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Medicare Reimbursement and the Use of Biologic Agents: Incentives, Access, the Public Good, and Optimal Care

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The Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) represented the most important change in the way the federal government supports medical care for the elderly since the inception of Medicare in 1965. Among its most significant provisions was the establishment for the first time of a benefit program, known as Part D, for outpatient prescription drugs. Despite its deductibles, doughnut holes, and dizzying differences among formularies, Part D has been lauded for redressing a major omission in health insurance coverage for the elderly (1,2). As of January 1, 2006, when Part D was implemented, Medicare patients with rheumatoid arthritis (RA) could enroll in plans to cover part of the costs of outpatient medications, including the self-injectable biologic agents etanercept and adalimumab. Prior to January 1, 2006, Medicare patients had two primary means to access biologics: buy supplemental private insurance that would cover part of the cost of self-injectable biologic agents, or receive infliximab at their physician's office or hospital outpatient department, with the costs largely paid by Medicare.

Medicare Part B traditionally has covered the medication and administration costs of treatments given by infusion, including chemotherapy, and with the advent of biologic agents, medications such as infliximab (3). Prior to 2004, Medicare reimbursements were based on the average wholesale price of the drug (the list price), which was often substantially higher than the costs to physicians and hospitals of acquiring the drug. Audits by the US Government Accountability Office reported that differences between the average wholesale price and the acquisition costs (i.e., the spread) for infused medications in 2001 were commonly between 15% and 30%, a difference that the physician or hospital could keep (4). The spread for infliximab was 32% in 1999 and 2001 (5).

In many ways, this was a win-win-win situation. Patients had access to a valuably effective but expensive medication, which for many would not otherwise be available; physicians and hospitals could provide needed treatment and increase their incomes; and companies could sell more without the worry of price controls. Surveys between 1998 and 2003 confirmed that Medicare patients preferentially used infliximab (6,7). The losers in this scenario were US taxpayers and businesses who, through Medicare, were paying the bill. Recognizing that each actor was responding to incentives that it had put in place, the federal government sought to reduce these incentives to help control Medicare spending and exert better stewardship of the public's money. Provisions were included in the MMA that from 2004 to 2006 sequentially changed the standard by which physicians and hospitals were reimbursed for infusion treatments. These changes had the effect of reducing the spread to 6–8%, which was a lower mark-up, but a mark-up nonetheless (8). Although the MMA also increased reimbursements for drug administration, there were concerns, primarily among hematologists and oncologists, that reductions in payments would cause practices to close or to stop providing infusion treatments, that hospital outpatient departments would be overwhelmed with patients not able to receive treatment at physician offices, and that access to treatments would be reduced (9). The American College of Rheumatology also presented these concerns in Congressional hearings (10).

Limited evidence to date suggests that these potential problems have largely not been realized among patients with cancer (11,12). However, the impact of the MMA on the use of biologic agents among patients with RA has not been explored. Four key questions arise to determine if the MMA has had its intended, or any unintended consequences, and if it has been a wise policy. Has the MMA reduced Medicare spending on infliximab? Has the MMA made it easier for patients with RA to access biologic agents or has it limited access to biologics? Has the MMA induced a shift in the type of biologic agent prescribed toward those that are more cost-effective? Has the MMA promoted optimal care of patients with RA?

In this issue of *Arthritis Care & Research*, Doshi et al report the first analysis of changes in the use of, and expenditures for, infliximab among Medicare beneficiaries with RA before and after the MMA went into effect (13). The authors abstracted data on a 5% random sample of Medicare beneficiaries over the transition period of 2002–2006, and examined trends in the number of infliximab users, the number of units of infliximab dispensed (1 unit of infliximab in Medicare's accounting system = 10 mg), and total payments for infliximab, including and excluding the costs of drug administration. Doshi et al reported that the number of patients who were treated with infliximab increased sharply from 2002 to 2003, before the MMA took effect, and total payments for infliximab increased by 39%. The number of patients treated with infliximab increased at a much slower pace in subsequent years, and total payments leveled off in 2005–2006. Rather than decreasing, total payments remained stable because the decreases in payments for the medication imposed by the MMA were largely offset by higher payments for drug administration and increases in dose among those receiving infliximab. Introduction of the Part D outpatient prescription drug benefit in 2006 did not have a demonstrable effect on the overall use of infliximab or total payments. In a longitudinal analysis, the proportions of patients who discontinued infliximab in 2006 or who started infliximab in 2006 were similar to the proportions in previous years, suggesting that the new benefits for coverage of self-injectable biologics in Part D did not induce many patients to switch treatments or alter their initial choice of tumor necrosis factor α (TNF α) inhibitor.

These results convincingly demonstrate that the MMA was successful in limiting the rise in Medicare spending on infliximab. The analysis by quarter-year demonstrates that the reductions in payment were implemented as designed. If payments had remained at the 2002 rate, total payments for infliximab by Medicare in 2006 would have been more than \$708 million, rather than the \$537 million that was paid. Although this represents a 31% decrease from projected expenditures, total payments still increased over time. Payments per patient with RA also increased over time, but payments per patient treated with infliximab remained stable (\$13,218 in 2002 versus \$13,543 in 2006), despite an increase in the average dose of infliximab from 338 mg/infusion to 401 mg/infusion. Although critics might argue that the MMA did not succeed in reducing Medicare spending on infliximab, it is clear that it held spending in check.

Has the MMA limited or facilitated access to biologics? Although the analysis of Doshi et al indicates that the number of Medicare beneficiaries treated with infliximab increased from 2002 to 2006, the rate of increase slowed dramatically after 2003. Was this a consequence of changes in reimbursement stipulated by the MMA, or was this a natural settling in the rate of use of a new medication after introduction to the market? Although the data cannot answer this question definitively, the circumstantial evidence suggests natural causes. The prevalence represents the balance between patients entering treatment and leaving treatment (through either discontinuation or death). Patients who died were excluded from these analyses, so mortality was not responsible for the slowdown in growth of infliximab use, and the longitudinal analyses suggested that large numbers of patients were not

discontinuing infliximab. Although the incentives might have been reduced by the MMA, infliximab remained a win-win situation for patients and physicians, so there is little reason to suspect that the MMA would have directly limited access to infliximab for patients with RA who needed it. Unfortunately, data on the use of etanercept and adalimumab by Medicare beneficiaries under Part D were not available, so this analysis could not determine if the expanded benefits in 2006 increased the access of patients with RA to these biologic agents.

Without data on the use of other TNF α inhibitors, and without data after 2006, the analysis of Doshi and colleagues cannot address the important question of whether the MMA has induced a shift in the type of biologic agent that is prescribed for patients with RA. Several studies have concluded that infliximab is the least cost-effective TNF α inhibitor (14,15). If the MMA resulted in a change toward the use of more cost-effective medications, this would further enhance Medicare's protection of the public good by emphasizing value for money. However, despite coverage under Part D, the self-injectable biologic agents have high out-of-pocket expenses, and financial incentives for many patients still favor infliximab (16). This leaves open the question of whether further changes in reimbursement policy guided by cost-effectiveness will be forthcoming.

Ultimately, the most important question regarding any policy change is whether it improves patients' lives. To know if the MMA helped to promote optimal care for patients with RA will require not only data on access to biologic agents but information on whether access to other antirheumatic medications increased, whether comorbid conditions were better controlled, and whether health outcomes improved.

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