Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2006-2012

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THE MORAN COMPANY

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Introduction

Research on the pricing of prescription drugs tends to focus on individual products, rather than the overall pricing trend for the market as a whole.[1] This larger trend—which is influenced by multiple competitive forces, including competition among products in therapeutic classes and entry of generic drugs into the market—tends to differ markedly from the pricing trends of individual products. This broader perspective more accurately captures marketplace dynamics, providing a more appropriate picture of drug cost trends.

The Pharmaceutical Research and Manufacturers of America (PhRMA) asked The Moran Company (TMC) to study the larger trend of Average Sales Price (ASP) changes for Medicare Part B drugs.[2] Medicare Part B is the program that covers physician and other services in the outpatient setting. Part B coverage includes drugs and biologicals that are covered as a part of physician services, as well as some additional categories of drugs and biologicals.[3] According to MedPAC, claims for drugs submitted through Medicare's carriers accounted for approximately $11.5 billion in spending in 2010.[4]

We examined changes in volume-weighted ASP over the 2006 to 2012 period and found that while there appear to be seasonal changes within each of the years of our analysis, volume-weighted ASP has remained steady year over year.

The volume-weighted ASP has declined from $6.75 in the first quarter of 2006 to a projected $6.11 for the fourth quarter of 2012. Volume-weighted ASP has remained steady throughout the period, ranging between $5.79 and $6.75, following a cyclical seasonal pattern. Over the same period total spending for Part B drugs has also remained stable. Because it reflects an average of the prices for individual drugs and biologicals, volume-weighted ASP is influenced by the utilization of particular products, including generics and higher or lower cost drugs.

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[1] See for example, S.W. Schondelmeyer and L. Purvis for the AARP Public Policy Institute: Rx Price Watch Report, Trends in Retail Prices of Brand Names Prescription Drugs Widely Used by Medicare Beneficiaries, 2005 to 2009, August 2010.

[2] The Centers for Medicare and Medicaid Services (CMS) publishes, on a quarterly basis, ASP Drug Pricing Files. These files contain ASP pricing data reported by drug manufacturers.

[3] Prescription drugs that generally do not require physician administration are covered by Medicare Part D. Part D drugs are not reimbursed under the ASP system and thus were not included in this analysis.

[4] This amount is lower than total drug spending estimated in our analyses, mainly because it does not include claims submitted by Outpatient Hospital Departments or dialysis facilities. MedPAC estimates that total spending in these settings was $7.1 billion in 2010. Source: MedPAC's A Data Book, Health Care Spending and the Medicare Program, June 2012.

This analysis suggests that the cost of prescription medicines covered by Medicare Part B is influenced by broader marketplace dynamics that drive changes in the mix of brand and generic drugs used by patients. Analyses focusing on the pricing of individual products tend to miss an important part of the story by ignoring changing competitive pressures within therapeutic categories over the course of a drug's lifecycle, including the impact of generic drugs.[5] Such changes will continue to be a part of the Part B drug pricing story, as they affect the weighted-average price of products by shifting the mix of drugs used. According to a recent report from the Office of Inspector General (OIG), 26 of the 48 top dollar-volume brand Part B drugs either already have or could have generic versions approved in the next several years.[6]

Medicare Part B Coverage for Drugs

The Medicare program is the primary source of health coverage for most senior citizens, and also provides coverage for certain disabled people and most people with End Stage Renal Disease (ESRD). Part A of the program generally covers hospitalizations and other inpatient services, while Part B focuses on the services of physicians and other treatments received in the outpatient setting.

While most coverage of prescription drugs is provided separately under Medicare Part D, drugs that generally require physician administration are covered under Part B, as are certain other products as determined by Congress.[7] This coverage is particularly important for cancer patients: chemotherapy drugs and related therapies account for 7 of the top 10 therapies covered by Part B.[8]

Because they often require physician administration, many of the products covered under Part B are biologicals. According to the OIG, 22 of the 48 top dollar-volume products covered by Part B are biologicals.

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[5] See, E.R. Berndt and M. Aitken, "Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation." NBER Working Paper w16431, October 2010 and IMS Institute for Healthcare Informatics, "Medicare Part D at Age Five: What Has Happened to Seniors' Drug Prices?" July 2011.

[6] Department of Health and Human Services Office of Inspector General, Medicare Payments for Newly Available Generic Drugs, OEI-03-09-00510, January 2011.

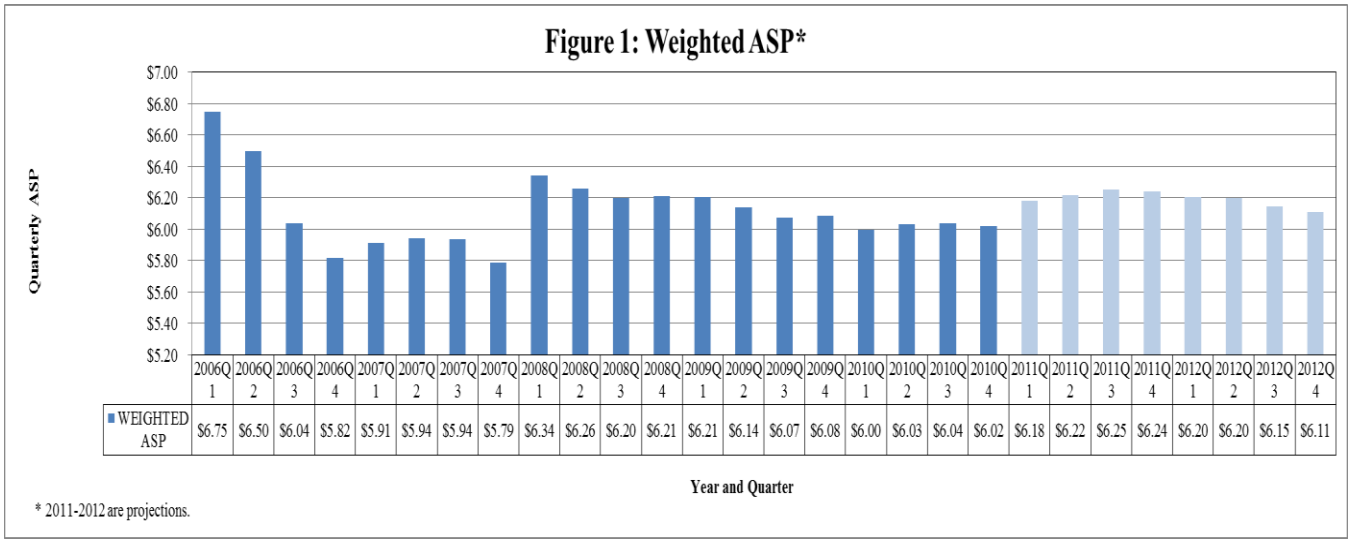
[7] See §1862(s)(1)(A) of the Social Security Act and the subparagraphs that follow for a delineation of this coverage, which includes certain oral cancer therapies, immunosuppressive products used as the result of a Medicare covered transplant and erythropoietin for dialysis patients.

[8] Moran Company analysts tabulated the top ten drugs based on Part B spending in 2009. Six of the top ten drugs were chemotherapy agents. Two were drugs designed to treat chemotherapy related anemia. The remaining drugs included a treatment for macular degeneration and a treatment for rheumatoid arthritis and other disorders.

The Role of ASP

In the Medicare Modernization Act of 2003 (MMA), Congress enacted the ASP reimbursement methodology for Part B drugs. ASP reflects the average price of a drug's sales to all purchasers in the United States, subject to certain exclusions.[9] Based on data received directly from manufacturers, the Centers for Medicare and Medicaid Services (CMS) calculates the ASP for each Healthcare Common Procedure Coding System (HCPCS) code covered under Medicare Part B. A HCPCS code may include drugs from more than one manufacturer in the case of multiple source drugs, or in the case of single source drugs that shared the same HCPCS code prior to enactment of the MMA.

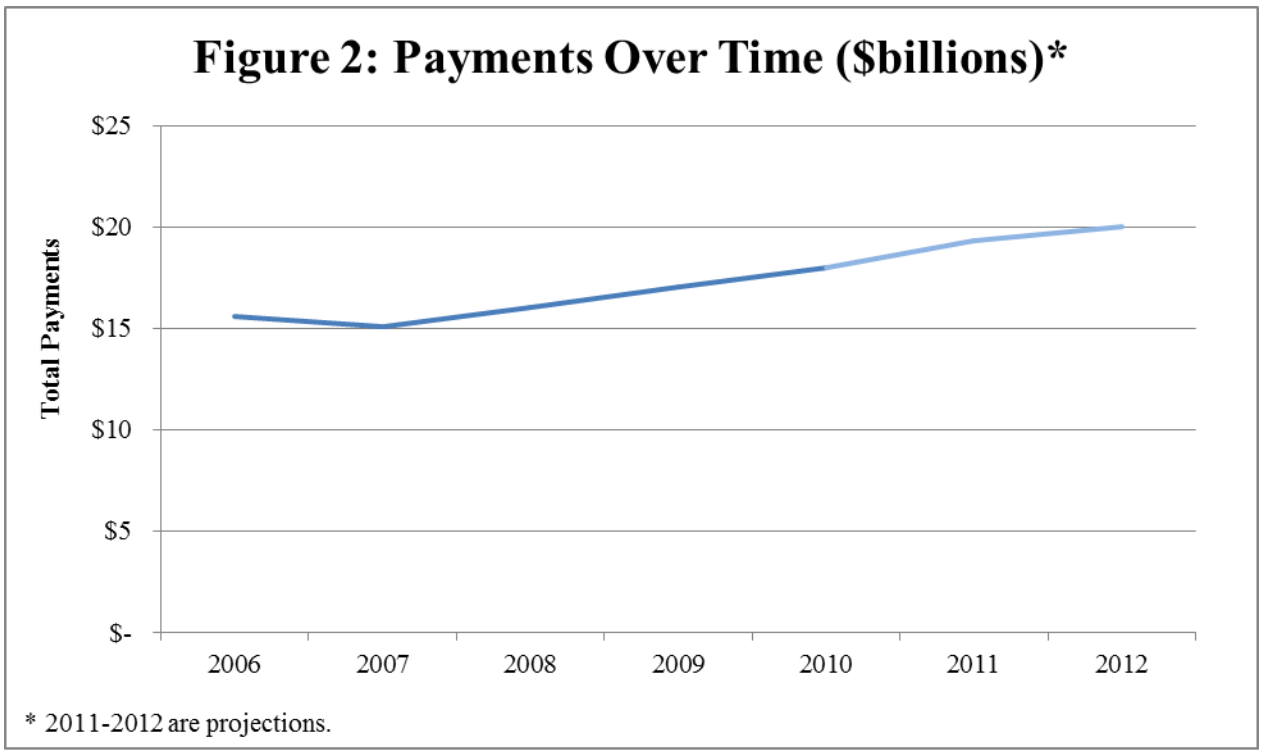
Analyzing the Weighted Average ASP for 2006-2012



As shown in Figure 1, despite some cyclical variation, volume-weighted ASP remained roughly stable from 2006 to 2010, and we project that the volume-weighted ASP will increase for 2011 and 2012. For most years in our analysis, the first quarter shows a slightly higher ASP than the other quarters in the year. However, as Figure 1 indicates, the pattern is different for 2010 and 2011 where the highest volume-weighted ASP is seen in the third quarter rather than the first quarter.

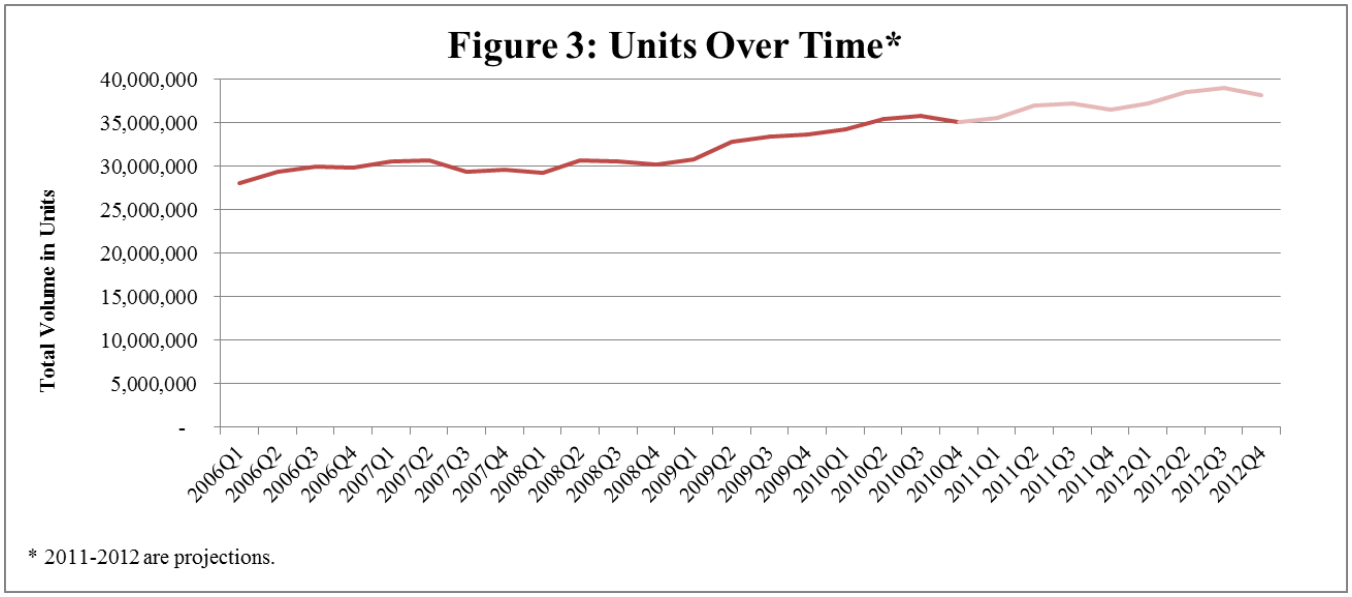
We would note that our projection of weighted average ASP is $6.15 for the first quarter of 2013 based on the methodology employed in our analysis for other quarters, but it is too early to conduct a complete estimate for 2013.

[9] See §1847A(c)(1). Exclusions are based mainly on the sales that are exempt from the Medicaid program's "best price" used in calculating Medicaid rebates and include sales to Part D plans and many government programs.



As shown in Figure 2 above, total ASP-based payments estimated in our analysis from 2006 to 2012 are largely stable, with moderate increases occurring from the beginning of 2008 to the present. Total payments range from $15.6 billion in 2006 to an estimated $20.0 billion in 2012.[10]

[10] These amounts shown are weighted from the 5% Medicare Standard Analytical files by a scalar of 20 to estimate total payments for the entire Medicare population.



As shown in Figure 3, units during the 2006 to 2012 time period show a similar pattern to ASP payments.[11] Units generally increase, slowly and steadily, from the first quarter of 2006 through the fourth quarter of 2010; the number of units was approximately 28 million in the first quarter of 2006, and the number reaches a projected peak of just over 39 million in the third quarter of 2012.

[11] Please note that we are presenting units from the 5% Standard Analytical Files used to project the weighted average ASP trend. In contrast with the payment estimates presented in Figure 3, these units have not been inflated to the Medicare population as a whole. The units reflected are based on the HCPCS units concept for each of the products in the ASP pricing file.

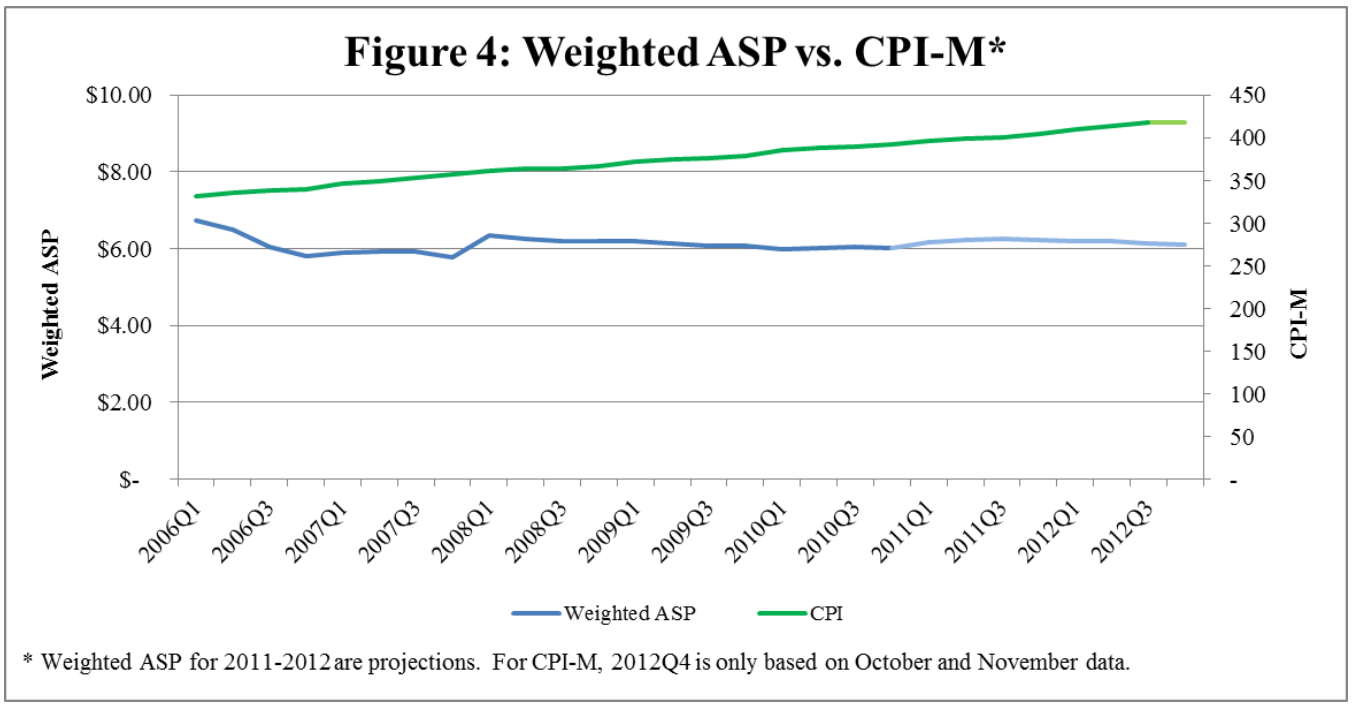


Figure 4 presents a comparison of the volume weighted ASP trend calculated in this analysis against the Consumer Price Index for Medical Care (CPI-M). The CPI-U, which is maintained by the Bureau of Labor Statistics[12], is a measure of the average price at a point in time for a market basket of goods and services commonly purchased by urban consumers in the United States. CPI-M is a separate index that is maintained for medical care. Our comparison shows that while CPI-M has gradually been increasing from 2006 to the present, the volume-weighted ASP has maintained a much flatter line.

Figures 2, 3, and 4 clearly show that prescription drugs and biologicals are not a key driver of costs for the Medicare Part B program. Over the past several years, total payments and units have remained stable, while changes in the weighted average ASP show that pricing in the aggregate for drugs and biologicals in Medicare Part B, adjusted to reflect generic and therapeutic competition, has remained flat.

[12] http://www.bls.gov/cpi/

Technical Appendix

Additional Background on Average Sales Price

Manufacturers were required to submit to CMS ASP data on a quarterly basis beginning April 30, 2004.[13] Under the ASP system, payment for multiple source drugs within the same HCPCS code is set equal to 106% of the blended ASP for all products in the code; payment for a single source drug (which generally would have its own HCPCS code) is generally equal to the lesser of 106% of the ASP or 106% of the wholesale acquisition cost of the various strengths of a product that fall within a particular HCPCS code. When more than one brand of drug (or generic version of a drug) is mapped to the same HCPCS, the pricing data from the respective manufacturers are blended on a volume-weighted basis to determine the ASP that will be used for payment purposes.

Regulations implementing ASP reporting specify that manufacturers must account for price concessions, such as volume, cash, and prompt pay discounts, charge-backs and rebates (other than rebates under the Medicaid drug rebate program) in the ASP calculation (i.e., price concessions are subtracted when calculating the ASP numerator). Price concessions that a manufacturer provides on a lagged basis (e.g., rebates) must be estimated, based on data from the most recent 12-month period.

Based on its experience in implementing the program, CMS has clarified various reporting requirements, both in rules implementing policies under the physician fee schedule and in stand-alone rulemaking.[14]

Methodology

To calculate the volume-weighted ASP, we performed the analysis on a HCPCS level basis. The ASP data were derived from the quarterly ASP Drug Pricing Files published by CMS. We divided the payment limit amount—which reflects physician office payments of ASP plus 6%—by a factor of 1.06 to get the ASP. We matched the ASP to the count data based on the payment quarter. In other words, we used the ASP amount that was used to reimburse the claims during each quarter (rather than the ASP that was reported to CMS in that quarter, or the ASP that was calculated based on sales in that quarter).

The drug unit (by HCPCS) count data used to calculate the weighted average were derived from the Medicare Outpatient and Carrier Standard Analytical Files (SAF) claims data. SAF data are a series of public use research files generated from Medicare claims. All outpatient services and carrier-processed claims from a nationally-representative 5% of the Medicare population were included in our analysis. We inflated these numbers where necessary to represent national totals by multiplying by 20.

[13] Prior to 2005, payment for Part B drugs was based on a different pricing concept, Average Wholesale Price (AWP).

[14] The regulations implementing ASP reporting requirements are codified in 42 CFR § 414.800 through §414.806.

We applied a smoothing methodology by standardizing the unit concept and price for certain HCPCS codes over time to account for coding changes that would have caused a significantly reduced weighted average ASP in a manner that distorted the overall trend observed in our analysis. We feel that this approach, which results in a higher weighted average ASP than would otherwise be calculated, is more conservative than other options for dealing with this issue and presents the most realistic picture of the trend in weighted average ASP.

We matched the ASP and unit count data by unique HCPCS codes. The weighted ASP was only calculated based on drugs with a valid unit count from the SAF and a payment limit in CMS's ASP Drug Pricing File. The weighted average ASP was calculated from the first quarter in 2006 to the fourth quarter in 2010.

Our formula was:

Σ (Average Sale Price $\times$ Unit Count) / Σ Unit Count.

Although ASP data are available for 2011 and 2012, the SAF data for these years are not yet available. To calculate the weighted average ASP for 2011 and 2012, we projected the ASP and unit counts based on the 2006-2010 growth rates. To determine the annual growth rate, we used the geometric mean (4.66%), which was very close to the arithmetic mean (4.71%).

The payment amounts we show throughout the report are estimates based on our methodology for creating weighted average ASP. These amounts are reasonably close, but not identical to the payment amounts our analysts (and others such as MedPAC) have calculated using Medicare claims data.

To calculate total payment amounts, we multiplied the units in our analysis by ASP plus 6%, which is the payment amount for drugs and biologicals in the physician office (or pharmacy, for pharmacy-dispensed Part B drugs). We then applied a scalar of 20 to inflate these amounts to the total Medicare population, since the units in our analysis come from the 5% SAFs. Reimbursement for payments in the hospital outpatient department may be overstated, both because our estimates do not tie to the reimbursement rates used in years where the Hospital Outpatient Prospective Payment System (OPPS) paid less than ASP plus 6% and because our analysis includes units for drugs and biologicals that were packaged (not paid for separately) under the OPPS.

Throughout this report, we are using ASP values that were used for payments under Part B during the calendar quarter corresponding with the Medicare volume information used in weighting. Under the CMS methodology, there is a two-quarter lag before the sales for a particular quarter are represented in the ASP values used in reimbursement.[15]

[15] Thus, in the first quarter of 2005, physicians were reimbursed on ASP values calculated from manufacturer reports for sales during the third quarter of 2004.