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# An Opportunity with Challenges: Blueprints for Indication-Specific Pricing in the United States

Anna Kaltenboeck, M.A.

Raina H. Jain

Jennifer A. Ohn, M.P.H.

Peter B. Bach, M.D., M.A.P.P.

# Table of Contents

<b>Overview</b> .....	3
<b>Model 1: Pre-distribution Model – Packaging by indication</b> .....	3
<b>Model 2: Post-distribution Model (Conventional and Simplified) – Varying price along the supply chain</b> ..	5
Medical Benefit Drugs – Conventional supply chain.....	5
Medical Benefit Drugs – Simplified supply chain.....	6
Pharmacy Benefit Drugs – Conventional supply chain.....	7
Pharmacy Benefit Drugs – Simplified supply chain.....	8
<b>Model 3: Post-distribution Discount Card Model – Using copayment and coinsurance cards</b> .....	8
Medical Benefit Drugs – Using copayment and coinsurance cards.....	9
Pharmacy Benefit Drugs – Using copayment and coinsurance cards.....	10
<b>Discussion</b> .....	10

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## Overview

Interest in value-based pricing has increased in recent years as an analytic alternative to current pricing methods that are distorted by financial incentives across the industry and supply chain.<sup>1-4</sup> Because value-based pricing links a drug's price to the magnitude of the benefit it provides, the approach must accommodate the frequent reality that a single drug can have different benefit profiles in different conditions. For instance, one study describes a four-fold difference in the value-based price for Roche's drug Herceptin (trastuzumab) when used in different indications (metastatic and adjuvant HER-2 positive breast cancer).<sup>5</sup>

A solution to this problem is for Herceptin to have two prices, one for its metastatic indication, and another for its adjuvant indication. Termed "indication-specific pricing" (ISP), this approach is being tested by ExpressScripts and CVS Caremark, who each announced that they had implemented strategies to manage certain drugs according to price relative to indication-specific value.<sup>6</sup> Its advantages aside, ISP requires mechanisms to reimburse by indication, which are hampered by the complexities of drug purchasing and delivery.<sup>7</sup> In the absence of more formal pathways, we propose several approaches that rewire existing reimbursement conventions as alternatives to facilitate ISP. These alternatives can be broadly categorized into three models, with each model distinct in the point of the supply chain at which payment and reimbursement for a drug diverges by indication:

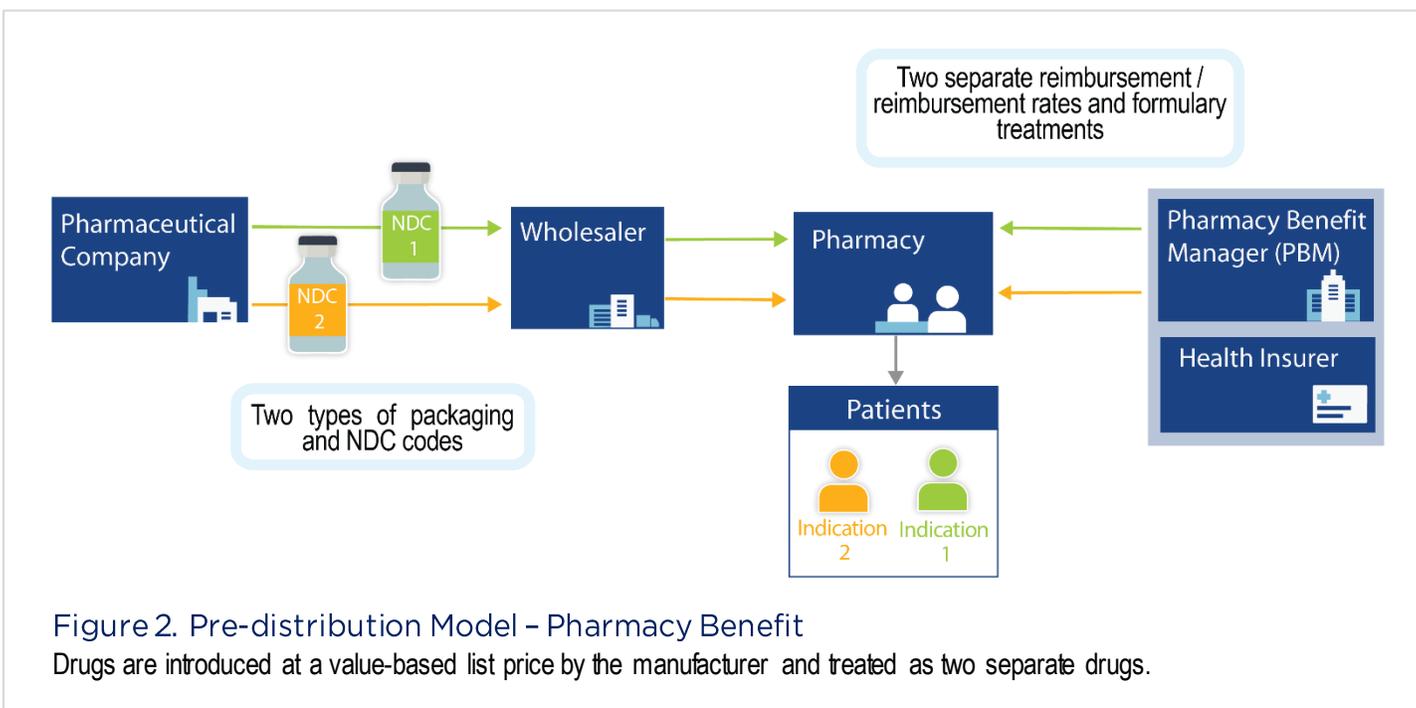
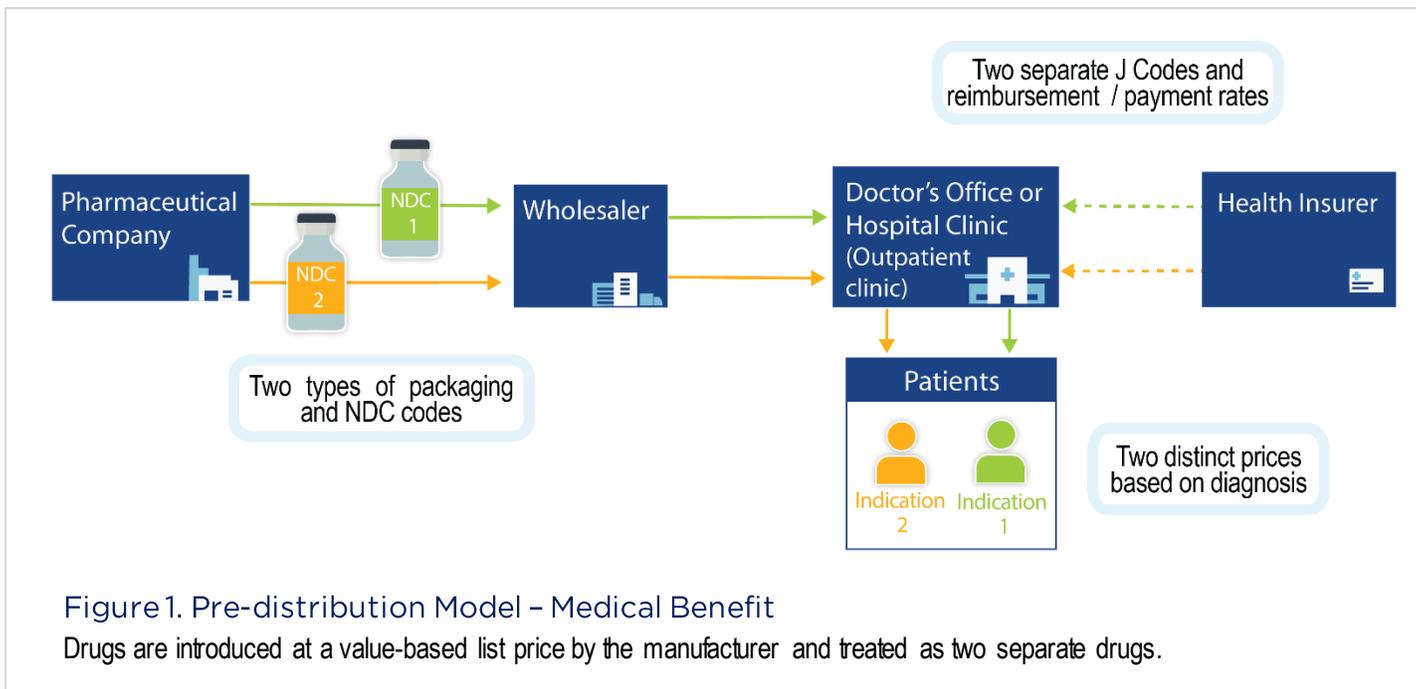
1. Pre-distribution Model – Packaging by indication
2. Post-distribution Model (Conventional and Simplified) – Varying prices along the supply chain
3. Post-distribution Discount Card Model – Using copayment and coinsurance cards

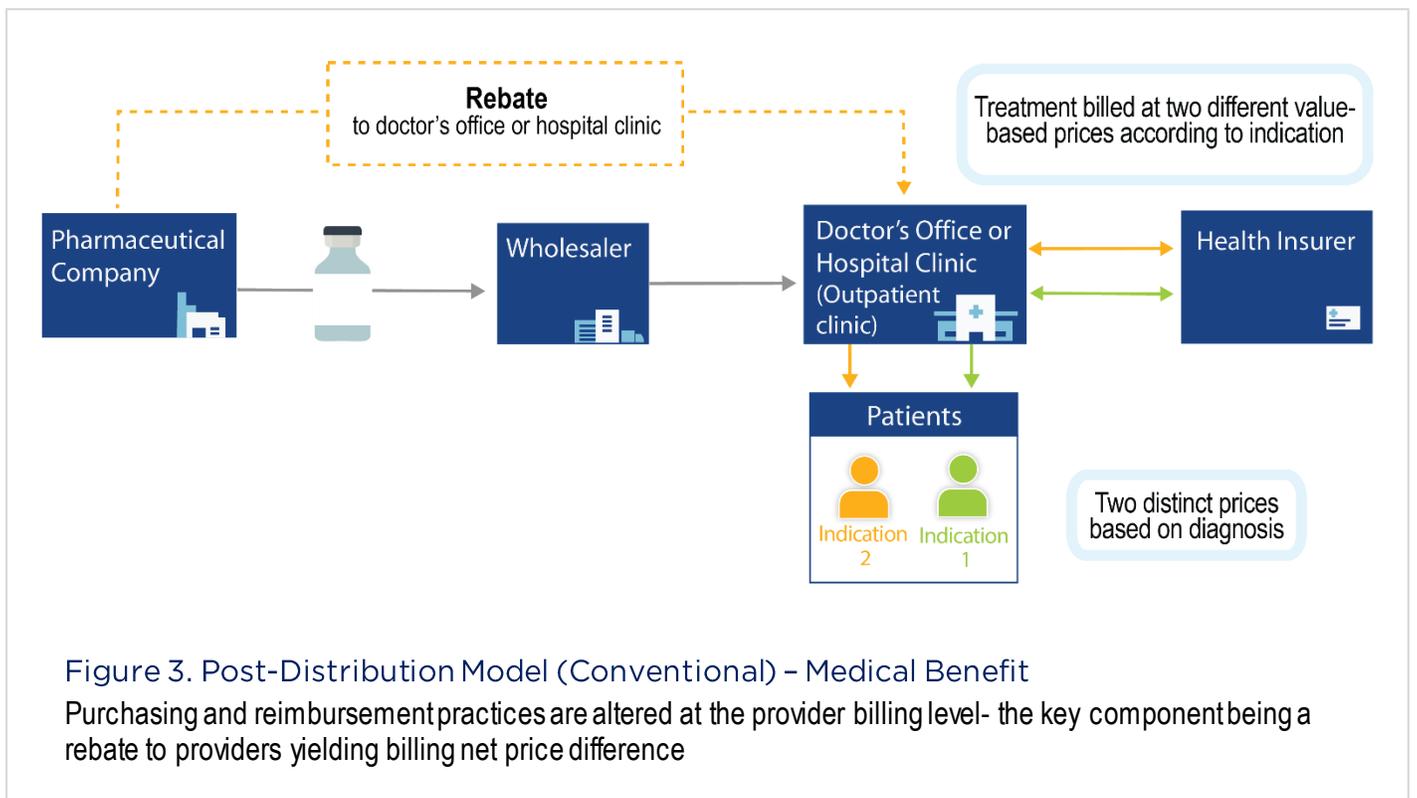
Within these models, mechanisms are further tailored, depending on whether the therapy is covered by the pharmacy benefit or the medical benefit.

## Model 1: Pre-distribution Model – Packaging by indication

**Overview:** The most straightforward approach to indication-specific pricing for a drug approved for two different indications is to simply treat it as two different drugs (**Figure 1, Figure 2**). This would require two types of packaging, unique sets of National Drug Codes (NDC)<sup>8</sup> for each of the packages, and for injectable drugs, two different Healthcare Common Procedure Coding System (HCPCS) J codes. This requires manufacturers to produce packaging according to indication and U.S. Centers for Medicare and Medicaid Services (CMS) to assign separate J Codes, which contrary to convention. Average Sales Price (ASP) and Medicaid Best Price reporting would be separate as well, giving the drug two separate reimbursement and payment rates. Using this approach, the manufacturer would introduce the drug at a value-based list price for each indication. This would allow different formulary treatment of the drug by indication and would also align patient out-of-pocket (OOP) costs with the value of the drug in each indication.

**Challenges and limitations:** There are three potential challenges to this model. For medical benefit drugs, CMS would need to assign unique HCPCS J codes for each indication. The availability of one product at multiple price points also presents opportunities for fraud and diversion. With ill intent, medical offices or pharmacies could obtain the drug packaged for the lower priced indication, but then dispense or deliver it to patients with the higher priced indication, charging the patient and insurer at the higher reimbursement rate associated with it and pocketing the difference. The more closely monitored prescribing is, the lower the risk of such fraud; if perpetrated in government programs it would constitute a false claim. This type of diversion should be nearly impossible in the context of drugs customized to the patient, such as CAR-T therapies, where the chain of custody and manufacturing is specific to a patient.





## Model 2: Post-distribution Model (Conventional and Simplified) – Varying price along the supply chain

**Overview:** Another approach to implement ISP is to alter purchasing and reimbursement practices within the supply chain. This approach would have different details depending on whether the drug is paid for through the medical benefit or pharmacy benefit. In either case, the essential feature is a rebate after administration or dispensing, paid in a manner that yields different net prices by indication.

An alternative to operating within the existing supply chain is to simplify it, particularly as it relates to the last step in which providers and pharmacies acquire the product before administering or dispensing it. Instead, a large-scale distributing intermediary would differentiate the product by indication and then match distribution to individual patients who are to receive it. This intermediary would also reconcile the price differences between indications.

### Medical Benefit Drugs – Conventional supply chain

Achieving multiple prices for a single drug that is administered in the doctor's office or hospital outpatient clinic (e.g., paid for by the medical benefit) begins with the provider purchasing the drug at a single price (Figure 3). The provider then differentiates the net price of the drug by billing according to indication. For instance, the provider would bill the insurer at the full cost of the drug if used for the higher-value indication. But for the lower-priced indication the provider would bill the insurer a reduced amount, equating to the value-based price for that indication, and would bill the remaining portion to the manufacturer and receive a rebate. Both approaches would include the customary proportional markup, known as "Buy-and-Bill", but index it on the ISP. This approach would keep the provider whole on the purchase of the drug, but the provider's mark-up would be based on the lower-priced indication. Patient co-

insurance would align with the drug's price for that indication, as it is based on the reimbursed amount from the insurer.

A related approach would have the insurer reimburse the provider in full, with no variation in mark-up. The insurer would then reconcile the price with the manufacturer through a rebate arrangement. Although the provider would likely receive the mark-up on the higher priced indication and the patient co-insurance would be based on that as well, the approach reduces billing complexity and offers economies of scale that providers are too decentralized to capture.

### Medical Benefit Drugs – Simplified supply chain

Rather than reimbursing the doctor's office or hospital outpatient clinic for drugs they purchase and mark up, payers could instead require that providers order and receive the drug from a specialty pharmacy or wholesaler on behalf of the patient (**Figure 4**). Once it is administered to the patient, the physician's office would be responsible for submitting a claim to the payer for the services rendered in administering the drug, including the diagnosis code. However, they would not bill for the drug itself; instead, the "distributor" would submit a separate claim to the payer for the drug. The payer would then reimburse this distributor based on ISP, and the manufacturer would provide them with a rebate or chargeback for the difference with the purchase price. In part, this model has already been tested by private payers (known as "white bagging"), and in the form of the Competitive Acquisition Program (CAP), in which claims for medical products and devices were submitted by the distributor to Medicare Part B.<sup>9</sup>

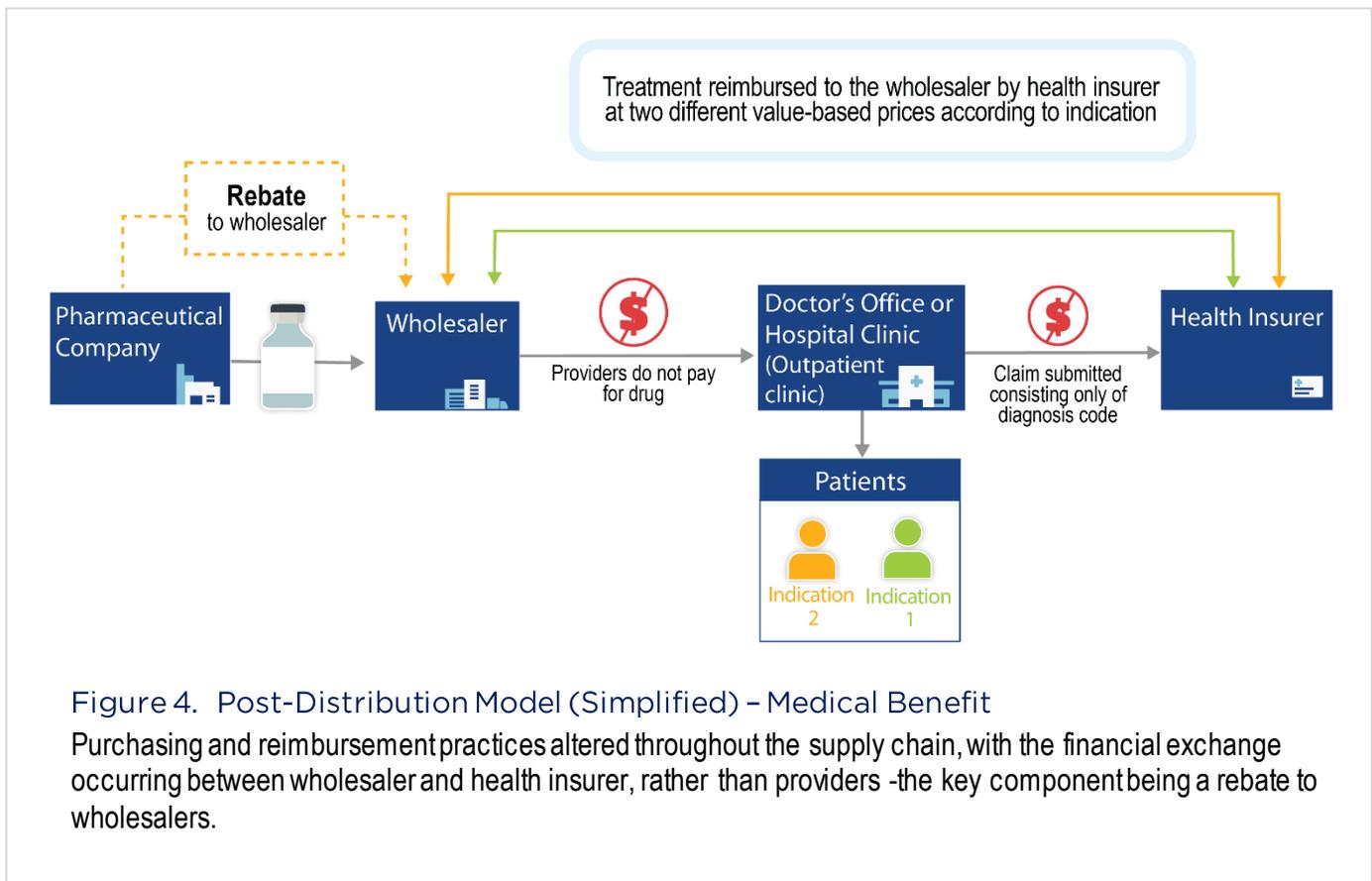


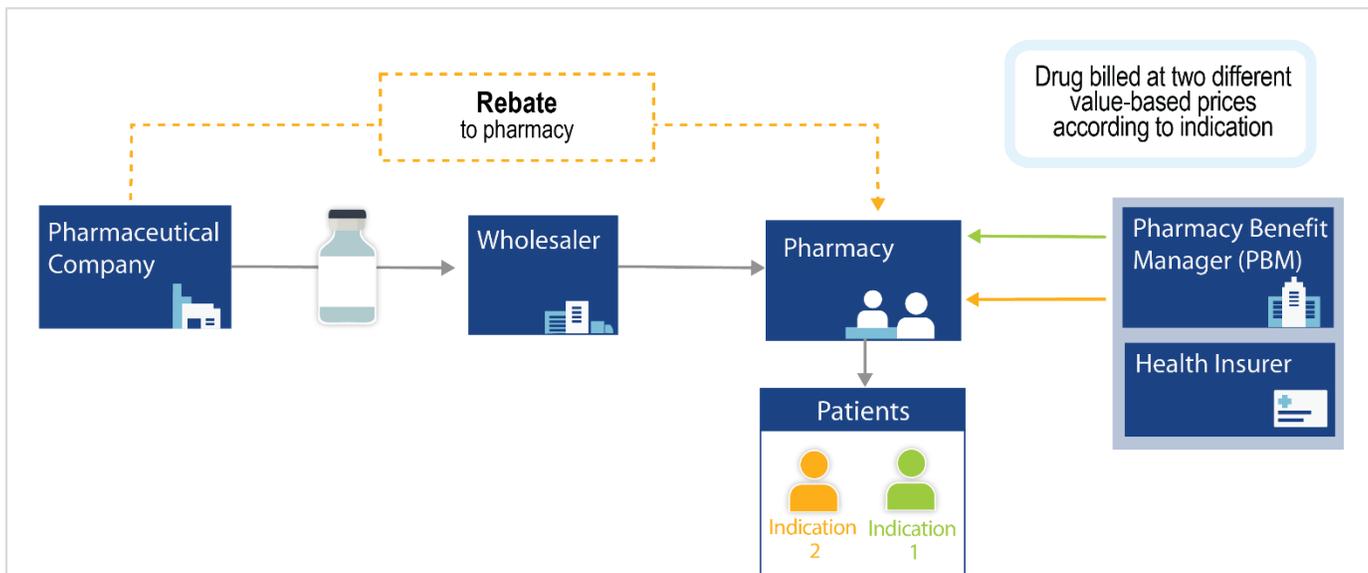
Figure 4. Post-Distribution Model (Simplified) – Medical Benefit

Purchasing and reimbursement practices altered throughout the supply chain, with the financial exchange occurring between wholesaler and health insurer, rather than providers -the key component being a rebate to wholesalers.

**Challenges and limitations:** Both variations of this model face technical pitfalls. One is that to implement ISP, diagnosis must be tracked, and this is not currently a core capability of distributors. To address this, a third party to collect diagnosis codes or analyze claims from the distributor and the physician's office would need to be involved. More complicated are the issues of Average Sale Price (ASP) and Best Price. Unless exempted by CMS through a waiver that exempts indication-specific payments from the ASP calculation, reimbursement for physicians not participating in the model would erode. Without similar provisions for Best Price, manufacturers might also prefer to avoid taking this route. Additionally, the storage and handling of some specialty drugs makes white-bagging burdensome for physicians.

### Pharmacy Benefit Drugs – Conventional supply chain

As with medical benefit drugs, prescription (pharmacy) benefit drugs (e.g., those dispensed to the patient by pharmacies) could have indication-specific prices by altering reimbursement after they are dispensed (**Figure 5**). Specialty pharmacies, which have the capability to capture and track indication with claims, would obtain contracted reimbursements from the PBM that vary by each indication, and then collect a rebate from the manufacturer for the lower-priced indication. One benefit of this approach is that patient OOP would be determined based on the indication-specific rate from the PBM, resulting in a lower payment burden for patients using the drug for the indication in which it is less effective.



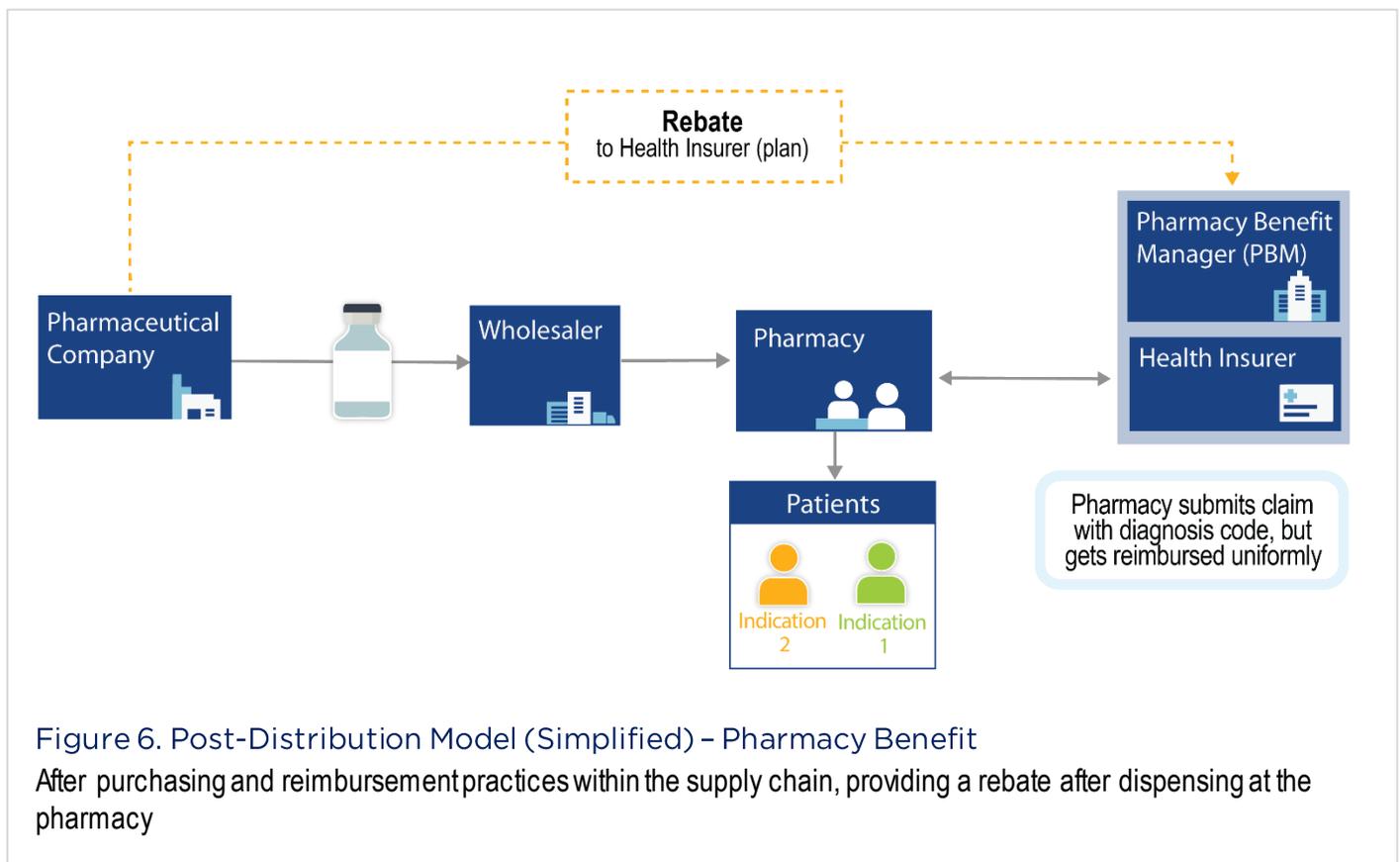
**Figure 5. Post-Distribution Model (Conventional) – Pharmacy Benefit**

After purchasing and reimbursement practices at the pharmacy billing level to the PBM, with the key component being a rebate to pharmacy yielding billing net price difference

Alternatively, the PBM could provide full reimbursement to the pharmacy regardless of indication, and then obtain indication-specific rebates from the manufacturer. Under some interpretations of the law, rebates to PBMs need not be reported as part of Best Price, which may advantage this approach. However, unless these rebates are factored into the patients' payments at point of sale, they would likely face higher OOP costs for the lower-priced indication than under the pharmacy-based approach.

### Pharmacy Benefit Drugs – Simplified supply chain

For pharmacy benefit drugs, this approach would rely on a limited number of specialty pharmacies with exclusive distribution rights to ship the drug directly to the patient (Figure 6). The differential prices would be reconciled at the specialty pharmacy level. In this scenario, the specialty pharmacy would submit a claim to the plan with the diagnosis code, and the plan would be responsible for paying a negotiated price and dispensing fee to the pharmacy. The plan would then report the claims with the lower-priced indication to the manufacturer, which would issue a rebate to attain the ISP. This model is particularly appealing for Part D plans (PDPs) – no statutory changes would be needed, and manufacturers already pay rebates to PDPs

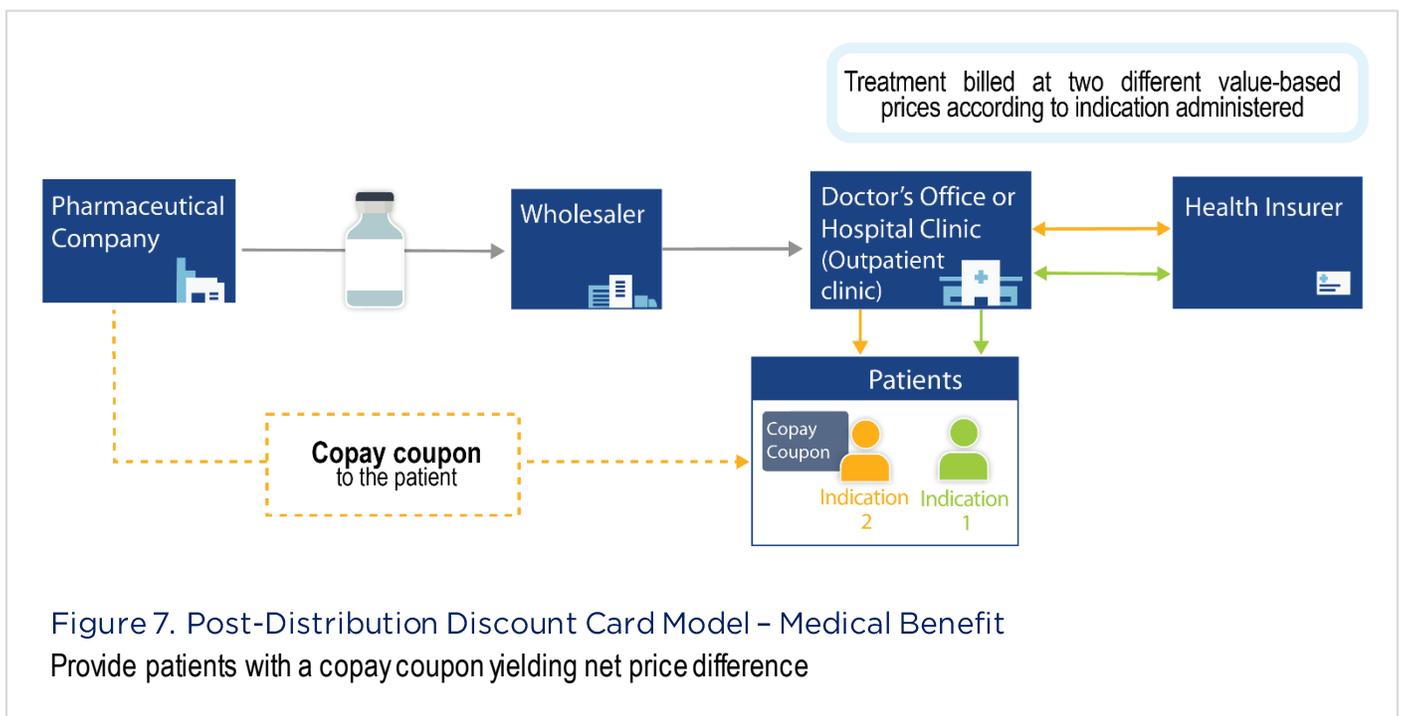


**Challenges and limitations:** Even more so than for drugs administered in the doctor's office or hospital outpatient clinic, the tracking of indication poses a significant challenge for prescription drugs. At least in the near term, this limits opportunities to specialty pharmacies, unless retail pharmacies begin to develop this capability. Further complexities also include the need for a waiver or alternative reporting mechanism to address implications for Best

Price, although this is not a concern in Medicare Part D, as discounts and rebates in Part D are not incorporated into Best Price determinations.

### Model 3: Post-distribution Discount Card Model – Using copayment and coinsurance cards

Manufacturer copayment coupons and coinsurance cards serve to lower a drug's net price by replacing part or all of the patients' OOP payment with funds provided by the drug's manufacturer. This means that by varying the amount of copay support it provides by indication, a manufacturer could align net price with ISP. In effect, a patient obtaining a drug for its higher priced indication would be charged a lower co-insurance amount by the payer than a patient using it for the lower-priced indication. The difference in patient OOP would be covered through a copayment coupon from the manufacturer. Today's transactions involving copayment cards are often invisible to providers and pharmacies, so that they would not be burdened administratively, or face any risk that the cards are not delivered or result in payments. Copayment support is also not included in the determination of ASP or Medicaid Best Price, reducing the complexity of this approach.



### Medical Benefit Drugs – Using copayment and coinsurance cards

Under the medical benefit, the provider and insurer would operate as they do currently for the higher-priced indication (**Figure 7**). For the lower-priced indication, the insurer would reduce the amount it pays to the provider to attain the net price (to the insurer) appropriate for that indication. The remaining difference between this net price and the list price would then be added to the patient's coinsurance obligation. To pay for this, the patient would reimburse the provider by using a manufacturer copay or coinsurance assistance card, which would act as a voucher for the provider to send to the manufacturer in exchange for payment. Because this approach directly focuses on patient

OOP costs, the manufacturer and insurer could construct such an arrangement to also allow a lower patient out-of-pocket obligation for the lower-priced indication. The provider would be kept whole, as the patient obligation would be simply calculated as the appropriate share of the contracted reimbursement amount.

### Pharmacy Benefit Drugs - Using copayment and coinsurance cards

Under the pharmacy benefit, a similar transaction would take place, in which the pharmacy would receive reimbursement from the PBM that would vary based on the indication for the dispensed medication (**Figure 8**). For the lower value indication, the out-of-pocket expense for the patient would be higher, but the manufacturer would provide a coinsurance coupon or card that would cover that larger amount.

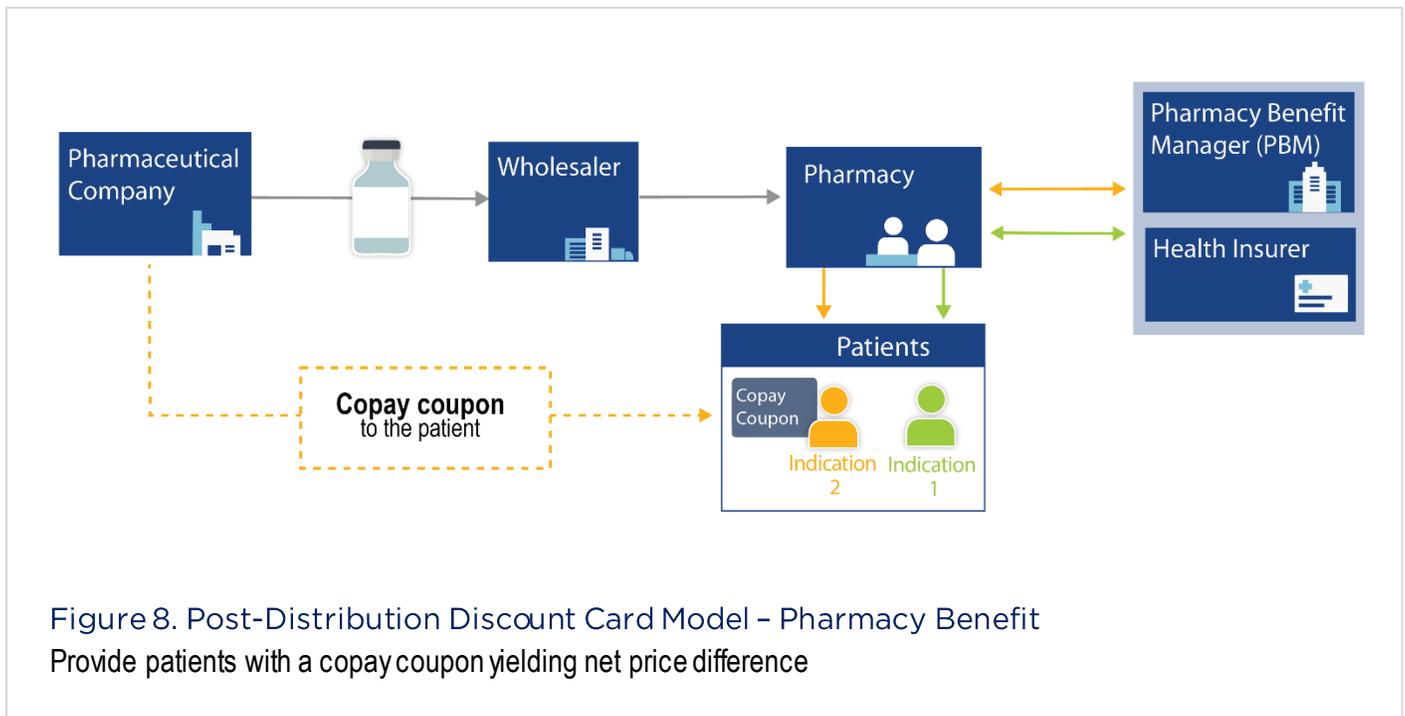


Figure 8. Post-Distribution Discount Card Model - Pharmacy Benefit  
Provide patients with a copay coupon yielding net price difference

**Challenges and limitations:** The approach would require that insurers be able to take on coinsurance charges whether or not the patient has exceeded their out-of-pocket maximum, which may conflict with some state and Federal regulations. Another drawback is that copayment support to Medicare beneficiaries violates the anti-kickback statute, limiting this approach to only commercially insured patients. Finally, copayment and coinsurance cards remain uncommon in outpatient practice settings, which lack the technology that allows pharmacies to process them. However, use of prepaid debit cards, which have become increasingly popular among manufacturers in lieu of copay coupons, could be feasible in this setting.

### Discussion

Value-based pricing rests on the idea that when a drug is priced according to evidence of its value, payers make them available without restrictions driven by financial incentives, offering access to those patients who would stand to benefit. However, in many instances, the benefits and harms of many recently approved drugs vary substantially

across their indicated uses, and in comparison, with existing treatment options. Indication-specific pricing aims to address this problem by creating separate mechanisms for reimbursement depending on a drug's use. Both manufacturers and patients benefit from less onerous coverage restrictions when a drug is used for lower value indications.<sup>10</sup>

A shift to ISP requires adjustment to existing purchasing and reimbursement practices. Although the implementation models we have outlined offer options for a path forward, each requires that its participants be “bought in”, which runs afoul of a basic tension between interests of business and policy. ISP requires that prices be value-based, which in and of itself represents a departure from the status quo. Absent an explicit link between a drug's benefits and other features to the price in a given indication, implementing the proposed models will do little to disrupt the persistent distortions in the purchasing and reimbursement environment. Chandra and Garthwaite summarized this potential risk, noting that monopolists can capture more surplus, leaving less to the consumer, if they can price maximize by indication.<sup>11</sup> In other words, only by aligning prices with benefits in each indication using a systematic analytic approach can the surplus be appropriately shared between the manufacturer, patient, and payer. Particularly for high-priced drugs with multiple indications, that is often not the case, and it would be financially unfavorable in the short term for the manufacturer and other stakeholders to depart from the existing pricing model. At the same time, implementation must be feasible under existing business models in order to be practical.

Compatibility with existing practice is a barrier for ISP and addressing it will likely entail resource and capital commitments only possible for organizations with sufficient size and scale, at least initially. A number of the proposed models may be too complex to be practical, or only of interest for specific scenarios, particularly in the short term. Those that are more broadly feasible will need strong political and organizational will to justify the investment and properly scope the commitments. Initial efforts would likely be focused on the drugs with the highest unit prices and the greatest differences in value by indication, with the ambition of scaling up at a later time. Even so, the investment would likely only make sense for the largest players - payers, providers, pharmacies, and providers with the scale to implement the changes and to benefit from them.

However, recent policy actions may prove helpful in easing the transition. Development of HCPCS and NDC coding standards that allow claims to simultaneously capture the drug and its indication would allow payers and other intermediaries to more easily develop the tools needed to efficiently determine reimbursement levels. CMS has recently signaled that it is exploring ways to enhance Part D plans' abilities to implement ISP. A proposed demonstration program in Part B that resuscitates the Competitive Acquisition Program may also build operational expertise across the industry and offer and opportunities to put ISP into practice. In August 2018, CMS announced it will allow indication-based formulary design for Medicare Part D to take effect in 2020.

Industry, regulators, and legislators can take further steps to enable ISP. One is to learn from and build on the experience CMS has gained with Kymriah (tisagenlecleucel), which is currently being reimbursed at different prices for its two indications. Efforts to alter the price of Avastin (bevacizumab) and Tecentriq (atezolizumab) when used in together, rather than as single agents may help to build this momentum. Another is to explore the development of a system for implementing HCPCS that require certain ICD-10 codes to qualify for reimbursement. Pilot programs by the Center for Medicare and Medicaid Innovation (CMMI) and state Medicaid programs may offer practical opportunities to explore implementation.

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