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MEDICARE PART B DRUGS: PRICING AND INCENTIVES

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Key Points

- The Part B payment method provides weak incentives for physicians to consider value – that is choose the lowest cost therapy to effectively treat a patient
- The Medicare program has not implemented various value based practices typically used by commercial insurers and Part D sponsors for self-administered drugs

Introduction:

Medicare Part B covers infusible and injectable drugs and biologics administered in physician offices and hospital outpatient departments; as well as certain other drugs required by law that are provided by suppliers such as pharmacies (e.g., inhalation drugs and certain oral anticancer, oral antiemetic, and immunosuppressive drugs). Payment for Part B drugs are made directly to these providers and suppliers based on the average sales price (ASP) calculated for each item. There is growing concern that several features of the current Part B program do not create appropriate incentives for either providers, suppliers or patients to make high value choices among treatment options. First, under current law, most Part B drugs are paid separately; that is based on their own ASP with no reference to other drugs of similar therapeutic effectiveness. In addition, the Medicare program has not applied the types of pricing policies or formulary management practices that are commonly used to achieve better value for self-administered drugs by commercial insurers, including those sponsoring plans in Medicare Part D. In this

paper we describe the current pricing system; discuss the system's financial incentives and provide descriptive data concerning Part B drug spending and utilization.

Calculation of ASP Based Payment

In accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), most Part B drugs are billed and paid separately by Medicare. That is, they are not packaged with other services provided nor are the payments grouped with similar drugs.[1] In addition, payments for Part B drugs are calculated using a drug's average sales price (ASP). More specifically, Medicare must pay ASP + 6 percent of ASP for these drugs when furnished in physicians' offices and in hospital outpatient departments.[2]

ASP is calculated by the Centers for Medicare & Medicaid Services (CMS) using quarterly data on price and volume of sales to all purchasers in the U.S. Manufactures are required to report these data for a drug associated with each the National Drug Code by unit. By definition, ASP is the volume-weighted average of the manufacturer's ASP of the drugs in the same healthcare common procedure coding system (HCPCS code). The ASP is net of any price concessions such as volume discounts, prompt pay discounts, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those obtained through the Medicaid drug rebate program[3]. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program[4]. Each drug with a HCPCS[i] code has a separately calculated ASP. To allow time to submit and calculate these data, the ASP is updated with a two-quarter lag.

Medicare payment rates vary based solely on each drug's ASP. As noted, providers and suppliers are paid 106 percent of ASP, regardless of the acquisition costs they actually incur. The ASP formulas for Part B drugs are separated into three categories by statute: single-source drugs or biologics, multiple-source drugs, and biosimilars. Single-source small molecule drugs -- without generic substitutes -- and biologics are both reimbursed at 106 of their own ASP. For multiple-source small molecule drugs, all therapeutically equivalent brand-name and generic products within the same HCPCS code are reimbursed at 106 percent of the weighted average of their ASPs. In other words, each single-source drug has a unique ASP, regardless of the similarities between drugs, allowing two single-source drugs that have comparable effectiveness to have

[1] As described below, multi – source drugs are grouped for purposes of payment. In addition, when provided in hospitals' outpatient departments, drugs that are under a cost per day threshold cost (currently $100) are packaged with associated procedures or visits for payment. In addition, since 2014 drugs used as a supply with diagnostic procedures and drugs used as a supply with a surgical procedure are packaged regardless of the cost of the drug.

[2] Under MMA's provisions for payment of hospitals' outpatient department services, the Secretary has the authority to base payment for these drugs on hospitals' average acquisition costs and consider overhead/handling costs in setting payment. The Secretary can also use the same payment as for physicians' offices instead of calculating acquisition costs. In recent years, CMS has chosen the latter option so that most drugs are paid the same rate in the two sites of service.

[3] CMS receives ASP data net of the rebates and price concessions which are not separately reported.
[4] 42 U.S.C. § 1395w-3a(c).

very different payment rates. Both the generic and brand name versions of multiple-source small molecule drugs, on the other hand, share the same ASP based payment rate.

In contrast, biosimilar products will not be grouped with the reference biologic product for purposes of Medicare payment. Relative to approving generic versions of small molecule drugs, there are a number of unique considerations FDA must make in approving biosimilar products.[5] The Public Health Service Act defines two new types of biological products- biosimilar and interchangeable. Biosimilars are a type of biological product that are demonstrated to be highly similar to an already FDA-approved biological product, known as the reference product, and have been shown to have no clinically meaningful differences from the reference product. An interchangeable biological product, in addition to meeting the biosimilar standard, is expected to produce the same clinical result as the reference product in any given patient. "Interchangeable" with respect to an interchangeable biological product, means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.[6] Standards for interchangeability have not yet been fully developed by FDA. CMS recently clarified through rulemaking in 2015 that FDA-approved biosimilars of the same reference product will be billed under a same HCPCS code and the ASP would reflect the weighted average ASP of the biosimilars within that code. The 6 percent add-on, is required to be based from the ASP of the reference product. Chart 1 illustrates the various pricing calculations.

[5] Generic drugs are copies of brand-name drugs, have the same active ingredient, and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. That means the brand-name and the generic are bioequivalent. Biologics are large, complex products produced in living systems meaning that similar but not exact copies can be produced. Biosimilars are highly similar to the reference product they were compared to, but have allowable differences because they are made from living organisms.

[6] 42 U.S.C. § 262(k)(4)

Chart 1 - Illustrative Example of Medicare Payments for Prescription Drugs in Part B

			Part B Payment Policy	Example			
				Sales Price	Market share	Average Sales Price (ASP)	Medicare Payment (ASP+6%)
Small molecule	**Single source**	Brand	ASP + 6%	$50.00	100%	$50.00	$53.00
	Multiple source	Brand	Weighted average of ASP for brand and generic +6%	$50.00	50%	$33.75	$35.78
		Generic 1		$20.00	25%	$33.75	$35.78
		Generic 2		$15.00	25%	$33.75	$35.78
Biologics		Reference	ASP + 6%	$50.00	100%	$50.00	$53.00
		Biosimilar 1	Weighted average of ASP for biosimilar + 6% of reference ASP	$20.00	50%	$17.50	$20.50
		Biosimilar 2		$15.00	50%	$17.50	$20.50

Economic Incentives, Cost and Value

One key to obtaining higher value health care is to assure that providers, suppliers and patients have financial incentives for minimizing costs while maintaining or improving the quality of care. Providers and suppliers of Medicare Part B drugs are currently reimbursed at a rate of 106 percent of average sales price of each drug they administer to beneficiaries.

The ASP methodology for Part B drugs falls short of providing value based incentives in several ways. Physicians can often choose between several similar drugs for treating a patient. Although the current system may encourage providers and suppliers to pursue the lowest price for drugs that are multiple source, payment based on drug specific ASP leaves little incentive to make choices among the therapeutic options with an eye towards value -- that is, choose the lowest price among all drugs available to effectively treat a patient.[7] Moreover, the fixed 6 percent of ASP provides a larger dollar "add-on" for higher price drugs than for lower price drugs. The 6 percent add-on may be for administrative complexity and overhead costs, but these issues are not exactly proportional to the price of a drug. Therefore, the larger dollar "add-on" for the higher price drugs may result in increased profit margins for the physicians' office and hospitals –

[7] For multisource drugs, the brand and generic versions are grouped under one billing code and ASP reflects a weighted average of their prices. For these drugs, providers do have an incentive to choose with cost in mind.

creating an incentive to choose the high price drugs as opposed to lower price alternatives of similar effectiveness. One study estimated that the change in Medicare Part B payments to ASP + 6% pricing in 2005 resulted in a shift from lower cost to higher cost chemotherapy agents where the 6% margin resulted in higher dollar "add-ons".[8]

Legislation and court rulings have limited Medicare's ability to modify current pricing mechanisms with value-based policies – such as least costly alternative (LCA) or consolidated billing approaches. The Medicare contractors used LCA pricing from 1995-2010 for selected drugs. LCA is a policy that covered certain drugs at the rate currently paid for the least costly medically appropriate alternative. The United States Court of Appeals for the D.C. Circuit, however, ruled that the ASP payment methodology forecloses the use of the LCA policy for individual drugs. Between July 1, 2007, and March 31, 2008, Medicare also used a consolidated payment approach for two drugs used to treat asthma and chronic obstructive pulmonary disease by assigning them a single billing code and paying the weighted average ASP. The Medicare, Medicaid, and SCHIP Extension Act of 2007 effectively reestablished separate payment rates for these drugs.

In addition to the statutory pricing requirements, other legislative and legal restrictions provide significant obstacles to implementing value based purchasing for Part B drugs. Part D plan sponsors and commercial insurers use a variety of pharmacy benefit management tools to influence choices made by physicians and patients; particularly by providing rules and payment incentives for using higher value medicines. These tools include tiered copayments, prior authorization and step therapy. Medicare does not use those tools today for Part B. Coinsurance is fixed at 20% and there are no provisions for varying that rate based on the value of a particular drug or any other criteria.[9] Moreover, there are no clear mechanisms for implementing formulary management practices such as step therapy or prior authorization.

Incentives: Multi-Source Drugs and Biosimilars

For multiple-source small molecule drugs under Part B, the incentives may differ somewhat from those described above with single source drugs. The brand drug and the generic equivalents are grouped under one HCPCS billing code and ASP is calculated as a weighted average for the group. Thus, if providers choose this drug for treatment, they have the incentive to purchase the lower price alternatives within the group. However, as described above they may still have a greater incentive to purchase a higher price single source drug that would also effectively treat a particular patient.

Use of biologics has grown rapidly over the past ten years and they now account for the majority of Part B drug spending (Table 1). Thus, value-based policies will be critical for biologics; in particular assuring that the best value possible is achieved from the use of biosimilars as they are approved by FDA. As described above, although biosimilars for the same reference product will

[8] Jacobson M, Earle CC, Price M, Newhouse JP. "How Medicare's Payments Cuts for Cancer Chemotherapy Drugs Changed Patterns of Treatment." Health Affairs, 29(7): 1394-1402, 2010.
[9] Because patients without supplemental insurance would face higher out-of-pocket costs for more expensive drugs, they may be incentivized to request lower cost options.

be grouped together under the same HCPCS billing code, they will be coded and paid separately from the reference product. Thus, providers will receive higher payment for continuing to prescribe the reference product even if biosimilars are available. There may be some incentives for physicians to prescribe biosimilars because it will reduce out-of-pocket spending for some beneficiaries. In addition, the 6% "add–on" will be based on the reference product ASP, which will be higher than the biosimilar ASP. Because only one biosimilar had been approved to date, it is unclear how these incentives may affect utilization.

The European experience with biosimilars shows that in addition to financial incentives an active purchasing role by regulators and payers may be effective at encouraging biosimilar use. Germany has realized the largest uptake of available biosimilars among European Union nations.[10] In addition to including biosimilars in the reference pricing system for drugs,[11] the Social Health Insurance (SHI) funds have implemented a number of other policies including: regional quotas for uptake; prescription utilization management; education sessions for clinicians on biosimilars; publication of data on safety and efficacy of biosimilars; and direct support for biosimilar use through "Dear Doctor" letters.

Part B Drug Spending and Use

Tables 2- 4 summarize trends in Part B drug spending from 2005 – 2014. Overall, Medicare Part B prescription drug spending increased from $9.4 billion in 2005 to $18.5 billion in 2014 (Table 1), an average annual increase of 7.7% (Table 2).[12] The share of spending in hospital outpatient departments, as opposed to physicians' office, grew rapidly in these years from 21% to 34%. The increase was mostly due to higher volume of patients served in this setting[13], which may have resulted from a continuing trend to shift inpatient procedures to the outpatient setting and the increasing number of vertically integrated arrangements between hospitals and physicians. Another notable trend was the rapid growth in biologics under Part B. These grew from 39% to 62% of total spending. A significant share of this growth was attributable to price increases in these drugs rather than to growth in the number of users over time.

As displayed on Table 3, a relatively small number of Part B drugs account for a significant share of the spending. The top 20 drugs in terms of Medicare payment account for 57% of the total while the top 10 account for 38% of total payments.

[10] Grabowski, H, Guha, R, Salgado, M, "Biosimilar competition: lessons from Europe, Nature Reviews/Drug Discovery, Volume 13, February 2014.

[11] Reference pricing systems group similar drugs together for the purposes of determining reimbursement. In Germany, the SHIs pay a fixed rate for the group regardless of the particular drug chosen. Patients are responsible for the difference between the fixed rate and the actual drug price.

[12] We have removed most ESRD related drugs from the calculations in all years. In 2005 they accounted for 40% of Part B drug spending but are now mostly bundled with ESRD composite rates and thus, no longer billed separately under Part B.

[13] As displayed on Table 2, the average annual increase in per service and per user spending in outpatient departments (1.9% and 2.9% respectively) were small relative to the overall spending increase (13.6%) implying that patient volume was the key growth factor.

Conclusion

Currently, Medicare makes payments directly to physicians and hospital outpatient departments for Part B drugs administered to beneficiaries. In both sites of service, payments are based on ASP plus 6 percent. The incentives associated with the current payment system are generally not consistent with the provision of high value care to beneficiaries. The direct payment to providers and suppliers may encourage providers and suppliers to obtain the lowest possible acquisition prices for their drugs. For high cost drugs that do not have therapeutic alternatives, this method may have some beneficial effect in slowing growth in Medicare payments. It is when there are therapeutic alternatives available that the current system may not be consistent with value based purchasing. Indeed, the system may encourage the use of higher price drugs when lower cost drugs of equivalent effectiveness are available.

Of equal importance, Medicare has not been able to employ a variety of formulary management practices that that would potentially improve value for beneficiaries and the Program. Practices such as tiered cost sharing, step therapy and other utilization management tools have found widespread use by commercial insurers including those sponsoring Part D plans. Thus, it is likely that implementing a variety of pricing and formulary policies could produce substantial savings for both the Program and its beneficiaries without impairing quality of care.

Table 1 - Medicare Spending Levels for Part B Drugs, 2005-2014

	2005		2014	
	Medicare Pay	Percent of Total Payment	Medicare Pay	Percent of Total Payment
All Part B drugs	$9,442,845,226.16	100.0%	$18,482,128,894.94	100.0%
Biologic				
biologic	$3,694,506,326.26	39.1%	$11,415,657,203.81	61.8%
all others	$5,748,338,899.93	60.9%	$7,066,471,690.60	38.2%
Drug groups				
anti_coagulant	$12,787,493.22	0.1%	$91,670,592.73	0.5%
antigen	$264,845,467.68	2.8%	$628,872,698.77	3.4%
blood_clotting	$174,578,462.55	1.8%	$448,660,834.60	2.4%
cancer	$3,868,929,787.79	41.0%	$7,787,387,021.05	42.1%
clot_buster	$46,479,914.22	0.5%	$48,846,611.58	0.3%
esrd				
ig_intramuscular_admin	$72,355,706.72	0.8%	$124,590.15	0.0%
immunosuppresive	$287,923,855.71	3.0%	$351,844,854.99	1.9%
ivig	$206,843,816.60	2.2%	$900,720,772.51	4.9%
oral_anti_nausea	$10,195,860.40	0.1%	$1,174,583.41	0.0%
oral_cancer	$3,228,884.16	0.0%	$3,524,291.37	0.0%
osteoporosis	$277,765,552.26	2.9%	$745,190,510.81	4.0%
parenteral_or_enteral	$349,233,836.66	3.7%	$287,034,146.81	1.6%
rheumatoid_arthritis	$542,204,283.15	5.7%	$1,507,640,749.23	8.2%
single_antigen_admin	$24,642,274.23	0.3%	$11,534,372.43	0.1%
Physicians				
Oncology	$3,399,720,221.45	36.0%	$4,299,609,761.22	23.3%
Ophthalmology	$222,491,767.22	2.4%	$2,080,633,814.26	11.3%
Rheumatology	$346,562,011.94	3.7%	$979,318,704.28	5.3%
Primary care	$917,997,715.90	9.7%	$943,868,291.31	5.1%
Urology	$393,244,994.20	4.2%	$288,730,424.89	1.6%
Infectious disease	$22,114,009.56	0.2%	$58,613,997.20	0.3%
Other specialties	$912,418,938.69	9.7%	$1,555,688,497.77	8.4%
Place of service				
Hospital outpatient	$1,981,943,227.75	21.0%	$6,256,659,627.80	33.9%
Physian office	$5,983,178,500.51	63.4%	$9,574,793,906.00	51.8%
ASC	$297,015.41	0.0%	$9,965,232.04	0.1%

Source: Acumen analysis of Medicare Part B claims data, 2005-2014, for HHS/ASPE

Notes:

* Net of ESRD drugs (as most of them got bundled into APCs over time and therefor were not in the claims)

1 Includes data from the carrier (PB), outpatient (OP) and durable medical equipment (DM) file types.
Charges counted at the line item level.

2 Place of Service (PLCSRVC) not defined in OP claims

3 Physician specialty (HCFASPCL) only found in PB claims
Other Specialties, any code not in the HCFASPCL codes specified above

Table 2 - Average Annual Spending Growth Rates for Part B Drugs, 2005-2014

	2005-14		
	Medicare Pay	Medicare Pay per service	Medicare Pay per user
All Part B drugs	7.7%	4.0%	3.2%
Biologic			
biologic	13.4%	10.0%	10.8%
all others	2.3%	-1.4%	-3.3%
Drug groups			
anti_coagulant	24.5%	4.7%	2.1%
antigen	10.1%	8.2%	8.1%
blood_clotting	11.1%	-1.4%	5.0%
cancer	8.1%	5.0%	3.8%
clot_buster	0.6%	3.6%	1.7%
esrd			
ig_intramuscular_admin	-50.7%	-31.2%	-37.1%
immunosuppresive	2.3%	-4.6%	-3.3%
ivig	17.8%	9.0%	9.7%
oral_anti_nausea	-21.3%	-26.5%	-31.3%
oral_cancer	1.0%	1.6%	0.0%
osteoporosis	11.6%	1.1%	-8.6%
parenteral_or_enteral	-2.2%	0.2%	2.5%
rheumatoid_arthritis	12.0%	3.6%	5.5%
single_antigen_admin	-8.1%	3.5%	1.6%
Physicians			
Oncology	2.6%	7.8%	7.3%
Ophthalmology	28.2%	3.4%	12.5%
Rheumatology	12.2%	10.8%	10.4%
Primary care	0.3%	0.0%	-0.8%
Urology	-3.4%	-0.1%	0.1%
Infectious disease	11.4%	14.6%	14.9%
Other specialties	6.1%	5.1%	4.6%
Place of service			
Hospital outpatient	13.6%	1.9%	2.9%
Physian office	5.4%	6.1%	4.9%
ASC	47.7%	32.4%	35.6%

Source: Acumen analysis of Medicare Part B claims data, 2005-2014, for HHS/ASPE

Notes:

* Net of ESRD drugs (as most of them got bundled into APCs over time and therefor were not in the claims)

1 Includes data from the carrier (PB), out patient (OP) and durable medical equipment (DM) file types.
Charges counted at the line item level.

2 Place of Service (PLCSRVC) not defined in OP claims

3 Physician specialty (HCFASPCL) only found in PB claims
Other Specialties, any code not in the HCFASPCL codes specified above

Table 3 – Percent of Spending for Top 20 Part B Drugs

HCPCS	Description	Medicare Pay	Percent of payment	Pay per user	Pay per service
-all-	all codes	$18,482,128,894.94	100%	$273	$154
top 20$		$10,521,943,447.76	57%		
J9310	Injection, rituximab, 100 mg	$1,244,342,757.08	7%	$17,216	$3,900
J2778	Injection, ranibizumab, 0.1 mg	$1,065,930,445.02	6%	$7,413	$1,498
J0178	Injection, aflibercept, 1 mg	$1,037,179,191.58	6%	$7,724	$1,572
J2505	Injection, pegfilgrastim, 6 mg	$975,037,388.15	5%	$9,375	$2,561
J1745	Injection infliximab, 10 mg	$967,728,172.47	5%	$15,255	$2,568
J9035	Injection, bevacizumab, 10 mg	$880,552,228.12	5%	$3,969	$897
J0897	Injection, denosumab, 1 mg	$630,354,083.07	3%	$2,034	$917
J9355	Injection, trastuzumab, 10 mg	$464,068,327.38	3%	$23,873	$2,284
J9305	Injection, pemetrexed, 10 mg	$464,010,488.09	3%	$19,437	$3,738
J9041	Injection, bortezomib, 0.1 mg	$387,219,621.84	2%	$18,107	$997
J2353	Injection, octreotide, depot form for intramuscular injection, 1 mg	$281,992,114.97	2%	$24,986	$3,017
J0129	Injection, abatacept, 10 mg (code may be used for medicare when drug administered u	$278,327,057.23	2%	$13,139	$1,561
J9033	Injection, bendamustine hcl, 1 mg	$252,166,975.09	1%	$18,109	$2,425
J0885	Injection, epoetin alfa, (for non-esrd use), 1000 units	$248,965,081.62	1%	$2,407	$283
J9228	Injection, ipilimumab, 1 mg	$242,149,065.57	1%	$80,932	$24,008
J9264	Injection, paclitaxel protein-bound particles, 1 mg	$241,545,862.09	1%	$3,504	$578
J2323	Injection, natalizumab, 1 mg	$225,329,177.41	1%	$12,222	$1,380
J1569	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g. liquid), 500 mg	$211,997,684.90	1%	$25,619	$3,129
J9055	Injection, cetuximab, 10 mg	$211,835,123.79	1%	$16,344	$2,115
J9217	Leuprolide acetate (for depot suspension), 7.5 mg	$211,212,602.29	1%	$21,330	$1,923

Source: Acumen analysis of Medicare Part B claims data, 2005-2014, for HHS/ASPE

Notes:

* Net of ESRD drugs (as most of them got bundled into APCs over time and therefor were not in the claims)

1 Includes data from the carrier (PB), out patient (OP) and durable medical equipment (DM) file types.
Charges counted at the line item level.

2 Place of Service (PLCSRVC) not defined in OP claims

3 Physician specialty (HCFASPCL) only found in PB claims

Other Specialties, any code not in the HCFASPCL codes specified above

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Medicare Prescription Drug, Improvement,

[i] Healthcare Common Procedure Coding System