



Coverage and Payment for Prescription Drugs Under Medicare Part B: A Complex Patchwork

BACKGROUND
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OVERVIEW — As part of the diverse discussions around health care reform, many have looked to refining Medicare payment systems as a way to give health care practitioners and providers greater incentives to deliver care more efficiently, and thus slow health care spending growth. Understanding how Medicare currently pays for Part B services, including drugs covered under Part B, is essential to understanding the potential impact of these types of reforms. Most items and services covered under Part B, including most Part B drugs, are paid individually, which means practitioners and providers generally receive more payments for providing more services. Some reform proposals would expand the use of bundled payments under Medicare to pay for items and services as a group, rather than separately, to curb incentives to provide unnecessary care. If such reforms were to include Part B drugs, it would be a significant change from current payment policies. A close look at coverage and payment for Part B drugs reveals complex policies and interactions with Part D drug coverage.

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Medicare Part B covers certain outpatient drugs used in specific settings or to treat specific conditions, and its coverage has expanded incrementally since Medicare was created in 1965. Multiple payment systems and fee schedules are used to establish the payments for Part B drugs. Those payment systems and fee schedules may produce different payment amounts for practitioners and providers and different cost-sharing for beneficiaries for the same drug, depending on the setting in which it is administered. As a result of various coverage requirements and payment methodologies, practitioners, providers, beneficiaries, Medicare claims processing contractors, and prescription drug plans must determine which part of Medicare should be paying for a drug under particular circumstances, which, in turn, will determine how much Medicare and the beneficiary will pay.

This paper explores (i) coverage: the types of drugs and circumstances under which they may be covered by Part B and (ii) payment: how Part B payment and beneficiary cost-sharing is determined in different treatment settings.

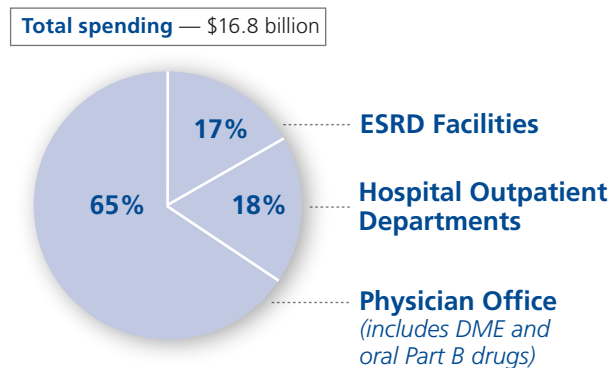
MEDICARE DRUG COVERAGE

All of the different parts of Medicare—Parts A, B, C and D—pay for prescription drugs. Parts A and B of Medicare pay for inpatient and outpatient medical services, respectively. Together they are referred to as traditional, or fee-for-service (FFS), Medicare. Part C, the Medicare managed care program, pays private plans a monthly rate to cover the same services covered under traditional Medicare.¹ Part D, the Medicare prescription drug benefit, pays private plans to administer most outpatient drug coverage, but under certain circumstances some outpatient drugs may be covered under Part B.² The Centers for Medicare & Medicaid Services (CMS) has responsibility for the four parts of Medicare and contracts with claims processing contractors and private plans to administer the program.

Basics of Part B Drug Coverage

Part B drugs are primarily administered in physician offices, hospital outpatient departments, or end stage renal disease (ESRD) facilities or with the use of durable medical equipment (DME), such as an infusion pump. In 2007, the Medicare Payment Advisory Commission

FIGURE 1 | **Part B Drug Spending in 2007 by Setting**



Source: Medicare Payment Advisory Commission (MedPAC), *A Data Book: Healthcare Spending and the Medicare Program, June 2009*; available at www.medpac.gov/documents/Jun09DataBookEntireReport.pdf.

(MedPAC) estimated that payment for Part B drugs in these settings totaled \$16.8 billion.³ To put this number in perspective, Part B drugs accounted for roughly 10 percent of all spending on Part B services in 2007 and one-third of the amount spent on Part D drugs in that year.⁴ Figure 1 shows a breakdown of spending on Part B drugs in 2007 by setting.

While Part B covers more than 675 individual drugs, spending is concentrated on a small number of drugs: 10 account for almost half of Part B drug spending.⁵ Most of those high-cost drugs are for treatment of cancer or the side effects of chemotherapy such as anemia.

Part B drug coverage grew in a piecemeal fashion over many years through many different pieces of legislation. Table 1 (next page) shows examples of specific coverage added by some of the major Medicare bills

passed over the last two decades. The cost of expanded coverage was often an important consideration, so the statutory language can be extremely specific about when and for whom a drug is covered.

To be covered under Part B, a drug must fulfill two requirements. First, it must be included in one of the groups of items and services listed in the statute that are covered by Medicare.⁶ Second, individual items that fall within a covered group must also be considered “reasonable and necessary” under the Medicare law.

Most Part B–covered drugs are considered part of a larger group of services such as physician services, hospital outpatient services, or ESRD services.⁷ Generally, Part B covers five types of drugs:

- Physician-administered drugs
- DME-administered drugs
- Certain oral drugs
- Vaccines
- Other drugs in certain circumstances

Physician-administered drugs — Drugs that are administered by a physician or professional staff in a clinical setting, such as a hospital outpatient department or physician’s office, typically through infusion

TABLE 1
Examples of Bills Expanding Coverage of Part B Drugs

BILL	COVERAGE PROVISION
Omnibus Budget and Reconciliation Act (OBRA) of 1993	Covered off-label uses of anti-cancer drugs that are cited in certain compendia or supported by clinical evidence in peer-reviewed medical literature
Balanced Budget Act (BBA) of 1997	Covered oral anti-nausea drugs for use within 48 hours after chemotherapy
Balanced Budget Refinement Act (BBRA) of 1999	Extended time period of coverage of immunosuppressive drugs
Benefits Improvement and Protection Act (BIPA) of 2000	Eliminated time limitation on coverage of immunosuppressive drugs
Medicare Modernization Act (MMA) of 2003	Covered intravenous immunoglobulin (IVIG) for treatment of primary immune deficiency in the home

or injection, are covered under Part B. Because the act of administering the drug is covered as a physician or hospital outpatient service, the drug being administered is also covered. Such drugs are often referred to as “incident to” drugs because they fall into the group of covered services that are “incident to a physician service.”

The law requires that “incident to” drugs be classified as “not usually self-administered,” which means that the drug cannot be administered by the patient or caregiver more than 50 percent of the time. Drugs that are administered intravenously or intramuscularly are presumed to be not self-administered, whereas oral drugs are presumed to be self-administered. Drugs that are administered through injection into the layer of fatty tissue just below the skin (called a subcutaneous injection) may or may not be self-administered. Subcutaneous drugs used to treat chronic conditions are more likely to be considered self-administered than those to treat acute conditions.⁸

CMS has instructed its claims processing contractors to determine whether or not a drug is usually self-administered for their jurisdictions.⁹ Each contractor publishes its list of usually self-administered drugs, and those drugs are not covered under Part B in the contractor's jurisdiction, even if the drug is administered by a physician. In 2008, the number of drugs on the usually self-administered lists ranged from 14 for one contractor to 41 for others.¹⁰

DME-administered drugs — CMS interprets the Medicare DME benefit to include certain drugs because they are essential to the functioning of items that are covered under Part B as DME. For example, a nebulizer is a device that administers aerosolized medicine to treat respiratory disease; it stands repeated use and is covered under the DME benefit. Inhalation drugs are covered under Part B when used with a nebulizer, because the nebulizer could not fulfill its medical purpose without the drug. Inhalation drugs provided through other mechanisms that are not considered DME, such as multi-dose inhalers, are not covered under Part B. In addition to inhalation drugs, infusion drugs may be covered under the DME benefit if administered through an infusion pump that is covered under the benefit.

Limitations that apply to other DME items also apply to drugs covered under the DME benefit. For example, as defined by statute, the DME benefit does not apply to beneficiaries in an inpatient setting such as a skilled nursing facility (SNF) or hospital. If administered in an inpatient facility, a drug covered under the DME benefit in a patient's home would not be covered under Part B, even if Medicare is not paying for the inpatient stay.¹¹

Oral drugs — Most oral drugs are not administered by a physician and generally are considered self-administered. However, the law does allow for Part B coverage of certain oral drugs under specific circumstances:

- Immunosuppressive drugs for beneficiaries who have received a Medicare-covered organ transplant
- Oral anti-cancer drugs that have the same active ingredients and are used for the same indications as forms of the drug that are covered incident to a physician service
- Oral anti-nausea drugs if used as part of an anti-cancer regimen as a replacement for intravenous drugs within 48 hours of chemotherapy administration

Oral drugs are typically obtained from community or mail order pharmacies, whose interaction with Part B is limited. This may introduce additional administrative complexities for these pharmacies. Prescription drug plans must sort out whether these drugs are covered under Part B or Part D. (See text box below.)

Vaccines — The law requires Part B coverage of preventive vaccines for influenza, pneumococcus, and hepatitis B. Part B does not cover most other preventive vaccines, but they may be covered under Part D. However, Part B will cover vaccines when they are used for the treatment of illness or injury (for example, a tetanus shot after stepping on a nail).

Other drugs — The Medicare statute requires coverage of a few other drugs under very specific circumstances. For example, Part B covers parenteral nutrition (feeding a person intravenously), but only for patients who are receiving such therapy because of a non-functioning digestive tract. Intravenous immunoglobulin (IVIG) provided in the home is covered under Part B for patients with primary immune

Part B vs. Part D

The same drug may be covered under different parts of the Medicare program, depending on the circumstances under which it is administered. By law, drugs covered by Part A or B of Medicare are not Part D drugs. The complexity and variation in Part B coverage can make it challenging to determine whether a drug is covered under Part B or Part D. Medicare fee-for-service claims processing contractors and Part D plans must sort through these intricacies to determine which part of Medicare should be paying for a particular drug. Prescription drug plans must be familiar with both general Part B coverage and with the specific drugs that are covered under Part B by contractors in their plan coverage area. Drugs that are considered usually self-administered by one contractor in one area—and therefore could be Part D drugs—may be covered under Part B by other contractors in other areas. Mode of administration suggests whether Part B or Part D is probably responsible for coverage, but is not a definitive guideline. The key factor is how the drug is prescribed and dispensed in the specific circumstance for a particular patient. A drug typically covered by Part B may be a Part D drug if it is filled at a community or mail order pharmacy.

This complexity precludes prescription drug plans from basing coverage determinations solely on the item being prescribed, although this may be the only information initially provided to them. The structure of Part D, which puts plans at risk to manage beneficiary drug costs, creates incentives for plans to ensure that they do not pay for drugs that should be paid for under Part B.

The Part B versus Part D determination can affect how much is paid for the drug in question and how much cost sharing the beneficiary must pay. See the "Beneficiary Out-of-Pocket Costs" (p. 15) and Appendix B (p. 22) for more information.

deficiency disease. Blood clotting factor for hemophilia patients is covered even if it is self-administered. Also covered under Part B are blood products, antigens, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals and contrast media for imaging.

MEDICARE PAYMENT POLICY

Setting an appropriate payment rate for Part B drugs has been challenging for policymakers. Paying too much or too little can distort clinical decision making about the use of certain drugs, which can have repercussions on the health of Medicare beneficiaries and the financial well-being of the program.

Paying for drugs at rates that are significantly greater than the cost of acquiring the drugs creates incentives for physicians to provide more drugs.¹² Paying too little for drugs also has adverse consequences. Continued underpayment for a drug could affect beneficiary access if providers are unable or unwilling to offer that drug because the payment does not cover their costs. The effect of underpayment may not be that a drug becomes unavailable but rather that it is administered in a different setting. For example, rather than administering the drug in the office where the physician practice is responsible for purchasing the drug, the physician could refer the beneficiary to the hospital to receive the drug. Under this scenario, the hospital would be responsible for purchasing the drug. Changing where the drug is obtained could inconvenience the beneficiary, and it could change the Medicare payment for the drug and its administration. Alternatively, the physician may be willing to administer the drug in the office but not provide it, recommending that the patient obtain the drug from a community pharmacy and bring it to the office to be administered. This practice, called “brown bagging,” raises concerns for some about the appropriate handling of the drug between the time it is dispensed by the pharmacy and administered by the doctor.¹³

Payment Basics for Part B Drugs

In understanding Medicare payment policy, it is important to remember that Medicare pays physicians, hospitals, and suppliers who have purchased drugs from manufacturers, wholesalers, or group purchasers. The Medicare program does not pay drug manufacturers

directly for their products. The rates paid to practitioners and providers are set prospectively, based on market prices for the drugs.

Because of the size of the Medicare program, the appropriate price in a market without Medicare as a purchaser may be very different from the price determined by a market that includes Medicare. With 45 million, primarily aged, beneficiaries, the Medicare program has a substantial effect on drug sales volume and market price. Medicare approximates what an appropriate price should be through different approaches in different settings. These approaches include the average sales price (ASP), the average wholesale price (AWP), and the acquisition cost of the drug.

Medicare law specifies the basis of payment in different clinical settings and, in most cases, also specifies the percentage of the amount that Medicare will pay. Payment for drugs administered in physician offices and ESRD facilities and inhalation drugs administered through DME is based on the ASP. Since the ASP reflects the average sales price, some sales occurred at or below that price and others occurred above that price. In most instances, the payment rate required by law is greater than the ASP, allowing most providers to be able to obtain the drug without losing money on the transaction.¹⁴ Payment for infusion drugs administered through DME and the three preventive vaccines covered by Part B when provided in a physician office is based on the AWP. Payment for drugs administered in a hospital outpatient department or an ambulatory surgical center is based on the average hospital acquisition cost, plus an amount for pharmacy overhead and handling costs. Table 2 shows the payment percentages for each setting. The different approaches to calculating prices under Part B are described below, and Appendix A provides a table summarizing the terms.

Average wholesale price — Prior to 2005, payment for most Part B drugs was based on the AWP as listed in certain data sources such as Red Book. Often referred to as a “sticker price” that does not incorporate common discounts and rebates, AWP is a misnomer because it is neither an average price nor the price paid by wholesalers. Several organizations, including the Government

TABLE 2
Basis for Part B Drug Payments by Setting

SETTING		PAYMENT BASIS
Physician Office		106% of ASP
ESRD Facility		106% of ASP
DME	Inhalation Drugs	106% of ASP
	Infusion Drugs	95% of AWP*
Hospital Outpatient Department / Ambulatory Surgical Center		Average hospital acquisition cost for the drug**
Preventive vaccines		95% of AWP
Oral drugs provided by a pharmacy supplier		106% of ASP

* As calculated October 1, 2003.

** In 2009, hospital outpatient department and ambulatory surgical center payment rates based on hospital acquisition costs are 104% of ASP.

Accountability Office and the Office of the Inspector General (OIG) at the U.S. Department of Health and Human Services, studied the relationship between AWP and practitioner and supplier acquisition costs and found that practitioners and suppliers could obtain the drugs for considerably less than Medicare's AWP-based payment rate.¹⁵ The Medicare Modernization Act of 2003 (MMA) subsequently shifted the basis for Medicare payment for most Part B drugs provided in the physician's office from AWP to the average of the actual prices paid by all purchasers in the United States (the average sales price) for the drug beginning January 1, 2005.

Following enactment of the MMA, the only payment for Part B drugs still based on AWP are drugs provided through infusion pumps under the DME benefit, certain blood products, and the three Part B preventive vaccines when provided in settings other than a hospital outpatient department.¹⁶ The payment rates for the vaccines and blood products are updated to reflect current AWP. For DME infusion drugs, payment is based on the AWP in effect on October 1, 2003.

Average sales price — CMS calculates the ASP using data submitted by manufacturers on the sales prices of their drugs. Excluded from the ASP calculation are sales to certain government programs and safety net hospitals, as well as sales under state pharmaceutical assistance programs and Part D.¹⁷ ASP is not to be confused with the average manufacturer's price (AMP) used in the Medicaid drug rebate program.¹⁸ AMP is a similar calculation (see text box).

ASP vs. AMP

Medicare's ASP and Medicaid's AMP are both measures of average sales but they differ in several important ways. The universe of drug sales included in the AMP calculation is more limited, including only sales to the "retail class of trade"; in other words, pharmacies available to the general public. ASP includes sales for all classes of trade except those under certain government programs. Specific exclusions for government programs do not apply under AMP, so a sale to the retail class of trade may be excluded from ASP and included in the AMP calculation.

Most discounts and rebates are included in the calculations of both ASP and AMP. The exception is customary "prompt pay" discounts, which are included in ASP but excluded from AMP. In general, AMP is greater than ASP.

Source: CMS, Medicaid: Prescription Drug Final Rule, July 17, 2007, available at <http://edocket.access.gpo.gov/2007/07-3356.htm>.

Unlike AWP, ASP includes the various discounts and rebates offered by manufacturers that reduce the price paid for their drugs. The arrangements between manufacturers and purchasers are varied and complex and can include discounts for prompt payment as well as those tied to the quantity or combination of drugs purchased. CMS has revised its regulations multiple times to attempt to fully account for the diverse arrangements used in the marketplace. However, questions remain about how well ASP captures the discounts and rebates that apply to the price paid by providers. Some discounts are difficult to assign to specific drugs for particular periods because they are based on total purchases for the year or tied to the combination of drugs purchased. ASP might overstate the actual price for the drugs subject to these price concessions if they are not appropriately attributed to the drugs involved. ASP might understate the price paid by providers if it reflects discounts to wholesalers that are not passed on to providers or if it does not fully reflect additional fees charged by wholesalers.¹⁹

Manufacturers provide product-specific sales data and CMS calculates the ASP, taking into consideration other products assigned to the same payment code. In some cases, only one drug is assigned to a payment code. In other instances, multiple drugs may be assigned to the same code, such as a brand name drug and its generic alternative.²⁰

Manufacturers must submit the ASP data for their products within 30 days of the end of each calendar quarter. CMS reviews the data and then calculates and releases the payment-level ASP data to its contractors and the public. Because of the time necessary to gather, submit, and process ASP data, there is a six-month lag between when the sales occur and when the price of those sales will affect the Medicare payment rates.

The MMA required the OIG to compare the ASP with two other methods for calculating price: AMP under Medicaid, and the price a prudent purchaser would pay for the drug (the widely available market price, or WAMP). The statute requires that CMS adjust payments for drugs that exceed AMP or WAMP by a certain threshold (to date the threshold has been 5 percent). Most recently, the OIG found that 5 percent of the drugs studied exceeded the threshold for the third quarter of 2008, and 80 percent of those drugs had exceeded the threshold in previous quarters.²¹ Because of concerns about the lag between the time period involved in the study and when the

ASP study findings become available, CMS has not made any adjustments to the payment rates based on the OIG findings.

Acquisition cost — In addition to AWP and ASP, Medicare may determine payment for a drug based on its acquisition cost, or the amount a Medicare provider actually pays for the drug in combination with the overhead costs to prepare the drug for administration. Because providers do not report their actual costs to Medicare, CMS must estimate those costs.

For drugs provided in hospital outpatient departments, CMS uses the information providers submit on claims to estimate the combined acquisition cost of drugs plus allocated pharmacy overhead. When a provider bills Medicare for treating a patient, it submits a claim that includes dollar values called charges for the services provided. The charge data are used to estimate the cost of providing the service. Because of the time necessary to receive and process claims and then for CMS to analyze information on those claims, the claims data used to set payment rates for a given year are typically two years old (that is, the data used to update the 2009 prospective payment systems are from 2007). The data are adjusted to approximate the later year costs.

The payment for certain drugs is packaged into payment for associated procedures. For others, the payment is made separately. For those drugs that are separately paid, the payment is based on the overall relationship between the costs of average acquisition and pharmacy overhead for hospital outpatient drugs (derived from the claims data) and the ASPs for those drugs. Separately payable drugs under the Outpatient Prospective Payment System (OPPS) were paid at ASP + 5 percent in 2008 and ASP + 4 percent in 2009.²²

There have been attempts to obtain acquisition data through provider surveys. Most recently, GAO conducted a survey of drug acquisition costs for hospital outpatient departments in 2004 that was considered in setting OPPS payment rates.²³ Providers maintain their acquisition data in a myriad of ways, making it difficult for the providers to gather the data and present it in a standardized form. Furthermore, a sufficient number of providers must participate in the survey in order to make its findings representative of providers who are not included. These complications make provider surveys costly and time-consuming, both to participate in and to administer. Once completed, the survey results present a snapshot of acquisition

costs at a particular point in time that can be difficult to accurately update for later periods.²⁴

Bundled Versus Separate Payment

In some instances, Medicare pays for an item or service in combination or bundled with payment for other associated services. For example, Medicare pays for most inpatient hospital care by providing a prospectively determined lump sum payment for all items and services furnished during a hospital stay. Providing more services during a hospital stay generally will not increase Medicare payment. In contrast, most items and services under Part B are paid separately. Furnishing more items and services will increase Medicare payment. Most, but not all, Part B drugs currently receive separate payment.

The setting in which a drug is administered affects whether it is paid separately. Drugs provided in a physician office are paid separately. In other settings such as hospital outpatient departments and ESRD facilities, payment for some items and services is provided together, including some drugs. In those settings, newer or more expensive drugs often receive separate, individual payment. In ESRD facilities, drugs that were not included in the base payment unit (called the composite rate) when it was developed in the early 1980s, are paid separately. The ESRD payment system is being revised to expand the base bundle of services. By law, the expanded bundle, which is expected to be implemented January 1, 2011, will include drugs that are now separately payable.

The OPSS uses a dollar threshold cost per day to determine whether a drug is paid separately. If the per-day costs for a drug are less than or equal to the annual drug packaging threshold, payment for the drug is included in payment for the services with which it is used. If the drug's costs are greater than the threshold, then hospitals may receive separate payment for the drug. The threshold is updated annually and is set at \$60 for 2009.

Some have suggested that expanding the use of bundling could help address increasing spending on Part B drugs.²⁵ Under current law, CMS could potentially expand bundling under certain payment systems such as the OPSS, or could experiment under a demonstration project with bundling payments for all services related to a certain disease such as cancer.²⁶ However, Congress would

need to change the Medicare statute to incorporate bundled payments for drugs on a broader scale.

Payments in Different Settings

Because payment rates and bundling policies differ, payment for the same drug can vary considerably from setting to setting. The most significant contrast is between the physician office and the hospital outpatient department, since most Part B–covered drugs can be provided in either setting. Drugs provided in physician offices are, by law, paid at ASP + 6 percent. Separately payable drugs under the OPPTS were paid at ASP + 5 percent in 2008 and ASP + 4 percent in 2009.

The disparate payment rates and policies are evident for anti-cancer drugs. Such drugs may be provided in a physician office, hospital outpatient department, or, for certain drugs, through an infusion pump in a beneficiary’s home. Table 3 shows the first quarter 2009 payment rate in these different settings for four cancer drugs. OPPTS payment rates for drugs are consistently lower than physician office rates. DME rates may be considerably above or slightly below payment rates in other settings. Payment for some DME drugs is more than nine times the amount paid in other settings. Whereas the ASPs are updated quarterly, the payment rates for DME-provided drugs are frozen at the October 1, 2003, AWP.²⁷

TABLE 3 | Payment May Vary Depending on Site of Service

GENERIC NAME	Trade Name	HCPCS Code	2009 PAYMENT RATES		
			Physician Office	Hospital Outpatient Department	DME External Infusion Pump
Bleomycin sulfate	Blenoxane	J9040	\$ 31.83	Packaged (not paid separately)	\$ 289.37
Doxorubicin HCl liposome	Doxil	J9001	\$ 441.25	\$ 432.93	\$ 393.48
Cladribine	Leustatin	J9065	\$ 29.25	\$ 28.70	\$ 61.72
Trastuzumab	Herceptin	J9355	\$ 61.64	\$ 60.48	\$ 58.13

Source: CMS, "January 2009 ASP Pricing File," available at www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/01a1_2009aspfiles.asp#TopOfPage; and "January 2009 OPPTS Addendum B," available at www.cms.hhs.gov/HospitalOutpatientPPS/AU/list.asp?filterType=none&filterByDID=0&sortByDID=3&sortOrder=descending&intNumPerPage=10.

Beneficiary Out-of-Pocket Costs

In most cases, beneficiaries in traditional Medicare pay a portion of the cost of their health services. For Part B drugs, once a beneficiary meets the annual deductible, the Medicare program pays 80 percent of the total payment amount and the beneficiary is responsible for the remaining 20 percent (called the coinsurance or cost-sharing). Therefore, the higher the total payment amount, the higher the beneficiary coinsurance amount. Depending on the beneficiary's situation, the coinsurance may be paid by the Medicaid program, a supplemental insurance plan, or by the beneficiary themselves. Almost 90 percent of beneficiaries have some form of supplemental coverage to help meet their cost-sharing requirements.²⁸ Under Part B, the beneficiary continues to be responsible for 20 percent of the cost of their drugs no matter how much they have already spent on drugs; there is no protection against catastrophic costs as exists under Part D.

Decisions about the specific drug that is provided and the setting in which that drug is administered can have significant effect on the amount the beneficiary will pay out of pocket for the drug. The disparate payment rates shown in Table 3 result in equally disparate beneficiary cost-sharing. For example, a beneficiary receiving cladribine for treatment of hairy cell leukemia would be responsible for \$5.85 for every unit administered in a physician office, \$5.74 for every unit administered in a hospital outpatient department, and \$12.34 for every unit administered through a DME infusion pump.

Understanding the effect of drug administration choices on beneficiary cost-sharing is further complicated when Part D is taken into consideration. In some instances, physicians and beneficiaries may have a choice between multiple treatment options, some of which are covered under Part B and others under Part D. Appendix B describes key elements of Part D cost-sharing. As a percentage, coinsurance under Part B tends to be lower than under Part D (20 percent compared with 25 percent). However, each Part D plan negotiates its own prices for covered drugs, and that price may be lower than the price for the Part B alternative.²⁹ Therefore, even though the coinsurance percentage tends to be higher under Part D, the amount the beneficiary has to pay out of pocket may be lower for a treatment option under Part D if the beneficiary is enrolled in a plan with a negotiated price below the payment rate for the Part B option. In addition, Part D cost-sharing for the same drug can increase or decrease over the course of the year depending on the beneficiary's total drug costs

under Part D. See Appendix B for an example illustrating the financial impact of choosing a treatment option under Part B or Part D.

ASSESSING PART B DRUG PAYMENT POLICY

The Medicare Modernization Act of 2003 (MMA) changed the basis of payment for Part B drugs to better align Medicare payment with the actual prices paid. Prior to 2005, Medicare payment generally exceeded costs, in some instances by more than 600 percent.³⁰ Prior to the passage of the MMA, spending on drugs administered in physician offices was increasing at 25 percent per year. With the implementation of MMA payment changes in 2005, actual spending dropped almost 8 percentage points. Since then, Medicare spending on Part B drugs has started to increase again, although at a less rapid pace.³¹

With the transition to ASP, physicians and suppliers raised concerns that Medicare beneficiaries would no longer have access to all drugs, or that beneficiaries in certain parts of the country, such as rural areas, would have to travel farther to receive Part B drugs. Congress mandated that Medicare pay 6 percent more than ASP with the expectation that most physicians and suppliers would be able to purchase drugs below that rate. Studies of the transition suggest that this expectation is being met. MedPAC assessed the impact of payment changes for oncology services and found that neither access nor quality of care was affected. Both small and large practices were able to purchase drugs for less than the Medicare payment rate.³² GAO similarly found that oncology practices were generally able to purchase the most-used chemotherapy drugs at or below ASP.³³

Some observers note that the transition to ASP revises the calculation of the payment amount but does not fundamentally change the way Medicare pays for Part B drugs, nor does it remove the incentives to “game” the system. The Medicare payment rate still exceeds the sales price of most drugs. Further, because the difference between cost and the payment rate is smaller under the ASP methodology than under AWP, the incentive to maximize profits by providing greater quantities of drugs may have increased.³⁴

If Medicare payment rates are not so low as to negatively affect beneficiary access to those drugs, are they too high? Some observers point to rates paid by other government agencies such as the Department of Veterans Affairs, Department of Defense, or the Indian Health

Service, which are typically below the Medicare amount, and conclude that Medicare is paying too much. They recommend setting the Medicare payment at the price paid by these other programs. Critics call such an approach shortsighted because of the size of the Medicare program and the number of sales that would then occur at the lower rates if those prices were adopted. They predict that any Medicare savings would be temporary because manufacturers would increase their price to all entities to avoid the mandated prices to the enormous Medicare population. Expenditures under the other programs, they argue, would also increase.³⁵

CONCLUSION

Changes under the MMA appear to have addressed concerns about significant overpayments by Medicare for Part B drugs. However Part B drugs continue to account for a sizeable portion of total Part B spending. The extent to which Part B drugs are included in reforms, such as bundled payments, intended to better align payment incentives to avoid overutilization of services is a tough policy decision. Such decisions must be made recognizing both the complicated framework of Part B coverage and payment and its complex interaction with Part D coverage.

ENDNOTES

1. For an overview of Medicare and its different parts, see Mary Ellen Stahlman, "Medicare," National Health Policy Forum, The Basics, January 15, 2009; available at www.nhpf.org/library/details.cfm/2545.
2. Medicare Part A pays for inpatient services delivered by institutions such as hospitals and skilled nursing facilities (SNFs). Part A covers drugs provided during an inpatient stay, but generally does not make separate payment for drugs. The cost of providing the drugs is included in the Medicare payment for the hospital or SNF stay. Part C (Medicare Advantage) plans must cover the same drugs that would be covered under Parts A and B.
3. Medicare Payment Advisory Commission (MedPAC), *A Data Book: Healthcare Spending and the Medicare Program*, June 2009, p. 163; available at www.medpac.gov/documents/Jun09DataBookEntireReport.pdf.
4. Medicare Boards of Trustees, *2008 Annual Reports of the Boards of Trustees of the Federal Hospital Insurance and Supplementary Medical Insurance Trust Funds*, p. 5; available at www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2008.pdf.
5. MedPAC, *A Data Book*.

6. Groups of covered services are called “benefit categories.” A drug that is coverable because it falls into one of the Part B benefit categories still may not be covered by Medicare if it is determined that it is not reasonable and necessary for the diagnosis and treatment of disease or injury. In some cases, CMS or its contractors may use their authority to determine whether an item is reasonable and necessary to make an explicit coverage determination such as a national coverage determination (NCD) or a local coverage determination (LCD) for a drug. Drug coverage determinations are based on clinical and scientific evidence and describe the specific diagnosis for which the drug will be covered. Coverage determinations may require that other treatment options be pursued before the drug is used. Most coverage determinations are made at the local level by a Medicare contractor and apply only within an individual contractor’s jurisdiction. The number of LCDs that specify coverage or non-coverage of drugs varies by contractor. In the absence of a national or local coverage determination on a drug, contractors make a case-by-case determination as to whether the drug is covered.
7. CMS has identified 13 groups of services or benefit categories under Part B that include coverage for drugs. For a more extensive discussion of the Part B drug benefit categories, see appendix C of chapter 6 of the Medicare Prescription Drug Benefit Manual, available at www.cms.hhs.gov/Transmittals/Downloads/R2PDB.pdf.
8. CMS, “Chapter 15: Covered Medical and Other Health Services,” *Medicare Benefit Policy Manual*, section 50.2; available at www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.
9. For background on how CMS uses contractors to process and pay Medicare claims, see Laura Dummit, “Paying the Bills: Medicare Administrative Contractors,” National Health Policy Forum, The Basics, July 29, 2009; available at www.nhpf.org/library/details.cfm/2751.
10. Author analysis of contractor self-administered drugs lists for 2008, conducted December 2008.
11. CMS, “Chapter 15,” section 110.1(D).
12. J.D. Kleinke, “Re-naming and Re-Gaming: Medicare’s Doomed Attempt to Reform Reimbursement for Injectable Drugs,” *Health Affairs*, Web exclusive (December 8, 2004); p. w4-561; available with subscription at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.561v1.pdf>.
13. CMS does not prohibit brown-bagging for Medicare patients but indicated that it would work with specialty societies to discourage it.
14. The MMA also included a program to allow physicians to avoid having to purchase the drugs themselves. Under the Competitive Acquisition Program (CAP), CMS contracted with vendors to provide certain physician-administered drugs and to bill Medicare and collect the beneficiary coinsurance for those drugs. Medicare pays the CAP vendors based on rates included in the vendor’s bids. Physicians who voluntarily enroll in the program agree to obtain their drugs from a participating vendor and bill for the administration of the drug. The CAP program operated with one vendor between 2006 and 2008. CMS initiated the bidding for the next contract cycle but chose to postpone the program due to contractual issues with potential vendors. The postponement calls into question the viability of the CAP model, and CMS has solicited input on improvements to the program including ways to increase its appeal to vendors and physicians.

15. General Accounting Office (GAO), "Medicare: Payment for Covered Outpatient Drugs Exceed Providers' Costs," GAO-01-1118, September 2001, available at www.gao.gov/new.items/d011118.pdf; Office of the Inspector General (OIG), "Medicare Reimbursement of Prescription Drugs," OEI-03-00-00310, January 2001, available at <http://oig.hhs.gov/oei/reports/oei-03-00-00310.pdf>.

16. Preventive vaccines provided in hospital outpatient departments are paid based on the reasonable cost methodology.

17. Social Security Act, Section 1927(c)(1)(C)(i); available at www.ssa.gov/OP_Home/ssact/ssact.htm.

18. The Medicaid program offers insurance for low-income individuals and is jointly administered by the federal government and the states. The Medicaid drug rebate program requires drug manufacturers to provide a rebate to the states based on the best price offered for the drug and the average manufacturer's price (AMP) for the drug. The rebate is the greater of two numbers: (i) the difference between the best price offered to any entity (excluding the prices under certain government programs) and AMP, which is calculated as the average price for the retail class of trade including discounts other than prompt pay discounts, and (ii) 15.1 percent of AMP.

19. MedPAC, "Report to Congress: Impact of Changes in Medicare Payments for Part B Drugs," January 2007; available at www.medpac.gov/documents/Jan07_PartB_mandated_report.pdf.

20. Manufacturers submit their data for each product as recognized by a national drug code (NDC). Medicare does not pay for drugs at the NDC level but instead uses the healthcare common procedure code system (HCPCS) codes to make payment. HCPCS codes are 5-digit alphanumeric codes classified into series that start with different letters. Most drug codes begin with the letter "J" although some may begin with a "Q" or a "C" (Medicare only uses C codes for payment under the outpatient prospective payment system.) While limited updates to the HCPCS code set are made quarterly, most new codes are established January 1 of each year. The process for establishing new codes is separate from Medicare's coverage and coding processes, and determination and creation of a HCPCS code does not mean Medicare will cover or pay for a new drug. Not all drugs have specific HCPCS codes; some are paid under miscellaneous or "not otherwise classified" (NOC) codes. Manufacturers of items paid under NOC HCPCS codes must still submit ASP data. CMS uses the NDC level data to calculate ASP at the HCPCS level.

21. OIG, "Comparison of Third-Quarter 2008 Average Sales Prices and Average Manufacturer Prices: Impact on Medicare Reimbursement for First Quarter 2009," OEI-03-09-00150, April 17, 2009, available at <http://oig.hhs.gov/oei/reports/oei-03-09-00150.pdf>.

22. Certain new drugs and biologicals may qualify for additional payments under the outpatient prospective payment system (OPPS), which are called transitional pass-through payments. Pass-through payments are temporary payments during the two- to three-year period in which a drug is first available before CMS has claims data on the new item. By law, pass-through payments are the difference between the OPPS payment rate for the drug and the payment rate in the physician office. The entire pass-through amount is paid by the Medicare program; beneficiaries do not pay coinsurance on the pass-through amount.

23. Government Accountability Office (GAO), "Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting," GAO-05-581R, June 30, 2005; available at www.gao.gov/new.items/d05581r.pdf.
24. Centers for Medicare & Medicaid Services (CMS), "Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006; Proposed Rule," August 8, 2005, p. 4585; and CMS, "Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates," July 25, 2005, p. 42726.
25. MedPAC, "Report to Congress: Improving Incentives in the Medicare Program," June 2009, pp. 128–129; available at www.medpac.gov/documents/Jun09_EntireReport.pdf.
26. Peter B. Bach, "Limits on Medicare's ability to control rising spending on cancer drugs," *New England Journal of Medicine*, 360, no. 6 (February 5, 2009): pp. 626–633; available with subscription at <http://content.nejm.org/cgi/content/extract/360/6/626>.
27. The payment rates for DME-administered drugs may be adjusted if those drugs are included in future rounds of the DME competitive acquisition program.
28. Kaiser Family Foundation, "Medicare at a Glance Fact Sheet," November 2008; available at www.kff.org/medicare/upload/1066_11.pdf.
29. For drugs that could be covered under either Part B or Part D, Part D plans generally report negotiated prices that are higher than the Part B payment rate. See Elizabeth Hargrave, Jack Hoadley, and Jennifer Thompson, "Coverage and Pricing of Drugs That Can Be Covered Under Part B and Part D," conducted for MedPAC, October 2007; available at www.medpac.gov/documents/Oct07_PartB_D_contractor_JS.pdf.
30. GAO, "Medicare: Payment for Covered Outpatient Drugs Exceed Providers' Costs."
31. MedPAC, *A Data Book*.
32. MedPAC, "Report to Congress: Effects of Medicare Payment Changes on Oncology Services," January 2006; available at www.medpac.gov/publications/congressional_reports/Jan06_Oncology_mandated_report.pdf.
33. GAO, "Medicare Chemotherapy Payments: New Drug and Administration Fees are Closer to Provider Costs," GAO-05-142R, December 2004; available at www.gao.gov/new.items/d05142r.pdf.
34. Kleinke, "Re-naming and Re-Gaming."
35. Joseph P. Newhouse, "How Much Should Medicare Pay for Drugs?" *Health Affairs*, 23, no. 1, (January/December 2004): pp. 89–102; available with subscription at <http://content.healthaffairs.org/cgi/content/abstract/23/1/89>.

APPENDIX A | Drug Pricing Alphabet Soup

Acronym	Term	Description	Program Used By...	Treatment of Discounts and Rebates
AWP	Average Wholesale Price	Price listed in certain compendia (such as Red Book, Price Alert, or First Databank)	Medicare Medicaid	Does not include any rebates or discounts
AMP	Average Manufacturer's Price	Average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade	Medicaid	Includes discounts other than customary prompt pay discounts.
ASP	Average Sales Price	Average price for sales to all purchasers excluding sales that are exempt from the Medicaid best price calculation	Medicare	Includes volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, charge-backs, and rebates
—	Best Price	Lowest price available to any wholesaler, retailer, provider, HMO, non-profit entity or government entity excluding sales to: IHS, VA, DOD, or certain Public Health Service programs; Federal Supply Schedule; state pharmaceutical assistance programs; Part D plans or qualified retiree drug subsidy plans	Medicaid	Includes cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates
WAC	Wholesale Acquisition Cost	The manufacturer's list price for a drug to wholesalers or direct purchasers	Medicare Medicaid	Does not include any rebates or discounts
WAMP	Widely Available Market Price	Price that a prudent physician or supplier would pay for the drug or biological as determined by the HHS Inspector General	Medicare	Includes discounts, rebates, and other price concessions routinely made available to prudent physicians or suppliers

APPENDIX B

Weighing the Options
Is Part B or Part D
Better for the Beneficiary?

For some conditions, like rheumatoid arthritis or some forms of cancer, available drug treatments include options that are covered under Part B and others that are covered under Part D. Even if only financial (not clinical) considerations are taken into account, determining whether a Part B drug or a Part D drug is right for a beneficiary is complicated.

Consider the following scenario...

Beneficiary A and Beneficiary B are enrolled in Part D plans. Both have annual Part D drug costs and out-of-pocket cost-sharing (deductible and coinsurance).

	Part D	Beneficiary A	Beneficiary B
Drug costs		\$1,200	\$6,000
Cost-sharing		\$595	\$4,196

Suppose both beneficiaries are diagnosed with a new condition for which there are two treatment options. The first option is a Part B drug (Drug X) that costs \$1,000 a month. The second option is a Part D drug (Drug Y) that costs \$500 a month.

This table shows the impact on the out-of-pocket costs for each beneficiary of choosing either Drug X or Drug Y.

Out-of-Pocket Costs		BENEFICIARY A		BENEFICIARY B	
		Drug X	Drug Y	Drug X	Drug Y
PART B	Drug costs	\$12,000	\$0	\$12,000	\$0
	Cost-sharing	\$2,400	\$0	\$2,400	\$0
PART D	Drug costs	\$1,200	\$7,200	\$6,000	\$12,000
	Cost-sharing	\$595	\$4,402	\$4,196	\$4,642
Total Drug Cost-sharing		\$2,995	\$4,402	\$6,596	\$4,642

As this example shows, the bottom line can be surprising. For Beneficiary A, who has relatively low drug costs, choosing Drug X that costs twice as much as Drug Y actually results in lower out-of-pocket costs. This happens because, typically under Part D, the coinsurance percentage changes as the beneficiary's drug costs increase. The percentage starts at 25 percent for the initial cost-sharing period, increases to 100 percent after that, and then drops to 5 percent when the beneficiary qualifies for catastrophic coverage. In contrast, Part B coinsurance is constant at 20 percent.

Using Drug Y would increase Beneficiary A's Part D drug costs significantly, but not enough to qualify for catastrophic coverage. Beneficiary B already had relatively high Part D drug costs. For him, choosing Drug Y would result in lower out-of-pocket costs because the additional Part D drug costs would qualify him for catastrophic coverage. There is no catastrophic coverage for Part B drugs.

Using Drug Y would increase Beneficiary A's Part D drug costs significantly, but not enough to qualify for catastrophic coverage. Beneficiary B already had relatively high Part D drug costs. For him, choosing Drug Y would result in lower out-of-pocket costs because the additional Part D drug costs would qualify him for catastrophic coverage. There is no catastrophic coverage for Part B drugs.