

Saving Medicare through Patient-Centered Changes — The Case of Injectables

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As we debate Medicare's solvency and the ever-rising cost of health care and health insurance, it makes sense to examine easily implementable policies that will reduce costs. Total Medicare expenditures were \$549 billion in 2011.¹ Pursuing more prudent (though perhaps less than ideal) policies, such as those in place in Canada, might have saved over \$2 trillion between 1980 and 2009.² Ideally, we would find ways to reduce costs without harming beneficiaries, so the \$716 billion "cut" to Medicare under the Affordable Care Act (ACA) actually represents savings to be achieved over a 10-year period from anticipated reductions in payments to health care providers, not reductions in benefits for patients. In fact, under the ACA, Medicare patients have seen increases in benefits, such as access to copayment-free preventive care and reduced-price prescription drugs. Other approaches, such as the premium-support system proposed by Senator Ron Wyden (D-OR) and Representative Paul Ryan (R-WI), would be expected to shift costs to beneficiaries, 59% of whom, under the Wyden-Ryan plan, would face premium increases.

One example of a way to reduce Medicare expenditures by establishing care practices that reduce the cost of care without compromising treatment effectiveness or patient safety has been highlighted by Bach and colleagues: using less expensive but equally effective drugs in their cancer center.³ A second exam-

ple, we believe, would be altering the Medicare policy on injectable drugs.

Currently, injectable drugs are covered only when they are administered in a hospital or physician's office. The Centers for Medicare and Medicaid Services (CMS) explains that this policy applies to drugs that are "usually" administered in a doctor's office, and the Medicare Benefit Policy Manual defines "usually" as "more than 50% of the time for all Medicare beneficiaries who use the drug."⁴ Not surprisingly, in order to be reimbursed, doctors and patients choose office administration of injectables. The rule is therefore self-fulfilling and does not allow deviations even if physicians believe that self-injection will both reduce costs and increase treatment effectiveness.

Considerations of convenience, cost, and quality all argue for encouraging patients to participate in their own care by allowing self-administration of injectable drugs. Consider the example of azacitidine, used for treating the myelodysplastic syndrome (MDS). The drug is administered through daily subcutaneous injections for 7 days every month. Azacitidine may be easily and safely injected by the patient, as was allowed in the pivotal trial that led to its regulatory approval. Approximately 20,000 to 45,000 Americans receive a diagnosis of MDS every year,⁵ and there are currently an estimated 60,000 to 135,000 patients with MDS in the United States (the median duration of

survival after diagnosis is 3 years). The clinic charge for using a room and injecting azacitidine in an office setting ranges from \$300 to \$500 per injection. If we presume that, as in some of the relevant clinical trials, each patient would undergo six cycles of injections per year, the annual per-patient charge would be \$12,600 to \$21,000; since approximately 85% of these patients are covered by Medicare, the estimated total Medicare costs are \$600 million to \$2.4 billion. Although it is difficult to calculate the costs more precisely (owing to variations in clinic charges and estimates of the prevalence of MDS), there is no doubt that allowing coverage of self-injected drugs such as azacitidine could translate into substantial savings for Medicare.

Aside from the costs, the current policy on injectables imposes other burdens on patients. The Food and Drug Administration recommends a 7-day treatment regimen for azacitidine, but it is estimated that less than 20% of patients are treated on a consecutive 7-day schedule; the other 80% or more receive treatment according to variations of this schedule that may not be as effective. Since many doctors' offices are not open on weekends, the treatment is either shortened to 5 days or given in an interrupted fashion. Thus, the mandate that patients receive the drug in a physician's office forces deviations from published guidelines, with unknown clinical consequences.

The policy may impose sub-

stantial socioeconomic burdens on patients in addition to the additional direct costs of care. Some patients do not live near treatment centers and must therefore incur expenses for transportation, fuel, food, and lodging in order to receive their injections. Travel is often made more difficult by these patients' health status, age, or both. While undergoing treatment, they must spend more than a quarter of their time away from their family and friends. The psychological and emotional effects of this disruption may impair quality of life and should not be overlooked. Reducing these types of costs might contribute to increased functional status and improved rates of remission and survival.

Azacitidine is not unique. Other injectables, such as growth factors and anticoagulant agents, are subject to the same mandate. Antibiotic agents are also frequently given intravenously to treat infections in patients with cancer. CMS mandates that these drugs be given in a hospital or doctor's office, even though patients can be taught to safely take the remaining doses of a hospital-initiated treatment course (up to 1 or 2 weeks' worth) at home, typically assisted by a home health aide. Instead, patients must

frequently remain hospitalized for an extended period to complete a course of treatment. This requirement increases both the cost of treatment and the risk of nosocomial complications. Allowing self-administration (as we do routinely and safely at the M.D. Anderson Cancer Center when a patient is covered by insurance other than Medicare) will also free up hospital and clinic capacity for other patients. This step alone would save Medicare billions of dollars in reimbursement for hospital stays.

If this policy change were implemented, it would certainly have to be coupled with monitoring and standard care procedures appropriate to each particular drug. These would include initial supervised self-administration of the drug (with verification of sterility and dose), follow-up calls or e-mail interactions with appropriate medical personnel (physicians, physician assistants, or mid-level care providers), standard blood monitoring (e.g., blood counts every 1 to 4 weeks with azacitidine and colony-stimulating factors to monitor for myelosuppression and need for transfusion), and testing of drug blood levels or organ function (e.g., assessment of vancomycin and creatinine levels with vancomycin

administration), among other procedures. We believe that if all these safeguards were in place, revising the Medicare injectable-drug policy to allow for patient self-administration would reduce costs and improve patients' well-being, socioeconomic situations, and compliance with treatment without compromising patient safety.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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DOI: 10.1056/NEJMp1213485

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