The study by Dickson and Kent explored the implications of generic and biosimilar competition for prices of clinician-administered drugs and found that current Medicare Part B reimbursement rules might be preventing Medicare from achieving substantial savings through biosimilar competition. As prescription drug spending continues to rise, biologic drugs have become a more integral part of the problem. As with simpler brand-name small-molecule drugs, originator biologics are granted a period of market exclusivity before more affordable follow-on products, known as generic and biosimilar drugs, respectively, can enter the market under abbreviated approval pathways. Competition by generic drugs after the end of this market exclusivity period has been the cornerstone of US policy to rein in prescription drug spending for more than 30 years. Today, generic drugs account for 9 of 10 prescriptions filled in the US and have saved the health care system $2.2 trillion in the past decade.

Yet biosimilar competition, made possible by the passage of the Biologics Price Competition and Innovation Act of 2009, has so far not been associated with similarly impressive savings. For each of the first 9 biologics to face biosimilar competition, prerebate invoice prices declined by less than 10% within the first 2 years, and each originator biologic drug maintained more than a 60% market share. There are many reasons that the biosimilar market has not lived up to its promise. One such reason, how Medicare pays for these drugs, lies at the center of the study by Dickson and Kent. Their findings provide evidence that revising the existing rules could save the US government billions of dollars by spurring greater biosimilar competition.

The Medicare reimbursement rules in question apply to drugs that are administered by clinicians in an outpatient hospital or clinic setting, such as intravenous injections or infusions. For the millions of patients with Medicare coverage, these clinician-administered drugs are reimbursed under Medicare Part B (retail pharmacy drugs are reimbursed under Part D). In the past decade, Medicare Part B spending on clinician-administered drugs increased 8.3% per year, reaching $24 billion in 2017. Biologics are disproportionately represented, accounting for three-quarters of this spending.

For these Part B drugs, Medicare reimburses hospitals and clinics based on a prospective fee schedule, with reimbursement set at the average sales price plus a 6% markup to account for other supply chain costs. For small-molecule drugs with generic competitors, the brand-name and generic versions are paid under a single billing code, with the average sales price set according to a weighted mean of the price for each version. The result is direct price competition between a brand-name drug and its generic equivalents, incentivizing clinicians to purchase and administer the least expensive option. By contrast, each biologic drug and biosimilar product receives its own reimbursement code and is paid on the basis of its own average sales price. This process means that, even if prices fall for 1 biosimilar product, the prices of the originator biologics and other biosimilars can remain high. This arrangement limits direct price competition and provides an inverse incentive for clinicians to administer the highest-cost product to obtain the greatest reimbursement from Medicare.

In their article, Dickson and Kent quantified the differences between generic and biosimilar competition for clinician-administered drugs in Medicare Part B. Among 50 small-molecule clinician-administered drugs, these authors found that generic competition was associated with dramatic price decreases of up to 71% with 4 or more competitors. These results are similar to the impact of generic price competition in the commercial retail market. However, price reductions for the 6 biologic drugs with biosimilar competition from 2015 to 2019 were substantially lower, even accounting for the small number of biosimilar competitors for each drug (only infliximab [Remicade]...
had more than 2 biosimilar versions). Had the prices of originator biologics and biosimilars decreased comparably to those of brand-name small-molecule and generic drugs, the authors estimated that Medicare spending on the 6 drugs would have been reduced by about 27%, or $1.6 billion during the 5-year study period.1

Under the original Centers for Medicare and Medicaid Services (CMS) regulations that were enacted during the Obama Administration, biosimilar drugs were set to be paid under a single bundled code, separate from the originator biologics. This policy faced fierce pushback from biosimilar manufacturers, which argued that paying for biosimilars under a single billing code would reduce competition by discouraging entry into the biosimilar market given the possibility of a race-to-the-bottom pricing strategy amid an already high bar to market entry (unlike generic drug manufacturers, biosimilar manufacturers must generally conduct a phase 3 clinical trial that compares the biosimilar drug to the originator biologic drug).

During the Trump Administration, CMS announced new reimbursement rules, which took effect in April 2018, that allow for separate billing codes for each biosimilar drug.7 Dickson and Kent1 highlighted the problem with this approach: adequate competition requires more than just biosimilar market entry. The bundled billing code model for clinician-administered generic products has been far more successful at inducing price competition than the separate billing code model for biosimilars, and there is no evidence that the Trump Administration-era reimbursement rules have spurred greater biosimilar market entry. Since its June 2017 report to the US Congress, the nonpartisan Medicare Payment Advisory Commission has recommended bundled billing codes for originator biologics and their biosimilars to promote greater competition.6 The policy was also included in the September 2021 Comprehensive Plan for Addressing High Drug Prices report that was released by the Biden Administration.

Revising Medicare Part B reimbursement rules will not solve all of the problems with the biosimilar market. Some biologic drugs, including the top-selling drug adalimumab (Humira), are self-administered by patients and distributed through retail pharmacies. Such drugs would be unaffected by changes to Medicare Part B billing rules. In addition, Medicare represents only a portion of the prescription drug market, although commercial insurers often base their own reimbursement policies on CMS rules. Moreover, biosimilars have been slow to enter the market, not because biosimilar manufacturers lack financial incentives but rather because of the thickets of patents that biologic drug makers have built to protect their brand-name exclusivity and the resulting patent litigation settlements.8 Policies that encourage lower prices when biosimilars become available will not change originator biologic prices during their lengthy period of brand-name exclusivity.

After a slow start, biosimilars are finally starting to arrive on the US market. Judging from the experience with generic drugs, biosimilars may bring substantial savings for US patients and payers. However, the achievement of these savings hinges on adequate competition, which is being hindered by current Medicare Part B billing rules. Congress and CMS should ignore the pharmaceutical industry’s self-interested lobbying efforts on this subject and rewrite the biosimilar reimbursement rules to help patients and the federal government save billions of dollars.
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