Shifting Drugs from Medicare Part B to Part D

Learnings from Medicare Coverage of Vaccines

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Introduction

Spending on Part B medicines represented 4% of total Medicare spending in 2015[i] but a strong specialty drug pipeline and growing number of approvals, coupled with higher utilization rates and increased Part B enrollment, have drawn attention to the Part B program by stakeholders across the healthcare industry.

The Trump administration has increasingly focused on managing Part B drug costs, including exploring opportunities to bring Part D and private market tools into the benefit, such as utilization management and review tools (e.g., formularies, prior authorization, step edits). The goal would be to foster competition among drugs with similar health effects and to drive providers and patients towards lower-cost options. In its drug pricing blueprint[ii] released on May 11, 2018 and the subsequent request for information released May 16, 2018, the administration included a proposal that envisions leveraging Medicare Part D plans' negotiating power to obtain deeper discounts and price concessions for certain drugs covered under Part B. Specifically, the blueprint contemplates a pilot program to move certain products or product classes from Part B into Part D.

Few details are available on the parameters for the proposed shift of Part B drugs under Part D, but such a policy modification would likely present a significant change for providers in terms of revenues and their role in purchasing, storing, and billing for physician-administered drugs. This transition could also result in unintended patient access barriers caused by differences in payment, cost-sharing, reimbursement, and settings of care in Part B and Part D.

Medications for seniors are covered by Medicare Part B or Part D, depending on how the product is administered. Under the Part B program, drug coverage is generally provided for medications administered by a healthcare professional in a physician's office and "incident to" a physician's service. The Part D benefit was designed to provide coverage for outpatient prescription drugs that are usually self-administered by the patient and are most often dispensed by a pharmacy.

Similar to physician-administered specialty drugs, vaccines are also biologics that are generally not self-administered by patients and require complex storage and handling to ensure safety. Due to a long history of incremental statutory changes by the United States Congress, coverage of vaccinations routinely recommended for adults age 65 and older is now divided between Part B and Part D. As such, the experience of Medicare coverage of vaccines offers an informative example of how covering provider-administered products under what is largely an outpatient retail drug program can affect patient access and create administrative, financial, and operational burdens for patients and providers.

Understanding the vaccines experience is instructive for policymakers and the public to anticipate the potential risks of shifting drugs from Part B to Part D. This paper reviews some of the operational and access challenges that patients and providers have faced with Part D

vaccines to illustrate the key considerations that should be examined by policymakers evaluating a policy to transition certain Part B drugs into the Part D program.

Background on Medicare Coverage of Vaccines

Coverage for individual preventive services, including immunizations, under Medicare was first added in 1980 and has expanded over time. Since 1981, Medicare gradually added vaccinations for influenza and pneumonia for all beneficiaries, as well as hepatitis B for medium- and high-risk seniors under the Part B benefit. However, since the enactment of the Medicare Modernization Act of 2003 (MMA), which created the Part D program, coverage for all other commercially available adult vaccines recommended for the Medicare population (e.g., shingles, Tdap, hepatitis A) has been available under Part D.

Despite high childhood vaccination rates, adult vaccination rates in the US continue to lag behind public health targets, including the Healthy People 2020 goals. Many factors contribute to low adult immunization rates, including limited public awareness, gaps in recommending vaccines for adults during healthcare visits, and complex insurance coverage for adult vaccines, among others. However, it is important to note that among Medicare beneficiaries, immunization levels are significantly higher for the products covered under Part B, such as influenza and pneumococcal (70.4% and 66.9% respectively)[iii], than those offered under Part D, like shingles (33.4%) and Tdap (26.6%)[iv]. This potentially signals that access challenges associated with Part D coverage of vaccines present a barrier to uptake.

Key Learnings and Considerations

Since most vaccine products are administered by a healthcare provider, beneficiaries may receive their Medicare Part B- or Part D-covered vaccinations in a physician's office or, if state scope of practice laws permit, from a pharmacist. Due to differences in benefit design and contractual and network arrangements under Part B versus Part D, billing, reimbursement, and cost-sharing for vaccines can differ dramatically between the two programs. CMS has issued guidance on some workaround options[v] to help address administrative challenges, such as routinely using white- or brown-bagging[1], but these approaches have been insufficient to address provider and patient concerns about cost sharing, handling, and patient safety, and have not been shown to result in meaningful vaccination uptake.

More than a decade after the creation of the Part D program and the split coverage of vaccines between Medicare Parts B and D, the issues outlined below suggest that a potential shift of complex physician-administered therapies from Part B into Part D could result in similar operational and access challenges.

[1] Brown-bagging is when a patient obtains a drug or vaccine from a pharmacy and takes it to the physician's office for administration. White-bagging is when a pharmacy ships the product directly to the physician office on demand in advance of the patient's visit for administration.

Billing and Reimbursement for Vaccines

Under Part B, immunizers administer eligible vaccines and submit a claim to their local Medicare Administrative Contractor (MAC) for both the vaccine and its administration. However, under Part D, standalone Prescription Drug Plans (PDPs) typically contract with pharmacies, not physicians, which results in billing and reimbursement challenges for providers. Even Medicare Advantage organizations, which manage both medical and prescription benefits, generally include physicians in their networks for medical services only, and therefore physicians may not be able to bill the plan directly for Part D vaccines. When providers are unable or unwilling to file Part D vaccine claims, this places the burden on patients to pay their prescriber up front and submit a claim to their Part D plan for reimbursement.

Since they are not included in the Part D plan's network, physicians who prescribe and administer pharmacy benefit vaccinations may be unable to verify beneficiary coverage and cost-sharing liability. In a survey conducted by the Government Accountability Office (GAO), 8 in 10 physicians cited the amount of time used to identify beneficiaries' coverage and submit claims as a barrier to administering Part D vaccines.[vi] A number of third-party vendors have emerged to fill this reimbursement gap and offer services to providers to facilitate benefit verification and online billing for Part D vaccines. However, according to a recent survey[vii], only 9% of responding family physicians and general internists were aware of these services, and of those who were aware, only 46% reported being members.

As a result, more than half of providers[viii] who prescribe vaccines to seniors refer beneficiaries to pharmacies to purchase them. Pharmacists have online access to real-time systems to verify beneficiaries' coverage, determine the cost-sharing amount, and bill Part D plans. The pharmacist in turn either administers the vaccine directly or supplies it to the prescribing physician or patient via white- or brown-bagging, respectively. This added step can serve as a barrier to access and adherence and can be particularly challenging in rural areas with provider and pharmacist shortages. Moreover, medications may be inadvertently damaged or compromised during shipping or patient transit, leading to safety concerns, liability issues, and potential waste.

Physicians would likely face similar billing and reimbursement barriers if Part B drugs were covered under Part D without addressing these associated issues. Most categories of Part B drugs dispensed by entities other than pharmacies are typically included in commercial insurers' medical benefits, rather than their drug benefits. Consequently, pharmacy benefit managers (PBMs) and other entities that administer drug benefits may not have relationships with physicians or experience with the particular circumstances unique to the provision of these drugs. Providers who currently administer Part B specialty drugs will likely have "out-of-network" status with Part D plans and increasingly rely on white-bagging for medication supply. In turn, large scale reliance on white-bagging for Part B drugs may present challenges with a pharmacy's ability to provide timely drug ordering. Additionally, complex Part B biologics that require dosing and other adjustments at the point of care could be difficult to properly administer under such a scenario.

Finally, expanding administration rights to pharmacists for certain Part B drugs may not be feasible due to patient safety concerns. After years of advocacy efforts, pharmacists are authorized to administer vaccines in all 50 states[ix] but still face restrictions in certain states on the types of vaccine they can administer and/or prescribing rights without a standing order arrangement with a physician. Any modifications of state scope of practice laws to allow pharmacists to administer other injectable or infused medications beyond vaccines will likely be an uphill battle, in part due to the rigorous adverse event monitoring and reporting that would be needed.

Storage, Handling, and Inventory Management

Reimbursement for Part D vaccines is a single payment inclusive of the vaccine ingredient cost, dispensing cost, and administration fee.[x] In the early years of the Part D program, physicians who administered Part D vaccines could bill Part B for the administration, separate from the cost of the drug, but since 2008 the separate reimbursement for vaccine administration has been eliminated.[xi] Moreover, under Part D, immunizers do not benefit from designated payment to cover storage and handling. Insufficient payment often leads providers to not stock and administer vaccines. Based on a GAO survey[xii] of physicians, nearly 70% chose not to stock the Part D-covered shingles vaccine, while only about 10% did not stock the Part B-covered pneumococcal vaccine.

This problem could be magnified in the case of Part B specialty drugs, as physicians are expected to properly store, manage, and handle these complicated medications. To compensate physicians for these overhead functions, Medicare adds a 6% add-on payment[2] to the reimbursement for the drug, which is based on average sales price (ASP). Shifting Part B drugs to Part D would eliminate this add-on payment that covers storage, handling, and inventory management. Under such a scenario, the Part D negotiated price would have to adequately compensate for both the drug administration and the administrative overhead, or else physicians may face financial barriers to administering these vital medications, potentially creating access issues.

Patient Cost-Sharing

For beneficiaries who have Part D coverage, the amount of out-of-pocket costs under Part D varies considerably by plan and depends on which phase of the benefit the beneficiary is in at the time of vaccine administration (e.g., before the deductible has been satisfied, in the coverage gap, or in the catastrophic phase), as well as the eligibility for Low Income Subsidies (LIS). This ambiguity about cost may discourage patients from getting vaccinated, despite recommendations from their provider and Advisory Committee on Immunization Practices (ACIP) guidelines. The GAO found that physicians report that beneficiaries decline shingles vaccinations, which are covered under Part D, much more frequently than pneumococcal vaccinations, which are covered by Part B, possibly due to affordability concerns.[xiii]

[2] The reimbursement is ASP plus 4.3% after accounting for sequestration

Moreover, since physicians do not have the capability to verify coverage and cost-sharing prior to Part D vaccine administration, the amount the physician charges may be different from the Part D plan's allowable charge, and the patient may become responsible for paying the differential (referred to as balance billing).

In the case of Part B and D drugs, beneficiary out-of-pocket costs also differ significantly between the two benefits, so the cost-sharing impact of a transition from Part B to Part D would vary by beneficiary, depending on their income and health status, as well as the availability of supplementary coverage. The issues of benefit variability, lack of transparency, and potential for balance billing could pose challenges for specialty drugs as is currently the case for vaccines.

Conclusion

Current experience with Medicare's split coverage of vaccines between benefit categories highlights obstacles that patients and providers may face should Part B drugs move under the Part D benefit structure. These obstacles – relating to billing and reimbursement, storage/handling and inventory management, and patient cost-sharing – may be contributing to lower adult immunization rates for Part D vaccines than for Part B vaccines.

Similar issues could arise for Part B drugs shifted to coverage under Part D. If not addressed appropriately, such a policy could create access barriers to drugs that, in some cases, patients have become accustomed to receiving under the Part B benefit. Reviewing the example of vaccine coverage under Part D provides insight into the challenges that would require careful examination and consideration if this policy proposal is pursued.

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