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**PATHWAYS BY PAYERS.** Findings presented at the Academy of Managed Care Pharmacy 2021 meeting showed that despite the growth of oncology clinical pathways, there are still plenty of barriers to adoption, even when doctors want to use them, [SP124](#).

**WHAT FDA GIVETH ...**

In 3 days of hearings, FDA panelists recommended that a pair of accelerated approvals should be withdrawn, after subsequent trials did not confirm early findings that led to the indications, [SP126](#).

**IN SCLC, NOW WHAT?**

Practically speaking, what does it mean when 2 well-known PD-1 inhibitors are no longer indicated in small cell lung cancer (SCLC)? Fox Chase's Martin J. Edelman, MD, weighs in, [SP128](#).



EDELMAN

## CONFERENCE COVERAGE



In its second virtual annual meeting, the Community Oncology Alliance tackles pricing and payment reform, [SP130-SP134](#).

Recent advances and new methodologies in treating cholangiocarcinoma, [SP134](#).



Overcoming hurdles to biosimilar uptake in oncology, [SP136](#).

## PRACTICE TRANSFORMATION

**A Social Worker Leads ACCC, and Her Timing Is Perfect**

Mary Caffrey

**IMPROVING HEALTH EQUITY.** Developing practice-based solutions for reducing barriers and improving outcomes. Making the case for supportive care. Building a culture that supports professional well-being. Championing resiliency.

This would be an important agenda for any president of the Association of Community Cancer Centers (ACCC), but given the year that health care workers have just experienced, the ACCC has the right message at the right time. And that's because the group has selected a timely messenger: For only the third time in its history, the ACCC president is a social worker.

Krista Nelson, MSW, LCSW, OSW-C, took the reins of ACCC on March 5, 2021, during the group's 47th Annual Meeting and Cancer Center Business Summit, held virtually.<sup>1</sup> Nelson's theme for her presidency "Real-World Lessons from COVID-19: Driving Oncology Care Forward," incorporates a mission of promoting psychosocial and supportive care, not just externally but also among internal stakeholders. This fits with her call to support the needs of the multidisciplinary cancer care team. From Nelson's vantage point, the emerging care model is one where the case manager is far from an afterthought, and may, in fact, be the patient's first stop.

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Krista Nelson, MSW, LCSW, OSW-C, has made resiliency and well-being of the cancer care team a core tenet of her term as president of the Association of Community Cancer Centers.

## POLICY

**Observations Regarding the Average Sales Price Reimbursement Methodology**

Susan Weidner; Michael Diaz, MD; Cass Schaedig; and Lucio N. Gordan, MD

**Introduction**

**IN THE UNITED STATES,** CMS is the single largest payer for health care. In 2019, Medicare enrolled more than 60 million beneficiaries, and enrollment is expected to exceed 80 million by 2030.<sup>1,2</sup> Medicare Part B provides coverage for beneficiaries for drugs and biologics that are administered in physician offices or hospital-based clinics by infusion or injection. It also covers certain other drugs, including some oral anti-cancer therapies, oral antiemetics, immunosuppressive drugs, and home infusions.<sup>3</sup> In 2017, 7 of the top 10 drugs reimbursed by Medicare Part B were mainly, or exclusively, for oncology or related supportive care indications and accounted for over \$8.7 billion in spending.<sup>4</sup> This amount is expected to increase as the majority of new cancers in the United States are diagnosed in the Medicare-aged population, which is expanding as baby boomers age.<sup>5</sup>

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## PAYMENT MODELS

**Biosimilars Drive Savings in Medicare's Oncology Care Model**

Keely Macmillan, MSPH

**MEDICARE VALUE-BASED** care programs are under great scrutiny to ensure that they can drive demonstrable savings and quality improvement. Adoption of higher-value biosimilar drugs by participants in Medicare's Oncology Care Model (OCM) could drive the pilot program closer to its goal of generating net savings to Medicare.<sup>1</sup>

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# Observations Regarding the Average Sales Price Reimbursement Methodology

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CONTINUED FROM COVER

## Medicare Part B Reimbursement Methodology

Medicare Part B provides reimbursement at a rate of the average sales price (ASP) plus a 6% add-on fee (ASP 6), a methodology that relies on market-based prices to set reimbursement rates.<sup>6</sup> The 6% is provided as an add-on payment to cover expenses related to the needs of physician-administered drugs. Among these are purchasing variability, shipping fees, complex administration, ongoing patient monitoring and education, and overhead for storage and handling requirements.<sup>7,8</sup>

ASP was enacted in 2005 as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and generally reflects the average price of a drug's sales to all purchasers in the United States, including commercial payers. The ASP is calculated for each Healthcare Common Procedure Coding System (HCPCS) code included in Part B coverage with a 2-quarter lag, as shown in **Figure 1**. HCPCS codes may include drugs from a single source or, more commonly, from more than 1 manufacturer. Drug manufacturers provide data for the calculation to CMS quarterly.<sup>6</sup>

As HCPCS codes frequently include drugs from multiple manufacturers, ASP 6 provides reimbursement at 106% of the *blended* ASP for all products within an HCPCS code on a volume-weighted basis. Payment for a single-source drug with a unique HCPCS is, in general, based upon either 106% of the ASP or 103% of the wholesale acquisition cost (WAC), whichever is lower.<sup>7,9</sup> When reporting price, manufacturers must account for concessions, including volume discounts, prompt-pay discounts, cash discounts, free goods contingent on any purchase requirement, chargebacks, and rebates.<sup>6</sup>

Due to additional legislation via the Budget Control Act of 2011 and the Balanced Budget and Emergency Deficit Control Act beginning in 2013, the actual Medicare Part B reimbursement to providers effectively became ASP plus a 4.3% add-on fee (ASP 4.3). This legislation required payment reductions in federal expenses through a sequestration order. The effects of sequestration on Part B drug reimbursement resulted in a drop in ASP from 6% to 4.3% and in WAC from 3% to 1.35%. This, in turn, resulted in the reimbursement methodology currently in use for Medicare Part B. Additionally, due to a known error surrounding prompt-pay discounts provided to distributors but not passed on to providers, actual realized reimbursement is likely closer to ASP plus 2.3%.

## Issues Facing Medicare Part B Reimbursement

Despite a paucity of published data, the Medicare Payment Advisory Commission (MedPAC) provided a report to Congress in 2017 detailing their concerns with ASP, which included a lack of competition creation and the potential for incentivizing providers to choose higher-priced drugs.<sup>10</sup> Additionally, Ridley et al recently published a conceptual model showing that launch prices have increased under this reimbursement model due to its reliance on lagged pricing.<sup>11</sup> These publications maintain the perception that physicians are incentivized and driven by increased prices of drugs and that higher prices indicate higher profit and margin. In this review, we will explore recent literature that provides evidence directly contradicting these concerns.

In 2018, President Trump's administration proposed *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (Trump Blueprint).

This proposed policy included aggressive concepts such as new negotiation tactics for Part B drug prices, movement of some drugs covered under Part B to Part D to allow for formulary management and utilization review, reimbursement for therapies based on their indication, an international pricing index (IPI), flat administration reimbursement, and higher prices for therapies when used off-label, among others.<sup>12,13</sup> The impact of this policy on the ability of community oncology practices, where the majority of patients receive their anticancer care, to continue to provide optimal care to patients—with potential reductions in reimbursement—is concerning.

As part of the Trump Blueprint, reimbursement could have changed to a flat fee add-on payment rather than a percentage-based add-on payment.<sup>14</sup> The addition of the percentage-based add-on payment in the Medicare Modernization Act, was intended to ensure that providers are reimbursed for overhead costs, such as proper storage of medications, compounding compliance, and administration of complex regimens, among others.<sup>15</sup> However, flat fee add-on payments are highly unlikely to capture all the nuances and complexities of cancer care. A flat fee is not dynamic, meaning it cannot reflect market and inflationary pressures and does not account for multidrug, complex treatment regimens or the administration of necessary supportive care medications.<sup>15</sup> This proposed change in add-on fee structure could result in inconsistencies in reimbursement for any site of service and eventually prevent the delivery of proper care as far as treatment selection. It also would restrict access to care, as it would likely disproportionately affect vulnerable smaller practices in rural locations or underserved areas.

In a volatile political environment with potential policy changes that could affect more than 60 million Americans, it is important to understand the basis of the current Part B reimbursement system and the current benefits of ASP that would be imperative to preserve for future success. Herein, we aim to review ASP in the context of oncology therapies and provide comments on its methodology, as well as present our research on alternative models that may be employed in the future to ensure sustainable oncology practices.

## Discussion

Before the introduction of Part B ASP reimbursement in 2005, Medicare used an average wholesale price (AWP) methodology with which providers were reimbursed at a rate of 95% of the AWP. AWP was a manufacturer's suggested list price, which did not have to correspond to a market-based transaction price and did not reflect price discounts. Consequently, expenditures for Medicare Part B grew more than 25% per year from 1998 to 2003, and a

FIGURE 1. ASP Calculation

$$\text{ASP} = \frac{\text{Manufacturer's sales of drug to all purchasers in US in calendar quarter}}{\text{Total number of units of drug sold by manufacturer in same quarter}}$$

ASP, average sales price; US, United States.

report from the Government Accountability Office noted that Medicare payment rates under the AWP methodology consistently were well above providers' acquisition costs. For this reason, the transition to the ASP methodology in 2005 represented a vast improvement in Part B reimbursement, with rates much closer to actual acquisition costs.<sup>16</sup>

### Impact on Pricing and Reimbursement Trends ASP PAYMENT METHODOLOGY MODULATES MACRO SPENDING TRENDS.

Studies evaluating diverse aspects of the cost of cancer care, the impact of physician-incentive models, or value formulations are difficult to conduct; however, literature on ASP methodology indicates that the driving force in product selection is clinical effectiveness. Data suggest that ASP has lowered drug prices, reduced variation around drug pricing, limited year-over-year price increases, reduced chemotherapy treatment within 14 days of death, and discouraged the use of higher-priced drugs.<sup>17-28</sup>

Additionally, ASP has lowered overall Part B drug spending. As noted above, before ASP, Part B drug spending was rising at an average of 25% per year. Under ASP, that rate dropped to just 4.4% per year and, after adjusting for inflation, drug spending rose from 2007 to 2013 at an annual rate of 2.8% for all Part B drugs.<sup>26</sup> Despite the entrance of numerous expensive biologics and targeted therapies, the total payments, number of units, and weighted ASP remained flat from 2006 to 2014.<sup>7,26</sup>

In recent years, drug spending has been increasing rapidly. Between 2005 and 2016, total drug spending grew at an average rate of 7.4%, with slower growth from 2005 to 2009 (3.7% per year) and more rapid growth from 2009 to 2016 (9.5% per year). This growth is largely attributed to increases in drug prices of existing drugs and shifts in the mix of drugs, including the adoption of new, higher-priced drugs.<sup>4</sup> However, the price growth from 2006 to 2015 (Figure 2) for Part B was still lower than that of Part D, in part due to ASP reimbursement methodology.

### THE ASP PAYMENT METHODOLOGY AVOIDS PRICE SETTING BY GOVERNMENT AGENCIES AND ITS EXTENSIONS WHILE YIELDING MARKET-DRIVEN REIMBURSEMENT RATES NEAR OR AT ACQUISITION COST.

In contrast to Part D, Part B reimbursement lacks gross-to-net issues, as value is eventually returned back to Medicare and patients. Gross-to-net issues exist when rebates and discounts are provided for high-cost drugs and then absorbed by pharmacy benefit managers (PBMs) or other intermediaries to offset part of the cost of non-drug treatments to reduce their patient premiums. This contract mechanism results in a large disconnect between the gross revenues and net revenues realized by drug manufacturers, increasing pressure on an already fragile system.<sup>29</sup> Using ASP methodology allows Part B to avoid this issue and provides further evidence that moving Part B drugs to Part D, as proposed by the Trump Blueprint, would have presented new and larger problems.

### THE ASP METHODOLOGY ELEGANTLY CREATES FINANCIAL RISK FOR THE PROVIDER THAT IS DIRECTLY PROPORTIONAL TO THE COST OF THE DRUG CHOICE AND NOT REPLICATED SO PRECISELY

### BY NUMEROUS ALTERNATIVE PAYMENT MODELS UNDER DISCUSSION.

Physician incentive programs currently being explored, including shared savings, pay-for-performance, medical home, and those of accountable care organizations, present logistical issues: they are potentially difficult to understand and diffuse, and too far removed in time to be resilient reinforcements of individual physician behavior. In contrast, the ASP methodology and the risk associated with buy-and-bill or fee-for-service systems for providers are precise, tangible, immediate, and directly proportionate to the cost resulting from a clinical decision.<sup>29</sup>

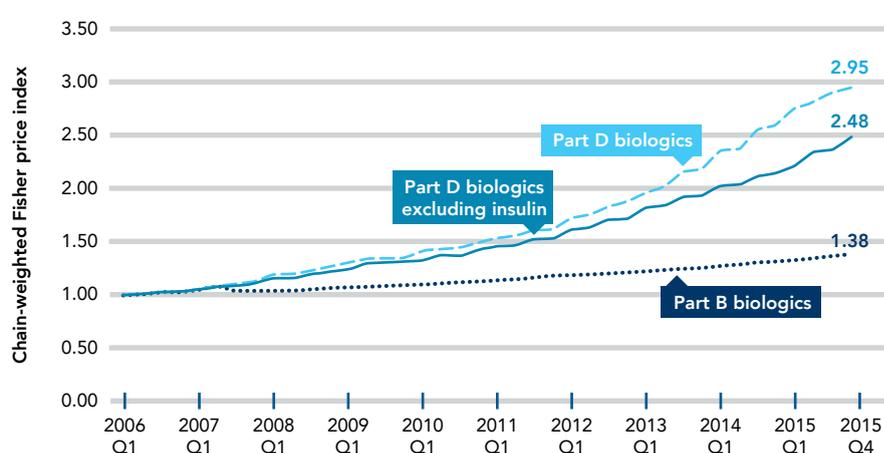
Considering the lag time of ASP, there are several nuances for a provider to consider in terms of financing their practice.<sup>30</sup> When a provider purchases a drug for a specific patient, they immediately incur the financial risk as a direct result of that decision. Under a standard transaction, they are reimbursed by Medicare reliably within 14 days of the claim submission, with subsequent supplemental insurance and patients to pay the balance. Major hurdles in accepting and sustaining this risk include needing the acquisition cost to be near or below the ASP, securing favorable financing terms to buy higher-priced drugs, installing an accurate claims-processing system, having near-perfect collection rates, incurring low to no price increases, and absorbing minimal overhead cost to execute the entire process. Because of these operational challenges, the driving incentive for physicians under ASP is not reward, but the avoidance of financial risk when using the most clinically attractive therapies for their patients.

In fact, rather than over-reimburse for drugs, the current ASP methodology at times underpays. For example, in June of 2016, MedPAC reported an analysis of proprietary invoice data for 34 high-expenditure Part B drugs. Results showed that at least one-third of drugs sold to clinics were likely inadequately reimbursed.<sup>16</sup>

Further supporting this point, a recent publication analyzed the effective market price created by accounting for patient assistance program discounts of 18 ASP-based drugs. According to the results, ASP reimbursement exceeded the effective market price by more than 1% for only 5 of 18 drugs (range, 1.4%-7.8%). The illustration shows the fact that despite a lower effective market price in some instances, ASP reimbursement methodology can maintain an appropriate reimbursement rate that is reflective of the market in the majority of cases.<sup>31</sup>

Minimal evidence exists to indicate that drugs are over-utilized, with most never reaching their

FIGURE 2. Comparison of Price Growth for Part B and Part D Biologics, 2006-2017



Source: A data book: health care spending and the Medicare program. Medicare Payment Advisory Commission. June 2019. [http://medpac.gov/docs/default-source/data-book/jun19\\_databook\\_entirereport\\_sec.pdf?sfvrsn=0](http://medpac.gov/docs/default-source/data-book/jun19_databook_entirereport_sec.pdf?sfvrsn=0)  
The measures of price growth reflect growth in the price of the individual products but do not reflect changes in price due to new products or changes in the mix of products used.  
Q, quarter.

“brand-potential index”—in other words, the total number of patients who can receive the drug based on its indication(s). Furthermore, multiple publications have indicated that oncology practitioners are unlikely to change their treatment patterns or their decision to administer treatment to cancer patients, even when offered a higher reimbursement for using specific drugs.<sup>24,32</sup>

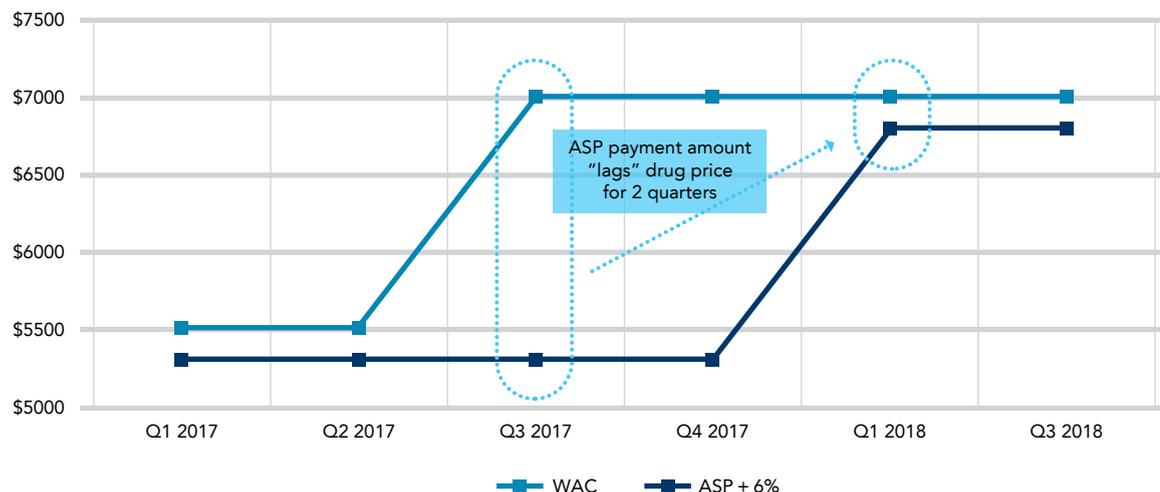
### THE CURRENT ASP METHODOLOGY PROPERLY ALIGNS PHARMACEUTICAL PRICING BEHAVIOR IN THE DIRECTION OF PRICE INHIBITION BY INCLUDING MANDATORY REPORTING DOMAINS IN THE ASP CALCULATION.

Although discounts and rebates given to intermediaries, such as PBMs, are not considered in the ASP calculation (because those price reductions are passed through subsequent entities), rebates and discounts given to purchasing providers through ASP are included. This results in lower reimbursement rates and savings to the Medicare program. As noted above, other activities that are deemed to reduce the purchaser's cost are also included in the ASP calculation.<sup>6</sup> This inclusion restricts the pharmaceutical industry from directly influencing drug selection through pricing mechanisms and provides a benefit to Medicare—and, ultimately, patients—via a lower reimbursement rate.

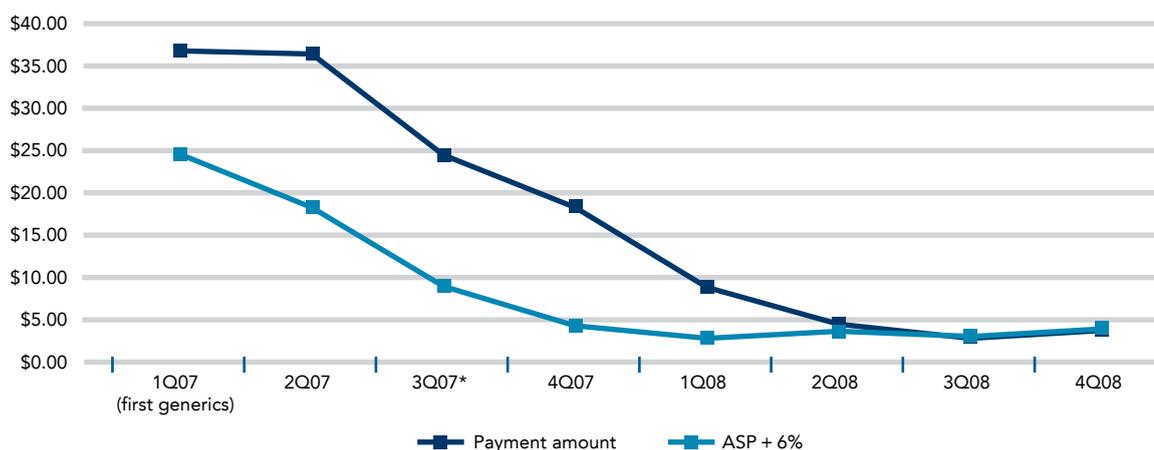
### Impact on Generic and Biosimilar Use THE PRESENT ASP METHODOLOGY INHIBITS SIGNIFICANT YEAR-OVER-YEAR BRAND AND GENERIC DRUG PRICE INCREASES.

To understand this concept, it is important to note the 2-quarter lag between when sales occur and when the payment amount reflects those sales in the ASP methodology. This lag implies that price increases are absorbed directly by the provider for 6 months until the Medicare reimbursement rate for ASP is updated. Therefore, providers are required to purchase drugs with the possibility of inadequate drug reimbursement.<sup>30</sup>

This scenario is illustrated in Figure 3, which shows the impact of the 2-quarter lag on ASP reimbursement in a simplified version with an example

**FIGURE 3.** 2-Quarter Lag in ASP Pricing

ASP, average sales price; Q, quarter; WAC, wholesale acquisition cost.

**FIGURE 4.** Introduction of Generic Drug Lowers ASP-Based Payment Amount and Generates Reimbursement Advantage

\*First quarter in which generic sales were reflected in payment amount.  
ASP, average sales price; Q, quarter.

drug. The WAC of the drug in Q1 2017 has been stable at \$5500 and ASP-based reimbursement has also been stable at \$5300. In Q3 of 2017, the example drug's price increases to \$7000 (as shown in the large red circle). Due to the 2-quarter lag in ASP-based reimbursement changes, the ASP 6 reimbursement does not "catch up" to the WAC until 2 quarters later in Q1 2018 (as shown in the smaller red circle). The risk of this scenario creates a natural inhibition to price increases for drugs dependent on Part B that is not easily overridden by manufacturers without rendering products commercially inviable.<sup>30</sup>

#### ASP METHODOLOGY ENGENDERS LOWER GENERIC DRUG PRICING RELATIVE TO BRAND INNOVATORS.

Price increases are not immediately reflected in the ASP reimbursement, but price decreases, such as occur when a generic enters the market, are immediately apparent in a provider's acquisition cost.<sup>30</sup> Providers can then realize a potential increase in the actual reimbursement over acquisition cost proportionate to the price decrease enacted during the 6-month lag period.

For example, when a generic enters the market, it has an immediate reimbursement advantage if it is priced lower than the brand innovator. More often than not, the brand innovator is forced to react to the generic's entry and lower its price. Over time, as multiple generic manufacturers enter the market, the ASP methodology continuously recalibrates at lower price points resulting from the discounts and rebates that competitors are placing in the market. Due to the 2-quarter lag, there is always a proportionate advantage sequentially generated for the generic as the price spirals down. It is therefore not surprising that generic oncology drugs dependent on Part B reimbursement have quickly cannibalized their branded predecessors. Providers are incentivized to prescribe the generic over the brand due to its lower cost and reimbursement advantage, as depicted in **Figure 4**.

This ability of the ASP methodology to naturally spur lower generic drug prices is a hallmark of its success and is in stark contrast to that of the previous AWP system. However, the ASP methodology does more than lower the price.

**ASP INCENTIVIZES THE CONVERSION TO, AND CONTINUED USE OF, GENERIC DRUGS OVER THEIR BRAND INNOVATORS.** In addition to the improved reimbursement that is proportionate to the price decrease during the 2-quarter lag, providers also have the benefit of a markedly lower risk of bad debt when using generics as opposed to the higher-priced brand alternative. Therefore, even if price increases are seen in generics, the risk of inadequate reimbursement (**Figure 3**) represents a more reasonable monetary value than that of previous brand innovators.

From the outset of a generic's introduction and resulting price decrease to its final lower price, the ASP methodology aligns Part B drug incentives for providers to use the lower-priced option and creates barriers for manufacturers to raise prices.<sup>30</sup>

#### CURRENT ASP METHODOLOGY ALLOWS FOR DIFFERENTIAL REIMBURSEMENT ADVANTAGES FOR BIOSIMILARS WHILE GENERATING LOWER PRICING.

Just as ASP has created this situation for generics, it has likewise affected the biosimilar market. Similar to the addition of generics to the marketplace, the introduction of biosimilars is expected to lower prices. According to the Patient Protection and Affordable Care Act, reimbursement for biosimilars will also be ASP plus 6%, but the 6% add-on is based on the innovator product's ASP.<sup>33</sup> This approach gives the biosimilar the advantage of a lower price with a proportionally larger add-on payment. Because of the benefits, described throughout this paper, inherent portions of the ASP methodology are worth preserving or imitating in future reimbursement methodologies.

#### Alternative Reimbursement Methodology

With the recent focus on drug price controls, such as the International Pricing Index Model, and criticism of the current ASP reimbursement method, we investigated alternative ASP-based reimbursement methods to determine whether they are worth pursuing. The objectives we desired with these alternatives included:

- Incentivizing the use of generics and biosimilars when available
- Continuing to support the sustainability of specialty practices of all sizes
- Supporting stability over time given changes in ASPs and drug mix, with Year 1 meeting at least ASP 6 in 2018
- Allowing providers to select appropriate therapies to meet individual patient needs

#### Methods

Current proposed alternative methodologies to ASP include cap models, tiered models, and value frameworks. Brief definitions of these strategies are provided in **Table 1**.

We used InfoDive, a strategic financial intelligence solution, to examine 101 practice sites of varying sizes that reported medical claims information on patients covered by Medicare or Medicare Advantage from January 2017 to June 2020. The patients saw a medical oncologist or hematologist within the observation period. The ASP for each drug was based on the Medicare ASP specific to the quarter in which the service was being rendered.

**TABLE 1.** Examples and Definitions of Alternative Reimbursement Models

Model	Definition
Cap	When an administrative claim exceeds a predetermined cap amount, providers are paid out at the cap amount for the add-on percentage <sup>34</sup>
Tiered	Add-on payment is based on different tiers tied to specific pricing thresholds, potentially determined by drug use and category, average ASP per claim, or average reimbursement per administration <sup>15</sup>
Value framework	Reimbursement to providers is linked to quality and total cost of care results and is shifted away from volume <sup>35</sup>

ASP, average sales price.

**TABLE 2.** Examples and Definitions of Alternative Reimbursement Methodologies

Method	Concept	Tiers used	Reimbursement add-on*
ASP + 6%	Standard	N/A	6%
ASP + 4.3%	Sequestration	N/A	4.3%
SD 3	Utilizes average ASP per claim Average ASP: \$1187.55 SD: \$2697.40 for all drugs	Level 1 threshold (1 SD from average): \$3884.50	9%
		Level 2 threshold (2 SD from average): \$6582.26	8%
		Level 3 threshold (3 SD from average): \$9261.13	4%
		Level 4 threshold: above \$9261.13	2%
Fixed tier	Utilizes a maximum per claim per administration	Level 1 threshold: \$7500	10%
		Level 2 threshold: \$15,000	6%
		Level 3 threshold: \$30,000	5%
		Level 4 threshold: above \$30,000	4%

\*No difference for brand, generic, or biosimilar.  
ASP, average sales price; N/A, not available.

The methods we present here include ASP 6, ASP 4.3, and 2 alternative ones labeled “SD 3” (standard deviation) and “Fixed Tier.” The fixed tier method assigned tiers based on the maximum reimbursement per administration of a drug; the reimbursement add-on fee was dependent upon the claim’s tier. Similarly, the SD 3 method established thresholds utilizing the average ASP per administration claim and then considered standard deviations from that average. Depending on how many standard deviations from average, the claim was determined the thresholds applied and the reimbursement add-on. Details for these models are further illustrated in Table 2. Other tiered or capped models were evaluated but are not presented due to their failure to provide the desired outcomes.

### Results

The reimbursement based on the proposed methodologies for 2019 is shown in **Figure 5**. Both the SD 3 and fixed tier methods are at or slightly above ASP 6.

Each model affected drug categories differently relative to ASP 6. The SD 3 model had the largest effect on the targeted therapy category, which represents some of the greatest costs of oncology care; the effect of the fixed tier model on these categories distributed the add-on to incentivize the use of lower-cost drugs, such as chemotherapy and

supportive care. The effects of fixed tier and SD 3 models relative to ASP 6 are shown in **Figure 6**.

Practice settings were divided into 3 sizes: those with 5 or fewer medical doctors (MDs), those with 6 to 10 MDs, and those with 10 or more MDs. The models affected each practice size differently. The fixed tier and SD 3 models generated results similar to ASP 6. The average reimbursement per administration is shown in **Table 3**.

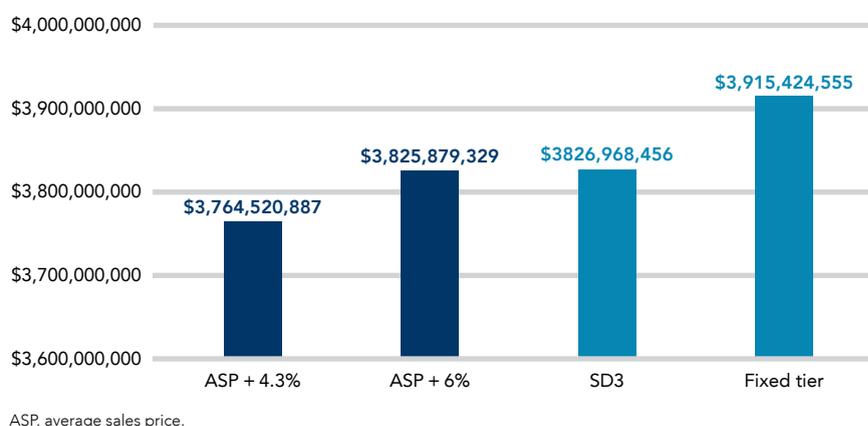
Finally, the impact of each model on the top 30 drugs based on total ASP and claim volume were evaluated. The results are shown in **Table 4**.

### Future Directions

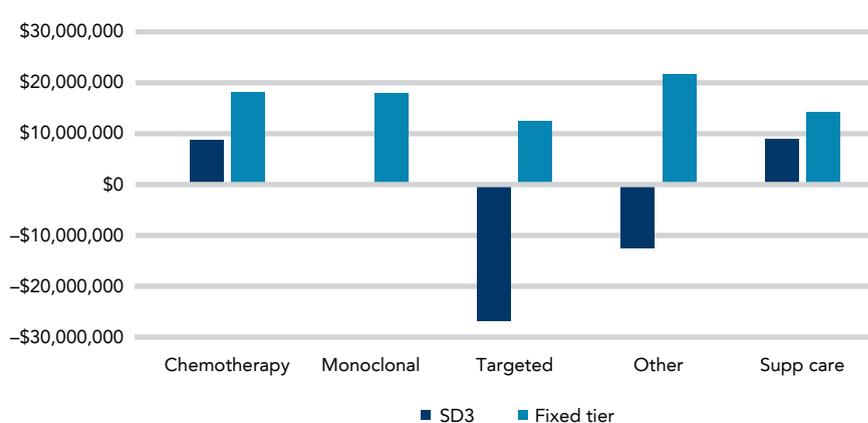
Our research showed that 2 alternative methods, 1 based on tiered reimbursement and 1 on average reimbursement and standard deviation, were able to provide the benefits of ASP 6, provide appropriate reimbursement to various sizes of oncology practices, and curb the growth rate of claims over time. These methodologies provide information for future methods that use ASP as their basis and build upon this construct to provide reasonable rates for payers and sustainability for practices of different sizes, ultimately resulting in optimal patient care.

### Conclusion

Medicare Part B reimbursement using ASP methodology has qualities worth preserving in future

**FIGURE 5.** 2019 Reimbursement Based on Proposed Models

ASP, average sales price.

**FIGURE 6.** Impact of Proposed Models on Different Drug Categories<sup>a</sup>

Supp, supportive.

<sup>a</sup>Two categories, miscellaneous and rheumatology/gastrointestinal, are not shown, as the impact was minimal.

systems. It has tempered the overall growth of Part B expenditures and met the demands of an increasingly cost-concerned society, as well as a defensive medical community and pharmaceutical industry. As the oncology community expects more value from drugs reimbursed through Part B, it is imperative to maintain the beneficial attributes of ASP and incorporate them into future reimbursement models. Otherwise, community oncology practices may no longer be able to acquire life-saving treatments during any given Medicare reimbursement period.

Incorporating a reimbursement model that engenders strong constraints rather than regulating absolutely allows for both patient and provider benefits. For the patient, such a model enables them, in conjunction with their provider, to remain a key stakeholder in determining clinical desirability weighed against financial risk. For providers, it allows the medical community to continue to align their desire for personalized or precision-based treatment, clinical experimentation, and clinical research with the multifaceted costs or savings of any given deviation from common standards by spreading the direct and indirect cost or benefit of a given variance across a range of participants.

Despite the difficulty of experimental design in public policy-based research, it is imperative moving forward that decisions regarding changes

**TABLE 3.** Average Reimbursement per Administration

Practice size	ASP 6	SD 3	Fixed tier
5 or fewer MDs	\$1188.17	\$1189.92	\$1216.91
6 to 10 MDs	\$1300.30	\$1299.56	\$1330.34
10 or more MDs	\$1267.97	\$1268.19	\$1297.51
Relative to ASP		+ 0.04%	+ 2.35%

ASP, average sales price; MD, medical doctor.

**TABLE 4.** Average Reimbursement per Administration

Model	Top 30 drugs by total ASP reimbursement*	Relative to ASP 6	Top 30 drugs by claim volume reimbursement*	Relative to ASP 6
ASP 6	\$3,095,327,110	--	\$1,738,325,550	--
SD 3	\$3,091,969,592	- 0.1%	\$1,729,677,209	- 0.5%
Fixed tier	\$3,167,603,759	+ 2.3%	\$1,774,302,872	+ 2.1%

ASP, average sales price.

\*Top 30 drug lists are located in the **Appendix**.

to Medicare Part B reimbursement be based upon empiric data. Currently, actuarial evidence rather than population-based data is utilized to estimate changes in price trends and adjustments to reimbursement. Additionally, recent criticisms of ASP are generally based on theoretical models; they lack the incorporation of confounding factors such as the uptake of 340B drug pricing, continued changes in pricing, and orphan drugs launching at high prices but then expanding to additional indications. Overall, ASP is a market-based tool that can be leveraged in the future to create a sustainable reimbursement model that is beneficial to patients, payers, and providers. ♦

For Appendix, see:

[www.ajmc.com/view/weidner-et-al-appendices](http://www.ajmc.com/view/weidner-et-al-appendices)

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# Observations Regarding the Average Sales Price Reimbursement Methodology

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## APPENDIX. Top 30 Drugs Reimbursed by Medicare Part B

Top 30 Drugs Based on Total Average Sales Price	
1. Pembrolizumab (J9271)	2. Paclitaxel (J9264)
3. Nivolumab (9299)	4. Pertuzumab (J9306)
5. Rituximab (J9312)	6. Romiplostim (J2796)
7. Pegfilgrastim (J2505)	8. Ipilimumab (J9228)
9. Denosumab (J0897)	10. Pegfilgrastim-cbqv (Q5111)
11. Daratumumab (J9145)	12. Bevacizumab-awwb (Q5107)
13. Bevacizumab (J9035)	14. Epoetin alfa (J0885)
15. Atezolizumab (J9022)	16. Eculizumab (J1300)
17. Pemetrexed (J9305)	18. Fulvestrant (J9395)
19. Trastuzumab (J9355)	20. Carfilzomib (J9047)
21. Durvalumab (J9173)	22. Trastuzumab-anns (Q5117)
23. Bortezomib (J9041)	24. Ferric carboxymaltose injection (J1439)
25. Immune globulin IV (J1569)	26. Bendamustine HCl (J9034)
27. Octreotide (J2353)	28. Rituximab/hyaluronidase human (J9311)
29. Lanreotide (J1930)	30. Ado-trastuzumab emtansine (J9354)

Top 30 Drugs Based on Claim Volume	
1. Dexamethasone (J1100)	2. Epoetin alfa-epbx (Q5106)
3. Diphenhydramine (J1200)	4. Aprepitant (J0185)
5. Palonosetron (J2469)	6. Pegfilgrastim (J2505)
7. Epoetin alfa (J0885)	8. Leucovorin (J0640)
9. Denosumab (J0897)	10. Ferric carboxymaltose injection (J1439)
11. Sodium chloride, TICE Accessories (J7030)	12. Filgrastim-sndz injection (Q5101)
13. Ondansetron (J2405)	14. Nivolumab (J9299)
15. Fluorouracil (J9190)	16. Gemcitabine (J9201)
17. Pembrolizumab (J9271)	18. Granisetron (J1626)
19. Carboplatin (J9045)	20. Sodium Chloride (J7040)
21. Ferumoxytol injection (Q0138)	22. Zoledronic acid (J3489)
23. Low osmolar contrast (Q9967)	24. Magnesium sulfate (J3475)
25. Bortezomib (J9041)	26. Oxaliplatin (J9263)
27. Azacitidine (J9025)	28. Rituximab (J9312)
29. Paclitaxel (J9267)	30. Granisetron extended release (J1627)