Medicare Reform – A Major Economic Impact on Private Urological Practice

a report by
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The Medicare Modernization Act (MMA) of 2003 has radically changed the way urologists are reimbursed for drugs administered in the office setting. This editorial will focus on drug therapy for prostate cancer and the specific consequence of Medicare reform on prostate cancer patients and on the private urology practice. Luteinizing hormone-releasing hormone (LHRH) agonists used in the treatment of advanced prostate cancer are the most commonly administered drugs and account for the majority of the economic impact; however, all drugs, including bacillus Calmette-Guérin (BCG), interferon, and chemotherapies, are included in these changes. Prior to implementation of the MMA, drugs administered in the physician's office under Part B of Medicare were reimbursed at 95% of average wholesale price (AWP) as reported by the pharmaceutical industry. Physicians were able to negotiate sizeable discounts from the published AWP through buying groups and volume discounts, creating significant net profit from the administration of these drugs. This profit was used to offset drastic reductions in surgical fees estimated at 50% over the past 10 years. Most urology practices used the income to expand office staff, services and improve the overall quality of urologic care delivered to patients. The profit from these drugs also increased the net revenue of most urology practices, with estimates suggesting an average revenue increase of US$100,000 per urologist in the US. In established practices with large numbers of prostate cancer patients, the income from drug therapy was significantly more. In January 2004, the MMA was phased in, reducing the reimbursement for Part B drugs to 80% to 85% of average wholesale price (AWP). The reforms of the MMA took full effect on 1 January 2005, with reimbursements drastically cut to 106% of the average sales price (ASP) of the drug, effectively eliminating the profits associated with administration of drugs in the office.

The new reimbursement methodology mandated by the MMA of 2003 changes the reimbursement formula from AWP to average sales price (ASP). The ASP must be reported by each pharmaceutical company to the federal government quarterly using actual sales information based on detailed and standardized rules and include all sales discounts, early pay discounts and volume discounts. Centers for Medicare and Medicaid Services (CMS) will then average all manufacturers' ASP data charged under a particular 'J' code. For example, the ASP data for Lupron and Eligard is averaged to develop a single ASP for code J9217 (leuprolide acetate). The least costly alternative (LCA) adopted by almost all states' Medicare carriers further complicates this issue. LCA is the payment policy that allows the Medicare carrier in each state to limit payment to the least costly 'medically equivalent' drug available. For example, leuprolide is considered to be medically equivalent to goserelin acetate in LCA states. Currently, all states, with the exception of Illinois, Michigan, Minnesota, Wisconsin, and Montana, have adopted the LCA policy. Utah has suspended the LCA policy from 1 January 2005 to 30 June 2005. Starting in 2006, MMA provides for a new programme called competitive acquisition to be phased into place as an option to the current 'buy and bill' program. The competitive acquisition program will set up regional third party contractors who will purchase drugs from the manufacturer, dispense the drug to a physician's office on behalf of a particular patient and then bill Medicare and the secondary insurances. This program will remove the physician from the financial transaction associated with administering Part B drugs in the office. At the beginning of each year, each practice will have the option of selecting between buy and bill at the 106% ASP reimbursement rate subject to LCA policies and competitive acquisition.

Actual Medicare reimbursements in 2005 for LHRH therapy are:

- J9217 (leuprolide acetate) – US$253.13;
- J9202 (goserelin acetate) – US$189.79;
- J9219 (leuprolide acetate 12 month implant) – US$2206.27; and
- in LCA states, Lupron, Eligard, and Zoladex – US$189.79.

The reimbursement rates for these popular prostate cancer drugs are very close to actual acquisition costs in LCA states. The total cost of administering these drugs to prostate cancer patients includes the overhead associated with billing, administration, incomplete

payment of 20% co-pay by patients or secondary insurance companies, inventory costs, and bad debt. The author has estimated these additional costs at 22% in his private practice. The breakeven point for many urology practices on the administration of Part B drugs is therefore estimated at 122% of acquisition costs, which may well be less than actual reimbursement levels. The true scope of the MMA can now be appreciated. Prior to 2005, the administration of Part B drugs in the office setting resulted in a net profit to the urology practice. Current reimbursement levels at 106% ASP will now result in a net loss for the urology practice. The change in urologists' take-home pay will reflect the complete loss of profits from Part B drugs and the actual losses incurred in providing drug therapy to Medicare patients in LCA states. While this was not the likely intent of the MMA of 2003, it is the likely result and will have profound consequences on the overall quality of care delivered to patients with prostate cancer.

The use of LHRH therapy has become more widespread over the past decade and its use has become a mainstay of therapy for prostate cancer patients. The clinical indications have expanded to include neoadjuvant and adjuvant use in high-risk patients undergoing radiation therapy, primary therapy for locally advanced prostate cancer and for early use in the patient with biochemical failure after local therapy. Many studies have suggested that LHRH therapy has significantly impacted the disease-free survival and overall survival for many of these patients. Studies also suggest that patients widely prefer LHRH agonist therapy to orchiectomy. The challenge of how urologists provide state-of-the-art prostate cancer therapy to Medicare patients given the current reimbursement levels as mandated by the MMA, is currently quite clear.

Many urology practices have stopped administering LHRH therapy to their patients in the office setting. They have referred their patients to the out-patient department of the hospital or sent the patient to the pharmacy with a written prescription, shifting the cost of the drug to the patient, or their prescription drug insurance program. This creates a major challenge for patients who have no secondary insurance or prescription drug insurance. The cost of LHRH therapy at the retail pharmacy is much higher than the cost of therapy given in the office. Many patients cannot afford this. Many of the same patients cannot afford the 20% office co-pay, as they are truly indigent. Since the urology practice cannot afford to absorb these losses, some prostate cancer patients may receive sub-optimal care for their disease.

Many urologists have decided to continue to deliver LHRH therapy this year even if a loss is incurred until the competitive acquisition program begins in 2006; however, their economic survival will require major restructuring of overheads combined with attempts to maximize other revenue streams in the practice. Regardless of whether or not urology practices continue to administer LHRH therapy in 2005, efficiency and aggressive practice management will be critical to survival.

Consequences of changes in reimbursement for LHRH affect many aspects of private urological practice and will have far-reaching consequences with regards to levels of service and convenient access to care for patients. In an attempt to control costs, many practices are finding it necessary to close satellite offices, especially in rural areas. Office staffing levels and pay scales may need to be reduced in an attempt to control costs. Participation in some highly discounted managed care programs, as well as Medicaid programs, may not be financially feasible given the loss of drug revenues. Recruitment of new urologists out of training will be much more difficult for small practices, especially in rural areas, as new urologists will value quality of life issues more in the setting of reduced salary levels. Urologists can expect to see more patients each day with less time spent with each individual patient. Many urologists nearing retirement age will make the decision to quit early if they are financially able to do so. Taken all together, these adaptations to loss of drug revenues will result in a lower overall quality of the patient experience with regards to access, satisfaction and timeliness of care.

The challenge for today's urologist is to find a way to deliver excellent high-quality care in the current economic climate. This will require efficient practice management with a clear focus on strategies to maximize revenues and control expenses. On the revenue side, opportunities exist to improve collection efficiency, renegotiate managed care contracts, improve coding, expand well-reimbursed office procedures and expand ancillary revenue generation. It will be essential to optimize performance in the collection of fees. A 100% collection rate of patient co-payments at the time of service should be the goal for all practices. The author's practice has successfully implemented a pre-procedure surgical deposit policy where patient co-payments for elective surgical procedures are calculated before surgery, and the patient is informed of their required co-payment. The co-payment is then collected before the procedure date as a surgical deposit. Attention to correct coding will ensure that the physician is being paid for the work actually done. Electronic medical records offer the opportunity to increase efficiency, assist with correct coding and cut transcription, and record storage expenses. Expanding laboratory and imaging services within the urology practice also offers opportunities for additional revenue generation.

On the expense side, opportunities for efficiency exist in the areas of staffing, employee benefits, supplies, and general expenses. A careful analysis of staffing requirements is important, as is matching the tasks that employees perform to their pay scales. Flexible time scheduling is popular with employees and allows the office manger to match staffing needs with patient volume on a daily basis. Incentives and positive reinforcement help to build staff morale and decrease staff turnover. Employee benefits should be re-evaluated. The author's practice realized significant savings in the health insurance premiums by implementing a high deductible health insurance program combined with setting up health savings accounts (HSA) for employees. Strategies to reduce rent, such as sub-leasing excess office space to other healthcare providers or downsizing to a smaller office, should be considered.

Large groups will have a distinct survival advantage in the future. Large groups can afford professional office management, sophisticated billing software, and most importantly, can easily capture ancillary revenues. Many large urology groups currently own their own imaging equipment such as CT scanners, nuclear cameras, and ultrasound machines. The largest groups have in-house laboratory and pathology services. With the loss of Medicare drug revenues, these other ancillary sources of revenue become even more important. It is likely that there will be continued consolidation of small practices to achieve economic advantages.

The MMA of 2003 is now law and has been implemented. This is the most significant economic challenge to urologists in the past 20 years. The very survival of some practices will be threatened and the need to innovate, and operate efficiently, will be mandatory for all urologists. Patients are caught in the middle of these changes. The value of LHRH therapy has been well established and incorporated into standard care patterns for prostate cancer. The challenge for urologists across the US will be to continue to offer high quality state-of-the-art care to prostate cancer patients. This will require efficiency in the office and keeping an open mind to new practice paradigms. The alternative is reduced access and a lower quality of care for patients. ■