In 2019, the first-ever national plan to end HIV in the US was announced. Treatment and prevention with antiretroviral drugs (ie, preexposure prophylaxis [PrEP]), both highly effective strategies, are at the core of this plan. However, access to medications to prevent or treat HIV is not ensured currently, particularly because drug costs are high and insurance coverage can sometimes leave gaps that may limit uptake and detract from adherence.

The study by Tseng and colleagues helps to answer a critical, practical question about such gaps: exactly how much do individuals with Medicare Part D health plan coverage pay in out-of-pocket costs for antiretroviral drugs for treatment or prevention? They analyzed 3326 Part D plans from around the US for the first quarter of 2019 to determine the annual treatment cost for 18 HIV treatment regimens and 2 HIV PrEP drugs and calculated how much each involved entity (ie, patient, plan, Medicare, or manufacturer) would pay monthly for patients with or without low-income subsidies. What they found is staggering: in the face of median annual antiretroviral prices exceeding $35 000 for treatment and $20 000 for prevention, individuals lacking low-income subsidies could have to pay as much as $3000 to $4000 out of pocket annually for HIV medications alone. Tseng et al also reported that cost-sharing varied throughout the year, with the highest burden to patients early on. Once the catastrophic coverage threshold was breached between February and May, Medicare bore the brunt of costs, shouldering 53% to 67% of the costs for treatment and 50% of the costs for prevention.

Yet, as shocking as the estimated out-of-pocket costs are, they may actually underrepresent the severity of the situation. Medicare recipients living with HIV, especially the 21% who are recipients by virtue of their age (and not disability), often use several prescription medications beyond their antiretroviral therapy. Yet the estimate provided by Tseng et al included only antiretroviral therapy or PrEP and no other prescription drugs, therefore likely significantly underestimating actual out-of-pocket costs, especially for people with HIV, although the antiretroviral drug class is certainly among the most expensive, with among the fewest generic options.

Furthermore, at the same time that the US has experienced a 3-fold increase in the proportion of Medicare recipients who are living with HIV since the mid-1990s, the number of Medicare enrollees in need of antiretroviral drugs for treatment (or prevention) will continue to increase as more people with HIV (and people who are at increased risk of HIV) age into Medicare in the years ahead. In fact, Medicare is the single largest source of federal funding for HIV care and treatment, and the proportion of care that is funded by Medicare will likely only continue to increase.

Tseng et al used 2019 data for their analysis, but we can expect out-of-pocket costs to increase, as 2020 brings change to Medicare Part D. As in the past, there are increases in the deductible and the initial coverage limit. However, the most substantial change, one that comes as a result of an expiration of a provision of the Patient Protection and Affordable Care Act that constrained increases of out-of-pocket costs for Medicare Part D enrollees during 2014 to 2019, is an increase of $1250 in the out-of-pocket spending threshold. Although only approximately 1.0 million of 44.6 million enrollees (2.2%) without low-income subsidies reached the catastrophic phase in 2017, that proportion will likely increase in 2020, and presumably a greater proportion of enrollees than ever will be living with HIV, although the proportion will likely be fewer than 1%. However, for these individuals, the burden is likely significant: relatively few Medicare recipients are wealthy enough to
afford thousands of dollars in drug costs. For reference, in 2016, the median annual income for Medicare recipients was $26,200, and only 5% of Medicare recipients had incomes higher than $103,450 per year. The concern with such a high cost burden on the individual is that adherence and, ultimately, health outcomes, are likely to deteriorate. It is now well documented that treatment for HIV blocks viral replication, which improves individual health and prevents onward transmission to sexual partners, a phenomenon popularized as undetectable equals untransmittable, or U = U. Belenky et al found that antiretroviral therapy adherence and viral load suppression remained stable despite increased out-of-pocket spending in the context of Medicare Part D plans, but this should not be particularly reassuring: that study was conducted among dual-eligible (i.e., Medicaid and Medicare eligible) women who were followed in a longitudinal cohort study; thus, this cohort was perhaps less representative of Medicare Part D recipients in general and much more likely to have received low-income subsidies as dual Medicaid and Medicare recipients. In these and other studies, focusing solely on HIV outcomes may miss other important outcomes. What is the effect of greater individual expenditures on the families of these recipients? As out-of-pocket costs increased, were their health and other needs met? What about those of their dependent family members? All of this leads to another critical question: what would be the effect of eliminating these high copayments for antiretroviral drugs? For now, this is a theoretical query. But a decade ago, a commercial health plan undertook just such a study among a different set of patients who were chronically ill: those discharged from the hospital after myocardial infarction. The plan randomly assigned these men and women to either full prescription coverage (i.e., absence of copayment) or usual prescription coverage for all statin, β-blocker, angiotensin converting enzyme inhibitor, or angiotensin-receptor blocker medications. These were not people living with HIV, but they were living with an illness for which highly effective medications could avert adverse outcomes. Although there was no reduction in first major vascular event or revascularization (the primary end point), patients in the full-coverage group had a 4% to 6% increase in adherence and a decrease in the incidence of total major vascular events or revascularization; patient cost was also decreased, all without increasing total spending, offering compelling support for taking a similar approach with antiretroviral drugs.

As the study by Tseng et al indicates, individuals who are eligible for low-income subsidies—77% of Medicare beneficiaries with HIV in 2014—would be spared the burden of such high out-of-pocket costs through the Part D Extra Help Program and AIDS Drug Assistance Program (ADAP). While the combination of the 2 effectively reduces what any person with HIV has to pay out of pocket for medications, this outcome is achieved through an administratively complex program, and in the case of ADAP, income eligibility thresholds that vary more than 2-fold among states. Additionally, individuals without an HIV diagnosis do not benefit from ADAP. Although some states maintain ADAP-like programs for those in need of PrEP, and the manufacturer also runs co-pay assistance programs, these are for individuals without insurance.

Tseng et al highlight recent efforts to reduce patients’ cost-sharing through proposed legislation to redesign Part D; possible interventions might involve capping out-of-pocket costs annually, passing discounts and rebates to patients directly, or at least making the out-of-pocket costs more predictable from month to month. Ideally, whatever Part D restructuring is ultimately undertaken will further incorporate principles of value-based insurance design, in which financial incentives are better aligned with what is determined to be high-value care, helping to signal to patients in the most concrete terms—through their wallets—that antiretroviral drug uptake and adherence are worth it, the opposite of the message conveyed by thousands of dollars in costs they have to shoulder now. But how to lighten the load for patients without passing on these costs to the public?

One answer is both simple and incredibly complicated: address the high prices of drugs themselves. Drug prices are high for myriad reasons, including certain aspects of US patent law that effectively allow manufacturers to set prices and then constrain competition. Short of more
narrowly interpreting and enforcing existing antitrust laws and policies, allowing Medicare to negotiate drug prices paid for by Medicare Part D plans would likely help us move toward more affordable antiretroviral drug prices. For although success in ending HIV/AIDS in the US will obviously come at a price, we need to find a way to avoid burdening the people who are underserved and draining public coffers—a way to pay these costs fully without paying dearly.

REFERENCES