Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE REIMBURSEMENT FOR LUPRON

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ABSTRACT

Medicare and its beneficiaries paid $677 million for Lupron in calendar year (CY) 2002, accounting for 8 percent of all Medicare drug reimbursements that year. In 2003, the Medicare reimbursement amount for Lupron was set at 95 percent of the drug's average wholesale price, as required by Federal law. Medicare carriers often use local medical review policies (LMRPs) in order to further specify the circumstances under which a service is covered and paid by the program. One type of LMRP, a least costly alternative policy, states that the carrier will not cover the additional cost of a more expensive product if a clinically comparable product costs less. According to the LMRPs of many carriers, a single dose of the drug Zoladex has been found by many experts to be clinically comparable to a single dose of Lupron. In the second quarter of 2003, the Medicare reimbursement amount for a single dose of Zoladex was $446.49, 27 percent less than the reimbursement amount for a single dose of Lupron ($611.56). Therefore, in jurisdictions where a carrier applies a least costly alternative policy, physicians that administer Lupron are generally reimbursed the Zoladex amount. We obtained and reviewed LMRPs from all Medicare carriers. We found that carriers in 10 of 57 jurisdictions did not apply a least costly alternative policy to Lupron. In 2002, the carriers in these 10 jurisdictions reimbursed a total of $147 million for the drug. If these carriers implemented a least costly alternative policy, their reimbursement amount for Lupron would be cut by 27 percent, saving Medicare and its beneficiaries $40 million per year. We recommended that CMS encourage all Medicare carriers to apply a least costly alternative policy to Lupron.

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INTRODUCTION

OBJECTIVE

To determine the amount Medicare would save if all carriers established a least costly alternative policy for Lupron (leuprolide acetate 7.5 milligrams (mg) depot suspension).

BACKGROUND

Medicare Reimbursement of Lupron

Currently, Medicare Part B does not pay for over-the-counter or most outpatient prescription drugs. However, under specific circumstances, Medicare Part B covers drugs used with durable medical equipment or infusion devices. Medicare also covers certain drugs used in association with organ transplantation, dialysis, chemotherapy, and pain management. One such drug, leuprolide acetate (brand name Lupron), is used in the treatment of advanced prostate cancer. Lupron is manufactured by TAP Pharmaceutical Products Inc.

The Centers for Medicare & Medicaid Services (CMS) contracts with companies, known as carriers, to process and reimburse most Part B claims, including claims for prescription drugs. Twenty carriers currently serve 57 specific jurisdictions. Physicians submit claims for Lupron to the carrier in their area, and are subsequently reimbursed by Medicare.

Medicare=s reimbursement methodology for Lupron and other prescription drugs is defined by section 1842(o) of the Social Security Act (the Act), as amended by section 4556 of the Balanced Budget Act of 1997. The Act states that reimbursement for a covered drug is to be set at 95 percent of the drug's average wholesale price (AWP). CMS directs carriers to obtain AWP data from the *Red Book* or similar pricing publications used by the pharmaceutical industry.

Recently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 lowered payments for many Part B drugs by revising section 1842(o) of the Act. According to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the payment for a drug contained in the table "Medicare Part B Drugs in Most Recent GAO and OIG Studies" published in the Federal Register will be the percentage of the AWP indicated in the table. If the percentage in the table is less

than 80 percent, then the percentage applied to reimbursement will be 80 percent. Based on the data presented in this table, in 2004, Medicare reimbursement for Lupron will be 81 percent of the AWP.

Medicare beneficiaries are responsible for paying a 20 percent copayment for Lupron and other covered drugs. In 2002, Medicare and its beneficiaries paid $677 million for Lupron (7.5 mg depot suspension), accounting for 8 percent of all Medicare drug reimbursement that year.

Local Medical Review Polices

Medicare carriers issue local medical review policies (LMRPs) in order to further specify the circumstances under which a service is covered by the program. According to CMS's Medicare Program Integrity Manual (Chapter 13, Section 1.3):

> Contractors develop LMRPs by considering medical literature, the advice of local medical societies and medical consultants, and public comments. If a contractor develops an LMRP, its LMRP applies only within the area it services. While another contractor may come to a similar decision, CMS does not require it to do so.

The contractors are required to ensure that all LMRPs are consistent with all statutes, rulings, regulations, and national coverage, payment, and coding policies.

Carriers' Use of Least Costly Alternative Policy

According to carrier LMRPs, a least costly alternative policy means that the carrier will not cover the additional cost of a more expensive product if a clinically comparable product costs less. Carriers' use of a least costly alternative is supported by CMS in its Program Integrity Manual (Chapter 13, Section 5.4), which states, "Least costly alternative is a national policy provision that must be applied by contractors when determining payment for all durable medical equipment (DME). Contractors have the discretion to apply this principal to payment for non-DME services as well."

Over the last several years, many carriers have implemented a least costly alternative policy for Lupron. According to carrier LMRPs, a single dose of the drug goserelin acetate (i.e., 3.6 mg implant, brand name Zoladex) has been found by many experts to be clinically comparable to a single dose of Lupron (7.5 mg depot suspension). As of the second quarter of 2003, the Medicare reimbursement amount for a

single dose of Zoladex is $446.49, 27 percent less than the reimbursement amount for a single dose of Lupron ($611.56). Therefore, in jurisdictions where a carrier applies the least costly alternative policy, physicians that administer Lupron are generally reimbursed the Zoladex amount. In some instances, however, the full reimbursement amount may still be paid if the physician can document why the more costly treatment option (i.e., Lupron) is medically necessary. Furthermore, some carriers allow reimbursement to be made at the higher amount if the beneficiary was already being treated with Lupron at the time the least costly alternative policy was enacted.

Related Work by the Office of Inspector General (OIG)

OIG has consistently found that Medicare's usual reimbursement amount for Lupron (based on average wholesale price) is excessive. For example, in our report *Medicare Payments for Prescription Drugs--Response to Request from Representative W. J. Tauzin* (June 2001), we calculated that the Medicare reimbursement amount for Lupron in 2000 was more than double the Department of Veterans Affairs (VA) purchase price. According to our findings, excessive reimbursement for Lupron alone was costing the Medicare program up to $359 million per year.

In another of our reports, *Medicare Reimbursement of Prescription Drugs* (January 2001), we found that Medicare would have saved almost $100 million in 1999 by reimbursing for Lupron at the actual wholesale price available to the physician/supplier community.

METHODOLOGY

We reviewed laws and regulations concerning Medicare drug reimbursement. We obtained and reviewed LMRPs from all Medicare carriers in order to determine which carriers currently apply a least costly alternative policy to Lupron. We accessed CMS's Part B Extract Summary System to determine each carrier's 2002 total reimbursement for Lupron. To calculate the potential savings that would be achieved if carriers not using least costly alternative implemented such a policy, we (1) added the total reimbursement for Lupron by all carriers not using a least costly alternative policy, and (2) multiplied this figure by 27 percent.

Note on Savings Estimates: The savings estimates presented in this report are based on 2003 reimbursement amounts. In 2003, Medicare reimbursed 95 percent of the AWP for both Lupron and Zoladex. Based on provisions of the recently passed Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare will reimburse Lupron at 81 percent of the AWP in 2004. Zoladex will be reimbursed at 80 percent of the AWP.

This study was conducted in accordance with the *Quality Standards for Inspections* issued by the President=s Council on Integrity and Efficiency.

FINDING

Currently, Medicare carriers in 47 of 57 jurisdictions apply a least costly alternative policy to Lupron. Carriers in these 47 jurisdictions reimburse $446.49 for 7.5 mg of Lupron, 27 percent less than carriers in the 10 jurisdictions without a least costly alternative policy (who reimburse $611.56 for the same amount). In 2002, the carriers that did not have a least costly alternative policy reimbursed a total of $147 million for Lupron, accounting for 22 percent of all Medicare payments for the drug. If these carriers implemented a least costly alternative policy, their reimbursement amount for the drug would be cut by 27 percent. This reduction would save Medicare and its beneficiaries $40 million per year.

Medicare and its beneficiaries would save $40 million per year if 10 carriers not using least costly alternative implemented such a policy.

RECOMMENDATION

Medicare carriers representing 10 of 57 jurisdictions have not implemented a least costly alternative policy for Lupron. As a result, these carriers are paying substantially more for the drug than carriers serving 47 other localities. If carriers in these 10 jurisdictions adopted a least costly alternative policy, Medicare and its beneficiaries could save $40 million per year. Although CMS does not require carriers to have identical medical policies, this seems to be a situation where all carriers would benefit from utilizing a least costly alternative policy for Lupron.

Therefore, we recommend that CMS encourage all Medicare carriers to apply a least costly alternative policy to Lupron.

Agency Comments

CMS partially concurred with our recommendation, agreeing to facilitate communication between carriers that have adopted a least costly alternative policy and those that have not. CMS stated that they will continue to monitor the use of these policies for Lupron and other drugs while also pursuing other initiatives to reduce excessive growth in drug spending. However, CMS stated that although they provide oversight of the development of contractor LMRPs, they do not generally influence the application of these guidelines in specific circumstances. The full text of CMS's comments is presented in the appendix.

APPENDIX

Centers for Medicare & Medicaid Services Comments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: NOV 15 2003

TO: Dara Corrigan
Acting Principal Deputy Inspector General
Office of Inspector General

FROM: Thomas A. Scully
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Reimbursement for Lupron (OEI-03-03-00250)

Thank you for giving the Centers for Medicare & Medicaid Services (CMS) the opportunity to review the draft report, "Medicare Reimbursement for Lupron," which found that Medicare and its beneficiaries would save $40 million per year if all carriers established a least costly alternative (LCA) local medical review policy (LMRP) for Lupron. Lupron Depot is an injectable drug, manufactured by TAP Pharmaceuticals, that is applied for the palliative treatment of advanced prostate cancer, for management of endometriosis, in combination with iron for the preoperative treatment of anemia caused by uterine fibroids, and for the treatment of children with central precocious puberty.

As the OIG report notes, carriers adopting an LCA policy will not pay the additional cost of an expensive drug, like Lupron, if a clinically comparable drug is available at less cost. All LCA policies affecting payment for Lupron specify that full payment will be made if the physician states that the use of Lupron rather than the LCA drug is medically necessary.

The rapid growth in recent years in Medicare spending under Part B for drugs, such as Lupron, that are administered in a physician's office raises serious questions for payment policy. Although the Medicare program has no broad prescription drug benefit, it does cover drugs used with durable medical equipment or infusion devices, as well as a number of drugs used in conjunction with organ transplantation, outpatient kidney dialysis, chemotherapy, and pain management.

In shaping policies to rein in the growth of drug spending, CMS has to be especially careful not to impede access to medically necessary care or to interfere with the clinical judgment of the treating physician. To the extent that the growth in drug expenditures reflects the substitution of drugs for other more intrusive or less effective therapeutic options, the increasing drug costs may be offset in part by savings in other sectors of Medicare spending. However, CMS has found a number of examples where drug prices have been artificially inflated.

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In the past year, CMS has taken several initiatives designed to curtail unnecessary spending for drugs without intruding on the physician's medical judgment. First, CMS has initiated the use of a Single Drug Pricer, under which one Medicare contractor determines a national payment allowance limit for each covered drug that is then applied consistently by all Medicare contactors.

In addition, CMS has published a proposed rule that would simultaneously address the problem of overpayments for expensive oncology and other drugs, while improving payments to physicians for the costs of administering those drugs.

Finally, it should be noted that CMS has been involved in litigation over payment policies for Lupron, and any efforts to curb Medicare drug spending should be consistent with the outcome of that litigation.

It is in this context that we address the OIG's recommendations with regard to payment for Lupron.

OIG Recommendation
The Centers for Medicare & Medicaid Services (CMS) encourages all Medicare carriers to apply an LCA policy to Lupron.

CMS Response
We partially concur, and will agree to facilitate communication between the carriers that have adopted least costly alternative LMRPs for Lupron and those that have not. We will also continue to monitor the use of LCAs for Lupron and other drugs in combination with our other initiatives to curb excessive growth in drug spending.

While CMS determines national guidelines and criteria that must be followed by all of its contractors in creating LMRPs, by their very nature LMRPs are local and, as the name implies, CMS generally does not influence the application of these guidelines in any specific circumstance.

ACKNOWLEDGMENTS

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia Regional Office, and Linda M. Ragone, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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