1% of Medicare Spending (0.21% of Total Health Spending)

Paying for Biologic PADs in Medicare Part B

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Issue Summary: Medicare spending on physician-administered drugs (PADs) continues to increase substantially and is being driven in large part by higher prices. PADs are covered under Medicare Part B for Medicare enrollees and under the medical benefit for most commercial enrollees. Under the current structure, the physician chooses a version of the drug to purchase, holds the inventory, and then prescribes and administers it. When administered, the physician receives a payment, which is typically equal to the cost to acquire the drug charged by the manufacturer plus a specified markup. In the US, each biologic PAD and each individual biosimilar PAD has its own reimbursement amount based on its distinct billing code, known as its J-code. As a result, current procurement policy for biologic PADs under Medicare Part B avoids all competitive market forces. It does not create any incentive to compete on price; rather, it rewards higher-priced drugs by permitting firms to set any price they want Medicare to pay and giving no incentive to physicians to avoid high-priced drugs. Compounding the problem, many commercial insurers follow Medicare reimbursement rules for PADs. The J-code regulations entirely defeat the purpose of biosimilar entry, which was designed to create price competition for old biologic drugs in the way that generic drugs lower prices in the pharmacy channel. With R&D pipelines filled with biologic drugs, it's imperative to modify the design of Medicare J-codes to generate competition amongst manufacturers of biologic PADs and incentivize physicians to prescribe lower-cost biosimilars.

Policy Proposal: This brief proposes changing the design of Medicare J-codes for PADs so that there is a single J-code for each molecule: the reference biologic and all of its biosimilar versions. Physicians should then be compensated a fixed amount for administering any product in the J-code group. The fixed amount could be the price of the least-costly alternative in the J-code plus 5%, or $500, whichever is smaller.

Total Savings: Biologic PADs are a large and growing share of Medicare. Moreover, many commercial plans follow Medicare payment schemes. Under conservative assumptions, this policy would save $2 billion per year, and it might save as much as $7.5 billion per year, which is approximately 1% of Medicare spending.

Related Literature and Evidence

The Impact of the Entry of Biosimilars: Evidence from Europe (2018). *Review of Industrial Organization* 53 (1): 173–210 (Fiona M. Scott Morton, Ariel Dora Stern, and Scott Stern).

The Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing (2006). *The Quarterly Journal of Economics* 121 (1): 1–130 (Mark Duggan and Fiona M. Scott Morton).

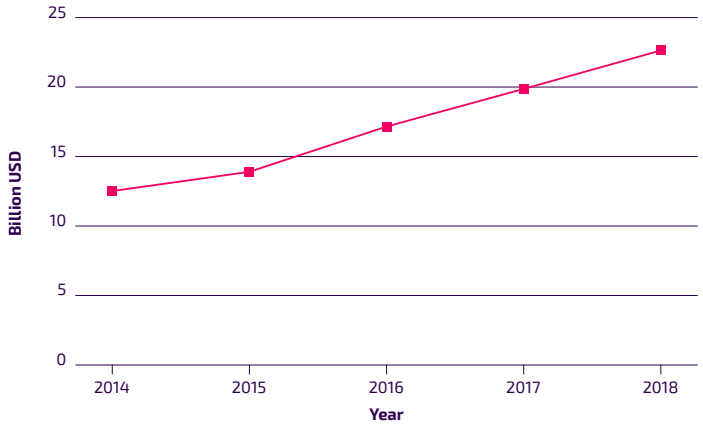
Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare Part B (2012). *Department of Health and Human Services*. https://oig.hhs.gov/oei/reports/oei-12-12-00210.pdf.

Background

PADs are treatments such as injections or infusions that are administered by physicians in an outpatient setting (e.g., doctor's office). Medicare covers PADs under Part B and, analogously, commercial health insurance plans typically cover PADs as part of the medical benefit. Two thirds of Medicare Part B drug spending is on biologic drugs (MedPAC 2017). In 2018, total Medicare PAD spending on biologics was $22.63 billion (FDA 2020; CMS 2020).

Spending on PADs is growing much faster than spending on self-administered drugs and represents the largest growth in spending for professional services (HCCI 2019, 16).[1] Medicare alone spent $32 billion on PADs in 2017, and, on average, expenditure grew by 9.7% annually between 2009 and 2015 (MedPAC 2018). This increase in spending was driven primarily by price rather than utilization; the average payment per Part B drug increased on average by 6.6% annually (MedPAC 2018). These steep price increases can be attributed to the way Medicare currently procures PADs. Physician practices or hospital outpatient departments purchase PADs from group purchasing organizations, distributors, wholesalers, or the manufacturers themselves (Ginsburg, Brandt, and Lieberman 2019).[2] Physicians choose a version of the drug to buy, stock the drug, and incur inventory costs. Unlike most small-molecule drugs, many PADs cost thousands of dollars (MedPAC 2015, 66) and are perishable (County of Suffolk v. Abbott Laboratories), so they have high inventory costs. Physicians then dispense the drug and receive a payment from a patient's medical insurer. Many commercial insurers follow Medicare reimbursement rules for PADs, so the Medicare rules take on outsized importance in terms of influencing the pricing behavior of manufacturers.[3]

Table 1: Estimated Spending on Biologic PADs by Medicare Part B



Source: FDA (2020); CMS (2020).

Current Remuneration for Biologic PADs

Medicare pays the physician an amount known as the Average Sales Price (ASP) plus 6%.[4] The ASP is calculated as the volume-weighted sales to all purchasers (with some exceptions[5]) across all drugs categorized under the same billing code, known as a J-code. Specifically, manufacturers submit their ASPs for all forms and sizes of the drug, and the Centers for Medicare and Medicaid Services (CMS) aggregates a volume-weighted ASP for each J-code. Physicians are paid the ASP from two quarters before the patient's visit plus 6% as a profit margin. For a biosimilar, the ASP is based on its J-code and the 6% markup is based on the reference biologic's ASP. Commercial insurers use the Medicare rate as a benchmark for negotiation, though they often pay a markup higher than 6%.

Herein lies the key issue: under the current Medicare rules, each biologic and each biosimilar receives its own distinct J-code and corresponding reimbursement price from Medicare.[6] From the manufacturer's perspective, the J-code reimbursement scheme with one manufacturer in it is a cost-plus contract. This creates no price competition. Instead, the manufacturer of a drug freely chooses a launch list price or raises its existing list price as much as it desires, and then sells to physician groups and hospital outpatient departments whose demand does not fall in response to the higher prices. The current system results in the government paying the price the manufacturer chooses, whatever the level of that price and regardless of the amount of competition in the market.

In addition, because physicians are reimbursed for their acquisition costs, the level of the manufacturer's price does not affect their demand. Physicians have no incentive to consider equally effective but lower-priced alternative drugs such as biosimilars. Physicians are constrained only by their patients; to the degree patients cannot afford, and do not pay, the 20% coinsurance that applies to the drug, the physician would be disincentivized to administer it. However, 34% of fee-for-service Medicare (i.e., original Medicare)

beneficiaries have supplemental coverage, and another 31% of beneficiaries have Medicare Advantage, both of which further insulate patients from costs (AHIP 2018). As a result, only a fraction of Medicare enrollees are responsible for the 20% coinsurance and could potentially exhibit elastic demand.

In short, current Medicare regulations insulate biologics from price competition. The way the government procures these drugs incentivizes manufacturers of both biologics and biosimilars to maintain high list prices. These prices are then paid by commercial customers as well and raise the cost of health care for all Americans.

Reform Needed

This brief proposes changing the design of Medicare J-codes for PADs so that there is a single J-code for each molecule: the reference biologic and all of its biosimilar versions. Physicians should then be compensated a fixed amount for administering any product in the J-code group. The fixed amount could be the price of the least-costly alternative in the J-code plus 5%, or $500, whichever is smaller.

Under this scheme, when multiple manufacturers have a drug paid by the same J-code, each will face downward pressure on its price because customers—the physicians—will be paid a fixed amount regardless of which drug in the group they choose to buy. The single J-code creates a financial incentive for the provider to purchase from the least-expensive manufacturer in the J-code. A physician or hospital will increase its margin by purchasing a drug in the J-code group with a lower price. They are also likely to notice if buying a particular drug leaves them with a loss; for example, because its price is above the fixed reimbursement amount. Therefore, the J-code creates an incentive for manufacturers in the same J-code to compete for the business of physicians by lowering their prices. Sharing a J-code is a way for Medicare to create price competition between manufacturers of the same drugs and to generate awareness by physicians for potentially lower-cost alternatives.

Studies have shown that when reference products compete with biosimilars, there is downward pressure on price. Scott Morton et al. (2018) estimate that average market prices decrease by 3.5 percentage points per year after biosimilar entry. For each additional distributor, there is an additional 2.4 percentage point decrease in price. These estimates are reflective of the experience of European countries plus Australia, where, in aggregate, a 30% reduction in savings is commonplace. Norway was able to achieve a 70% reduction in biologic spending from introduction of a biosimilar (Mack 2015).[7]

Savings Estimation

To estimate the potential cost savings of biologic competition in the US, this brief takes all biologic products (reference products and biosimilars) licensed by the Food and Drug Administration (FDA) as of March 2020.[8] By merging these biologics with spending data from Medicare Part B in 2018, estimated cost savings are simulated by applying a percentage discount in price to biologics with existing biosimilars in 2020, and then secondly to all biologics that have been on the market for a certain number of years.

This calculation is intended to represent the steady-state value of the J-code reform in an environment with biosimilar entry.

Table 2, using a range of these back-of-the-envelope calculations, shows that potential cost savings are large and range from approximately $1 billion to $7.5 billion. For example, Scenario 2 assumes that all biosimilars that are currently approved by the FDA enter the market and compete against reference biologic products. As is common in Europe, it is conservatively assumed that the biologics facing competition see a 30% decrease in spending. Overall, this leads to savings of $1.94 billion, which represents an 8.6% decrease in total spending by Medicare Part B on biologic PADs. Under this same scenario, if it is assumed that biologics facing competition experience a 50% decrease in spending, savings is estimated to be $3.24 billion, which represents a 14.3% decrease in spending by Medicare Part B on biologic PADs. Scenario 3 shows savings from a 30% decrease in price applied to all biologics that have been on the market for more than 20 years. This results in savings of $1.38 billion. Likewise, assuming a 50% decrease in price for all biologics on the market for more than 20 years results in savings of $2.29 billion, this represents a 10.1% reduction in total spending by Medicare Part B on biologic PADs. Each scenario assessed if biologics facing competition experience a 30%, 50%, and 70% decrease in spending, respectively. Based on the resulting savings calculations, under conservative assumptions this policy would save around $2 billion per year, and it might save as much as $7.5 billion per year, which is approximately 1% of Medicare spending.

	Savings in Billions in USD, if we assume biosimilar competition	Savings w/ biosimilar competition		
		30%	50%	70%
Scenario 1	After 12 years from reference product licensure (expiration of exclusivity)	3.20	5.33	7.47
Scenario 2	Among all currently licensed biosimilars	1.94	3.24	4.53
Scenario 2	After 20 years from reference product licensure	1.38	2.29	3.21
Scenario 3	Among all currently marketed biosimilars	0.88	1.47	2.06

Notes: (1) The table above calculates simulated savings if biosimilar competition were to have been introduced in the following hypothetical scenarios. (2) Total Medicare Part B spending on biologic PADs is 22.63 billion in 2018.

These savings estimates likely understate the full impact of this change in policy. As more biologics and biosimilars are developed, approved, and competitively priced within a J-code, physicians may consider therapeutic alternatives across molecules. This consideration will result in further competition amongst manufacturers of biologic PADs and corresponding savings.

Footnotes

1. Drugs that are taken at home by patients, or self-administered prescription drugs, are covered as part of the pharmaceutical benefit for commercial plans and by Part D for Medicare enrollees.

2. It also looks like these methods of distribution are determined by the manufacturer of the drug (see County of Suffolk v. Abbott Laboratories).

3. "Commercial payers frequently adopt the [Average Sales Price] with higher markups" (Ginsburg, Brandt, and Lieberman 2019).

4. The Budget Control Act of 2011 mandates a 2% reduction across Medicare expenditures. Because the sequester does not affect the patient copay component of reimbursement, as of 2013, physicians are paid 104.3% of the ASP until 2021.

5. Exclusions include the 340 B drug discount mandate and Medicare Best Price.

6. Prior to 2018, all biosimilars were placed together on a different J-code from the reference biologic product. Biosimilars were paid the ASP of their own J-code plus 6% of the reference biologic's ASP. Under this structure, if a physician was going to purchase a biosimilar, he/she was incentivized to purchase the least-expensive drug within the generic J-code. "Reforms" effective on January 1, 2018, provided that each biosimilar product is given its own J-code. The policy represents classic "regulatory capture"; it eliminated price competition between biosimilars and did not restore it between biosimilars and the reference biologic (Syrop 2017; AJMC 2017).

7. This is for the biosimilar Remsima® (infliximab), launched by Orion in December 2013 as a generic version of Remicade® (infliximab), sold by Merck and used in the treatment of patients with rheumatoid arthritis, Crohn's disease, ulcerative colitis, and psoriasis (Mack 2015).

8. Commonly, this data source is known as the Purple Book.

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