

# **Delinking US Antibiotic Payments through a Subscription Model in Medicare**

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## DISCLOSURES

**Mark B. McClellan, MD, PhD**, is an independent board member on the boards of Johnson & Johnson, Cigna, Alignment Healthcare, and Seer; co-chairs the Accountable Care Learning Collaborative and the Guiding Committee for the Health Care Payment Learning and Action Network; and receives fees for serving as an advisor for Cota and MITRE.

## BRIEF

# Delinking US Antibiotic Payments through a Subscription Model in Medicare

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### ABSTRACT

The Center for Disease Control and Prevention recently reported on the urgency of antimicrobial resistance, a public health issue that impacts nearly three million Americans each year. New treatment approaches could help address the problem, but antibiotics remain an unattractive area for development due to concerns about potential return on investment (ROI). Alternative pricing and reimbursement mechanisms for antibiotics have the potential to align ROI with public health value, while encouraging appropriate use. This analysis examines a subscription payment model within Medicare as a solution to lack of development incentives. If reimbursement for antibiotics is optimized through the creation of new payment pathways, the development process will be de-risked for manufacturers, leading to increased innovation and a more robust pipeline of antimicrobial products, which will be critical to effectively combat antimicrobial resistance.

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# Introduction

The public health urgency related to antimicrobial resistance (AMR) continues to grow.<sup>1</sup> While infections resistant to last-line antibiotics remain rare, they are occurring more frequently, and physicians are encountering a growing number of infections that are unresponsive to most traditional treatments.<sup>2</sup> New treatment approaches could help address the problem, but antibiotics remain an unattractive area for development due to concerns about potential return on investment (ROI). Even companies whose innovative antibiotics reach the market struggle to generate adequate revenues.<sup>3</sup>

Insufficient ROI for manufacturers of high priority antibiotics reflect a combination of factors. With traditional fee-for-service (FFS) payment, higher revenues require higher unit prices and/or increasing volume of use. Both are challenging for antibiotics. First, hospital willingness to pay higher prices for new antibiotics is limited due to prospective reimbursement and the availability of low-cost generics that are still effective against most infections and are often first and second line therapies. Such payment decisions are not likely to reflect value that extends beyond the hospital stay, including the “externality” benefits of effective antibiotics, which include preventing transmission of resistant infections to other people, as well as diversity, enablement, insurance and spectrum values. Second, antimicrobial stewardship programs seek to limit uses of novel antibiotics to appropriate cases. In addition, the market for new antibiotics is challenged by a lack of clinical superiority evidence due to ethical and practical issues with conducting superiority trials in patients with life-threatening resistant infections.

For Fiscal Year (FY) 2020, the Center for Medicare and Medicaid Services (CMS) finalized a new inpatient prospective payment system (IPPS) rule that improved reimbursement for qualified antibiotics.<sup>4</sup> The new rule modified provider reimbursement for antibiotics through the New Technology Add-on Payment (NTAP) from 50% to 75% of costs that exceed the set diagnosis group-related (DRG) payments. The FY 2020 IPPS rule also made qualification for the NTAP less onerous for antibiotics that receive a qualified infectious disease product (QIDP) designation from the U.S. Food and Drug Administration (FDA). For QIDP products, the “substantial clinical improvement” criterion is waived, so QIDP antibiotics only have to demonstrate that the product cost would exceed that of the DRG that it would be used for and that the product is new.<sup>5</sup> The FY 2020 IPPS rule also adjusted the severity level designations for a number of antimicrobial resistant infections, meaning that hospitals’ reimbursement will be increased to reflect the additional resources needed to care for the patient, which may include higher priced drugs. While these are welcome changes, they maintain volume-based reimbursement, which is not in line with stewardship and conservation of these important drugs.

Alternative pricing and reimbursement mechanisms have been applied to other areas of healthcare, and have the potential to align antibiotic ROI with public health value, while encouraging appropriate use. Several proposals from global stakeholders have suggested some form of a “delinkage” model, in which revenue for an antibiotic is de-linked from sales volume. Delinkage mechanisms shift from paying per use toward paying for availability of the antibiotic. Proposals for such models have included various forms of market entry rewards as well as population- and value-based payment mechanisms.<sup>6-10</sup>

Reflecting the delinkage principle, in June 2018, former FDA Commissioner Gottlieb suggested a model in which the CMS would pay a subscription or licensing fee for priority antibiotic access for Medicare beneficiaries.<sup>11</sup> Under such a proposal, FDA and CMS would undertake complementary steps to determine eligibility for this new pathway, and drugs in clinical development that meet the criteria could receive subscription payments from CMS after market entry. Payments to the manufacturer would not be a function of volume of use, but rather would involve payment for an adequate supply of the drug reflected in meeting certain milestones, including continued availability when needed.

Purchasing antibiotics on a subscription basis is one approach for achieving delinkage between revenue and volume. This type of model has recently gained attention through use by state Medicaid programs for hepatitis C drugs, though these are not true subscription models since they feature volume-based payment with a near-zero net price beyond a spending cap.<sup>12</sup> A subscription model would provide access to the antibiotic for a flat and predictable recurring payment, potentially linked to antibiotic performance goals. Paying for the availability rather than use of a priority antibiotic would enable several benefits. First, it would guarantee a revenue stream for a product, regardless of actual volume of use. Second, it would potentially enable payments to reflect additional components of population health value beyond that provided to patients who actually use the drug. Third, it would eliminate the need for companies to drive increased uptake, aligning their payments with support of effective stewardship. Finally, such a mechanism could support the collection of data on an antibiotic's real-world effectiveness in addressing the spread of resistance in the covered population.

However, details on how this type of model might work in a major public insurance program like Medicare are unclear. To address this gap, the following framework describes the potential structure of a population-based Medicare payment model for priority antibiotics.

## Sustaining High-Priority Antibiotics through Payment Reform

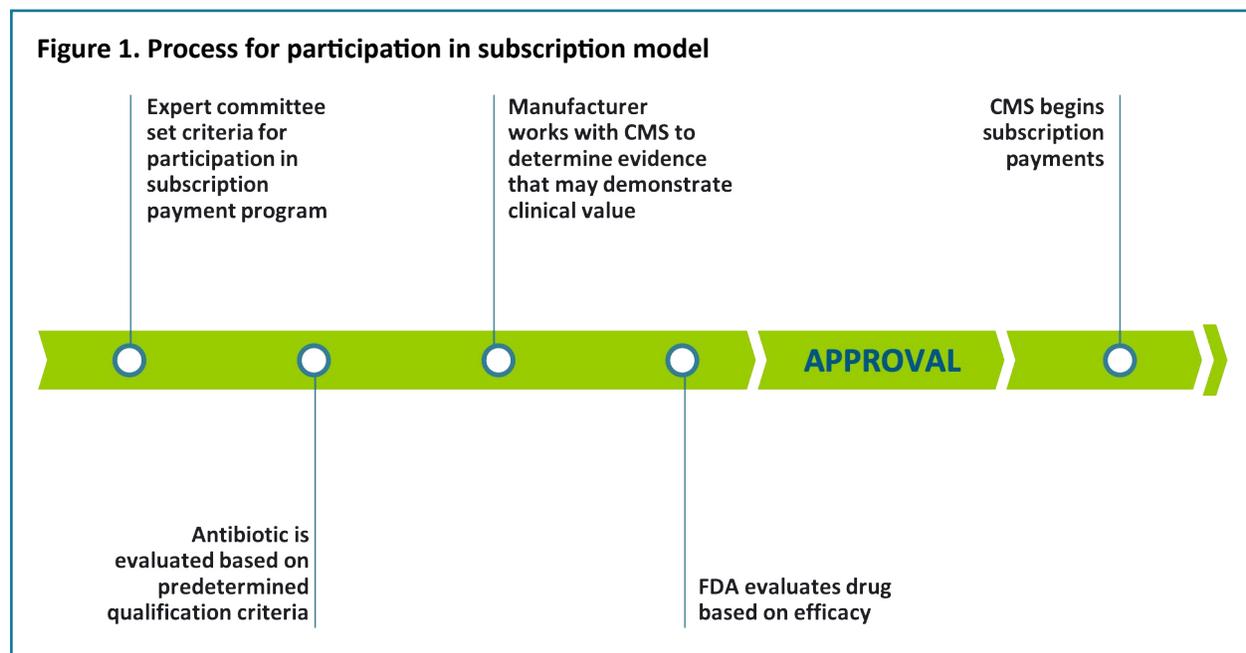
One path for developing a subscription model would be through the use of Medicare's authority to pilot new payment models in the Center for Medicare and Medicaid Innovation (CMMI), or through section 402 authority. The project could test the design of a subscription model for antibiotic products as an alternative to current FFS payments, to achieve not only the benefits of improved outcomes for patients, but also the population health benefits of diminished AMR, including fewer resistant infections and more avoided infections. We illustrate such a model here, reflecting approaches used or proposed in other CMMI payment pilots. The model would allow for a regular fee to be paid to the manufacturer through a competitively bid third party in exchange for access to the antibiotic. Payments would be adjusted based on measures reflecting the population value of the antibiotic rather than the volume of sales.

## MODEL ELIGIBILITY

This subscription model would initially be implemented to encourage the availability of high-priority drugs for resistant infections. Other antimicrobial incentives, such as the Generating Antibiotic Incentives Now (GAIN) Act, have included eligibility for any FDA-designated QIDPs intended to treat serious or life-threatening infections caused by bacterial or fungal pathogens, including infections caused by resistant pathogens.<sup>13</sup> Some stakeholders have argued that these criteria may be too broad; for a pilot with a substantial subscription payment, the initial focus might be on very promising products for the highest priority conditions to keep developers focused on areas of needed innovation. More stringent eligibility criteria might rely on the Center for Disease Control and Prevention (CDC) list of antimicrobial threats, restricting eligibility to products that target “urgent” or “serious” threats.<sup>14</sup> Alternatively, a broad subscription pilot might include less serious threats and lower subscription payments.

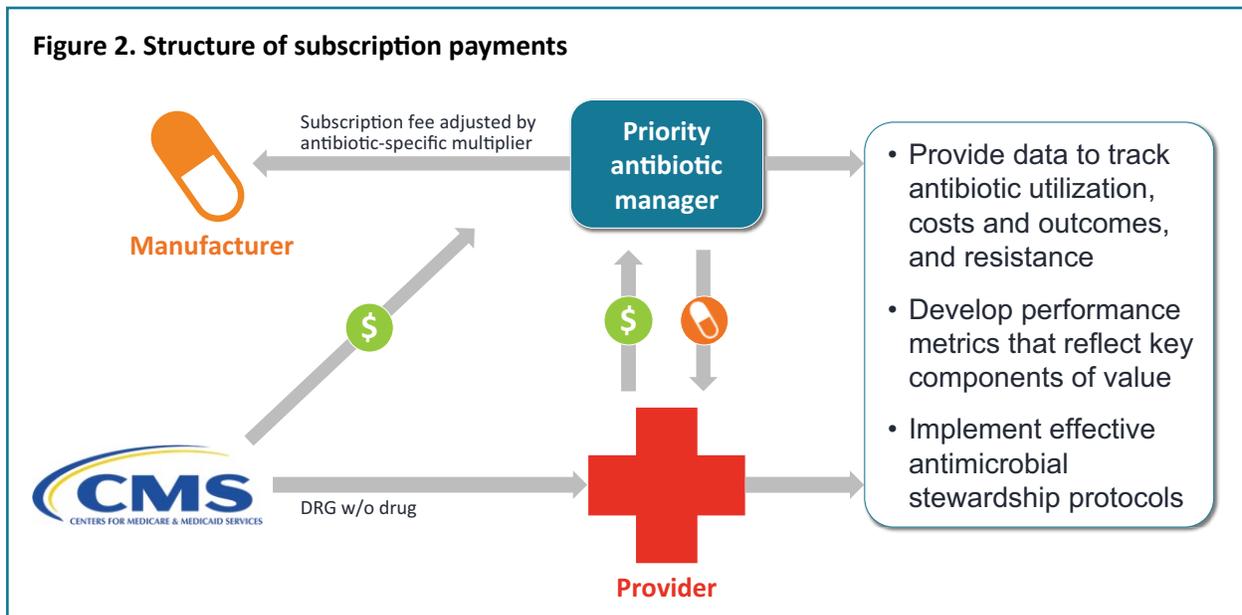
## QUALIFICATION FOR PARTICIPATION IN THE PAYMENT MODEL

Opportunities for manufacturer participation in this payment model should be clearly defined well in advance of drug approval, alongside FDA expedited review programs (e.g., Breakthrough Therapy, Fast Track), to have their intended effect on R&D investment. The manufacturer would meet with CMS during the development process to review likely expectations for qualification, such as determining what outcome evidence is needed for CMS coverage and for predictable review after the antibiotic is approved.<sup>15</sup> Manufacturers would also work with CMS, CDC, health care providers, and other payers to assure that needed post-market measurement and monitoring capabilities are in place (Figure 1).



## STRUCTURE OF PAYMENTS

This model would be applied in settings where serious infections are treated. For most medical products, hospitals make purchases from group purchasing organizations (GPOs), specialty pharmacy distributors, or direct from manufacturers on a volume basis. In contrast, this model would enable providers to obtain priority antibiotics through a population-based approach. Antibiotics could be acquired through a purchasing organization or “priority antibiotic manager” (PAM) that could contract on a subscription basis for acquiring a supply of the antibiotic, and distribute it to hospitals when appropriate. Some GPOs, specialty pharmacies, and other purchasing groups have this capacity now, for example to supply gene therapies and other specialized drugs to hospitals as an alternative to “buy and bill” payment. CMS could contract competitively with one or more such organizations to serve as a PAM to participating hospitals. The PAMs would be required to pay for the priority antibiotics on a subscription plus a fixed fee for data and outcomes tracking and reporting. This approach builds on recent proposals to rely on competing organizations to acquire and distribute Medicare Part B drugs to hospitals and physicians.<sup>16–18</sup> The PAM would negotiate a subscription rate with the antibiotic manufacturer, and the manufacturer would guarantee efficient access to the drug. Hospitals would then contract with the PAM for access to the antibiotics, paying a nominal fee for distribution. To receive the antibiotic at nominal cost, the hospital would be required to implement CDC recommended antimicrobial stewardship protocols and adhere to appropriate use, as well as provide limited data to the PAM to support performance measures. Data for tracking antibiotic use and resistance could be facilitated by the manufacturer. CMS would continue to pay the hospital at the normal diagnosis-related group rate, with the drug payment effectively carved out (Figure 2).



## DETERMINING MANUFACTURER SUBSCRIPTION PAYMENT RATE

Payments would be made to the manufacturer via the PAM on a periodic basis. The subscription payment would be expected to cover the cost of an antibiotic supply that meets population health needs and the facilitation of post-market evidence monitoring. Because the priority antibiotics provide

external societal benefits beyond their value to an individual treated payment, the subscription payment should exceed the volume-based price. However, the monetary valuation of these additional external benefits may be challenging to determine.<sup>19–21</sup> For drug payment, CMS generally relies on formulas that are a function of the average net price of a technology. For drugs administered in the hospital outpatient setting, payments are set based on the average sales price (ASP) plus 4 to 6 percent. In the inpatient setting, important new technologies can qualify for NTAP. A similar per-drug payment could be adapted to determine the base subscription payments for priority antibiotics.

That is, CMS could set a base subscription price for the antibiotic using its existing methods — for example, 100 percent of the ASP multiplied by the expected volume of the drug. This base subscription would then be adjusted by an antibiotic-specific multiplier to create a total subscription payment intended to reflect the full population value to Medicare beneficiaries. The subscription payment multiplier would reflect key benefits not captured in sales volume, such as: potential for reduced contagion (fewer downstream treatment costs for infected patients, and more beneficiaries who never get infected); expanded medical service access (more beneficiaries able to undergo surgeries and major procedures due to lower risk of a resistant infection); and drug novelty (drugs with new and distinct mechanisms of action may have a greater potential to reduce the spread of resistance).<sup>19,22</sup> The pilot program could use expertise from the Biomedical Advance Research and Development Authority (BARDA) and other federal agencies to guide determination of this population value adjustment to the base subscription payment.

## **PERFORMANCE METRICS AND EVIDENCE GENERATION**

CMS would specify a limited number of key measures that could be used to adjust the total subscription payment. These measures could be related to reliable availability, utilization tracking, adherence to stewardship guidelines (with support from manufacturers on appropriate use), continued pathogen sensitivity, and performance of post-market studies by the manufacturer to improve evidence on the drug's effectiveness.

Because of the limitations on feasible antibiotic clinical trials, developing additional post-market evidence is important for a better understanding of effectiveness and appropriate stewardship. Such evidence generation may also help address post-market regulatory requirements and support additional indications for use, though (as in the pre-market setting) it may not be possible for manufacturers to demonstrate superiority. This approach reflects the CMS policy of “Coverage with Evidence Development,” which CMS has used to address uncertainties remaining about effectiveness in the post-market setting while providing relatively broad or more timely coverage.

# Challenges to Implementation of a Subscription Model

While this priority antibiotic subscription model builds on existing CMS authorities and approaches to payment reform, it creates novel challenges in some respects.

## VALUATION OF NEW ANTIBIOTICS

As noted above, factors that contribute to the population value of a priority antibiotic are not generally reflected in the price of the drug that an individual hospital is willing to pay on behalf of a particular patient. These external population benefits may be substantial components of the overall value of a priority antibiotic. But they vary based on the resistant pathogen and patient population, and may be difficult to measure precisely.<sup>19</sup> The Department of Health and Human Services has established expert mechanisms for evaluating the magnitude of public health threats including resistance, and CMS could rely on this expertise. Moreover, implementing this program will likely generate substantial interest in refining such estimates, potentially with support from NIH, CDC, or BARDA.

## DATA COLLECTION ON UTILIZATION AND OUTCOMES

Currently, hospitals track the quantity and duration of antibiotic use.<sup>23</sup> For assessment of the impact of subscription payment, and for developing better post-market evidence, it will be important to improve data collection related to indications for use, outcomes of affected patients such as duration and severity of admissions and readmissions, and continued pathogen sensitivity. To collect such data, manufacturers and the PAM may need to collaborate with providers and expert groups such as the Infectious Diseases Society of America (IDSA). For stewardship protocols and surveillance efforts, CMS should work with CDC and expert groups to support up-to-date guidelines and to monitor the development of resistance to current antibiotics.

## STAKEHOLDER PARTICIPATION

Success of the subscription pilot will be dependent on participation of providers and antibiotic manufacturers. Enabling providers to obtain a valuable antibiotic at minimal direct cost should encourage their participation, and the PAM should be selected and evaluated based on their ability to work effectively to provide access to the treatment — as is the case for GPOs and specialty pharmacy suppliers today. For manufacturer participation, subscription fees will need to provide a predictable and substantial source of revenue at a level high enough to mitigate the financial hurdles they presently face. The contract for competitive selection of the PAM must also be designed in a manner that reflects input about feasibility from potential bidders.

## Conclusion

Ensuring that a robust arsenal of antibiotics is available to patients and providers is critical, but the lack of a predictable and substantial ROI reflecting the drug's population health benefits is a barrier. A subscription-based reimbursement model in Medicare represents a new direction in payment — removing the pressure of volume sales, strengthening stewardship, and enabling payment to reflect the population costs and morbidity associated with serious infections. Our framework illustrates how a subscription payment reform could be undertaken. Given the population that Medicare serves and the potential fit of this payment reform into its broader value-based payment reform goals, CMS is well suited to help lead the shift from calls for action to effective reform piloting.

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