Drug Coverage for Transplantation Turns into Political Football: Big Business Trumps Patients

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As Congress took on the issue of health care last year, they had a golden opportunity finally to extend Medicare coverage for immunosuppressive medications for kidney transplant recipients from the current 36 months to lifetime. This is an issue that the American Society of Transplantation (AST) and other members of the transplant community has long advocated, but this opportunity was squandered when the interests of big business triumphed over the needs of patients, and the provision was dropped from the Affordable Health Care for Americans Act. Although lifetime coverage almost became a reality, the dialysis industry and those whom they support have proved that money ultimately wins in politics.

Currently, Medicare covers 80% of the cost of immunosuppressive medications for 36 months after transplantation (for those whose Medicare entitlement is based on ESRD). In 1999, Congress authorized an extension of Medicare coverage for immunosuppressive medication to lifetime, but only for a minority of patients: Those who were Medicare eligible as a result of age or disability. Medicare coverage for dialysis, a more expensive and far less effective therapy for ESRD, has been and continues to be for the lifetime of the patient.

Many studies, going back well over a decade, including those conducted by the government itself, take issue with the policy. Kasiske *et al.*1, in 1999, presented an analysis of the costs and benefits of extending beyond 36 months payment for immunosuppression after organ transplantation. It was their conclusion that although there was a price tag (estimated at that time to be $830 million), it was irrational and immoral to allow kidney transplants to fail as a result of patients' inability to pay for their medications.

In fact, that point of view was advocated as far back as 1991 by the Institute of Medicine in their report *Kidney Failure and the Federal Government* (2). In the Omnibus Budget Reconciliation Act of 1987 (OBRA 1987), Congress had asked the Institute of Medicine to study the ESRD program with respect to a variety of issues, including the effect of reimbursement on quality of care. The report concluded, "The committee recommends that Congress eliminate the 3-year limit on Medicare eligibility for ESRD patients who are successful transplant recipients and authorize an entitlement equal to that of ESRD patients who are treated by dialysis." They further noted, "The implementation of these recommendations may increase program expenditures in the short run. . .. However, kidney transplantation is more cost-effective than dialysis as a treatment for ESRD. In the long run, the Medicare program should incur lower costs from encouraging kidney transplantation."

Lifetime Medicare coverage for immunosuppressive medications for kidney transplant recipients is a long overdue benefit, one for which the AST has long advocated on behalf of our patients. The Affordable Health Care for Americans Act seemed like a perfect vehicle finally to achieve this goal. Although the rationale is self-evident, legislators have not had adequate data to make a forceful case for expanding coverage.

To provide Congress with data on the prevalence and consequences of cost-related immunosuppressive medication nonadherence in kidney transplant recipients, the AST along with the United Network for Organ Sharing conducted a descriptive survey of US renal transplant centers. Amazingly, 99% of programs responded to the 12-question survey. The results have been submitted for publication. Highlights include the finding that >70% of patients in the programs reported very serious or extremely serious problems with paying for their medications, 68% reported deaths or graft losses as a result of cost-related medication nonadherence, and >70% reported at least occasionally refusing to list patients for transplantation because of projected inability to pay for immunosuppressive medications after transplantation. The results provide an even stronger basis for Congress to enact lifetime Medicare coverage.

Congress was receptive. There was virtually unanimous support for this measure in the House, and the provision was included in the Health Reform Bill passed by the House of Representatives (key sponsors included Pete Stark [D-CA], Ron Kind [D-WI], and Dave Camp [R-MI]); however, to offset the estimated added costs of extending immunosuppressive drug coverage, it was paired with another measure, which was judged to be a net cost savings. This measure called for bundling certain outpatient medications for dialysis patients, currently billable separately, into the monthly prospective payment composite rate ("oral drugs that are not the oral equivalent of an intravenous drug [such as oral phosphate

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binders and oral calcimimetics]"). This "bundling" provision was not a new proposal but only the implementation of a previous rule. Its pairing with the extension of coverage for immunosuppressive medications proved to be unfortunate and pitted the dialysis industry against transplant patients.

Senate Deputy Majority Leader Richard Durbin (D-IL) introduced the immunosuppressive extension measure as an amendment to the Senate version of the health reform bill. The dialysis industry, concerned that the bundling would affect their bottom line, took action against the provision under claims that the bundling might have an adverse impact on patient care. This action took the form of lobbying by Kidney Care Partners (KCP), an industry-dominated coalition of organizations that are involved with the care of patients with kidney disease. Members of KCP include large pharmaceutical companies with enormous profits derived from providing drugs and dialysis services to patients with chronic kidney disease (*e.g.*, Amgen, Fresenius, DaVita, Genzyme) as well as the National Kidney Foundation. In response to pressure from the corporate dialysis community and their kidney coalition, several members of Congress acted to prevent the patient immunosuppressive provision from being included in the final health care reform package. Some of these opposing voices on Capitol Hill have been generously supported by the large dialysis providers for years: "Amgen and DaVita, which dominate the kidney treatment and dialysis business nationwide, have donated as much as $1.5 million over the last five years to the [Congressional Black] caucus charities, and the caucus has been one of their strongest allies in a bid to win broader federal reimbursements" (3).

While disingenuously voicing support for extending immunosuppressive drug coverage, the KCP coalition opposed the bundling (despite both groups knowing full well that bundling was inevitable). By opposing bundling, they knew that the Durbin amendment would be withdrawn, and they were right, leaving immunosuppressive coverage out of the Senate bill. They were thus willing to sacrifice a clear benefit for transplant patients on the altar of financial gain for the dialysis industry. Why not use the projected savings from bundling—an already done deal—to benefit transplant patients? It is a shame that organizations that purportedly represent patient interests serve instead the corporate bottom line.

Disclosures

None.

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