, the rebate would not affect the Medicare ASP + 6 percent payment rates to providers and thus not affect beneficiary cost sharing. But other ways of implementing the rebate would allow the beneficiary to realize lower cost sharing. For example, CMS could reduce the cost-sharing amount for those drugs subject to a rebate (to the level it would have been if an ASP inflation cap had been imposed on the provider payment rate), and the Medicare program could increase its payment to the provider to make up the difference. The program would then receive rebates from the manufacturer afterwards, keeping the full amount of the rebates. The net result would be that the beneficiary realizes 20 percent of the rebate through lower cost sharing and the program realizes 80 percent of the rebate (i.e., total rebates minus the additional amount the program paid the provider to make up for the reduced beneficiary cost sharing).

Regardless of which rebate structure was chosen, certain key decisions would have to be made. An inflation benchmark would need to be selected. The Medicaid rebate uses CPI-U, but other inflation benchmarks could be considered. Policymakers would need to define the base year from which growth in ASP and inflation was measured. Options for a base year include the quarter of first marketing (which would be likely to produce the most savings but may be viewed as a retroactive penalty if applied to existing products) or some period shortly before consideration of the policy (e.g., 2015), which would give manufacturers notice of the policy while limiting their ability to respond by increasing prices before the policy went into effect.

Policymakers would also need to decide whether there would be any exceptions to this policy. One concern is that an ASP inflation limit might adversely affect a manufacturer of a low-cost drug that is in shortage—for example, if it increased the drug’s price in conjunction with efforts to bring more product to market. The FDA maintains a list of drugs in shortage, so policies could be developed to exempt products in shortage from the ASP inflation cap.

Consolidated billing codes

Under the ASP payment system, most drug products have their own billing code and receive a payment rate equal to 106 percent of their individual ASP. This method is used for the vast majority of single-source drugs and biologics. In contrast, generic drugs, along with their associated brand-name drug, are paid under one billing code based

on the volume-weighted average ASP for the products in the code. Because of the single billing code and the low research and development costs for generic drugs, Medicare payment rates for drugs that become generic generally decline substantially over time (Medicare Payment Advisory Commission 2010).

The structure of the ASP payment system does not promote strong price competition among single-source drugs and biologics where there are therapeutic alternatives. In some therapeutic classes, there are several single-source products with similar health effects. Because the Medicare program pays for each of these products in its own billing code based on its own ASP, there is less pressure for price competition among these products. For example, among the list of the top 20 highest expenditure drugs, some drugs that are competitors are each paid under separate billing codes based on their separate ASPs (for example, epoetin alfa (Procrit/Epo) and darbepoetin alfa (Aranesp), which are used to stimulate production of red blood cells, and ranibizumab and aflibercept, which treat wet AMD and certain other eye conditions). The upward trend in ASP payment rates for these drugs demonstrates that price competition has been limited among single-source competitor products under the ASP payment system. Despite moderate declines in ASPs for epoetin alfa and darbepoetin alfa during the first five years of the ASP payment system (at an average annual rate of roughly –2 percent and –4 percent per year, respectively), these products’ ASPs have grown significantly since that time (Table 5-7, p. 131). Between 2010 and 2016, the ASPs for epoetin alfa and darbepoetin alfa have increased at an average rate of roughly 4.0 percent and 6.5 percent per year, respectively. With ranibizumab and aflibercept, price competition has been very limited. Aflibercept’s ASP has not changed and ranibizumab’s ASP has declined modestly (0.6 percent per year on average).

The Commission has held that Medicare should pay similar rates for similar care. With respect to drugs, that principle may suggest paying single-source drugs and biologics with similar health effects under the same billing code at the same payment rate. Doing so would be expected to generate more price competition among products than separate billing codes. With two or more similar products paid under the same billing code and paid at a rate that is based on the volume-weighted ASP for the products, drug manufacturers would have an incentive to lower their price relative to their competitors to make their product more attractive to providers and garner market share. Because research and development costs

for single-source drugs and biologics are higher than for generic drugs, we would not expect the prices of these products under a combined billing code policy to decline to the level observed with generic drugs. Nonetheless, we would expect prices to be lower than they are currently, which would translate into savings for beneficiaries and taxpayers.

The issue of consolidated billing codes is also relevant to biosimilar and reference biologics. CMS proposed and finalized a policy that all biosimilar products associated with a particular reference product will be paid under a single billing code and receive a payment equal to 100 percent of the weighted average ASPs for the biosimilar products plus a constant dollar add-on equal to 6 percent of the reference product's ASP. The reference biologic remains in its own separate billing code and continues to be paid 106 percent of its own ASP.

Grouping biosimilar and reference products together under one billing code and paying them the same rate would be expected to generate greater price competition relative to two separate codes for these products. Reference biologics receive patent protection and 12 years of exclusivity before a biosimilar can enter the market, during which time the reference biologic faces little price competition. Once the patent and exclusivity periods elapse, competitive biosimilar manufacturers are able to enter the market facing less risk than the reference biologic manufacturer and are able to produce a similar product at lower cost. Under a single payment rate, the biosimilar and reference products would all face the same incentive to compete based on price and quality and generate the best price for beneficiaries (who are liable for 20 percent cost sharing for Part B drugs) and taxpayers. The effect of including the reference product and biosimilars under a single billing code was considered by the Congressional Budget Office in 2008 when it estimated that an abbreviated approval process for biosimilars would generate more savings if the reference product and biosimilars were assigned to the same Medicare Part B billing code rather than each product assigned separate billing codes (Congressional Budget Office 2008).

Some stakeholders have criticized a policy of consolidated billing codes for single-source drugs and biologics with similar health effects or for biosimilars and reference products as reducing incentives for research and development for these products. Others argue that given the large market for Part B drugs, there is likely to continue to be interest in the development of drugs even in

the presence of a consolidated billing code policy. If CMS were to develop a process for establishing consolidated billing codes for therapeutically similar drugs, it could include consideration of a variety of issues—for example, the potential effect on access to care, program spending, and future research on drugs in the category. Additionally, some industry stakeholders contend that high prices are needed in general to fund research and development. Currently, there is insufficient objective, transparent data available on the research and development costs of new drugs, biologics, and biosimilars.

Some stakeholders also contend that combined billing codes could have an adverse impact on beneficiary access. Some assert that if a beneficiary needs a particular product paid under a combined billing code and that product is more expensive than the code's other products, the clinician would be unwilling to supply the drug to the beneficiary. While a combined billing code would create incentives for use of the lowest priced product, the clinician would continue to have the choice to select the product most appropriate for the patient. The payment rate for a combined billing code is based on the volume-weighted average ASP for all the products, not the ASP of the lowest cost product. Under this methodology, the rate paid for a combined code's lowest priced product would be higher than if it were paid under a separate code. Thus, clinicians earn more net revenue than they otherwise would on the least costly drug, and that additional revenue could help offset the cost of a higher priced drug if needed by a particular patient.

A key issue to be considered with consolidated billing codes is how CMS would determine when products should be grouped together and when they should retain their separate billing codes. A choice is available about what types of products this policy could apply to. If the policy were applied to biosimilars and reference products, the FDA's determination that the products are biosimilar would serve as a basis for CMS putting the biosimilar and reference products under the same billing code. If the policy were applied to groups of single-source drugs and biologics with similar health effects, a process would be needed to identify groups of products that achieve comparable clinical outcomes. It would also be important that CMS solicit input from clinical experts (including practicing physicians in the relevant specialties) and a wide range of stakeholders, including beneficiaries and the public. As part of this process, CMS could seek a technology assessment from groups with clinical expertise. Examples of some existing bodies that could play a role in

this process include the Medicare Evidence Development & Coverage Advisory Committee and the Agency for Healthcare Research and Quality's Evidence-Based Practice Centers, among others. Any process for seeking clinical expertise and stakeholder input would need to be carefully designed to avoid conflicts of interest, give the public and stakeholders adequate notice and opportunity for comment, and allow for decisions to be reconsidered as clinical evidence evolved.

Restructuring the competitive acquisition program

Medicare implemented a voluntary competitive acquisition program (CAP) for Part B drugs from June 2006 to December 2008. The goal was to remove physicians from the business of buying and billing for drugs and eliminate any financial incentives for prescribing drugs. Under the program, Medicare paid a vendor to supply Part B drugs to physicians who chose to enroll in the program instead of paying the physicians directly for the drugs they administer. The program was viewed as unsuccessful largely because physician enrollment was low, the vendor had little leverage to negotiate discounts, and Medicare paid the vendor more than ASP + 6 percent for the drugs. The CAP has been suspended since the end of 2008, when the first CAP contract period expired. In 2008, CMS put a second CAP contract out to bid for the period from 2009 to 2011. CMS reported receiving several qualified bids, but because of contractual issues with the successful bidders CMS suspended the program at the end of 2008.²⁹ Although Medicare's original experience with the CAP faced challenges, the concept underlying the program—to eliminate financial incentives physicians face when prescribing Part B drugs—continues to have appeal. We explore ways to restructure the CAP to address the challenges it faced, particularly to increase physician enrollment and provide the vendor with tools to negotiate more favorable discounts and support high-quality care. A carefully reconstructed CAP with population-based incentives for quality and cost would be consistent with other efforts underway more broadly in the Medicare program to move toward delivery system and payment reform.

Background on Medicare's CAP

Under the CAP, physician practices chose whether to join the program and receive drugs from the CAP vendor or continue to buy and bill drugs under the ASP payment system. Before a patient's visit to the doctor for a drug administration, the patient's physician would place an

order with the CAP vendor to deliver drugs specifically for that individual patient. If the physician needed the drug urgently for a beneficiary and had not ordered it, the physician was permitted to administer the drug from his or her own inventory and the CAP vendor would replenish the physician's inventory afterwards. More than 45 percent of drugs furnished by the CAP vendor in 2006 and 2007 were provided through this emergency restocking provision. After the physician administered the drug, the physician would submit a claim to Medicare for the drug administration services (but not for the drug itself). Medicare would pay the CAP vendor for the drug, and the vendor would bill the beneficiary for the drug cost sharing.

CMS conducted a bidding process to select organizations to become CAP vendors. CMS offered contracts to several organizations but only one organization, BioScrip, chose to sign a contract and became the national CAP vendor.

CMS selected the drugs for inclusion in the program. Roughly 180 individually coded Part B drugs were included in the program, with CMS focusing on drugs administered by oncologists, rheumatologists, ophthalmologists, and psychiatrists. For drugs not included in the program, physicians participating in the CAP continued to bill Medicare for the drugs under the ASP payment system.

Roughly 1,000 physician practices participated in the CAP each of the 3 years it was in operation (with some practices leaving and new practices entering over this period). Among drugs furnished by the CAP vendor, rheumatology drugs were overrepresented and oncology drugs were underrepresented, suggesting that rheumatologists were more likely to enroll than oncologists. Physicians who participated in the program reported being generally satisfied with it (Drozd et al. 2009). However, roughly 50 percent of practices that participated in the program one year chose not to participate the next year. Beneficiaries who received drugs through the program reported few problems with access to drugs or cost-sharing billing by the CAP vendor.

An evaluation of the program by a CMS contractor, RTI International, found that the aggregate price Medicare paid the CAP vendor for Part B drugs exceeded ASP + 6 percent (roughly 3 percent higher in aggregate through 2007) (Drozd et al. 2009). Several factors contributed to CAP payments exceeding ASP + 6 percent. While CMS limited the vendor's bid in aggregate to no greater than ASP + 6 percent, the aggregate bid was calculated as a weighted average across all billing codes using historic

utilization data for the weights. The relative utilization of drugs furnished by the CAP vendor was different from the historic claims data, which contributed to the aggregate payments being higher than ASP + 6 percent. In addition, CMS updated the bid prices based on the producer price index for drugs. According to RTI, this index grew more quickly than the ASP for some drugs, leading to payments that exceeded ASP + 6 percent. Beyond these issues, there were broader challenges with this model that made it difficult to generate price savings. The CAP vendor was required to offer all biologics and single-source drugs and was not permitted to create a formulary, giving the vendor little leverage to obtain favorable prices from manufacturers.

Restructuring the CAP

To restructure the CAP, two key challenges identified during the original program need to be addressed: increasing physician enrollment in the program and enhancing the vendor's leverage to obtain favorable prices.

Encouraging physician enrollment For the CAP to be successful, physician enrollment in the program would need to increase. Two general approaches could be considered: (1) a voluntary program with incentives for participation or (2) a mandatory program with all physicians required to participate. A mandatory program would have the advantage of ensuring that the population for which the vendor was negotiating drug prices would be large, increasing the vendor's leverage. However, there would likely be resistance to a mandatory program, both because some physicians may not want to be dependent on a Medicare-selected vendor and because some physicians earn substantial profits from Part B drugs under the current reimbursement structure.

A voluntary program in which physicians are given incentives to participate in the CAP is another option. At least two types of incentives could be considered. Physicians who enrolled in the program could be given the opportunity to share in any savings achieved, creating a positive incentive for participation. At the same time, the Medicare add-on payment to ASP (6 percent or any future modification) in the traditional buy-and-bill payment system could be reduced or eliminated, creating an incentive for physicians to move away from that system and enroll in the CAP.

There may be additional ways to encourage enrollment in the program. Experience with Medicare's CAP showed that some physicians did not want to obtain drugs from

the CAP vendor. One concern they expressed involved the administrative burden of having to place an order with the CAP vendor for each Medicare patient in advance of the patient's office visit and having to keep track of the vendor-supplied drugs for each patient. In fact, nearly half of drugs furnished by the CAP vendor were not done so in advance of the patient's visit, as the design of the CAP had envisioned. Instead, physicians furnished the drug to the patient from their own supply under the emergency provision and the vendor restocked the drug afterwards. To address this design issue, the CAP could be restructured to be a stock-replacement model.

Under a stock-replacement model, physicians would estimate the type and quantity of drugs they require for all of their Medicare patients for a week (or some other short time period). The vendor would supply the drugs. When a drug was used, the physician would notify the vendor, and the vendor would then bill Medicare and the beneficiary for the drug and send the physician practice a replacement for the administered drug. This model would reduce the administrative burden on physicians and vendors. Physicians would not have to send the vendor in advance a separate prescription for each patient and would not have to separate inventory by patient (although they would still need to keep drugs for Medicare beneficiaries separate from drugs for their other patients). This model would also maintain the vendor's role in collecting beneficiary cost sharing, something that some physicians found to be an attractive feature of the CAP.

Another structure that could be considered is a group purchasing organization (GPO) model. Under a GPO approach, the vendor would negotiate the price at which participating physicians would acquire drugs but not supply the drugs directly to physicians. Instead, physicians would acquire drugs from wholesalers and distributors in the marketplace as they normally would, but at a price negotiated by the vendor, and Medicare would pay physicians the negotiated rate for the drugs. This arrangement would effectively eliminate any profit or loss the physician would otherwise make on the drug. Since physicians would not know at the time they purchased a supply of drugs how much would be used for Medicare patients versus other patients, there would need to be a retroactive reconciliation process to ensure that the appropriate price was charged for the units of the drug administered to Medicare beneficiaries.

Formulary authority In the original CAP, the vendor was required to offer all drugs specified by CMS (with

the exception of generics, from which the vendor could choose one product among a group of generics). This requirement gave the vendor little leverage to negotiate favorable prices. To give the vendor more leverage, the vendor could be permitted to create a formulary (i.e., a list of covered or preferred drugs).

A formulary would give the vendor leverage to negotiate more favorable prices in situations where multiple drugs with the same health effects exist. If the vendor had the ability to steer physicians toward using a preferred drug over its competitors, with sufficient volume for the preferred drug, the vendor would have leverage to obtain price concessions on the drug. For drugs without therapeutic alternatives, formulary authority would do little to increase the vendor's leverage. If the CAP were restructured to permit the vendor to create a formulary, decisions would have to be made about what constitutes an acceptable formulary and how the formulary would be developed.

A range of potential formulary structures exists. Under one approach, the vendor is able to exclude drugs if it can offer another drug with similar health effects for a lower price. Under another approach, the vendor is required to offer all drugs, but the vendor is able to designate lower cost drugs as preferred and can encourage physicians to use preferred drugs through shared savings opportunities. Depending on how the formulary was structured, an exceptions process and appeals process could be needed (particularly if the vendor was permitted to exclude drugs from the formulary or if the vendor had prior authorization functions).³⁰

In addition, under a formulary approach, requirements would need to be established regarding the vendor's process to develop the formulary and regarding the clinical or other experts participating in that process. In addition, criteria governing conflicts of interest would be needed to prevent participation of physicians or other experts who might have a financial stake in a particular pharmaceutical product. Decisions would also have to be made about how much oversight CMS would have over the formulary.

An important factor in building acceptance of a formulary would be to involve physicians who treat Medicare beneficiaries in the formulary's development, possibly through a collaborative process between the vendor and leading physicians in the relevant clinical specialties. There is some evidence from integrated delivery systems that when physicians participate in formulary development, they are more likely to adhere to the

formulary. The combination of physician involvement in the formulary development process and shared savings opportunities for physicians would strengthen the vendor's negotiating leverage.

Illustrative CAP To illustrate how a restructured vendor program could be designed and what issues would have to be considered in operating such a program, we considered the following features:

- Physician enrollment in CAP remains voluntary.
- The CAP uses a formulary with shared savings opportunities for beneficiaries, physicians, and the vendor.
- The add-on payment to ASP under the traditional buy-and-bill system is reduced or eliminated.
- The CAP would be a stock-replacement model.

The illustrative CAP described above would maintain the voluntary nature of the CAP. It would encourage physician participation by a combination of offering physicians a shared savings opportunity under the CAP, reducing the ASP add-on payment in the traditional buy-and-bill system, and making the CAP simpler for physicians by restructuring it into a stock-replacement model. Physicians would have an incentive to use preferred drugs through a shared savings opportunity. Under a CAP with these features, if physician enrollment was sizable and physicians generally adhered to the formulary, the vendor would have enhanced leverage to negotiate discounts on drugs with therapeutic substitutes.

An important design issue would be how to pay the vendor. As with the original CAP, the amount Medicare paid the vendor for each drug could be determined based on the vendor's bid price to supply the drug, with one or more organizations selected to be vendors through a competitive bidding process. The original CAP had problems updating the bids over time using the producer price index because it was not a good proxy for price changes at the individual drug level. To avoid this problem, the vendor could be required to structure its bid for each drug as a percentage of ASP, which would ensure that the price Medicare paid the vendor for drugs tracked trends in ASP.

Another important design issue would be how to measure and apportion savings. Savings could be shared with the beneficiary by basing the beneficiary's cost sharing on the vendor's price. If the vendor's price were lower than

**TABLE
5-8****Current Part B drug dispensing
and supplying fees**

Dispensing and supplying fees	Current payment rate
Inhalation drug dispensing fee:	
Initial one-time fee	\$57
30-day supply	\$33
90-day supply	\$66
Immunosuppressive, oral anticancer, and oral antiemetic drug supplying fee:	
Initial one-time fee for immunosuppressives	\$50
First drug in a 30-day period	\$24
Subsequent drug in the same 30-day period	\$16

Source: CMS Manual System Pub 100-04 Medicare Claims Processing, Transmittal 754, "Supplying Fee and Inhalation Drug Dispensing Fee Revisions and Clarifications." November 10, 2005.

the price paid by the traditional Medicare program, the beneficiary would save.

Offering physicians shared savings opportunities under a CAP would engage physicians in managing the total Medicare cost of Part B drugs (i.e., choice of agent, price, duration of treatment, and appropriateness of treatment). Such an approach has the potential to offer more robust incentives for efficient, high-quality care than what currently exist under the ASP payment system. To that end, it would be important that a restructured CAP measure savings in a way that takes into account how total spending has changed, reflecting both price and utilization changes. In contrast, it would not be beneficial for a savings measure under a restructured CAP to focus only on price since that approach could create unintended incentives for use of more expensive drugs. For example, hypothetically, if an expensive drug could be purchased for \$700 (30 percent below its \$1,000 ASP) and a cheaper alternative could be purchased for \$100 (100 percent of its ASP), Medicare would not want to create incentives for the provider and vendor to use the \$700 drug (because of potentially \$300 shared savings) over the \$100 drug (with potentially no shared savings). Estimating savings (or costs) from a restructured CAP based on changes in the total cost of Part B drugs would avoid these concerns about unintended incentives.

To measure the effect of the CAP on total spending, policymakers would have to identify the spending benchmark against which CAP spending would be compared. For example, should the spending benchmark be based on a historical estimate of drug spending updated for inflation or on a comparison of drug spending trends for CAP-participating physicians and for nonparticipating physicians? In addition, should spending be measured at the aggregate level across all drugs and all patients or across patient groups with certain conditions? Since drug prices at the product level move in a variety of directions, applying a broad inflation measure to aggregate drug spending might not be a good proxy for spending growth in the absence of the program. Comparing spending growth for participating and nonparticipating physicians would be a better indicator of performance. One approach could be to identify patient groups with certain conditions for which several drug therapeutic alternatives exist and compare drug spending for these patient groups over time for CAP-participating physicians and nonparticipating physicians. The apportionment of shared savings among the CAP's participating physicians raises other design questions. Would all physicians who participate receive a portion of any overall savings, or would savings be apportioned based on performance at the practice level? Measuring any savings at the practice level would create stronger incentives for use of preferred drugs. However, a sufficiently large number of patients would be needed to measure savings for an individual practice. To address measurement challenges for small practices, approaches could be considered to aggregate performance data across a number of small practices or to measure performance for an individual practice using multiple years of data.

Overall, we would expect a restructured CAP with the features we identified to generate savings because the ASP add-on in the buy-and-bill system would be reduced or eliminated. Whether such a program would be able to achieve additional savings beyond those generated by the reduced add-on would depend on a number of factors, including how much leverage the vendor had to negotiate price discounts, which would depend on how many physicians enrolled in the program and the extent to which these physicians used the preferred drugs over more expensive alternatives. The ability to achieve additional savings would also depend on what share of Part B spending is accounted for by drugs that have substitutes and thus offer savings potential, something that is currently unknown. Also, any savings through reduced prices or shifts in utilization would be netted against the vendor's operating costs—those associated with

developing a formulary, negotiating prices, accepting drug orders from physicians, shipping, billing, collecting cost sharing, auditing, and quality assurance.

The original CAP applied across a wide range of drugs, covering 180 drug billing codes. A restructured CAP raises the question of whether the program should be applied broadly or should focus on certain specialties or certain drugs across specialties for which opportunities for savings appear greatest. Since Part B drug spending is fairly concentrated among a small group of drugs (the top 30 billing codes account for more than 70 percent of spending) and since some drugs do not have therapeutic alternatives, there could be benefits to focusing the program, at least initially, on those areas where it has the best chance of success. For example, this approach could be tested for one specialty for which spending is substantial enough to make it worthwhile. Alternatively, the program could focus on high-expenditure drugs that have therapeutic alternatives (including biosimilars or products not biosimilar but considered by clinicians to have similar health effects).

Part B drugs furnished by suppliers

Medicare Part B pays dispensing and supplying fees for certain drugs furnished by suppliers. Medicare pays dispensing fees for inhalation drugs furnished by durable medical equipment suppliers, in addition to paying ASP + 6 percent for the drugs. Beneficiaries are liable for 20 percent cost sharing on these fees, similar to other Part B services. In 2014, Medicare and beneficiaries paid inhalation drug suppliers about \$800 million in ASP + 6 percent payments and \$120 million in dispensing fees for inhalation drugs. Medicare also pays supplying fees for Part B–covered immunosuppressive, oral anticancer, and oral antiemetic drugs furnished by pharmacies. In 2014, Medicare and beneficiaries paid suppliers \$700 million in ASP + 6 percent payments and \$35 million in supplying fees for these drugs.

The inhalation drug dispensing fee is \$33 per 30-day supply of drugs, with higher fees for 90-day supplies and for the first supply a beneficiary receives (Table 5-8). The supplying fees for immunosuppressive, oral anticancer, and oral antiemetics drugs are \$24 for the first prescription and \$16 for each subsequent prescription in a 30-day period, with a higher amount for the first immunosuppressive prescription ever.

Under the statute, CMS has discretion to pay a dispensing fee for Part B drugs furnished by pharmacies, but the statute does not specify what the dispensing fee is intended to cover.³¹ In regulation, CMS has not precisely defined the scope of the dispensing fee but has described it as including shipping, handling, and pharmacy services necessary to get the drugs to the beneficiary and has said it does not include pharmacy care management services (Centers for Medicare & Medicaid Services 2005).³² The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 gave the Secretary the authority to pay a supplying fee for immunosuppressive, oral anticancer, and oral antiemetic drugs. Although referred to as a supplying fee, it is similar to a pharmacy dispensing fee. CMS has said that the lack of online claims adjudication for Part B drugs means that pharmacies face higher costs when billing Part B compared with other payers. CMS has said it is appropriate for the supplying fee to be higher than other payers' dispensing fees because of the lack of online claims adjudication, but not for other reasons (Centers for Medicare & Medicaid Services 2005).

OIG has reported that the Part B dispensing and supplying fees are substantially higher than dispensing fees paid by Part D plans and Medicaid, and it recommended that Medicare's Part B fees be lowered to a level similar to other payers (Office of Inspector General 2014b). OIG found that in 2011, Medicare Part D plans paid a dispensing fee of about \$4.60 for inhalation drugs and about \$1.80 for immunosuppressive, oral anticancer, and oral antiemetic drugs; Medicaid paid about \$4.60 per prescription across these different types of drugs.

RECOMMENDATION 5

The Secretary should reduce the Medicare Part B dispensing and supplying fees to rates similar to other payers.

RATIONALE 5

Medicare Part B pays dispensing fees for inhalation drugs and supplying fees for oral anticancer, oral antiemetic, and immunosuppressive drugs that are substantially higher than the rates paid by Medicare Part D plans and Medicaid. These fee levels have been in effect since 2006, and the data on which the fees were based were quite limited. We believe that Medicare should not pay a dispensing fee higher than other payers. Reducing the dispensing and supplying fees to the level of other payers (e.g., \$5 per prescription) would generate savings for the Medicare program and beneficiaries.

Spending

- Reducing the Part B drug dispensing and supplying fees would decrease federal program spending by between \$50 million and \$250 million over one year and by less than \$1 billion over five years.

Beneficiary and provider

- Reducing the Part B drug dispensing and supplying fees would generate savings for beneficiaries through lower cost sharing. Reducing these fees would represent a reduction in suppliers’ total Medicare revenues of less than 5 percent. We would not expect this recommendation to have adverse effects on beneficiaries’ access to care or suppliers’ willingness or ability to furnish these drugs to Medicare beneficiaries.

Improving the efficiency of oncology care in fee-for-service Medicare

Medicare spending for anticancer drugs is substantial; in 2014, anticancer drugs accounted for about 55 percent of the nearly \$21 billion spent on Part B drugs paid under the ASP methodology in physician office and HOPD settings. Anticancer drugs include chemotherapy and supportive drugs (such as pegfilgrastim and darbepoetin alfa), which address the side effects of cancer treatment, including nausea and vomiting, low white blood cell counts, and anemia. In the Commission’s June 2015 report to the Congress, we explored episode-of-care and bundled-payment approaches as mechanisms to heighten providers’ sensitivity to the cost of Part B medications used in a cancer care treatment regimen (Medicare Payment Advisory Commission 2015). Specifically, we examined Medicare spending in the six-month period following the first oncology drug administration and reviewed issues in designing oncology bundling, such as what triggers an episode and the services included in the bundle. With the availability of a large evidence base and regularly updated clinical guidelines, oncology is a clinical area amenable to payment bundling.

In this section, we continue to examine episode-of-care and other approaches that seek to improve the efficiency of oncology services while improving care quality. Keeping in mind Medicare’s coverage and payment policies for Part B anticancer drugs and their

administration, we examined factors that can influence clinicians’ prescribing of anticancer drugs. In addition, we examined four examples of narrower versus broader approaches designed to improve the efficiency of oncology care in Medicare and non-Medicare populations. The two narrower approaches—risk sharing and oncology clinical pathways—attempt to improve the value of drug spending:

- Risk-sharing agreements made between product manufacturers and payers link payment for a drug to patient outcomes, such as a clinical measure (e.g., laboratory value) or an event (inpatient hospital admission). Product manufacturers and commercial payers have implemented these agreements in the United States and internationally.
- Oncology clinical pathways consist of treatment protocols adopted by commercial payers and providers (hospitals and clinicians) to standardize drug treatment, reduce unnecessary variation, improve quality of care, and reduce costs. Some payers and providers have implemented various approaches that link compliance to clinical pathways to financial incentives.

By contrast, the two other, broader approaches—medical homes and episode-of-care approaches—take a more holistic view of cancer care, seeking to improve care management and coordination:

- The oncology medical home is built on the concept of patient-centered care; the expectation is that enhanced services, such as team-based care, will expand patient access and education and that clinical practices will improve health outcomes and reduce cost. The Center for Medicare & Medicaid Innovation (CMMI) funded an oncology medical home under a three-year grant, which ended in 2015. Commercial payers also have implemented oncology medical homes.
- Bundling Part B oncology drugs with non-oncology services holds providers accountable for the total cost of services across an episode of care. UnitedHealthcare implemented such an approach under which practices were paid ASP for chemotherapy drugs (instead of ASP plus a negotiated add-on amount), an episode fee (based on the contracted drug add-on amount to ASP), and fee-for-service (FFS) contractual amounts for most other services. Practices were eligible for shared savings if quality improved or total costs decreased.

How Medicare covers and pays for Part B anticancer drugs and administration (infusion) services

Medicare Part B covers infusible and injectable drugs, including anticancer drugs, administered by clinicians in physician offices and HOPDs if the treatment is reasonable and necessary for the diagnosis or treatment of an illness or injury. In addition, Medicare Part B covers certain oral anticancer and oral antiemetic products. The Omnibus Budget Reconciliation Act of 1993 (Section 1861(s)(2)(Q) of the statute) provides Part B coverage for FDA-approved oral anticancer drugs prescribed as chemotherapeutic agents if they have the same active ingredients and are used for the same indications as chemotherapeutic agents that would be covered if they were not self-administered and were furnished incident to a clinician's service. The Balance Budget Act of 1997 (Section 1861(s)(2)(T) of the statute) provides Part B coverage for FDA-approved oral drugs prescribed as acute antiemetic (antinausea) products that are used as part of a chemotherapeutic regimen if the drug is prescribed for use immediately before, at, or within 48 hours after the time of the administration of the chemotherapeutic regimen and as a full replacement for the antiemetic therapy that would otherwise be administered intravenously.

Specific to anticancer drugs, the statute (Section 1861(t)) requires that Medicare cover any drug used in an "anticancer chemotherapeutic regimen," as long as the use is "for a medically accepted indication," which includes indications for uses listed on the product's label (written by its manufacturer for FDA approval) and off-label uses reported in one of several drug compendia and in peer-reviewed medical literature. The statute recognizes several compendia and gives the Secretary authority to revise the list as appropriate for identifying medically accepted indications for drugs. Medicare recently expanded its list of approved compendia to set coverage policies for off-label anticancer drugs.³³

Part B spending (program payments and beneficiary cost sharing) for anticancer drugs paid under ASP in the office and HOPD settings and to suppliers was \$11.5 billion, accounting for 55 percent of all drugs paid under ASP in 2014.³⁴ Anticancer drugs accounted for 7 of 10 leading drugs as measured by Part B ASP spending. In paying for anticancer and related drugs under Part B using ASP methodology, Medicare makes an additional separate payment for administration of the drug under the PFS or OPPS. In 2014, we estimate that Part B spending on the infusion (administration) of chemotherapy drugs

was roughly \$1.0 billion; about 60 percent of this total was associated with administration services furnished in HOPDs.³⁵

Anticancer drugs and the associated administration services account for a substantial portion of gross Medicare revenue for oncology practices. Together, Medicare-allowed charges for anticancer drugs and their administration accounted for nearly 60 percent of total Medicare-allowed charges billed by clinicians specializing in oncology. A Commission analysis found that for an oncology episode—defined as 180 days following the administration of an anticancer drug paid under Part B for beneficiaries newly diagnosed with breast, colon, or lung cancer in 2011 or 2012—nearly half of total Part A and Part B spending was associated with spending for anticancer drugs and their administration services (Medicare Payment Advisory Commission 2015).

Variation in the use of anticancer drug regimens

Researchers have found variation in clinicians' anticancer drug utilization and that various factors affect clinicians' prescribing decisions, including their choice among therapeutic alternatives. For example, drugs may vary in their effectiveness in treating patients with certain conditions or comorbidities, and they can have different side effects. Decisions can also take into account whether a drug is on label or off label for a patient's condition, or whether a drug is compounded.

Patients' preferences and demographic and clinical characteristics also affect use and choice of anticancer regimens. Researchers reported that age, comorbidities, and cancer stage were the primary determinants of chemotherapy use among Medicare beneficiaries with newly diagnosed ovarian cancer who received chemotherapy within one year of diagnosis (Polsky et al. 2006). These researchers found that (1) race, income, and geography (hospital referral region) also were significant in predicting chemotherapy use, although less so than age, cancer stage, and comorbidities; and (2) the presence of more hospitals with oncology facilities in a market predicted greater use of chemotherapy. Other researchers found that Medicare beneficiaries in the oldest age groups were less likely to receive chemotherapy than younger beneficiaries (Schrag et al. 2001, Sundararajan et al. 2002).

Researchers found substantial variation in FFS Medicare in 2011 and 2012 across medical oncology practices in

the use of anticancer drug regimens, advanced imaging, and acute medical inpatient admissions (as measured by Medicare spending per beneficiary after adjustment for demographic and clinical characteristics) (Clough et al. 2015). Overall, the study reported that the ratio of the mean spending per beneficiary between the highest spending practices (in the 75th percentile of practice costs) and the lowest spending practices (in the 25th percentile of practice costs) ranged from 1.2 to 1.4 for anticancer drugs, imaging, and medical admissions. Supportive care drugs (pegfilgrastim, darbepoetin alfa, and palonosetron), bevacizumab, and positron-emission tomography accounted for the greatest share of variation between the highest spending and lowest spending practices.

In addition, the researchers found significant practice-level variation in mean spending per beneficiary for the leading 10 anticancer drugs by cancer type. For example, the ratio of the mean beneficiary spending for the highest spending practices and the lowest spending practices for treatment of lung, breast, and colorectal cancers was:

- 2.8 for pegfilgrastim, 2.8 for bevacizumab, 1.6 for pemetrexed per lung cancer beneficiary;
- 2.2 for pegfilgrastim, 2.0 for bevacizumab, and 1.6 for trastuzumab per breast cancer beneficiary; and
- 4.4 for pegfilgrastim, 1.8 for bevacizumab, 1.4 for cetuximab, and 1.3 for oxaliplatin per colorectal cancer beneficiary (Clough et al. 2015).

The researchers also found an association between increasing practice size and increased use of chemotherapy and imaging (as measured by Medicare spending) (Clough et al. 2015). Practice-level factors that could influence use of services included treatment protocols, information technology, staffing patterns, access to ancillary services, and hours of operation.

Other research examined the variation in mean total FFS Medicare spending between 2004 and 2006 for beneficiaries in the one year after they underwent surgical resection for colorectal cancer (i.e., the index hospitalization). Spending was analyzed across hospitals, which were ranked from lowest to highest based on the index surgical hospitalization. The ratio of mean total payments between hospitals in the highest spending quintile compared with hospitals in the lowest spending quintile was greatest for chemotherapy drugs (4.2), followed by physician services (2.0), post-acute services (1.8), and hospital readmissions (1.4) (Abdelsattar et al.

2015a). The payments associated with the index surgical hospitalization, which had the largest share of total payments, did not vary substantially between hospitals in the lowest spending and highest spending quintiles; post-acute services had the second largest share of mean total payments and accounted for much of the variation in mean total spending.

In addition, two studies discussed in the prior section suggested that anticancer drug choice may to some degree be influenced by the higher add-on payment to ASP (Jacobson et al. 2010, Office of Inspector General 2012).

Last, clinician prescribing can be influenced by Medicare's local and national coverage determinations. Medicare claims processing contractors and CMS sometimes develop coverage determinations based on the presence of certain clinical conditions, prerequisite treatments, and other factors. Each coverage policy addresses a clinical topic and one or more types of service, including drugs and biologics. Contractors issue local coverage determinations that apply to the states in their jurisdictions. CMS develops national coverage determinations that apply to all beneficiaries across the country. Notably, Medicare coverage exists for most items and services without the need for individual coverage determinations (Office of Inspector General 2014a). Instead, most services are paid through CMS's prospective payment mechanisms, under which providers serve as the purchaser and make decisions about which items and services are furnished in the payment bundle.

Options for improving the efficiency of oncology services

CMS; the Institute of Medicine (IOM), now known as the Health and Medicine Division (a division of the National Academies of Sciences, Engineering, and Medicine); and others have discussed the need to improve health outcomes for patients with cancer, improve the quality of cancer care, and reduce spending for treatment. The current FFS payment systems in general can have the following undesirable effects on aspects of cancer care:

- *Encourage the selection of more costly drugs and discourage the use of lower cost products, even when clinical results are similar (Newcomer 2012)*—Bach (2007) contends that FFS payment incentives have promoted a culture of buying and selling cancer drugs at the expense of other aspects of cancer care. According to the American Society of Clinical Oncology (2015), “many patients are receiving

expensive drugs that increase the costs of care for both patients and payers without providing benefits to the patients.” Studies of Medicare beneficiary populations receiving chemotherapy report statistically significant practice-level and regional variation (Clough et al. 2015, Polsky et al. 2006).

- *Encourage the use of more costly types of radiation therapy with limited evidence to support clinical superiority compared with less costly alternatives*—For example, some contend that financial incentives may be one of the factors for the rapid adoption of intensity-modulated radiotherapy compared with three-dimensional conformal radiation therapy for localized prostate cancer treatment (Balogh et al. 2013, Carreyrou and Tamman 2010, Institute of Medicine 2013, Jacobs et al. 2012).
- *Lead to the overuse of oncology-related interventions*—According to the IOM, use of chemotherapy near the end of life is an example of overuse (Institute of Medicine 2013). Researchers reported that nearly 11 percent of FFS Medicare decedents in 2010 with cancer (and older than 65 years) received chemotherapy in the last 30 days of life (Bekelman et al. 2016).
- *Inhibit integrated care, which can lead to duplication of care and result in patient complications*—This lack of integration is particularly problematic for patients who have comorbidities that should be managed both by the cancer care and other specialist care teams (Institute of Medicine 2013).
- *Lack tools to promote care coordination, which can result in potentially avoidable emergency department (ED) visits and hospitalizations*—Researchers found that nearly 20 percent of hospital admissions in patients with gastrointestinal cancer were potentially avoidable (Brooks et al. 2014). Some researchers contend that improvements in the management of cancer patients, such as after-hours access to clinicians, may lead to reductions in hospitalizations and ED visits (American Society of Clinical Oncology 2015, Institute of Medicine 2013, Pyenson and Fitch 2010, Sanghavi et al. 2014).

As part of the Choosing Wisely campaign, the American Society of Clinical Oncology (ASCO) and the Quality Oncology Practice Initiative identified 10 opportunities for reducing waste through the appropriate use of cancer services. See online Appendix 5-A, available at

<http://www.medpac.gov>, for the 10 tests and treatments that ASCO identified (ABIM Foundation 2013).

Seeking alternatives to Medicare’s current FFS payment system, we examined four case studies of approaches designed to introduce value to oncology care payment (Table 5-9, p. 144). These are approaches that CMS and other payers and providers have tested or implemented.

Risk-sharing agreements

As discussed in our June 2010 report to the Congress, risk-sharing agreements link payment of a drug to patient outcomes through risk sharing with product developers (Medicare Payment Advisory Commission 2010). The reward tied to the outcome could be a higher price, while the penalty for undesirable results could be a lower price (through rebates, adjustments, or refunds).

Risk-sharing agreements are more commonly used in Europe than in the United States (Garrison et al. 2015). An example of an agreement for an oncology drug is the risk-sharing agreement between Johnson & Johnson and the National Health Service in the United Kingdom under which the manufacturer assumes the cost of bortezomib if testing indicates that a patient receiving the product is not responding (Young 2015). (Bortezomib is used to treat multiple myeloma.³⁶) According to Neumann and colleagues (2011), this approach involves an after-the-fact refund by the manufacturer to the government, covering the first four months of treatment for patients who do not respond to therapy. Response is based on a biomarker for disease progression. Tasks that the payer (the National Health Service) is responsible for include collecting evidence on patients’ outcomes, analyzing clinical data, and submitting claims (within 60 days) to the product developer for patients who do not respond (National Institute for Health and Care Excellence 2016, University of Washington 2016). For nonresponders, the manufacturer provides a complete refund or provision of the drug for another patient free of charge. Because the National Health Service pays for the drug only for those patients who respond to therapy, this agreement effectively gives the government a sizable discount. The agreement, however, differs from a pure discount because the manufacturer has a strong incentive to maximize the number of patients who respond, not merely the number treated or doses sold. In return, the manufacturer gains market access and maintains its list price. The government reduces drug budget risks, although it adds the burden of maintaining a tracking system to determine whether patients are responding to the drug.

**TABLE
5-9**

Summary of four case-study approaches illustrating strategies to improve the efficiency of oncology services

Payer or provider	Design summary
National Health Service, United Kingdom risk-sharing agreements (underway since 2007)	An agreement between payer and pharmaceutical manufacturers that links payment of a drug to patient outcomes.
Oncology clinical pathways implemented by and ongoing with various commercial payers and providers	Evidence-based treatment protocols that are intended to standardize drug treatment, reduce unnecessary variation, and improve quality of care.
Oncology medical home tested by CMS (completed summer 2015)	CMMI provided a grant to seven community-based oncology practices to test an oncology medical home, COME HOME. The COME HOME model included patients with seven cancer types, and practices were required to provide enhanced services including patient education, enhanced access through triage pathways, and extended night and weekend office hours.
UnitedHealthcare pilot with five physician practices (completed December 2012)	Five participating practices paid FFS for nondrug services, ASP (no add-on) for anticancer drugs, and an initial episode payment for case management. Length of episode varied for lung, colon, and breast cancer. Performance-based payment was based on reducing total spending and meeting quality metrics.

Note: CMMI (Center for Medicare & Medicaid Innovation), COME HOME (Community Oncology Medical Home), FFS (fee-for-service), ASP (average sales price).

For product manufacturers, risk sharing offers the potential to secure reimbursement for technologies whose treatment effects are uncertain, especially if the alternative is noncoverage. From a drug company’s perspective, the model offers predictability of pricing and the prospect of future financial rewards during the time when additional data are being collected. Risk sharing also allows companies to emphasize outcomes and can help differentiate their products from those of competitors. Moreover, it enables companies to offer certain payers discounts without lowering published or “list” prices.

A key implementation issue is selecting and specifying the outcome measured in risk-sharing agreements. According to Neumann and colleagues (2011), the outcome should be objective, clearly defined, reliable, easily measured, and not confounded by patients’ characteristics, and it must assess the selected treatment effect. According to these researchers, clinical outcomes (e.g., hospital admission) are preferable to surrogate endpoints (e.g., measures that rely on laboratory values), unless those endpoints are associated with positive patient outcomes (Neumann et al. 2011). Agreements with outcomes that are assessed during shorter time horizons have an advantage over longer term agreements, which may be difficult to execute (Neumann et al. 2011). Other issues and obstacles in establishing such agreements, identified in an online survey of

stakeholders, include (1) the significant administrative burden and time investment incurred by the payer and the drug manufacturer to establish the infrastructure, (2) the development of the data infrastructure to track patients’ outcomes, (3) the significant resources to adjudicate such agreements, and (4) the effect on Medicaid best-price calculations if the risk-sharing agreement links a drug’s performance to a price discount (Garrison et al. 2015).

According to the National Health Service in the United Kingdom, bortezomib lends itself to such a scheme because a protein marker exists that indicates whether a patient has responded to the drug or not (National Institute for Health and Care Excellence 2007). Given predicted response rates, the payer expected that the product developer would rebate at least 15 percent of the cost of bortezomib under the arrangement (National Institute for Health and Care Excellence 2016). Because risk-based arrangements between the payer and the product developer are proprietary, the results (e.g., actual rebates or quantity of replacement product) are typically not published. A survey of oncology pharmacists who implemented this arrangement reported issues with tracking patients and ensuring that claims were submitted (within the allotted time frame) to the product developer for patients who did not respond to treatment (Williamson 2009).

There is an increased interest in establishing risk-sharing agreements in the United States by manufacturers and payers (ISPOR Issues Panel 2014). For example, Novartis established separate performance-based agreements for its recently approved oral drug for the treatment of heart failure (sacubitril/valsartan) with Cigna and Aetna (Humer 2016).³⁷ Amgen and Harvard Pilgrim Health Care established a pay-for-performance plan for a recently approved oral drug for the treatment of hypercholesterolemia (evolocumab) (Appel 2015).³⁸

Oncology clinical pathways

Oncology clinical pathways are evidence-based treatment protocols that payers and providers are adopting to standardize drug treatment, reduce unnecessary variation, and improve quality of care (DeMartino and Larsen 2012).³⁹ Oncology pathways are based on and generally consistent with publicly available clinical guidelines, such as the National Comprehensive Cancer Network guidelines. In contrast to guidelines, oncology pathways may narrow treatment options and suggest when these options are appropriate, may be more prescriptive than guidelines, and may provide specific guidance on the sequencing of care steps and the time line of interventions. Most pathways begin by focusing on chemotherapy, but some have broadened to include other oncology-related services (e.g., radiation oncology services) (DeMartino and Larsen 2012). Oncology pathways typically evaluate competing regimens for a given condition based on efficacy, side effects (toxicity), strength of national guideline recommendations, and cost. One payer explicitly states that in selecting a particular therapy as a pathway, cost is considered only after consideration of all other factors (Anthem 2014).

Oncology clinical pathways are used by some commercial payers and providers in furnishing oncology care. One survey estimated that over half of responding practices used clinical pathways, and about 90 percent used guidelines (Barr and Towle 2011). Various companies (including eViti, New Century Health, Cardinal Health, US Oncology, McKesson Specialty Health, Kew Group, and Via Oncology) have developed pathways (DeMartino and Larsen 2012). In addition, some clinician practices and large cancer centers have developed their own pathways. There are two common business models for pathway development (DeMartino and Larsen 2012). In the first model, a payer sponsors a company to develop pathways and provides incentives to the payer's oncologists to use the pathways. In the second model, oncologists work directly with vendors to develop pathways (Sanghavi et al.

2014); the payers and the oncologists who bill them work together to develop incentives for oncologists to follow the pathways.

Payers and providers have implemented various approaches that link compliance with clinical pathways to financial incentives, including providers receiving a higher reimbursement rate on drugs or other services (e.g., evaluation and management services), an add-on per patient, and a lower risk of denied or delayed reimbursement (DeMartino and Larsen 2012). Under these approaches, providers typically have to meet a certain level of pathway compliance but can go "off pathway" to accommodate patient preferences and variation in disease development. For example, one commercial payer increases the add-on to the drug payment rate if clinicians meet a 60 percent compliance threshold (*Oncology Business Review* 2008). Another commercial payer makes additional payments for each patient who receives treatment as specified by the pathways for breast, lung, and colorectal cancer. If a practice follows the pathways, it receives a \$350 one-time fee at the onset of treatment and payments of \$350 per patient per month while the patient is actively in therapy and treated in compliance with a pathway (Anthem 2014). These arrangements are based on the premise that the additional payments will offset the amount of revenue the practice could gain from administering more costly drugs (Nelson 2013).

Compared with episode-of-care and bundled approaches, payment for pathway adherence may limit flexibility and (depending on the design) may not remove the incentive for some clinicians to furnish higher priced products when therapeutic equivalents exist. Compared with bundling approaches that require providers to be accountable for a wide range of care, use of pathways may not necessarily lead to more coordinated care or enhanced access for beneficiaries. In addition, there is the concern that some clinical pathways are not available to patients and others. In many instances, pathways are proprietary; that is, they are available only to the payers or providers who develop and use them. Applicable to both guidelines and pathways, there is also the concern that more evidence is needed (1) about the clinical effectiveness of a treatment (e.g., drug regimen) compared with its alternatives and (2) about a treatment's effect as measured by clinical outcomes (e.g., patient survival) rather than surrogate endpoints (e.g., tumor response rate).

Some clinicians and a physician specialty organization (i.e., ASCO) have raised the following issues about

the manner in which oncology pathways are currently developed and used:

- There is a lack of transparency and consistency in the design of some pathways.
- Some clinical pathways lack adequate grounding in the clinical literature.
- Some oncology practices experience increased administrative costs because commercial payers use different pathways for the same type and stage of cancer (Zon et al. 2016).

Likewise, some clinicians have raised concerns about the quality of oncology clinical guidelines that are used to develop some clinical pathways. For example:

- He and colleagues (2015) used the Appraisal of Guidelines and Research and Evaluation instrument to examine the quality of clinical practice guidelines for pancreatic cancer.⁴⁰ The researchers gave low scores to the following domains: “rigor of development” (the process used to gather and synthesize the evidence and the methods used to formulate the recommendations and update them), “stakeholder involvement” (the extent to which the guideline was developed by the appropriate stakeholders and represents the views of its intended), “applicability” (the barriers to and facilitators of implementation, strategies to improve uptake, and cost implications of applying the guidelines), and “editorial independence” (recommendations not being unduly biased with competing interests) (He et al. 2015).
- Abdelsattar and colleagues (2015b) found the quality of the processes used to develop clinical practice guidelines for rectal cancer was variable and found differences in the guidelines’ treatment recommendations. Using the Appraisal of Guidelines and Research and Evaluation instrument, the researchers gave low scores to the “applicability” and the “rigor of development” domains (Abdelsattar et al. 2015b).
- Reames and colleagues (2013) found that none of the clinical practice guidelines for lung, breast, prostate, and colorectal cancers met the eight standards that the IOM set forth for developing clinical practice guidelines.⁴¹ The researchers found that less than half of the guidelines were based on systematic literature reviews, only half addressed conflicts of interest, and most did not comply with standards for inclusion of

patient and public involvement in the review process and did not specify their process for updating (Reames et al. 2013).

Oncology medical homes

The medical home builds on the concept of patient-centered care under which a designated provider is responsible for complying with requirements for integrated or coordinated care, evidence-based medicine and performance measurement to assure quality and safety, and enhanced access. In 2010, the first oncology practice was recognized by the National Committee for Quality Assurance as a Level III patient-centered medical home (Sprandio 2012). The adoption of an oncology medical home by providers and payers appears to have been increasing over the past five years (Aetna 2013, Fox 2013).

Between 2012 and 2015, CMMI provided a grant for seven oncology practices to implement a three-year oncology patient-centered medical home. The Community Oncology Medical Home (COME HOME) model offered enhanced services to Medicare and Medicaid beneficiaries and commercially insured patients with one of seven cancer types (breast, lung, colon, pancreas, thyroid, melanoma, and lymphoma). These services included patient education and medication management counseling, team-based care, and enhanced practice access through triage pathways to manage patient symptoms on a 24/7 basis through a triage phone line, extended night and weekend office hours, and on-call providers. CMMI provided a \$19.8 million grant to the participating practices to fund the enhanced services; the grant funding could not be used for services billed with an evaluation and management service (to ensure that CMS would not be paying twice for the same service) (Centers for Medicare & Medicaid Services 2015). Medicare paid participating practices according to existing Medicare coverage determinations and FFS payment policies. This demonstration concluded in 2015.

In the grant’s announcement, CMS said that the oncology medical home model would improve the timeliness and appropriateness of care, reduce unnecessary testing, and reduce hospitalizations and ED visits. At the time of the grant’s award, the grantee projected net total Medicare savings of \$13.76 million (or projected net savings of \$1,715 per beneficiary per year, assuming Medicare enrollment of 8,022 patients over 3 years) due primarily to reductions in hospital admissions and ED visits (McAneny 2012).

At the time this report went to press, the final evaluation of the COME HOME model on total costs, hospital admissions, and ED visits was not available. The initial evaluation conducted by CMS's contractor included Medicare beneficiaries enrolled in the demonstration only in 2013; a comparison group was not included (NORC at the University of Chicago 2014). The initial evaluation examined whether there was an association between length of enrollment in COME HOME and all-cause hospitalizations, hospitalizations for ambulatory care-sensitive conditions, ED visits, and total cost of care.

The contractor reported that the average total cost of care per beneficiary was progressively lower across three-quarters of enrollment in 2013 after adjusting for other beneficiary covariates. The average total cost of care for beneficiaries enrolled for two or three calendar quarters in 2013 was significantly lower compared with care for beneficiaries enrolled in the model for one calendar quarter in 2013. A similar trend was reported for all-cause hospital admissions, with the number of all-cause admissions significantly decreasing as beneficiaries were enrolled in the model for two or three calendar quarters compared with one quarter in 2013. The contractor did not find a statistically significant relationship between length of beneficiary enrollment and rates of ambulatory care-sensitive hospitalizations and ED visits. The contractor could not determine whether the reduction in cost and all-cause admissions over greater lengths of program enrollment was a consequence of the model.

Episode-of-care approach for oncology and non-oncology services

Between October 2009 and December 2012, UnitedHealthcare implemented the initial phase of an oncology payment pilot with 19 distinct types of clinical episodes. The five participating practices were paid ASP instead of ASP plus the negotiated add-on amount for chemotherapy drugs, an episode fee at the initial visit that was based on the contracted drug add-on amount to ASP, and FFS contractual amounts for most other services (including physician services, chemotherapy administration, and diagnostic radiology). The five participating practices were eligible for shared savings if, compared with physician practices in a national payer registry, quality (as measured by survival) improved or total episode costs decreased (or both). The pilot's objectives were to decrease total medical costs by aligning financial incentives supported by use and quality data and remove the link between drug selection and medical oncology income (Newcomer et al. 2014).

The pilot included 810 patients with breast, colon, and lung cancer. The episodes varied based on type of cancer, clinical stage (Stage 0 through Stage IV), and tumor histology. The duration of an episode varied by cancer type and spanned from 4 months to 12 months. At the time of the initial patient presentation, participating practices reported clinical information—such as clinical stage, histology, and intent of treatment (curative or palliative)—to the payer to determine the correct episode.

To arrive at the episode payment for each of the 19 cancer episodes, the national drug margin for each episode was calculated by subtracting the aggregate ASP from the aggregate amount paid for chemotherapy drugs and dividing by the total number of patients in each episode. The episode payment (intended to cover physician hospital care and hospice management) also included a small fee for case management (Newcomer et al. 2014). To compensate providers for furnishing palliative care services, the episode payments continued every four months for patients with metastatic disease who were no longer receiving chemotherapy or were enrolled in hospice (Newcomer et al. 2014).

The participating practices collaborated with the payer to develop quality, cost, and use measures, and the practices met annually to review their outcomes. These outcomes included total cost of care; rates of emergency room and hospitalization use; use of laboratory, diagnostic radiology, durable medical equipment, and surgical services; time to first progression for relapsed patients; hospice days for patients who died; days from last chemotherapy to death; and rate of febrile neutropenia occurrence. During the meeting, providers discussed potential solutions for variation in performance (e.g., in rates of hospital admission and use of diagnostic radiology).

UnitedHealthcare found that their overall spending declined during the pilot while drug spending increased. Specifically, Newcomer and colleagues (2014) reported a 34 percent reduction in actual total spending compared with predicted total spending (\$64.8 million and \$98.1 million, respectively) and a 179 percent increase in actual drug spending compared with predicted drug spending (\$21.0 million versus \$7.5 million, respectively). The authors did not provide information about the changes in the specific components of drug spending and the factors that might have affected any changes. UnitedHealthcare redistributed one-third of the savings to the practices by increasing their episode payments in the second round of the pilot (Appleby 2015).

Although the Newcomer and colleagues (2014) analysis was not designed to determine the drivers of the differences in total medical spending, a subset analysis demonstrated a statistically valid decrease in hospitalization and therapeutic radiology usage for the episode model. Most quality outcomes had insufficient numbers for statistical analysis, but Kaplan-Meier survival curves were monitored for all patients with metastatic disease; lung cancer survivors were the only evaluable subgroup, and there was no significant survival difference between the episode and registry patients (Newcomer et al. 2014).

Since its completion, UnitedHealthcare expanded its model to include additional oncology practices (Appleby 2015). A press report stated that the continuation of the episode model includes five additional practices and that the design is the same as the pilot's, including its inclusion of patients with breast, colon, and lung cancer (Maas 2015).

In addition, in 2015, UnitedHealthcare announced a program for oncologists that offers real-time decision support and a fast-track drug approval program based on the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology. UnitedHealthcare automatically approves treatments that fall under the top three categories of this guideline (1, 2A, and 2B) (Maas 2015).

Under CMMI's authority, Medicare is testing an oncology episode-of-care approach, the Oncology Care Model, which is expected to start in 2016 and last for five years. An episode will last for six months and will begin when the patient receives chemotherapy administration for cancer under Part B or Part D. Current FFS payment policies and coverage determinations will apply to participating practices. Unlike the UnitedHealthcare pilot, practices will continue to be paid the 6 percent add-on to the drug payment's ASP. Practices will be paid an additional \$160 per beneficiary per month for furnishing

enhanced services, such as 24/7 access to clinicians with real-time access to medical records. Under the model, risk sharing includes a one-sided arrangement for the first two years and an optional two-sided arrangement for the last three years. Performance-based payment will be based on reducing total spending and meeting quality metrics.

Conclusions

This chapter has focused on two broad issues: potential modifications of the way Medicare Part B pays for drugs, in general, and approaches to improve the quality and efficiency of oncology care. To examine potential modifications of the way Medicare Part B pays for drugs, we focused on three aspects of Medicare's payment methodology for Part B drugs. First, we explored whether there is a better way to structure the add-on payment to ASP. Second, we examined whether there are payment policies that could be considered to promote more price competition among Part B drugs and put downward pressure on ASP. Third, the Commission recommended reducing the dispensing and supplying fees for certain Part B drugs furnished by inhalation drug suppliers and pharmacies to levels similar to those paid by other payers.

Chapter 5 also considered approaches to improve the quality and efficiency of oncology care since more than half of Medicare Part B drug spending is associated with anticancer drugs. For this chapter, we examined four examples of narrower and broader approaches designed to improve the efficiency of oncology care. The two narrower approaches—oncology clinical pathways and risk-sharing agreements—attempt to improve the value of drug spending. By contrast, the two broader approaches—oncology medical homes and bundling Part B oncology drugs with non-oncology services—take a more holistic view of cancer care by improving care management and coordination. ■

Endnotes

- 1 Section 1861(t)(1) requires payment for drugs or biologicals only if the product is included in the United States Pharmacopoeia National Formulary, the United States Pharmacopoeia Drug Information, or the American Dental Association Guide to Dental Therapeutics.
- 2 Certain vaccines, certain blood products, and home infusion drugs requiring durable medical equipment are paid based on 95 percent of the average wholesale price instead of ASP + 6 percent. Our work in this chapter excludes these products, unless otherwise noted.
- 3 At the time of publication, CMS had issued a notice of proposed rulemaking that seeks to test changes to the ASP add-on and other value-based approaches to payment for Part B drugs. A few of the topics in this chapter overlap with, but are not identical to, some of the areas CMS focuses on in its proposals.
- 4 Under the OPPI, in most cases, Medicare pays separately for drugs that have an estimated average cost per day that exceeds a packaging threshold. That threshold (\$100 in 2016) was \$90 in 2014, the period of our data analysis. Payment for drugs with an estimated average cost per day less than the threshold are packaged into payment for other separately payable services on the claim (e.g., drug administration). Beginning in 2014, drugs used as part of diagnostic tests or as supplies in surgical procedures are packaged regardless of their cost.
- 5 The sequester reduces payments providers receive for Part B-covered drugs by 1.6 percent, which results in a net payment equivalent to ASP + 4.3 percent. Unless otherwise noted, our analysis focuses on the pre-sequester ASP + 6 percent payment rate because that is the rate specified in the Medicare statute for most Part B-covered drugs provided by physicians and suppliers.
- 6 This chapter uses the term *biologic* synonymously with *biological products* or *biologicals*, referring to drug products derived from living organisms. (See Chapter 5 of the Commission's June 2009 report for more detail.)
- 7 In 2014, we estimate that Medicare and its beneficiaries paid roughly \$3 billion for drug administration services. This estimate includes therapeutic, prophylactic, and diagnostic injections and infusion of chemotherapy and nonchemotherapy drugs, but excludes certain types of injections such as intravitreal injections.
- 8 Total Part B drug spending for physicians, outpatient hospitals, and suppliers—without any adjustments for the changes in packaging or payment formulas—grew at an average rate of about 9 percent per year between 2009 and 2013.
- 9 Nonprofit hospitals with high shares of Medicaid and low-income Medicare patients (about one-third of all prospective payment system hospitals) qualify for the 340B Drug Pricing Program.
- 10 For example, the manufacturer submits its first-quarter ASP data within 30 days after the close of a quarter. CMS then has 60 days to calculate the new payment rates and update the claims processing systems so that the new payment rates can be effective in the third quarter.
- 11 By *margin*, we mean the difference between Medicare's ASP + 6 percent payment rate and the amount the provider pays to acquire the drug (taking into account all rebates, discounts, and price concessions the provider may receive).
- 12 Other aspects of the ASP methodology (e.g., how lagged price concessions and bundled price concessions are reflected in ASP) can increase or decrease providers' margins on a drug.
- 13 IMS obtains acquisition price data (i.e., the prices at which pharmaceuticals are sold by manufacturers, wholesalers, and chain warehouses to retail pharmacies, hospitals, and certain other classes of trade) from a subset of the manufacturers, wholesalers, and chains that supply other data to IMS. This subset represents approximately 65 percent to 70 percent of all transaction volume within the audited nonretail classes of trade. IMS-audited sales account for approximately 90 percent of all sales in the nonretail channel.
- 14 If a drug has more than one national drug code (NDC), we used the data for the NDC with the greatest volume sold.
- 15 To construct this measure, we calculate the ratio of the 75th percentile invoice prices to ASP for each of the 34 drugs for a quarter. Then we calculate the median of that ratio across the 34 drugs for that quarter.
- 16 Since prices as a percentage of ASP fluctuate on a quarterly basis, we tried to be conservative by selecting the first quarter of 2015. Over the most recent four quarters for which we have data, the first quarter of 2015 had higher invoice prices as a percentage of ASP than the other quarters.
- 17 Medicare's payment rate for bevacizumab for wet AMD is not based on ASP + 6 percent, but is instead contractor priced. The reason is that bevacizumab comes in vial sizes intended for cancer patients. Ophthalmologists often rely on compounding pharmacies to repackage the product into syringes for use in the eye. Medicare pays for compounded drugs through contractor pricing rather than 106 percent of the ASP for the FDA-approved product.

- 18 For drugs provided by HOPDs, some portion of the drug payment amount is intended to cover pharmacy overhead. Specifically, with respect to payment for separately paid drugs under the OPSS, CMS has stated that the drug payment rate (currently ASP + 6 percent; in prior years, as low as ASP + 4 percent) includes payment for drug acquisition costs and pharmacy overhead (Centers for Medicare & Medicaid Services 2012).
- 19 In our June 2015 report, we explored two budget-neutral options to restructure the 6 percent add-on to ASP. Those options were 100 percent of ASP + \$24 per drug per day and 102.5 percent of ASP + \$14 per drug per day. The Commission estimated those options to be budget neutral relative to the 6 percent add-on to ASP using 2013 claims data and assuming no utilization changes. The modeling work done in this chapter is based on the more recently available 2014 claims data.
- 20 The policy option we modeled includes a flat fee per drug administered per day by a provider. In this option, if the beneficiary received two drugs from a particular provider on a specific day, that provider would receive a flat fee of \$10 (2 × \$5) for the drugs provided to that beneficiary that day. The flat fee is unaffected by the dosage size or the number of units of the drug furnished in a day. For example, the flat fee for a drug in a day would be \$5 regardless of whether the beneficiary received a 100-mg infusion or 500-mg infusion of that drug.
- 21 In our modeling, we assume the policy option would not apply to low-cost drugs furnished under the OPSS that are packaged into payment for other services.
- 22 The add-on payment under current policy and the add-on payment under the policy option is the same for a drug with an ASP per administration of \$200 (6 percent of \$200 equals \$12 and 3.5 percent of \$200 + \$5 equals \$12). For a drug with an ASP per administration greater than \$200, the 6 percent add-on is larger than the policy option add-on of 3.5 percent plus \$5 per drug per day; for drugs with an ASP per administration less than \$200, it is the reverse.
- 23 Hospitals benefit from the increase in the add-on payments for low-priced drugs, but to a lesser extent than physicians. Under the policy option, add-on payments increase for drugs with an ASP per administration of less than \$200. Under the OPSS, drugs with an estimated cost per day of less than \$100 are packaged into payment for other services and would be unaffected by the policy option. Thus, OPSS hospitals would see an increase in add-on payments for drugs with an average ASP per administration in the range of \$100 to \$200.
- 24 On a percentage basis, neurologists would also see a decline in Part B drug revenues in this range (−1.7 percent). The effect on neurologists' total revenues (−0.4 percent) is lower because drug revenues account for roughly 20 percent of neurologists' total Medicare revenues.
- 25 The purpose of this example is to illustrate how the policy option to restructure the add-on would reduce, but not eliminate, the difference in add-on payments for two differently priced products with a similar use. However, we note that some stakeholders point out that patients frequently get both of these products over the course of their treatment because they become resistant to one and switch to the other.
- 26 Some may argue a constraint on ASP growth would make payment for Part B drugs more consistent with payment for other Part A– and Part B–covered services (Centers for Medicare & Medicaid Services 2012).
- 27 The Medicaid inflation rebate historically has applied to single-source drugs, but the Bipartisan Budget Act of 2015 extended the Medicaid inflation rebate to generic drugs.
- 28 Medicaid rebates are not included in the ASP calculation. If a manufacturer rebate to Medicare was modeled on the Medicaid rebate, these rebates would not be included in the ASP calculation.
- 29 The organization that served as the CAP vendor (Bioscrip) reported that it declined to renew the contract to continue as the CAP vendor for 2009 because of concerns about its organization's short-term and long-term profitability under the CAP.
- 30 It would be important that any exceptions or appeals processes be timely and incorporate input from clinical experts.
- 31 Before 2005, Medicare paid a dispensing fee of \$5 per monthly supply of inhalation drugs. With implementation of the ASP payment system, CMS increased the inhalation drug dispensing fee substantially in 2005, cut the dispensing fee slightly in 2006, and has maintained the dispensing fee at the same level since 2006.
- 32 To set the dispensing fee, CMS relied on a 2004 industry report on costs for inhalation drug suppliers by category of activity. CMS based the fee on industry-reported costs for establishing or revising the plan of care, delivery of services, refill calls and compliance monitoring, billing and collections, "other" direct costs, and indirect costs (excluding sales, marketing, bad debt, and profit). CMS excluded industry-reported costs for patient education, caregiver training, care coordination, and in-home visits. CMS also noted that the durable medical equipment supplier is responsible for educating the beneficiary on proper use of the nebulizer equipment or ensuring that another party has done so.

- 33 The statute also requires that no compendium be included on the list unless it has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.
- 34 The spending associated with drugs that have both oncology and non-oncology indications is included in the estimate of Medicare spending for anticancer drugs.
- 35 This estimate is based on chemotherapy administration codes 96401–96459, which may also include the administration of antineoplastic drugs for treatment of noncancer diagnoses.
- 36 Bortezomib is administered through intravenous injection, covered by Medicare, and paid under Part B according to its ASP.
- 37 According to Cigna, its agreement with Novartis ties the financial terms to how well the drug improves the relative health of Cigna’s customers. The primary metric is reduction in the proportion of customers with heart failure hospitalizations (Cigna 2016).
- 38 Under this agreement, the health plan (1) receives a discount for “preferring” the drug, (2) receives a rebate if the drug does not lower cholesterol levels in members to the degree indicated by the drug’s clinical trials, and (3) receives a rebate if more members use the drug than was anticipated during negotiations (Appel 2015).
- 39 Clinical pathways are also referred to as care pathways, patient pathways, and treatment pathways. The concept goes as far back as the 1980s to formalize patterns of care in the inpatient hospital setting. In addition to oncology, clinical pathways are also used in other clinical areas, including cardiology, gastroenterology, and immunology.
- 40 The Appraisal of Guidelines and Research and Evaluation instrument was developed to assess the variability in guideline quality and includes the following six domains: scope and purpose, stakeholder involvement, rigor of development, clarity of presentation, applicability, and editorial independence.
- 41 In 2011, the IOM issued eight standards that it viewed as essential elements in the development of trustworthy and high-quality clinical guidelines. The eight standards call for (1) a transparent process to develop and fund guidelines, (2) the disclosure of conflict of interest, (3) a development group that is multidisciplinary and includes patients, (4) a systematic evidence review process, (5) a clear explanation of the reasoning underlying treatment recommendations and rating recommendations, (6) recommendations communicated in a standardized form, (7) an external review process, and (8) an updating process.

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