

Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2006-2015

December 2016

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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 \$14.9 billion in spending in 2014.⁴

We examined changes in volume-weighted ASP over the 2006 to 2015 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 increased from \$6.75 in the first quarter of 2006 to a projected \$7.67 for the fourth quarter of 2015. Volume-weighted ASP has ranged from \$5.79 (in 2007Q4) to \$7.67 (in 2015Q4), 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.

Recently, there has been a growing focus on the cost of oncology drugs as a potential driver of overall cancer costs and Part B spending generally. We split the Part B drugs into oncology

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 Prescription Drugs Widely Used by Older Americans: 2006 to 2013: February 2016.

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 spending in the outpatient hospital on separately paid drugs was \$6.7 billion in 2013. Source: MedPAC's A Data Book, Health Care Spending and the Medicare Program, June 2016.

drugs⁵ and non-oncology drugs. While the volume-weighted ASP of oncology drugs was consistently higher than that of the other drugs, the volume-weighted ASP trend for oncology drugs remains comparable to medical inflation. The difference between the volume-weighted ASP of oncology and non-oncology drugs—which was about \$2 at the beginning of 2006—gradually increased to about \$3 at the end of 2011, before declining back to about \$2 at the end of 2013.

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.⁶ 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 2011 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.⁷

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.⁸ This coverage is particularly important for cancer patients: chemotherapy drugs and related therapies accounted for 7 of the top 10 therapies covered by Part B in 2014.⁹ Because biologicals often require physician administration, many of these products are also covered under Part B. According to the OIG, 22 of the 48 top dollar-volume products covered by Part B are biologicals.⁷

⁵ Oncology drugs are specified by 1) J9000 series (chemotherapy) of HCPCS codes; 2) Association of Community Cancer Centers (ACCC) Oncology Drug Database (<https://www.accc-cancer.org/publications/DrugReference.asp>).

⁶ 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.

⁷ Department of Health and Human Services Office of Inspector General, Medicare Payments for Newly Available Generic Drugs, OEI-03-09-00510, January 2011.

⁸ 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.

⁹ Medicare Payment Advisory Commission. A Databook: Health Care Spending and the Medicare Program, June 2016.

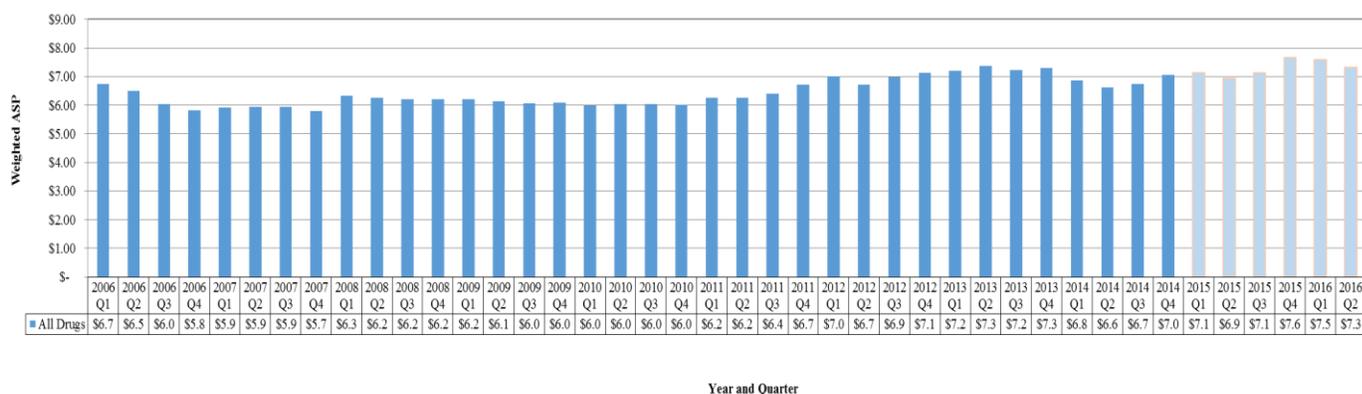
The Role of ASP

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.¹⁰ 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. Generally, single source drugs are assigned unique HCPCS codes. However, a HCPCS code may include drugs from more than one manufacturer, as in the case of multiple source drugs, or single source drugs that shared the same HCPCS code prior to enactment of the MMA.

Analyzing the Weighted Average ASP for 2006-2015

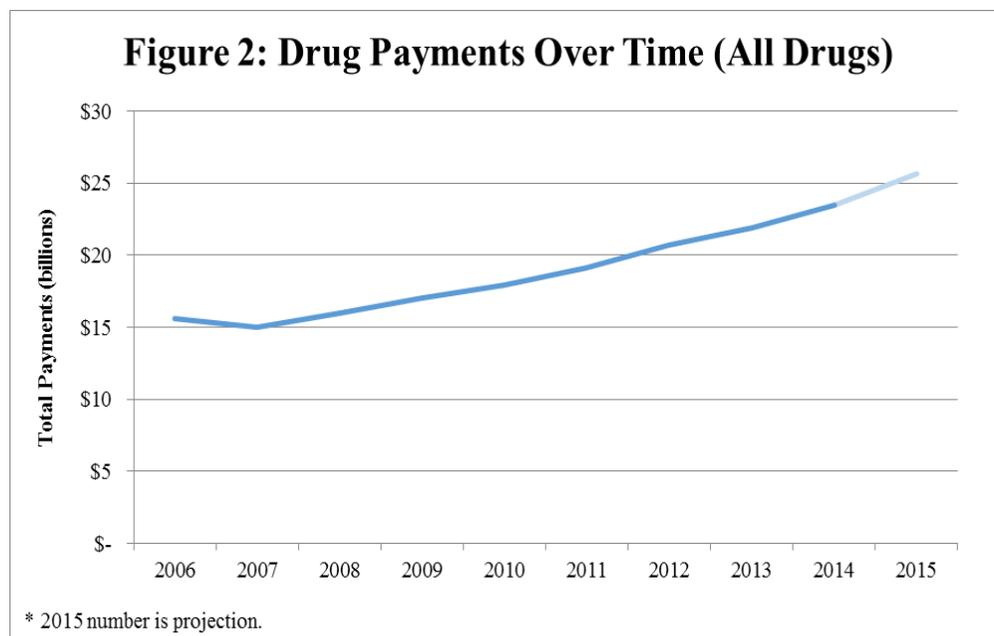
As shown in Figure 1, despite some cyclical variation, volume-weighted ASP remained roughly stable from 2007 to 2011 and increased moderately over the 2012 to 2013 period. For years 2006 to 2009 in our analysis, the first quarter shows a slightly higher ASP than the other quarters in the year. However, as Figure 1 indicates, the pattern is different for 2011, 2012, 2014, and 2015 where the highest volume-weighted ASP is seen in the fourth quarter rather than the first quarter. For 2013, the highest volume-weighted ASP is seen in the second quarter and fourth quarter rather than the first quarter, which most likely is normal market variability.

Figure 1: Weighted ASP (All Drugs)

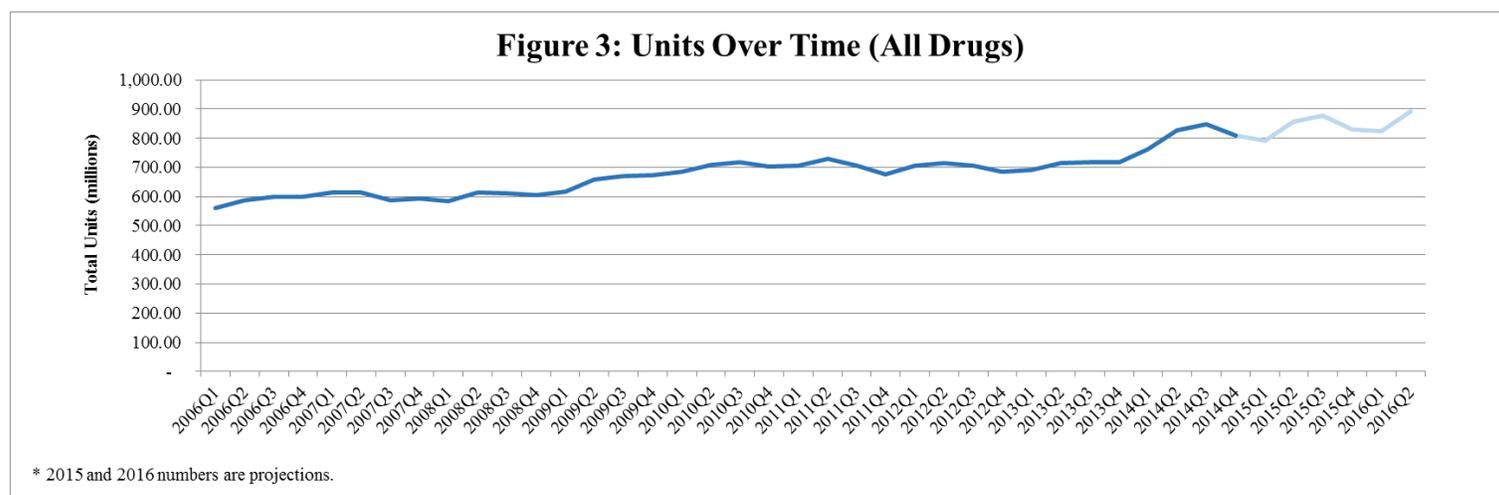


* 2015 and 2016 numbers are projections.

¹⁰ 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 2011 were largely stable, with moderate increases occurring from the beginning of 2007 to the present. Total payments range from \$15.6 billion in 2006 to an estimated \$25.7 billion in 2015.¹¹ A recent report from the Government Accountability Office found that moderate increases in expenditures for Part B drugs are largely the result of growing utilization of new Part B products following their approval by the FDA.¹²



¹¹ The 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. We note that 2015 payments are projected (since 2015 claims data are not yet available) and are potentially slightly overstated due to the effect of sequestration.

¹² Government Accountability Office. "Expenditures for New Drugs Concentrated among a Few Drugs, and Most Were Costly for Beneficiaries." October 2015. p. 21

As shown in Figure 3, units during the 2006 to 2015 time period show a more stable pattern than ASP payments.^{13,14} Units generally increase, slowly and steadily, from the first quarter of 2006 through the fourth quarter of 2015; the number of units was approximately 560.7 million in the first quarter of 2006, and the number reaches a projected peak of just over 831.4 million in the fourth quarter of 2015.

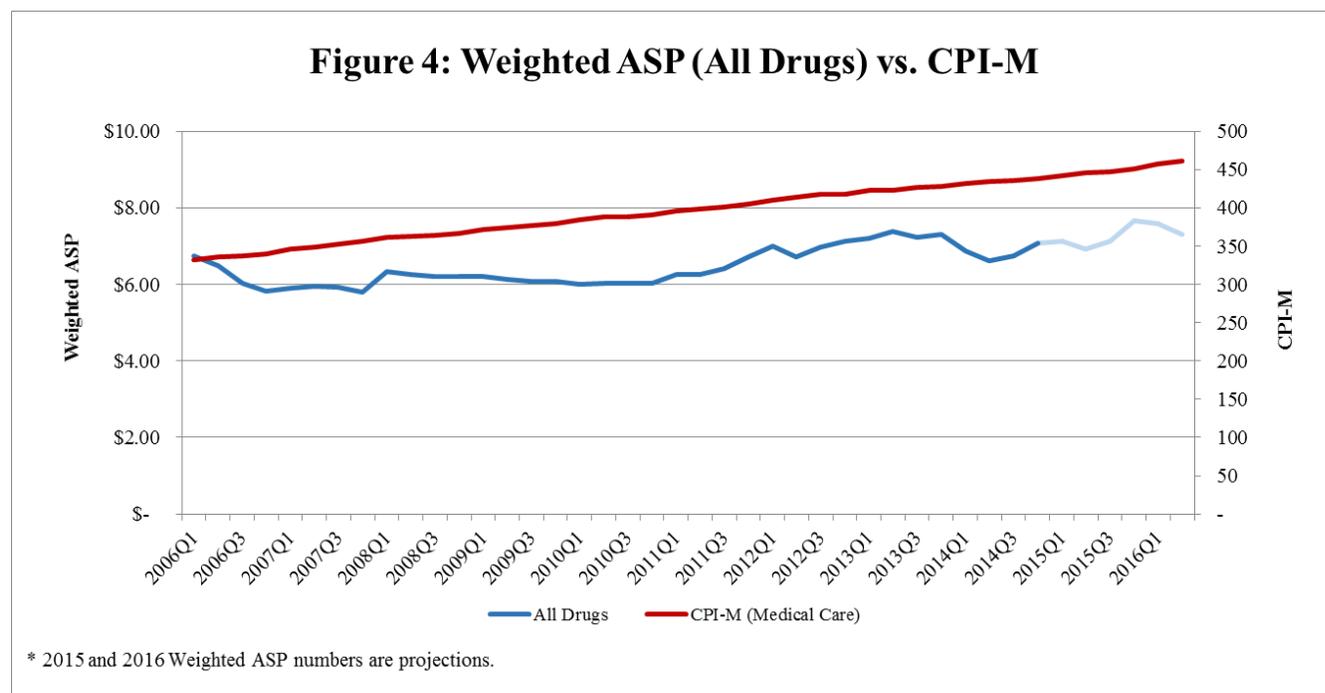


Figure 4 presents a comparison of the volume weighted ASP trend calculated in this analysis against the Consumer Price Index for Medical Care (CPI-M). The CPI-U, which is maintained by the Bureau of Labor Statistics,¹⁵ is a measure of the average price at a point in time for a market basket of goods 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 flatter line but with more variation.

In 2014, ASP-based payments for drugs and biologicals accounted for just over 3 percent of overall Medicare spending.¹⁶ Figures 2, 3, and 4 clearly show that prescription drugs and biologicals are not a key driver of increased costs for the Medicare Part B program. Over the past several years, total payments and units have remained stable, while changes in the weighted

¹³ Units from the 5% Standard Analytical Files are used to project the weighted average ASP trend. The units reflected are based on the HCPCS units concept for each of the products in the ASP pricing file. Please note that along with the payment estimates presented in Figure 2, these units have been inflated to the Medicare population as a whole in Figure 3.

¹⁴ We have shown inflated units in contrast to the previous 2006-2014 report.

¹⁵ <http://www.bls.gov/cpi/>

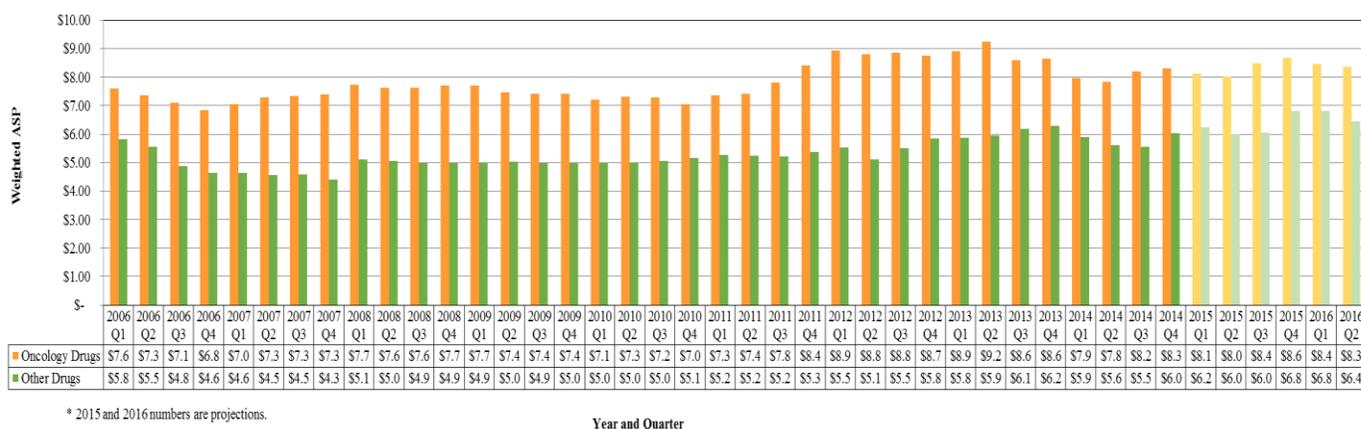
¹⁶ Medicare Payment Advisory Commission, A Data Book: Health care spending and the Medicare program, June 2015

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.¹⁷

Comparing Trends for Oncology and Non-Oncology Drugs

We further split the Part B drugs into cancer (oncology) drugs and other (non-oncology) drugs (Figure 5). The volume-weighted ASP of oncology drugs, which ranged from \$6.84 to \$9.26, was consistently higher than that of non-oncology drugs, which ranged from \$4.39 to \$6.81. The difference of volume-weighted ASP between the two types of drugs increased moderately from the fourth quarter of 2011 through the third quarter of 2013, and then reverted to the difference prior to 2011.

Figure 5: Weighted ASP (Oncology Drugs vs. All Other Drugs)



As shown in Figure 6 below, total payments for oncology drugs, ranging from \$9.1 billion to an estimated \$13.6 billion, were consistently higher than that of the other drugs, which ranged from \$5.8 billion to an estimated \$12.1 billion.¹⁸

¹⁷ We will need the actual SAF utilization data for year 2015 (and potentially the updated CMS ASP Drug Pricing File) to determine whether the moderate increase of weighted ASP in 2014 and 2015 is an ongoing trend.

¹⁸ 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. We note that 2015 payments are projected (since 2015 claims data are not yet available) and are potentially slightly overstated due to the effect of sequestration.

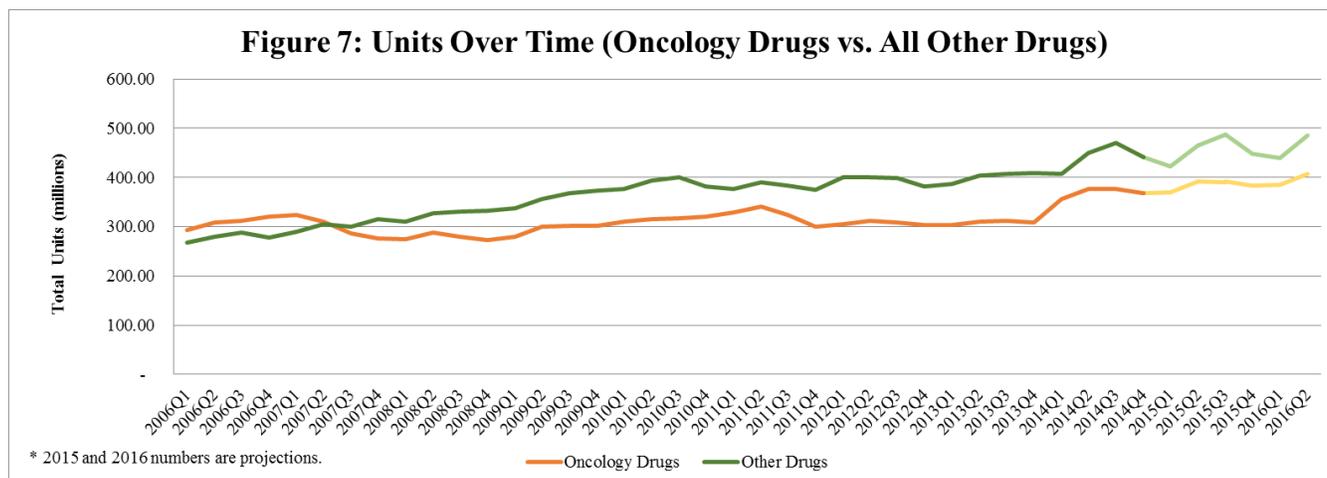
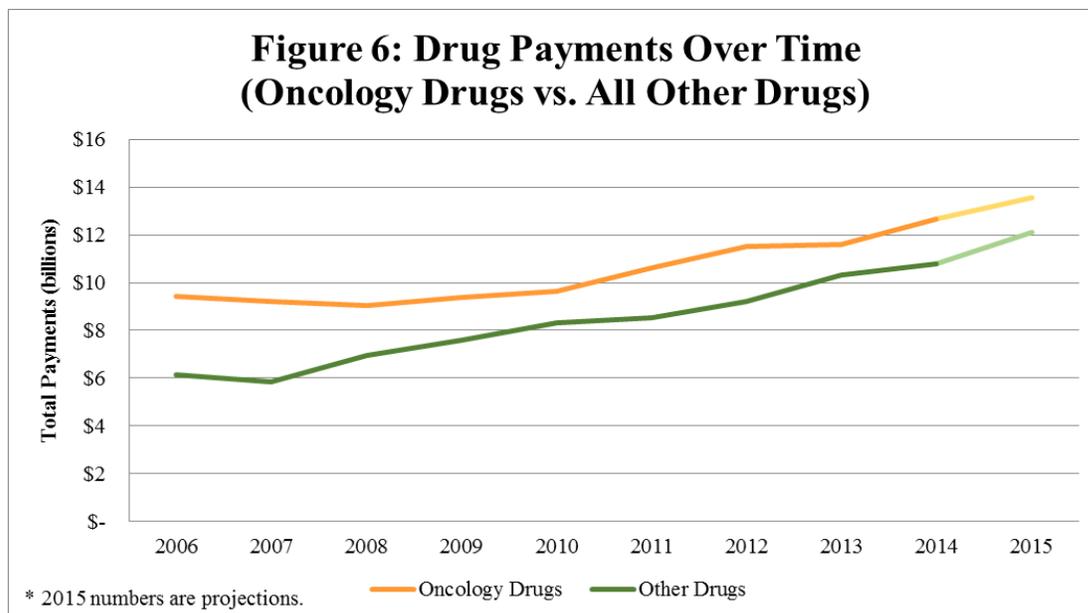
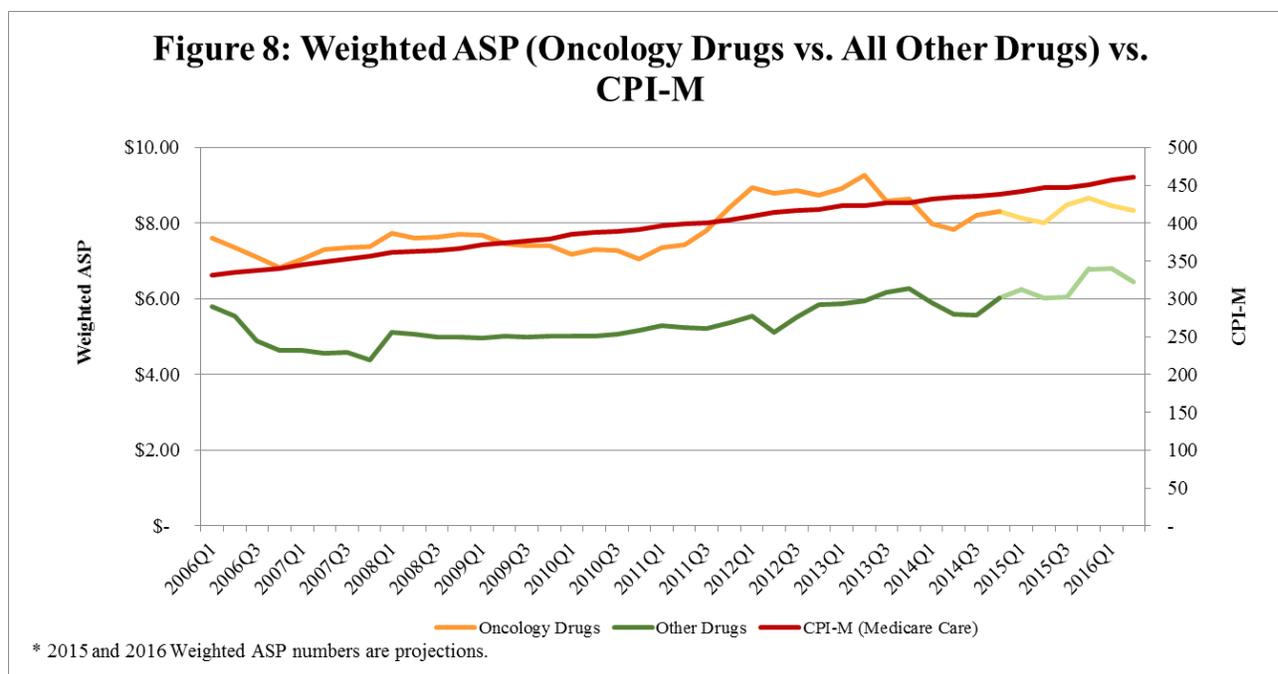


Figure 7 shows unit counts for oncology drugs vs. non-oncology drugs for each quarter during the 2006 to 2015 time period.¹⁹ The non-oncology drugs increased from 268 million units to around 487 million units over time. Oncology drugs remained at about 300 million units through 2013 and started to increase in 2014, reaching almost 400 million units in 2015.

¹⁹ Please note that we have shown inflated units in contrast to the previous 2006-2014 report.



In Figure 8, we compare the volume weighted ASP trend for oncology drugs and non-oncology drugs against the CPI-M. Unlike inflation, which increased steadily over the period, the trend for oncology was more variable, and has fallen below inflation in the most recent time period. Non-oncology drugs maintained a flatter line than the CPI-M. The oncology drugs show a relatively larger variation over time, however volume-weighted ASP for oncology products remains in line with overall medical inflation.

Impact of Competition

Market competition is a contributor to the overall stable trend in volume-weighted ASP. Research shows that generics are typically priced at levels slightly less than the branded drug, and prices typically decrease as the number of generic entrants increase. While the market for biosimilars is still too nascent to draw firm conclusions about biosimilar pricing trends, biosimilars are expected to offer significant competition to their innovator biologic products.²⁰ IMS estimates that the reduction in overall spending as branded medicines lose exclusivity is

²⁰ However, if CMS persists in its present policy of lumping all biosimilars into the same payment code, biosimilar discounts may not be all that great. This policy threatens to dampen competition by deterring entry into the biosimilar market by any manufacturer that is not the lowest-cost producer.

expected to total \$143.5 billion in the next five years.²¹ This figure includes the estimated impact of biosimilars.

Overall, nearly half of the top 40 Part B drugs (based on total Medicare spending) could see market competition from biosimilars in the next 10 years.^{22,23,24,25,26,27} Following typical patterns, the trend in weighted average ASP is expected to be stable in the future, assuming products with patent expirations become subject to generic or biosimilar competition.

²¹ Quintiles IMS Institute. Outlook for Global Medicines through 2021: Balancing Cost and Value. December 2016, p. 3.

²² Medicare Drug Spending Dashboard 2014 (https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Dashboard/Medicare-Drug-Spending/Drug_Spending_Dashboard.html)

²³ FDA database of drugs (<https://www.accessdata.fda.gov/scripts/cder/drugsatfda/>)

²⁴ CBER Licensed Biological Products with Supporting Documents(<http://www.fda.gov/BiologicsBloodVaccines/ucm133705.htm>)

²⁵ The FDA Orange Book: Approved Products with Therapeutic Equivalence Evaluations (<http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>)

²⁶ Product specific patent searches on Medtrack (<http://www.medtrack.com>)

²⁷ The US Patent and Trademark Office website (<http://www.uspto.gov/>)

Technical Appendix

Additional Background on Average Sales Price

Manufacturers have been required to submit ASP data to CMS on a quarterly basis since April 30, 2004.²⁸ Under the ASP system, payment for multiple source drugs within the same HCPCS code is set equal to 106% of the blended ASP²⁹ 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.³⁰

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.³¹ 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

²⁸ Prior to 2005, payment for Part B drugs was based on a different pricing concept, Average Wholesale Price (AWP).

²⁹ Payment has been reduced 2% since April of 2013 due to the effects of sequestration, but this payment reduction does not change ASP and therefore does not affect the weighted average ASP in our analysis.

³⁰ The regulations implementing ASP reporting requirements are codified in 42 CFR § 414.800 through §414.806.

³¹ The 2015 drug unit counts are projected. Only drugs with valid unit counts in 2014 and valid CMS published ASPs are included in the projection.

were included in our analysis. We inflated these numbers where necessary to represent national totals by multiplying by 20.

We applied a smoothing methodology by standardizing the unit concept and price, or trimming outlier data for certain HCPCS codes over time to account for apparent coding errors or other mistakes that would have significantly changed weighted average ASP in a manner that distorted the overall trend observed in our analysis. We feel that this approach 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 2015.

Our formula was:

$$\Sigma (\text{Average Sale Price} \times \text{Unit Count}) / \Sigma \text{Unit Count.}$$

Although ASP data are available for 2015, the SAF data for that year are not yet available. To calculate the weighted average ASP for 2015, we projected the ASP and unit counts based on the 2006-2014 growth rates. To determine the annual growth rate, we used the geometric mean (4.14%), which was very close to the arithmetic mean (4.25%).

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 OPSS.

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.