Reimbursement Issues With Hormonal Therapies for Prostate Cancer

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Reimbursement issues surrounding the treatment of prostate cancer with hormonal therapies have changed dramatically in the past 2 years. The ultimate goal for urologists when making treatment decisions regarding LHRH agonist use is to continue to provide hassle-free, complete care for patients, including whatever medications they need. This is still fully possible under the new rules without sacrificing the opportunity to profit from office-based administration of injectable medications.
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Reimbursement issues surrounding the treatment of prostate cancer with hormonal therapies have changed dramatically in the past 2 years. As one office manager stated, the "present is not like it used to be. The Christmas candy is gone." These changes were mandated by the Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003.[1] More recently, the Centers for Medicare and Medicaid Services (CMS) published, in the *Federal Register*, the final rules for revisions to payment policies under the physician fee schedule for the 2005 calendar year.[2]

According to Medicare statistics, urologists received approximately 37% of their total 2004 Medicare revenues from drugs and 60% from all other services. Medicare has estimated that the change in payment to physicians for drugs will decrease income to urologists from prescription of LHRH agonists by 38%. The overall impact on income will be a decrease of 14%. In 2004, this profit center accounted for up to 40% of the take-home pay for some urologists. Urologists are expected to lose a majority of that income, approximately $60,000 for the average practitioner.

The payment for chemotherapeutic injections has decreased more than originally anticipated. The national average payment to physicians for a single injection has dropped from $64.07 to $36.62.[3] A committee formed by the American Medical Association (AMA), at the request of CMS, reevaluated injections and other treatment modalities for cancer, and their recommendations ultimately led to changes in many delivery codes as well as the addition of new codes. CMS changed the payments as well.

Overall Impact of MMA 2003

- **Average annual decrease: $60,000.00 per urologist**
- **Some urologists: ↓ 30% net income**
- **Continuously changing market**
- **Current profits exceed 6%**

Reimbursement

The MMA 2003 changed the way physicians are paid for injectable drugs administered in the office. Before the new rules, urologists were paid a percentage of the average wholesale price (AWP) (95% of AWP in 2003, between 80% and 85% of AWP in 2004).[3] In 2005, urologists are being paid 106% based on average sale price (ASP) (not 106% of their purchase price for the drug).[4] Although there is still room for profit in this model, the margin is not as large.

What is the difference between AWP and ASP? AWP is the recommended wholesale price provided by the pharmaceutical company for each drug.[3] ASP is calculated by the pharmaceutical company, on a quarterly basis, using actual sales information and detailed, standardized rules and formulas. All drug sales, with a few exceptions including sales to Medicaid, the government, and a few other specific categories, are included in ASP calculations. All sales to physicians, purchasing groups, pharmacists, wholesalers, including all volume, cash, or other discounts are also included. After ASP figures are determined by the manufacturer (manufacturer's ASP),[4] CMS will average all manufacturers' ASPs charged under a single "J" code, according to their respective volumes, to determine an ASP for the code. For example, the ASP for luprolide acetates, Lupron Depot® (TAP Pharmaceutical Products, Inc., Lake Forest, IL) and Eligard® (sanofi-aventis, Paris, France) will be averaged to develop a single ASP for the Healthcare Common Procedure Code (HCPC) J9217.[4]

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Medicare carriers in each state decide whether to pay for the drugs using the least costly alternative (LCA) methodology or not. The LCA methodology (equal payment for drugs under different J codes, that have been determined by Medicare to be "medically equivalent," [eg, Lupron, Eligard [J9217], and Zoladex® [goserelin acetate, AstraZeneca Pharmaceuticals, LP, Wilmington, DE] [J9202]) would result in a third calculation. The lower ASP of the two J codes will be used to determine the payment for all 3 of these Medicare-deemed medically equivalent drugs.[5] Currently, all but 5 states (Wisconsin, Illinois, Michigan, Minnesota, and Montana) have adopted the LCA payment method. In addition, Utah has rescinded LCA payment methods for 6 months, pending final ruling.

The final Medicare payment schedule for the first quarter of 2005 was calculated using actual third quarter 2004 ASP data from the manufacturers.[7] The payment as published for J9217 is $253.13 for 2005, higher than was widely anticipated. As stated above, payment will be made at 106% of the calculations for actual ASP, not on the price paid. The payments will change quarterly based on the changes in reported ASPs. If a given manufacturer sells the drug at a price lower than ASP and a physician buys from that company, the physician will realize a greater profit. However, purchase of the less expensive drug will contribute to a drop in ASP in the next quarter. If a second manufacturer lowers its price to compete with the first company, the ASP will be even lower the following quarter.

Practice Issues

The ultimate goal for urologists when making treatment decisions regarding LHRH agonist use is to continue to provide hassle-free, complete care for patients, including whatever medications they need. With the decrease in profits resulting from these new rules, urologists will need to be selective when contracting with suppliers of LHRH agonist drugs. They must also be mindful of the high cost of

maintaining inventory, loss of money from poor insurance-coverage information, or lack of copayment collection, which could be financially disastrous in this new setting.[6]

Solutions

Contracts financially unfavorable to the physician must be avoided. Urologists should continue to get the best price they can for the drug most appropriate for their patients, be sure their contract price is at ASP or below, and be aware that the payment may decrease each quarter. The ability to adjust purchasing contracts to accommodate these changes is optimal.

Steps to Maintaining Profits

- **Minimize or eliminate inventory cost**
- **Contingency contract**
- **No free drugs**
  —Diligent insurance review
  —Refer for assistance
- **Continue to buy drugs and Rx pts**

Injections

Medicare payments for injectable therapies increased significantly in 2004.[3] Subcutaneous or intramuscular (IM) chemotherapy administration (96400), for example, was reimbursed at approximately $64.00 per. For 2005, the injection code has changed for all states. The new code is G0356 and the national payment is $36.62. Physicians can charge for Evaluation and Management (E&M) codes at the same visit, except for 99211, where modifier −25 is needed, as discussed below.

Office Visits

MMA 2003 changed the rules, beginning in 2004, for charging an E&M service on the same day as a chemotherapeutic administration (such as 96400, IM or subcutaneous injection). One can no longer charge a 99211 first-level established patient code (commonly called "the nursing code") on the same day that a chemotherapeutic administration such as 96400 has been charged. However, if the urologist sees a patient and provides a service that qualifies for the use of a modifier −25, then a higher-level 99213, 99214, or 99215 service code can be charged by attaching modifier −25 to the appropriate number. Physicians can also charge a consult or new patient code with modifier −25.[3]

Modifier −25

The correct use of modifier −25 by both payers and providers has again become a topic of some discussion.[7] Due in part to the filing of lawsuits by several medical societies against payers for wrongfully denied payments and 2 resultant settlements, with Aetna Inc. and Cigna HealthCare, the use of modifier −25 is on the rise. Unfortunately, the usage and recognition of modifier −25 is still somewhat variable and can frustrate both the provider and the payer.[8]

First, the definition and intended use of the modifier must be reviewed. The American Medical Association Current Procedural Terminology (CPT®) 2004 lists the definition of

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CMS clearly believes that physicians should continue to treat patients with the appropriate drug for their condition but will watch closely for major changes, including those in the frequency of injections. In particular, they have advised against shifting a significant number of patients from injection-based therapies to administration via implants prior to the end of 2005. It is important to thoroughly document any changes made in the treatment regimen of each patient.[4]

Main Points

- The Medicare Prescription Drug Improvement and Modernization Act of 2003 has negatively impacted the income of urologists and will continue to do so through 2005.
- In the past, urologists have been paid a percentage of the average wholesale price for injectable drugs; in 2005, urologists are being paid 106% based on the average sales price.
- Through careful negotiation of low pricing and flexible price-setting terms, it is still possible for urologists to derive profit from administration of LHRH agonists.
- In 2006, regulations will allow urologists to either continue to buy and store their own injectable drugs, or to have them delivered by a contracted agent. Whether this proves advantageous to the physician depends on the final terms of the new regulations.

modifier −25 as a "significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service."[9] As indicated within the CPT coding manual, the modifier is to be used to indicate that an E&M service, which is significant and clearly separate from other services, was provided on the same day. The definition further indicates that the E&M service is clearly beyond and separate from that which is provided normally as pre- or postoperative care for any global service provided on the same day. The CPT manual also states that a separate problem or diagnosis is not required to distinguish a separate or significant E&M service.

In terms of billing, the modifier −25 is used to indicate that E&M service, fitting the listed definition and supported by clear documentation, is payable on the same date as the injection procedure. Many private payers and Medicare will recognize the modifier −25 as was intended by CPT and will pay for those E&M services for which modifier −25 is used appropriately.

The key to undisputed payment is thorough documentation of medically necessary services and of E&M services that are clearly separate from the procedure(s) provided on the same day. Further, physicians should make sure the E&M note is physically separate from the service documentation. The E&M documentation does not have to be on a separate page from the documentation for the injection. However, it should be separated by line spacing and be self-contained.

2006 and Beyond

In 2006, physicians will be paid 106% of ASP for injectable drugs or they will have the option of buying their drugs from a contracting agent who will deliver the drugs to the office. The decision is one of all or nothing. If physicians choose to continue buying drugs, then they must buy all of their drugs. If they choose to use an acquisition agent, then they must buy all drugs through that agency. Making this choice will alleviate all charges for drugs to Medicare and will eliminate any income for storing or handling the drug. However, final regulations have not been published and the pros and cons of this arrangement are not yet clear.[5]

Summary

In summary, physicians should be prepared for an initial decrease in income and in 2005, plan to delay contracting for purchased drugs until all options and the exact amount to be paid by Medicare are known, automate documentation and billing, code correctly, and prepare for the resurgence of Medicare HMOs. Fortunately, the future is brighter than the projections of doom and gloom previously suggested for 2005. Systems automation and improved data will improve efficiency, thereby increasing income in a number of ways. ■

Overall Outlook for Urologists

- **Continue to buy low, sell high**
- **Selective contingency contracting**
- **Develop new profit centers**
- **Improve business practices**
  —Automated processes
  —Improved data for decision-making
- **Back to the basics—GPC**

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