

A Review of US Drug Costs Relevant to Medicare, Medicaid, and Commercial Insurers Post-Affordable Care Act Enactment, 2010–2016

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Abstract Since passage of the Affordable Care Act (ACA) in 2010, US stakeholders are increasingly being held accountable for the value of healthcare services and drugs administered to patients. Pharmacoeconomic analyses offer one method of demonstrating a product's value, yet there is a lack of resources specific to US drug costs relevant to each stakeholder. The aim of this study was to review current US drug costs (post-ACA). A literature review aimed at finding evidence on outpatient prescription drug costs was performed using the following sources: PubMed,

governmental agencies, news websites, the Academy of Managed Care Pharmacy (AMCP) website, and Google Scholar. Articles were limited to those published in the years “2010–2016” and the “English” language, and those that described drug acquisition costs, reimbursement costs, and rebates or discounting for Medicare, Medicaid, and commercial payors. The Drug Cost Focus Group (DCFG) was convened to supplement the literature review; the DCFG provided their expertise on US drug costs and emerging issues affecting drug costs. ACA legislation increased drug rebates for manufacturers participating in the Medicaid Drug Rebate Program. Acquisition costs commonly referred to in the literature include the wholesale acquisition cost and average manufacture price. Drugs reimbursed by Medicaid are currently based on the actual acquisition cost and ACA-Federal Upper Limit. Evidence suggests that reimbursement methods in the public market are varied. Current gaps in the literature regarding commercial insurers' drug costs (post-ACA) present barriers to the application of relevant drug costs to pharmacoeconomic analyses.

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Key Points for Decision Makers

Medicare Part B continues to reimburse on average sales price; however, reimbursement methods for Part D drugs are not evident in the literature.

Average wholesale price remains a prominent drug cost described in the literature; however, its current relevance in the private and public sectors are not clear.

Future drug costs may be influenced by value-based contracting and reimbursement for pharmaceuticals.

1 Introduction

Before health insurance was established in early 1900s, Americans primarily paid for drugs out-of-pocket. In the 1920s the first form of US health insurance as we know it began at Baylor Hospital in Texas as a means to maintain the hospital's facilities and help to assure payment for services rendered [1]. During the Industrial Age (late 1930s to early 1940s), Kaiser began a formalized employer-based healthcare plan in California focused on highly integrated hospital and preventative medical care [2]. By the mid-1940s, over 40% of the US population had some form of insurance to cover hospital expenses [3].

The rise of employer-sponsored, commercial insurance in the mid-late 1990s was largely unplanned [4]. During World War II, the National Labor Union froze wage increases, and thus employers began providing group health benefits as a means of an incentive for work with stagnant pay [5, 6]. Today, employer-sponsored insurance is the primary form of drug coverage for working-age adults, with 49% of Americans covered through employer-sponsored plans [7].

In an effort to provide health insurance to the most vulnerable populations (namely children and the elderly), the US Government enacted the Social Security Amendments of 1965, establishing Medicare insurance (for the elderly) and Medicaid entitlement (for economically disadvantaged women and children and individuals with disabilities). Medicaid is operated at the state level and funded by both state and federal funds. Medicaid covers inpatient and outpatient drugs that are deemed of 'medical necessity.' Medicare, in contrast, is a federally coordinated insurance program. Medicare is comprised of four parts: Medicare Parts A, B, C, and D.

Medicare Part A covers inpatient stays inclusive of drugs, and Medicare Part B provides coverage for some outpatient services and certain physician-administered drugs [8]. Medicare Part C, namely Medicare Advantage, is an alternative managed care option to Parts A and B that covers inpatient and outpatient services and drug benefits. Medicare Part D was established in 2003 under the Medicare Modernization Act (MMA), providing outpatient drug benefits to beneficiaries. Part D plans are also referred to as Prescription Drug Plans or PDPs because they represent standalone drug plans which beneficiaries can purchase in addition to Parts A and B. Prior to the MMA, many older adults paid for outpatient drugs out-of-pocket. In 2010, an estimated 13% of Americans reported having "unmet prescription drug needs" due to cost concerns [9].

Since passage of the Affordable Care Act (ACA) (2010), US healthcare stakeholders are increasingly being held accountable for demonstration of value of services and drug products administered to patients. Pharmacoeconomic

evaluations offer one method of demonstrating a drug's value. Drug cost values are important factors in pharmacoeconomic evaluations. However, publicly available resources detailing US drug costs often do not reflect the most current types of drug costs relevant to each stakeholder, and sources of actual drug cost values are disparate and scarce in the literature. Furthermore, evidence has demonstrated that there are discrepancies between listed drug prices and actual drug costs [10, 11].

The aim of this paper was to review US drug costs (post-ACA) to Medicaid, Medicare, and commercial payors. This information is an important underpinning to understanding relevant drug costs in the USA and application to pharmacoeconomic analyses.

2 Methods

2.1 Literature Review

We conducted a literature review from traditional (PubMed) and non-traditional (governmental agencies, news outlets, Academy of Managed Care Pharmacy [AMCP] website, and Google Scholar) sources. Articles were limited to "2010–2016" publication years and "English" language. Articles were also limited to those that described drug acquisition, reimbursement costs, or rebates/discounting for Medicare, Medicaid, and commercial payors. Drugs evaluated were limited to outpatient prescription drugs.

2.1.1 Search Strategy

MEDLINE was searched with the following terms in combinations or single search strategies: "drug costs," "reimbursement," "Medicare," "Medicaid," "commercial." The Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) websites were searched for articles, statements, and announcements focused on reimbursements for prescription drugs paid by Medicare and Medicaid. The HHS and CMS websites were searched using the terms "drug costs," "Medicare Part B drugs," "outpatient drugs," "reimbursement," and "Medicaid drug reimbursement." The AMCP website was searched using the terms "cost of drugs", "guidelines for payment", and "reimbursement." Google Scholar was searched using the key terms "historical drug costs in the US" and "health insurance." We used the snowball technique to identify additional articles that were relevant but not yet found in other sources.

Articles that met the inclusion criteria were subject to be included in the review. The results from the literature search were used to better inform the results that follow.

2.2 Drug Cost Focus Group

A focus group (the Drug Cost Focus Group [DCFG]) was convened to supplement the literature review. The DCFG explored the perceptions and knowledge of current drug costs, including, but not limited to, acquisition, reimbursements, rebates, discounts, and value-based contracts. The DCFG was composed of seven health economics researchers working in various practice roles: two academicians, two health economic consultants, one managed care professional, and two post-doctoral fellows. Discussions were focused on elucidating market complexities and achieving agreement between the literature and the DCFG understanding.

The DCFG was convened using a virtual meeting platform. The first author played the role of the moderator and transcribed the notes from the discussion. DCFG members were encouraged to ask questions, talk to one another, and exchange narratives on each other's experiences and points of view. After the initial focus group, the dialogue was continued through electronic communications. The DCFG focused on (1) the processes of drug acquisition, administration, reimbursement, and rebates in the outpatient setting; (2) relevant US drug cost terminology; and (3) emerging issues affecting US drug costs. DCFG participants reviewed and agreed to the information presented in this review.

3 Results

3.1 US Drug Costs

Tables 1 and 2 include drug cost terms according to the relevant US payor (Medicaid, Medicare, and commercial).

Terminology mainly pertains to drug acquisition and drug reimbursement costs, which are further discussed in Sects. 3.1.1 and 3.1.2.

3.1.1 Acquisition Cost

Acquisition cost refers to the cost that distributors, wholesalers, health systems, and pharmacies pay to purchase a drug from a manufacturer or distributor. Payors rely on acquisition costs to serve as benchmarks for reimbursement.

Typically, wholesalers purchase drugs from manufacturers, and pharmacies purchase drugs from wholesalers at the wholesale acquisition cost (WAC) (see Table 1) [10]. In short, the WAC represents the list price for retail pharmacies to acquire a specific drug product from a wholesaler. Counterpart to the WAC listed price is the average wholesale price (AWP). AWP is analogous to a listed drug retail price. Both AWP and WAC estimates are listed prices and do not account for rebates, discounts, and other reductions [10, 11]. In short, both AWP and WAC are market-based prices exclusive of rebates and other non-retail incentive payments through manufacturers. Despite its flaws, AWP was widely used for decades as the basis of pharmacy reimbursement [12].

In the early 2000s, a nationwide class-action lawsuit was brought forth by the Prescription Access Litigation (PAL) Project against First Databank and the drug wholesaler McKesson Corp. [13]. PAL alleged that First Databank worked with McKesson Corp. to increase the list prices of drugs, which increased pharmacies' and wholesalers' profit margins. Since litigation, two prominent publishers of AWP, First DataBank and Medi-SPAN, have ceased publication of AWP list prices [12–14]. Federally, the AWP came under scrutiny due to concern that AWP-based

Table 1 Acquisition costs

Acquisition costs	Definition	Payor
WAC	A drug cost as indicated by the manufacturer. Distributors, wholesalers, or health systems may utilize the WAC price as a baseline benchmark for the estimation of the acquisition cost for a particular drug WAC disadvantages Estimation is non-inclusive of rebates and discounts Listed price	NA
AMP ^a	“[T]he average price paid to the manufacturer for the drug in the United States by wholesalers for drug distribution to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer” [16] (p. 5172)	Medicaid
340-B	340-B prices apply to eligible entities, including Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and disproportionate-share hospitals and clinics participating in the 340-B Drug Program [17] Entities are eligible to receive significant discounts on certain drugs administered in the outpatient setting	NA

AMP average manufacturer price, NA not applicable, WAC wholesale acquisition cost

^a AMP may also be considered a reimbursement drug cost

Table 2 Reimbursement drug cost terms

Reimbursement costs	Definition	Payor
AWP ^a	A list price, which serves as an estimation of the average acquisition cost for pharmacies [10]. AWP was historically utilized as the drug cost basis for pharmacy reimbursement AWP disadvantages Estimates are not inclusive of rebates and discounting Estimates are not necessarily based on actual sales	Unclear
AAC ^a	“[T]he agency’s determination of the pharmacy providers’ actual prices paid to acquire drug products marketed or sold by specific manufacturers” [16] AAC disadvantages Estimates are the responsibility of the state States maintain flexibility in the method of calculating AACs, which leads to variations dependent on the state	Medicaid
ACA-FUL	The ACA redefined FULs for multisource products “to be no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis” [16] (p. 5172)	Medicaid
ASP	The manufacturer’s ASP is the total of all sales to purchasers in the USA for a drug (or biologic) within a calendar quarter divided by the total units sold in such quarter [27]. ASPs are representative of rebates and discounts provided by the manufacturer. ASP applies to Medicare Part B-covered drugs such as biologics and injectables not paid for under the prospective payment system or cost basis	Medicare Part B
MAC	Commercial insurers or entities that maintain pharmacy benefits, such as pharmacy benefit managers (PBMs) may utilize MAC-based pricing to determine the maximum reimbursement for generic drugs. MAC-based reimbursement is a cost-containment strategy used by many commercial insurers [26]	Commercial

AAC actual acquisition cost, ACA-FUL Affordable Care Act–Federal Upper Limit, AMP average manufacturer price, ASP average sales price, AWP average wholesale price, MAC maximum allowable cost

^a May also be considered acquisition drug costs

reimbursement resulted in Medicaid overpayment for pharmaceuticals [10]. Current use of AWP in pharmaceutical reimbursement among Medicare, Medicaid, and commercial insurers is unclear in the literature.

Average manufacturer price (AMP) is the average price paid to manufacturers for a pharmaceutical [15]. CMS requires that manufacturers submit quarterly AMP reports in order to sell outpatient drugs to Medicaid beneficiaries. AMP is used as the basis for manufacturer rebates in the Medicaid Drug Rebate program and reimbursement for certain generic drugs (with ACA-Federal Upper Limit [ACA-FUL] calculated). The ACA amended the Social Security Act, redefining the AMP as “the average price paid to the manufacturer for the drug in the United States by wholesalers for drug distribution to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer,” [16] (p. 5172).

Non-profit, eligible entities can receive significant discounts from manufacturers on select drugs through the 340-B Drug Program [17]. Eligible entities include organizations and health systems, such as Federally Qualified Health Centers, Ryan White HIV/AIDS Program grantees, and disproportionate-share hospitals and clinics. 340-B pricing applies only to consumers who have a clinical care relationship with the participating entity (e.g., clinic or hospital), other than simply the receipt of drugs (HIV drugs are an

exception). The 340-B program encompasses outpatient drugs, such as prescription drugs, insulin products, biologics (excluding vaccines), and over-the-counter drugs written as a prescription [18]. Purchasing drugs at 340-B prices from manufacturers can be advantageous to health systems because pharmaceutical reimbursement is independent of the lower acquisition cost [19], thus increasing the spread or margin between acquisition cost and reimbursement.

3.1.2 Drug Reimbursement

Reimbursement refers to payments that are retrospectively paid by insurers to a pharmacy, physician, or health system administering or distributing covered pharmaceuticals to consumers. Reimbursement to pharmacies is based on a pricing benchmark and a dispensing fee. Entities responsible for reimbursement include, but are not limited to, pharmacy benefit managers, commercial health insurers (with self-managed pharmacy benefits), Medicaid, and Medicare.

Reimbursement for outpatient drugs differs across insurers. Medicaid reimbursements for branded and generic products (without a federal upper limit calculated) are based on an actual acquisition cost (AAC) ([20]; see Supplementation Material Table 1). However, states are not mandated to employ a specific methodology to establish their AAC reimbursement [16]. Hence, states maintain flexibility in

determining sources for AAC-based reimbursement. Sources of drug cost data include, but are not limited to, National Average Drug Cost files, AMP, and state surveys. For example, Alabama utilizes state-wide surveys sent to retail pharmacies to determine the aggregate AAC payment for pharmaceuticals within their state [21]. For generic drugs that have an established ACA-FUL, states utilize ACA-FUL rather than AAC to determine reimbursement [16, 22].

Medicare Part B covers a limited number of drugs administered in the outpatient setting [8, 23]. Reimbursement for these drugs is based on the average sales price (ASP). In general, the ASP for each individual National Drug Code (NDC) is calculated by the respective manufacturer and submitted to the CMS within 30 days of the close of each quarter [24]. Medicare reimbursement for Part B drugs is 106% of the ASP ($106\% \times \text{ASP}$); however, there are exceptions to this general repayment methodology [25].

Maximum allowable cost (MAC) represents the highest cost that a payor will pay for a drug. MAC prices are used as a cost-containment strategy by many commercial plans as the basis of reimbursement for generic and multi-source branded drugs [26].

Reimbursement methodologies of commercially run plans, such as Medicare Advantage, Medicare Part D, and employer-sponsored health plans, are proprietary and not clear in the literature.

3.1.3 Affordable Care Act Reform of Medicaid Drug Rebates

Manufacturers that desire Medicaid patients to utilize their drugs in an outpatient setting are required to participate in the Medicaid Drug Rebate Program [28]. After an outpatient prescription is dispensed to a Medicaid consumer, the participating manufacturer must submit a rebate to the state that (by federal law) is the purchaser for the individual product. These rebates are paid to states on a quarterly basis and shared by states and the Federal Government. The ACA altered the Medicaid Drug Rebate Program and established new rebate rates for select outpatient drugs, including, but not limited to, single source and innovator multiple source drugs, clotting factors, non-innovator multiple source drugs, and multiple source drugs (see Table 3) [16]. The ACA also established that manufacturers apply rebates for Medicaid consumers enrolled in a managed care organization.

3.2 Value-Based Drug Contracts and Payment Models

As a means to help control cost, public and commercial payers are shifting to value-based contracting or value-

based pricing arrangements for pharmaceuticals. According to the Pharmacy Benefit Management Institute's *2016 Trends in Specialty Drug Benefits* report, 82% of employers expressed interest in value-based pricing models [29]. These pricing solutions are intended to measure and reward value as opposed to rewarding mere volume of pharmaceutical drug spend [30]. One of the earliest examples of drug value-based contracts in the USA was for the Proscar[®] (Merck, 1994) for the treatment of benign prostatic hyperplasia [31]. Merck offered to refund the drug cost if patients failed therapy within 2 years and needed surgery or if symptoms progressed within 6 months of being adherent to treatment. Other early examples of value-based contracting include Clozaril[®] (Sandoz, 1995) and Zocor[®] (Merck, 1998) [32]. More recently, Novartis released confirmation of value-based contracts with Cigna and Aetna for the heart-failure medication, Entresto[®] [33]. The results of this agreement have not yet been released.

Among public insurers, the development and implementation of value-based payment models have been spearheaded by the Center for Medicare and Medicaid Innovation (CMMI), which was established under Section 3021 of the ACA [34]. The CMMI is charged with furthering innovative payment and delivery models that decrease overall costs to publicly funded programs while sustaining or increasing the quality of care to Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries [35]. A number of CMMI programs focus on transforming payments in the inpatient setting (e.g., Maryland All-Payer Model [36], acute care bundled payments, and readmission reductions) [35]; however, there are programs focused on payment reform in the outpatient setting. The CMS has proposed a rule to test a new value-based purchasing method for Medicare Part B drugs [37]. Currently, Medicare pays administering physicians 106% of ASP for Medicare Part B drugs; however, there are concerns that this ASP-based reimbursement approach promotes increased use of higher-priced Medicare Part B drugs because higher-priced drugs have higher reimbursement [38]. In Phase 1, the CMS has proposed to test whether altering the payment model to 102.5% of ASP plus a flat fee (US\$16.80 per day) will drive greater value and quality of care delivered. The CMS has proposed to incorporate value-based purchasing strategies to reward positive patient outcomes. In Phase 2, value-based purchasing strategies will be tested, including discounting or elimination of patient cost sharing, utilization of evidence-based clinical decision support tools, indications-based pricing, reference pricing, and risk-sharing agreements. Phase 2 is planned to begin no sooner than 1 January 2017.

Table 3 Affordable Care Act reform of Medicaid drug rebates

Drugs affected ^a	Rebates
Most single-source and innovator multiple-source drugs	Increased the minimum rebate from 15.1 to 23.1% of the AMP
Clotting factors and drugs with exclusive pediatric indications	Established a “minimum rebate percentage of 17.1 percent of [the] AMP for certain single source and innovator multiple source clotting factors and single source and innovator multiple source drugs approved by the Food and Drug Administration (FDA) exclusively for pediatric indications” [16] (p. 5171)
Non-innovator multiple-source drugs	Increased the rebate percentage from 11 to 13% of the AMP
Multiple-source drugs	Established a maximum rebate percentage of 100% of the AMP

AMP average manufacturer price

^a Represents an abbreviated list of the Affordable Care Act’s reform on Medicaid rebates [16]

3.3 Emerging Issues

3.3.1 Consumer Out-of-Pocket Costs

Prior to the ACA, 129 million Americans had limited to no health insurance due to pre-existing conditions [39]. Through enactment of the ACA, approximately 20 million Americans have gained health insurance through state expansions of Medicaid, entitlement programs, purchase of individual insurance on the Health Insurance Exchange, and other coverage provisions [40]. Before the ACA, lack of coverage left millions of Americans at risk for high out-of-pocket payments and medical debt. The ACA has aimed to decrease consumers’ risks for medical debt and out-of-pocket costs through greater regulations and creation of Health Insurance Exchanges, where consumers may purchase a plan of their choice and apply for subsidies.

Despite some positive impacts of the ACA to consumers, evidence suggests that some patients may accrue high pharmaceutical out-of-pocket costs [41]. The Kaiser Family Foundation reported that approximately 50% of employees with three or more cost-sharing tiers face co-insurance for fourth-tier drugs [7]. Drugs included in fourth tiers are often oral therapies used to treat specialty conditions such as HIV/AIDS, rheumatoid arthritis, pulmonary fibrosis, and psoriasis, or lifestyle drugs. The structures of formulary drug plans differ across insurers; however, in general, higher-tier drugs are associated with a higher cost share [7].

Cost sharing is implemented in drug plans to direct patients towards utilization of clinically valuable products and to offset premiums [7, 29, 42]. However, evidence suggests that increased cost sharing is associated with worsening adherence [42]. Among 341 employers, 57% cited the use of a separate tier for specialty pharmaceuticals [29] (an increase from 23% in the year 2011). Recently, several states, including Delaware, Louisiana, Maine,

Maryland, Montana, New York, and Vermont, have limited the consumer cost share on specialty drugs for patients in private plans [43]. Evidence suggests that some patients may be at risk for high out-of-pocket expenses for select pharmaceuticals [43, 44].

3.3.2 Drug Shortages

Drug shortages represent another consideration relevant to pricing and reimbursement because shorted drugs come at a higher price. Drug shortages are defined as “a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences consumer care when prescribers must use an alternative agent” [45]. Drug shortages can be caused by factors in the supply chain including, but not limited to, raw material unavailability, delayed manufacturing, increased regulatory requirements, and voluntary recalls. The implications of drug shortages on pharmacies are beyond financial as there are potential injuries that may occur because of delays in receipt of drug therapy. In 2015, 142 new drug shortages were reported [46]. The rationale behind the drug shortages was wide ranging, from unknown causes (57%) to regulatory reasons (3%).

Distributors may mitigate a potential drug shortage by stockpiling or purchasing large quantities of the drug [45]. Financially, drug shortages increase the acquisition costs of the limited-supply drugs. Pricing gouging by secondary distributors (of drugs on shortage or those anticipated to be on shortage) represent another financial constraint for health systems with limited resources. Pricing gouging of ‘shortage drugs’ occurs when secondary distributors purchase large quantities of the drug and then aggressively raise prices. The purchase of shortage drugs from secondary distributors is discouraged by the Pharmaceutical Research and Manufacturers of America (PhRMA) due to potential inappropriate mishandling of products, and thus potential concerns for consumer safety [47].

3.3.3 Price Gouging

The practice of manufacturers aggressively increasing drug costs, commonly referred to as ‘price gouging,’ is an issue of growing concern within the context of drug cost. In 2015, the CEO of Turing Pharmaceuticals was accused of inappropriately raising the cost of pyrimethamine after becoming the sole manufacturer of the anti-parasitic therapy [48]. The overnight price change of the therapy from US\$13.50 to US\$750 per tablet resulted in an uproar from politicians, state agencies, and healthcare workers over the drug’s price.

Rodelis Therapeutics acquired the rights to manufacture cycloserine, a drug used to treat multidrug-resistant tuberculosis in 2015 [49]. Soon after cycloserine was acquired, the price increased from US\$500 per 30 pills to US\$10,800. The Purdue Research Foundation quickly reacquired the rights to manufacture the drug and reversed most of the price hike, i.e. Purdue Research Foundation priced cycloserine at US\$1,050 per 30 pills significantly less than Rodelis Therapeutics; however, the price was double the original price.

While Turing Pharmaceuticals received public backlash over the price hike of pyrimethamine [50], it is not illegal to aggressively raise prices in the US marketplace. In the absence of changed government regulation and/or middleman disruption in commercial business drug-related contracting practices, these events may continue to occur.

4 Discussion

The complexity of the drug costs for insurers is mirrored by the complex, evolving nature of healthcare delivery and payment in the USA. The aim of this paper was to review US drug costs post-ACA enactment to better understand the routes through which drugs are acquired and reimbursed among primary insurers. A thorough understanding of drug costs relevant to payors is important to decision makers proving or evaluating the value of products and to the development of pharmacoeconomic evaluations with relevant drug costs inputs. Given the ACA’s impact on the healthcare industry, including the increased focus on value, we believed that articles published after 2010 would not only reveal new drug costs, but also provide evidence that drug repayment structures are complex.

Some states have shifted to AAC-based and ACA-FUL reimbursement for select brand and generic outpatient drugs, respectively. The shift to AAC-based reimbursement is critical because AAC estimates are based on actual sales data, unlike the former AWP-based payment methodology which listed drug prices not based on actual sales. AAC-based reimbursement should drive down unnecessary drug costs for Medicaid states.

Since the ACA, the CMMI was created; it is charged with testing new models of value-based reimbursement for Medicare, Medicaid, and CHIP beneficiaries. Specific to outpatient pharmaceuticals, the CMMI has proposed new methods of reimbursement for drugs covered by Medicare Part B. The new payment model is aimed at altering physician prescribing toward the most effective drugs and rewarding positive outcomes. Among commercial insurers, there are few examples (in the literature) of value-based contracting specific to prescription drugs. Insurers, pharmacy benefit managers, and manufacturers are not required to release proprietary contract details; therefore, the actual prevalence of value-based contracting for pharmaceuticals is unknown. In the USA, value-based reimbursement and contracting are disrupting the historical fee-for-service reimbursement environment. The future use of value-based reimbursement for drugs remains to be seen.

Despite the ACA’s assurance of increasing health insurance for millions of Americans, evidence suggests that some patients may be at risk of high out-of-pocket costs for specialty drugs. Due to the single- and multiple-year variability in drug benefit plans, it is not possible to evaluate the financial impact of the ACA legislation on all consumers. Further studies on patients with similar pharmaceutical coverage are needed to model consumer costs within the same insurance or entitlement categories.

The International Society for Pharmacoeconomics and Outcomes Research Drug Cost Task Force recommends that the choice of drug costs for pharmacoeconomic evaluations be relevant to the study perspective [51–55]. However, the lack of publicly available sources on actual drug costs relevant to each stakeholder (consumers, insurers, caregivers, etc.) presents a challenge to those who desire to incorporate actual drug costs. Currently, due to the proprietary nature of rebates and discounting in the private sector, analyses from a commercial plan’s perspective (without access to claims data) will be limited as drug costs may not be relevant to the specific payor.

4.1 Limitations

The description of US drug costs in this review is largely representative of changes to reimbursement in the public market. Due to the proprietary nature of commercial agreements between distributors, health plans, pharmacy benefit managers, and other drug benefit plan administrators, evidence and cost transparency around private drug costs is limited. We offer a limited review of the available drug cost terms and emerging issues known to date in the pharmaceutical market.

5 Conclusion

Our review provides an overview of US drug costs (post-ACA). We aimed to provide current drug costs relevant to Medicare, Medicaid, and commercial insurers as this information is an important underpinning to application in pharmacoeconomics. Current gaps in evidence regarding commercial drug costs (post-ACA) present barriers to the applications of relevant drug costs to pharmacoeconomic analyses.

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Compliance with Ethical Standards

Author contributions JM served as the moderator for the Drug Cost Focus Group (DCFG), contributed significant input to the Results, Discussion, and Conclusion sections, and led the literature review. RV contributed significant input to the Introduction and Results sections and responded to comments. SB contributed significant input to the Results and Discussion sections and assisted in responses to reviewers. EM contributed significant input to the Methods section and provided commentary for revisions of the manuscript. SV contributed significant input to the Methods section and provided commentary for revisions of the manuscript. LP co-moderated the DCFG, provided significant input to the research design and assessment of literature, and provided commentary for revisions of the manuscript.

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Conflict of interest Jacquelyn McRae has no conflicts of interest. Randy Vogenberg is on a speaker's bureau for employer-sponsored health plans on healthcare trends and benefit plan strategy or design topics. Silky Beaty has no conflicts of interest. Elizabeth Mearns has no conflicts of interest. Stefan Varga has no conflicts of interest. Laura Pizzi has no conflicts of interest. The authors and members of the DCFG represent a diverse work group and experience in health economics and healthcare policy in the US market.

References

- Shi L, Singh D. Delivering health care in America. 6th ed. Burlington: Jones & Bartlett Learning; 2015.
- Kaiser Permanente. Our history. 2016. <https://share.kaiserpermanente.org/article/history-of-kaiser-permanente/>. Accessed 27 Jul 2016.
- Source book of health insurance data, 1999–2000. Washington: Health Insurance Association of America; 1999.
- Enthoven AC, Fuchs VR. Employment-based health insurance: past, present, and future. *Health Aff (Millwood)*. 2006;25(6):1538–47.
- Blumenthal D. Employer-sponsored health insurance in the United States—origins and implications. *N Engl J Med*. 2006;355(1):82–8.
- McDonnell K. History of health insurance benefits. Employment Benefit Research Institute; 2002. <https://www.ebri.org/publications/facts/index.cfm?fa=0302fact>. Accessed 27 Jul 2016.
- Employer Health Benefits Survey. The Kaiser Family Foundation; 2013. <http://kff.org/private-insurance/report/2013-employer-health-benefits/>. Accessed 27 Jul 2016.
- Medicare.gov. Your Medicare coverage: prescription drugs (outpatient). 2016. <https://www.medicare.gov/coverage/prescription-drugs-outpatient.html>. Accessed 27 Jul 2016.
- Boukus ER, Carrier ER. Americans' access to prescription drugs stabilizes, 2007–2010. Tracking report. Center for Studying Health System Change. 2011 Dec; No. 27. <http://www.hschange.org/CONTENT/1264/1264.pdf>. Accessed 24 Aug 2016.
- Levinson DR. Replacing average wholesale price: medicaid drug payment policy. Department of Health & Human Services, Office of Inspector General; 2011. OEI-03-11-00060. <http://www.oig.hhs.gov/oei/reports/oei-03-11-00060.pdf>. Accessed 27 Jul 2016.
- Wilke RJ. Beyond AWP... way beyond. *Value Health*. 2010;13(1):1.
- Anderson L. Average wholesale price (AWP) as a pricing benchmark. 2014. <https://www.drugs.com/article/average-wholesale-price-awp.html>. Accessed 18 Oct 2016.
- Settlement of conspiracy case forces major restructuring of prescription drug-pricing system. Prescription Access Litigation; 2006. <http://www.dc37.net/news/newsreleases/2006/PALdrugpricing.pdf>. Accessed 27 Jul 2016.
- Curtiss FR, Lettrich P, Fairman KA. What is the price benchmark to replace average wholesale price (AWP)? *J Manag Care Pharm*. 2010;16(7):492–501.
- Levinson DR. Medicaid drug price comparisons: average manufacturer price to published prices. Department of Health & Human Services, Office of Inspector General; 2005. OEI-05-05-00240. <http://www.oig.hhs.gov/oei/reports/oei-05-05-00240.pdf>. Accessed 30 Jul 2016.
- Department of Health and Human Services. Medicaid program; covered outpatient drugs; final rule. *Federal Register*. 2016 Feb 1. <https://www.gpo.gov/fdsys/pkg/FR-2016-02-01/pdf/2016-01274.pdf>. Accessed 27 Jul 2016.
- Health Resources and Services Administration. 340B Drug Pricing Program: eligibility & registration. <http://www.hrsa.gov/opa/eligibilityandregistration/index.html>. Accessed 27 Jul 2016.
- Levinson D. State Medicaid policies and oversight activities related to 340B-purchased drugs. Department of Health and Human Services, Office of Inspector General; 2011 Jun. <http://www.hrsa.gov/opa/programrequirements/reports/medicaidpoliciesandoversights062011.pdf>. Accessed 15 Jul 2016.
- Report to the congress: overview of the 340B Drug Pricing Program. MedPAC; 2015 May. <http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0?>. Accessed 29 Jul 2016.
- Wachino V. RE: implementation of the covered outpatient drug final regulation provisions regarding reimbursement for covered outpatient drugs in the Medicaid program [letter]. Department of Health and Human Services; 2016 Feb 11. <https://www.medicaid.gov/federal-policy-guidance/downloads/smd16001.pdf>. Accessed 18 Oct 2016.
- Myers and Stauffer LC. Alabama pharmacy: FAQs. <http://www.mscl.com/Alabama/PharmacyFAQs.aspx>. Accessed 27 Jul 2016.
- Medicaid.gov. Affordable Care Act federal upper limit methodology and data elements guide. 2016. <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/true-up/xxxxdraft-true-up-methodology.pdf>. Accessed 27 Jul 2016.
- Mullen P. The arrival of average sale price. *Biotechnol Healthc*. 2007;4(3):48–53.
- Giled S, Haninger K. Medicare Part B reimbursement of prescription drugs. ASPE Issue Brief. US Department of Health and Human Services; 2014 Jun 1. <https://aspe.hhs.gov/report/>

- medicare-part-b-reimbursement-prescription-drugs. Accessed 24 Sep 2016.
25. Medicare Part B drug average sales price: manufacturer reporting of average sales price (ASP) data. Center for Medicare & Medicaid Services; 2016. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html?redirect=/mcrpartbdrugavgsalesprice/10_vaccinespricing.asp. Accessed 27 Jul 2016.
 26. MAC pricing incents more affordable Rx. Express Scripts; 2016. <http://lab.express-scripts.com/lab/insights/drug-options/mac-pricing-incents-more-affordable-rx>. Accessed 27 Jul 2016.
 27. Social Security Office. Use of the average sales price methodology. 42 U.S.C. § 1395w-3a(c). https://www.ssa.gov/OP_Home/ssact/title18/1847A.htm. Accessed 29 Sep 2016.
 28. Medicaid.gov. Medicaid Drug Rebate Program. 2016. <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html>. Accessed 27 Jul 2016.
 29. Pharmacy Benefit Management Institute (PBMI). 2016 trends in specialty drug benefits report. 2016 Mar. <https://www.pbmi.com/shop/specialty-drug-benefit-reports/2016-specialty-drug-benefit-report/>. Accessed 29 Sep 2016.
 30. Connole P. Pay-for-value movement turns attention to prescription drugs. Atlantic Information Services; 2015. <https://aishealth.com/archive/nhpw071315-04>. Accessed 15 Jun 2016.
 31. Tonks A. Merck offers money back guarantee on finasteride. *BMJ*. 1994;309:1252–3. doi:10.1136/bmj.309.6964.1252a.
 32. Deloitte. Value-based pricing for pharmaceuticals: implications of the shift from volume to value. 2015. http://www.converge-health.com/sites/default/files/uploads/resources/white-papers/valuebasedpricingpharma_060412.pdf. Accessed 27 Jul 2016.
 33. Matthias A. Novartis strikes pay-for-performance deals for heart-failure drug Entresto. *PM360*; 2016 Feb. <https://www.pm360online.com/novartis-strikes-pay-for-performance-deals-for-heart-failure-drug-entresto/>. Accessed 27 Jul 2016.
 34. The Henry J. Kaiser Family Foundation. Summary of the Affordable Care Act. 2013. <http://kff.org/health-reform/factsheet/summary-of-the-affordable-care-act/>. Accessed 27 Aug 2016.
 35. Center for Medicare & Medicaid Services. About the CMS Innovation Center. 2016. <https://innovation.cms.gov/About/index.html>. Accessed 27 Jul 2016.
 36. The Maryland Health Services Cost Review Commission. Maryland All-Payer Model agreement. 2014. [http://www.hscrc.state.md.us/documents/md-maphs/stkh/MD-All-Payer-Model-Agreement-\(executed\).pdf](http://www.hscrc.state.md.us/documents/md-maphs/stkh/MD-All-Payer-Model-Agreement-(executed).pdf). Accessed 27 Jul 2016.
 37. Centers for Medicare and Medicaid Services. Medicare Part B Drugs Payment Model. 2016. <https://innovation.cms.gov/initiatives/part-b-drugs>. Accessed 18 Oct 2016.
 38. MedPAC. Ch. 3: Part B drug payment policy issues. Report to the Congress: Medicare and the health care delivery system. 2015. [http://www.medpac.gov/documents/reports/chapter-3-part-b-drug-payment-policy-issues-\(june-2015-report\).pdf?sfvrsn=0](http://www.medpac.gov/documents/reports/chapter-3-part-b-drug-payment-policy-issues-(june-2015-report).pdf?sfvrsn=0). Accessed 27 Jul 2016.
 39. CMS.gov. At risk: pre-existing conditions could affect 1 in 2 Americans: 129 million people could be denied affordable coverage without health reform. The Center for Consumer Information & Insurance Oversight. <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/preexisting.html>. Accessed 3 Oct 2016.
 40. Obamacare Facts. Obamacare facts: an independent site for ACA advice. <http://obamacarefacts.com>. Accessed 27 Jul 2016.
 41. Pearson C. Avalere analysis: exchange benefit designs increasingly place all medications for some conditions on specialty drug tier. Avalere Health An Innovation Company. <http://avalere.com/expertise/life-sciences/insights/avalere-analysis-exchange-benefit-designs-increasingly-place-all-medication>. Accessed 27 Jul 2016.
 42. Goldman D, Joyce G, Zheng Y. Prescription drug cost sharing: associations with medication and medical utilization and spending and health. *JAMA*. 2007;298(1):61–9.
 43. Ollove M. States limiting patient costs for high-priced drugs. The Pew Charitable Trusts; 2015 Jul 2. <http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/07/02/states-limiting-patient-costs-for-high-priced-drugs>. Accessed 18 Oct 2016.
 44. Reinke T. Benefit and formulary options appear in specialty pharmacy. *Managed Care*; 2014. <http://www.managedcaremag.com/archives/2014/1/benefit-and-formulary-options-appear-specialty-pharmacy>. Accessed 4 Sep 2016.
 45. ASHP Expert Panel on Drug Product Shortages, Fox ER, Birt A, James KB, Kokko H, Salverson S, et al. ASHP guidelines on managing drug product shortages in hospitals and health systems. *Am J Health Syst Pharm*. 2009;66:1399–406.
 46. Fox E. National drug shortages. University of Utah Drug Information Services; The American Society of Health-System Pharmacists; 2016. <http://www.ashp.org/menu/DrugShortages>. Accessed 27 Jul 2016.
 47. PhRMA. Drug shortages and supply chain info. <http://www.phrma.org/drug-shortages>. Accessed 27 Jul 2016.
 48. Pollack A. Drug goes from \$13.50 a tablet to \$750, overnight. *New York Times*. 2015 Sep 20. http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?_r=0. Accessed 27 Jul 2016.
 49. Pollack A. Big price increase for tuberculosis drug is rescinded. *New York Times*. 2015 Sep 21. <http://www.nytimes.com/2015/09/22/business/big-price-increase-for-tb-drug-is-rescinded.html>. Accessed 18 Oct 2016.
 50. Dyer O. Company reneges on promise to cut price of toxoplasmosis drug. *BMJ*. 2015;351:h6472. doi:10.1136/bmj.h6472.
 51. Garrison LP, Mansley EC, Abbott TA 3rd, Brenaghan BW, Hay JW, Smeeding J. Good research practices for measuring drug costs in cost-effectiveness analyses: a societal perspective: the ISPOR Drug Cost Task Force report-part II. *Value Health*. 2010;13:8–13.
 52. Hay JW, Seeding J, Carroll NV, Drummond M, Garrison LP, Mansley EC, et al. Good research practices for measuring drug costs in cost effectiveness analyses: issues and recommendations: the ISPOR Drug Cost Task Force report-part I. *Value Health*. 2010;13:3–7.
 53. Mansley EC, Carroll NV, Chen KS, Shah ND, Piech CT, Hay JW, et al. Good research practices for measuring drug costs in cost-effectiveness analyses: a managed care perspective: the ISPOR Drug Cost Task Force report-part III. *Value Health*. 2010;13:14–7.
 54. Mullins CD, Seal B, Seoane-Vazquez E, Sankaranarayanan J, Asche CV, Jayadevappa R, et al. Good research practices for measuring drug costs in cost-effectiveness analyses: Medicare, Medicaid and other US Government payers perspectives: the ISPOR Drug Cost Task Force report-part IV. *Value Health*. 2010;13:18–24.
 55. Mycka JM, Dellamano R, Kolassa EM, Wonder M, Ghosh S, Hay JW, et al. Good research practices for measuring drug costs in cost effectiveness analyses: an industry perspective: the ISPOR Drug Cost Task Force report-part V. *Value Health*. 2010;13:25–7.