The Medicare Modernization Act of 2003 substantially reduced reimbursements for outpatient drugs administered in physicians’ offices and covered under Medicare Part B. These changes were made in response to rapidly increasing expenditures for these drugs and reports that Medicare payments for the drugs were much higher than physicians’ costs for purchasing the drugs (1). Before this legislation was enacted, Medicare reimbursed physician and hospital providers 95% of the average wholesale price for Part B drugs. On January 1, 2004, Medicare lowered reimbursements on the drugs from 95% to 85% of the average wholesale price. Then, on January 1, 2005, Medicare began reimbursing 106% of the average national sales price over the previous two quarters.

Androgen deprivation therapy with a gonadotropin-releasing hormone (GnRH) agonist or bilateral orchiectomy has long been the standard therapy for metastatic prostate cancer (2–4), and it improves survival when used as adjuvant therapy for men with locally advanced disease (5–8). However, GnRH agonists are frequently used in other settings, such as primary therapy of local–regional disease and for biochemical recurrence following primary surgery or radiation, settings for which no studies have yet demonstrated benefit (9). In these settings, men are often treated indefinitely, although intermittent use of these therapies is being studied as a strategy to obtain similar anticancer effects with fewer side effects and lower costs (10).

Use of GnRH agonists increased greatly in the late 1990s and early 2000s (11,12). In 1999, two GnRH agonists, leuprolide (Lupron) and goserelin (Zoladex), accounted for 23% of all Medicare Part B drug spending, which totaled nearly $4 billion that year (1). The widespread use of these drugs has raised some concerns because these drugs have potentially serious side effects. Men on GnRH agonists have lower quality of life (13) and develop central obesity (14,15) and decreased insulin sensitivity (16) with as little as 12 weeks of use. GnRH agonists have been associated with an increased risk of diabetes, cardiovascular disease (17,18), and fracture (19), highlighting the importance of targeting these drugs to patients who are likely to benefit and avoiding them for patients who are not.

In this issue of the Journal, Elliott et al. (20) used the Surveillance, Epidemiology, and End Results–Medicare database to assess use of GnRH agonists for more than 70,000 men 66 years and older with prostate cancer diagnosed during 1992–2005. Specifically, they assessed whether use of GnRH agonists changed as a result of decreased reimbursements to providers resulting from the Medicare Modernization Act. They focused on two groups of patients: men with metastatic disease, for whom GnRH agonists are effective at palliating symptoms, and men with very low-risk cancers, for whom GnRH agonists have not been shown to offer benefit and may in fact cause harm. They found that for patients with metastatic disease, use of GnRH agonists did not change after 2003, when the Medicare Modernization Act took effect. However, for men with very low-risk cancers, there was a 39% decrease in the odds of GnRH agonist use between 2003 and 2005.

This work adds to findings from a prior study demonstrating that actual Medicare payments to physicians for GnRH agonists decreased by 65% between 2003 and 2005 (21). The nice contribution by Elliot et al. (20) was in demonstrating that the decreased reimbursement for GnRH agonists was associated with a substantial decrease in their use for an indication that very likely reflected overuse (primary therapy for very low-risk tumors) but no change in use for an indication that reflected appropriate use of this therapy. Unfortunately, the study did not assess use of GnRH agonists in the adjuvant setting, where the benefits of treatment almost certainly outweigh any harms (5,8), but one would hope that use of adjuvant GnRH agonist therapy for high-risk patients would not decrease in light of decreased payments to physicians.

Some recent research suggests that the Medicare Modernization Act had a powerful effect in decreasing inappropriate use of GnRH agonists while not negatively influencing appropriate use. But, the decreased use of GnRH agonists may have some other explanations as well, including litigation concerning illegal marketing and sales practices by the manufacturers of these drugs (22). In addition, research suggests that use of GnRH agonists declined between 2004 and 2007 even in the Veterans Health Administration (23), a system where physicians have no financial incentives to prescribe these drugs, although the decline in use was much less than in the Medicare program.

The fee-for-service system in the United States has long been identified as contributing to overuse of health care. Because controlling the growth of health-care costs will likely require major
changes in the way that health care is reimbursed, the Patient Protection and Affordable Care Act provides for pilot projects to test various approaches to structuring payment and delivery for Medicare and Medicaid to reduce expenditures while maintaining or improving quality of care (25). As new methods of paying providers for services are tried, rigorous studies such as the one by Elliot et al. (20) will be crucial to assuring that the goal of maximizing delivery of effective services is met while minimizing the delivery of ineffective care.

References


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