

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**LEAST COSTLY ALTERNATIVE
POLICIES: IMPACT ON
PROSTATE CANCER DRUGS
COVERED UNDER
MEDICARE PART B**



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Inspector General**

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EXECUTIVE SUMMARY – LEAST COSTLY ALTERNATIVE POLICIES: IMPACT ON PROSTATE CANCER DRUGS COVERED UNDER MEDICARE PART B, OEI-12-12-00210

WHY WE DID THIS STUDY

Between 1995 and 2010, certain prostate cancer drugs covered under Medicare Part B were subject to least costly alternative (LCA) policies, which based the payment amount for a group of clinically comparable products on that of the least costly one. However, in April 2010, LCA policies for Part B drugs were discontinued in response to a court ruling stating that the use of an LCA policy was not authorized under Medicare law. Recently, Congressman Ken Calvert expressed concerns that the withdrawal of LCA policies for prostate cancer drugs may have created an unintentional incentive for physicians to administer costlier drugs. Congressman Calvert requested an examination of the policy withdrawal and its impact.

HOW WE DID THIS STUDY

For each quarter between the beginning of the third quarter of 2010 and the end of the second quarter of 2011, we identified the lowest Medicare payment amount among clinically comparable luteinizing hormone-releasing hormone (LHRH) agonists used to treat prostate cancer and calculated the amount that Medicare would have saved if the more expensive LHRH agonists had been reimbursed at these lower amounts. To determine whether the withdrawal of LCA policies affected utilization patterns for LHRH agonists, we tracked quarterly shifts in utilization from 1 year before the policies were withdrawn to 1 year after.

WHAT WE FOUND

If LCA policies for LHRH agonists had not been rescinded, Medicare expenditures would have been reduced by \$33.3 million over 1 year, from \$264.6 million to \$231.3 million. After LCA policies were removed, utilization patterns shifted dramatically in favor of certain costlier products. However, the overall utilization of LHRH agonists to treat prostate cancer has been decreasing, a trend that began at least 1 year prior to elimination of LCA policies and continued for more than a year after.

WHAT WE RECOMMEND

Our results indicate that Medicare spending for LHRH agonists is higher in the absence of LCA policies. We also confirmed changes in utilization patterns for LHRH agonists, some of which appear to have occurred independently of LCA policies and some of which coincided with their removal. LCA policies may be a useful tool for conserving taxpayer funds, provided that patients retain access to appropriate care, but are not likely to be restored without legislative action. Therefore, we recommend that the Centers for Medicare & Medicaid Service (CMS) consider seeking legislative authority to implement LCA policies for Part B drugs under appropriate circumstances. CMS partially concurred with our recommendation.

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OBJECTIVES

1. To determine the financial impact of rescinding least costly alternative (LCA) policies for certain prostate cancer drugs covered under Medicare Part B.
2. To determine how Medicare Part B utilization for certain prostate cancer drugs changed after the LCA policies were rescinded.

BACKGROUND

Between 1995 and 2010, certain drugs covered under Medicare Part B were subject to LCA policies, which based the payment amount for a group of clinically comparable drugs on that of the least costly one. However, in April 2010, the Centers for Medicare & Medicaid Services (CMS) discontinued all LCA policies for Part B drugs in response to a December 2009 court ruling that considered the use of an LCA policy for a Part B-covered inhalation drug and found that Medicare law did not authorize the use of the LCA policy.¹

Recently, Congressman Ken Calvert expressed concerns that the withdrawal of LCA policies for certain prostate cancer drugs may have created an unintentional incentive for physicians to administer costlier drugs. In a letter to the Office of Inspector General (OIG), he requested an examination of the policy withdrawal and its impact on pricing.

Medicare Part B Coverage of Prescription Drugs

Most outpatient prescription drugs paid for by Medicare are covered under Part D; however, a limited number of drugs are covered under Medicare Part B, including physician-administered injectable drugs, certain self-administered oral anticancer and immunosuppressive drugs, and drugs used in conjunction with durable medical equipment.

Medicare Part B Payments for Prescription Drugs

CMS contracts with private companies to process and pay Medicare Part B claims, including those for covered drugs. To obtain reimbursement for covered drugs, health care providers submit claims to their Medicare contractors using Healthcare Common Procedure Coding

¹ *Hays v. Sebelius*, 589 F. 3d 1279, 1283 (D.C. Cir. 2009).

System (HCPCS) codes.² In 2011, Medicare and its beneficiaries spent over \$12 billion for drugs covered under Part B.³

Reimbursement Methodology for Most Part B Drugs

Since 2005, Medicare Part B has paid for most covered drugs using a reimbursement methodology based on average sales prices (ASP).⁴ Under the ASP pricing methodology, the Medicare allowance for most Part B drugs is equal to 106 percent of the volume-weighted ASP for the drug's HCPCS code.⁵ Medicare beneficiaries are generally responsible for 20 percent of this amount in the form of coinsurance.

Least Costly Alternative Policies for Medicare Part B Drugs

Historically, Medicare contractors have established LCA policies for various Part B items and services, including Part B drugs. LCA policies for Part B drugs set the payment amount for a group of clinically similar HCPCS codes using the ASP-based reimbursement amount for the least costly drug.

Under these policies, Medicare would generally not cover the additional cost of a more expensive drug product if a clinically comparable, lower priced drug product exists; however, a beneficiary may continue to receive the more expensive product, with the additional cost covered by either the provider or the beneficiary.^{6, 7} Beneficiaries may indicate their willingness to accept financial responsibility for additional costs by signing Advanced Beneficiary Notices of Noncoverage (ABN).

LCA policies for certain prostate cancer drugs. As part of treatment for prostate cancer, many patients undergo hormone therapy, either as a

² CMS established HCPCS codes to provide a standardized system for describing the specific items and services provided in the delivery of health care.

³ Medicare expenditures for Part B drugs in 2011 were calculated using CMS's Part B Analytics and Reports (PBAR). The PBAR data for 2011 were 98 percent complete when the data were downloaded in May 2012.

⁴ Pursuant to section 1847A(c) of the Social Security Act (the Act), an ASP is a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions, such as volume discounts, "prompt pay" discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in Medicaid's drug rebate program.

⁵ Section 1847A(b) of the Act.

⁶ All archived coverage documents for LHRH agonists containing LCA policies can be accessed at http://coverage.cms.fu.com/mcd_archive.

⁷ Certain Medicare contractors may also cover the additional cost of a more expensive drug under limited circumstances.

stand-alone treatment or in conjunction with other treatments, such as radiation therapy or prostatectomy.⁸ Although hormone therapy alone does not cure prostate cancer, it can suppress male hormones that stimulate the growth of prostate cancer cells.⁹ This hormone suppression is most commonly achieved by administering drugs called luteinizing hormone-releasing hormone (LHRH) agonists.¹⁰

In 1995, Medicare contractors began using LCA policies to control the cost of LHRH agonists used to treat prostate cancer.¹¹ Initially, contractors instituted LCA policies for two LHRH agonists that are administered as monthly injections.¹² These policies set the payment amount for the more expensive drug (Lupron) at the level of its lower priced alternative (Zoladex).^{13, 14}

Between 2001 and 2004, four additional LHRH agonists entered the prescription drug market. Contractors generally included two new monthly injections, Eligard and Trelstar, in the LCA policies along with Lupron and Zoladex. Most contractors established separate LCA policies for the other two new LHRH agonists, Vantas and Viadur, which are administered as annual implants.¹⁵ In 2011, Medicare and its beneficiaries paid approximately \$289 million for all LHRH agonists, representing about 2 percent of all spending on Part B drugs during that year.¹⁶

⁸ *Prostate Cancer Detailed Guide*. American Cancer Society. Accessed at <http://www.cancer.org> on August 17, 2012.

⁹ Ibid.

¹⁰ Increased health risks associated with hormone therapy, including LHRH agonists, may include anemia, loss of bone density, diabetes, vascular problems, and colorectal cancer.

¹¹ Medicare Payment Advisory Commission. *Report to the Congress: Impact of Changes in Medicare Payments for Part B Drugs* (January 2007). Accessed at <http://www.medpac.gov> on August 17, 2012.

¹² For example, see *Local Medical Review Policy for Leuprolide Acetate (Lupron) and Goserelin Acetate (Zoladex)*, Document ID L7657 (Retired), National Government Services, Inc. Accessed at http://coverage.cms.fu.com/mcd_archive on August 17, 2012.

¹³ Zoladex is administered as a small implant that is injected under the skin of the stomach. For the purposes of this report, we will consider Zoladex to be an injection.

¹⁴ The LHRH agonists included in these LCA policies are represented by more than one HCPCS code and marketed by different manufacturers. Therefore, the ASPs (and ASP-based payment amounts) may differ.

¹⁵ In December 2007, Bayer announced that it would phase out marketing of Viadur in April 2008, citing diminished market demand and growing manufacturing costs. The other LHRH agonist administered as an annual implant, Vantas, continues to be manufactured by Endo Pharmaceuticals.

¹⁶ Medicare expenditures for LHRH agonists in 2011 were calculated using PBAR data that were 98 percent complete when the data were downloaded in May 2012.

According to LCA policies for LHRH agonists, there is no difference in effectiveness among LHRH agonists used to treat prostate cancer;¹⁷ a 2010 study published in the *Journal of the National Cancer Institute* concluded that decreased physician reimbursement for hormone therapy was associated with a reduction in overtreatment without a reduction in needed services.¹⁸ However, some advocacy groups have voiced opposition to LCA policies, stating that they drive providers to base treatment decisions on cost rather than on clinical factors, such as an individual patient's response to a drug or its side effects.¹⁹ Others have expressed concern that LCA policies would ultimately push patients toward less expensive but more invasive methods for achieving hormone suppression, such as simple orchiectomy (i.e., the surgical removal of one or both testicles).

Proposed LCA policies for inhalation drugs. In April 2008, certain Medicare contractors proposed instituting LCA policies for Xopenex and DuoNeb, two Part B-covered inhalation drugs used to treat chronic obstructive pulmonary disease and other lung diseases due to external agents.²⁰ LCA policies for these inhalation drugs were scheduled to take effect July 1, 2008. However, after separate lawsuits were filed regarding LCA policies for Xopenex and Duoneb, the LCA policies for Xopenex were withdrawn and implementation of the LCA policies for DuoNeb was delayed pending further review by CMS.

Elimination of LCA policies for Part B drugs. In October 2008, the U.S. District Court for the District of Columbia ruled that the Secretary of Health and Human Services was required by statute to pay for Part B-covered drugs such as DuoNeb based on ASP and therefore lacked legal authority under Medicare law to establish LCA policies for DuoNeb.²¹ This prompted CMS to withdraw the proposed policies for that drug. The U.S. Court of Appeals for the District of Columbia Circuit upheld the lower court's decision in December 2009, ruling that Medicare

¹⁷ For example, see *Local Coverage Determination for Gonadotropin-Releasing Hormone Analogs*, Document ID L17602 (Superseded), NHIC Corp. Accessed at http://coverage.cms.fu.com/mcd_archive on August 17, 2012.

¹⁸ Sean P. Elliott et al., "Reduction in Physician Reimbursement and Use of Hormone Therapy in Prostate Cancer," *Journal of the National Cancer Institute*, 102, no. 24 (2010): 1826.

¹⁹ *Prostate Cancer Groups Demand Doctors and Patients Given Control Over Patients' Prostate Cancer Treatment*. Men's Health Network press release (published October 30, 2006). Accessed at <http://www.ustoo.org> on August 17, 2012.

²⁰ The unimplemented LCA policies for inhalation drugs can be found in the revision histories of contractors' current coverage documents for nebulizers, available online at <http://www.cms.gov/medicare-coverage-database>. For example, see *Local Coverage Determination for Nebulizers*, ID Number L11499, NHIC Corp.

²¹ *Hays v. Leavitt*, 583 F. Supp. 2d 62, 72 (D.D.C. 2008).

law did not authorize LCA policies for DuoNeb.²² In April 2010, CMS directed contractors to discontinue all LCA policies for Part B drugs.²³ At that time, LHRH agonists were among the few Part B drugs widely subject to LCA policies.²⁴

Previous OIG Work

According to an OIG report released in January 2004, Medicare contractors in all but 10 of 57 jurisdictions had LCA policies for Lupron and Zoladex in 2002.²⁵ If the 10 remaining contractors had applied similar LCA policies during that year, payments for the 2 drugs would have been reduced by 27 percent, saving Medicare and its beneficiaries \$40 million. OIG recommended that CMS encourage all Medicare contractors to apply LCA policies to Lupron. In response, CMS agreed to facilitate communication between contractors that had adopted LCA policies and those that had not. By 2010, Medicare contractors in all States and the District of Columbia had LCA policies for LHRH agonists.

METHODOLOGY

Data Collection

Medicare Part B Payment Amounts. We obtained the published Medicare payment amounts for LHRH agonists for each quarter between the second quarter of 2009 and the second quarter of 2011. Because one of the two LHRH agonists administered as annual implants has been discontinued (thus leaving no “alternative”), we examined payment amounts only for those HCPCS codes representing LHRH agonists administered as monthly injections, as shown in Table 1.

Table 1: HCPCS Codes Subject to LCA Policies for LHRH Agonists Administered as Monthly Injections

HCPCS Code	Description	Brand Name
J3315	Triptorelin pamoate	Trelstar
J9202	Goserelin acetate implant	Zoladex
J9217	Leuprolide acetate suspension	Lupron, Eligard

Source: CMS's Medicare Part B reimbursement files.

²² *Hays v. Sebelius*, 589 F. 3d 1279, 1283 (D.C. Cir. 2009).

²³ See, for example, *May 2010 LCA Updates*, NHIC Corp. (published April 29, 2010). Accessed at <http://www.medicarenhic.com> on August 17, 2012.

²⁴ Prior to April 2010, LCA policies were also applied to liposomal amphotericin B used in conjunction with external infusion pumps. However, Medicare expenditures for these drugs were very low relative to those for LHRH agonists, totaling only about \$2.7 million in 2011.

²⁵ OIG, *Medicare Reimbursement for Lupron*, OEI-03-03-00250, January 2004. This report was issued prior to implementation of ASP-based reimbursement for Medicare Part B drugs.

Medicare Part B Claims Data. For each of the HCPCS codes in Table 1, we obtained all of the claims paid by contractors for dates of service between April 1, 2009, and June 30, 2011. We selected all claims associated with prostate cancer (specifically, diagnosis code 185, malignant neoplasm of the prostate) and summarized expenditures and utilization for each HCPCS code in each quarter under review.^{26, 27}

We also obtained all of the claims for Vantas annual implants (HCPCS code J9225) and simple orchiectomies (procedure code 54520) with dates of service between April 1, 2009, and June 30, 2011. For each HCPCS code, we selected all paid claims associated with prostate cancer (diagnosis code 185) and summarized expenditures and utilization for each quarter under review.²⁸

Data Analysis

Analysis of expenditures for LHRH agonists previously subject to LCA policies. For each quarter between the third quarter of 2010 and the second quarter of 2011,²⁹ we identified the lowest of the Medicare payment amounts for the three HCPCS codes representing monthly injections (Table 1). To calculate the amount that Medicare would have saved if payment amounts had been based on the LCA, we multiplied the least costly amounts by the utilization for each of the more expensive drugs and subtracted the result from the actual expenditures for the drugs.

Analysis of utilization trends for LHRH agonists and other hormone therapy. To determine whether the withdrawal of LCA policies coincided with changes in utilization patterns for monthly injections, we used summarized Part B claims data to track quarterly shifts in utilization from

²⁶ Although certain Medicare contractors applied their LCA policies to more than one prostate cancer diagnosis code, we focused our analysis on diagnosis code 185, which appeared most frequently in contractors' LCA policies and accounted for 98 percent of the Medicare payments for all LHRH agonists during the period under review.

²⁷ We excluded any individual claim for more than six doses because such claims may represent billing errors. Individual claims for more than six doses constitute only 0.01 percent of all claims for monthly injections. We also excluded any claim with a modifier indicating that the beneficiary signed an ABN and therefore accepted financial responsibility for noncovered costs. Only about 0.6 percent of all paid claims for monthly injections used to treat prostate cancer had modifiers indicating that ABNs had been filed.

²⁸ For Vantas implants, we excluded any individual claim for more than one dose because we would generally expect providers to bill for only one annual implant at a time. We also excluded any claim with a modifier indicating that the beneficiary signed an ABN and therefore accepted financial responsibility for noncovered costs. Only about 0.3 percent of all paid claims for Vantas implants used to treat prostate cancer had modifiers indicating that ABNs had been filed.

²⁹ This time period represents the first full year following the withdrawal of LCA policies for prostate cancer drugs.

1 year before the LCA policies were withdrawn (i.e., the second quarter of 2009) to 1 year after (i.e., the second quarter of 2011).

As points of comparison for trends in the utilization of monthly injections, we also tracked quarterly shifts in utilization for Vantas implants and simple orchiectomies from the second quarter of 2009 through the second quarter of 2011.

Limitations

Medicare contractors' LCA policies for LHRH agonists varied with respect to certain criteria, such as the specific diagnosis codes subject to the policies and whether the contractors made exceptions for patients who had been receiving a more expensive drug prior to implementation of the policies. We did not tailor our analysis to account for all policy variations among contractors; rather, our analysis is based on the criteria common among the majority of LCA policies.

There may be instances in which LCA policies would not have generated savings for Medicare and its beneficiaries because the contractors, the providers, or the patients opted to pay for the additional cost of the more expensive drugs. To address this issue, we excluded claims with modifiers indicating that the beneficiaries signed ABNs and accepted financial responsibility for noncovered amounts. However, we did not identify or exclude claims for more expensive drugs for which the contractors or providers may have covered the additional cost.

We did not review the Part B claims for accuracy, nor did we review any documentation in support of the claims included in our study. Also, we did not examine utilization trends for additional types of hormone therapy used to treat prostate cancer, such as LHRH antagonists, antiandrogens, and estrogens. We also did not examine trends in other prostate cancer treatments, such as chemotherapy, radiation therapy, or prostatectomy.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Medicare and its beneficiaries would have saved \$33 million in 1 year if LCA policies for LHRH agonists had not been rescinded

If LCA policies had been in effect between the third quarter of 2010 and the second quarter of 2011, payment amounts for Lupron, Eligard, and Zoladex would have been based on that of the least costly alternative, Trelstar. As shown in Table 2, the potential savings per dose in each quarter would have ranged from \$1.61 to \$33.49 for Zoladex and from \$17.70 to \$40.85 for Lupron and Eligard.

If the more expensive products had been reimbursed at the lower price in each quarter under review, total expenditures for monthly injections over the year period would have been reduced from \$264.6 million to \$231.3 million, yielding a total savings of \$33.3 million (13 percent). Twenty percent of these savings (\$6.7 million) would have been realized by Medicare beneficiaries in the form of reduced coinsurance amounts.

Table 2: Payment Amounts for Monthly Injections

HCPCS Code	Brand	Third Quarter 2010	Fourth Quarter 2010	First Quarter 2011	Second Quarter 2011
Payment Amounts for the Least Costly Product					
J3315	Trelstar	\$164.59	\$181.93	\$176.27	\$197.31
Additional Amounts Paid for More Expensive Products					
J9202	Zoladex	+ \$33.49	+ \$12.36	+ \$26.08	+ \$1.61
J9217	Lupron, Eligard	+ \$40.85	+ \$26.28	+ \$32.83	+ \$17.70

Source: Medicare reimbursement amounts published by CMS for third quarter 2010 through second quarter 2011.

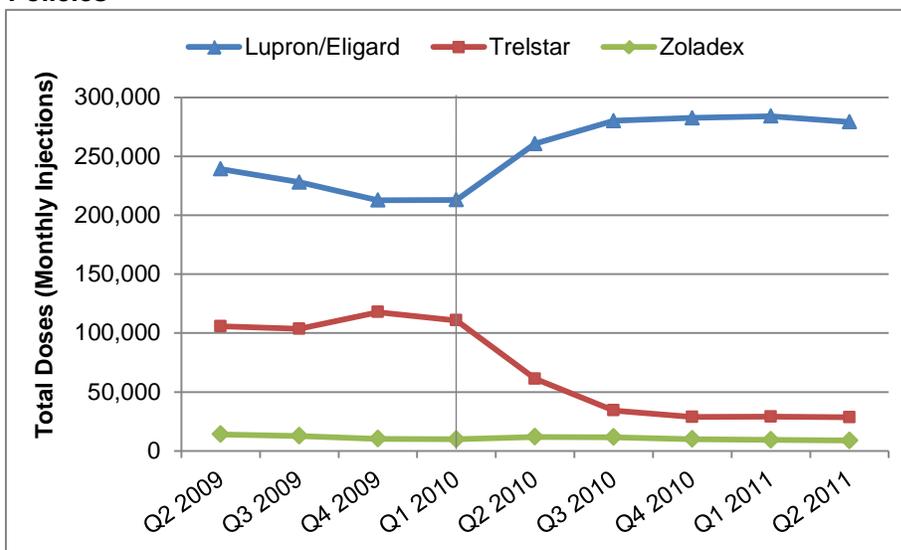
After LCA policies were rescinded, utilization patterns shifted dramatically in favor of costlier drugs

During the year before LCA policies were rescinded, the most costly LHRH monthly injections—Lupron and Eligard—were administered at about twice the rate of the least costly alternative, Trelstar (Figure 1).³⁰ However, utilization of these pricier drugs was declining during this time, decreasing 11 percent from the second quarter of 2009 through the first

³⁰ As mentioned previously, LCA policies do not require that the least costly drug be administered; they require only that *payment* for the more expensive drugs be limited to that of the least costly drug.

quarter of 2010. Meanwhile, utilization of Trelstar was rising, increasing almost 5 percent over the same four quarters.

Figure 1: Utilization of Monthly Injections Before and After Removal of LCA Policies



Note: Data points for each quarter represent the total utilization as of the end of that quarter. The vertical line distinguishes utilization under LCA policies from utilization after LCA policies were removed.
 Source: OIG analysis of Medicare Part B claims data, 2012.

As shown in Figure 1, utilization patterns for monthly injections shifted dramatically in favor of the costlier products almost immediately after LCA policies were rescinded. Utilization of Lupron and Eligard increased substantially, rising a total of 31 percent from the beginning of the second quarter of 2010 through the end of the second quarter of 2011.

During the same period, the administration of Trelstar plummeted by 74 percent, with the largest utilization drops occurring in the quarter during which the LCA policies were removed and the first full quarter after. By the end of the second quarter of 2011, Lupron and Eligard were administered at almost 10 times the rate of Trelstar.

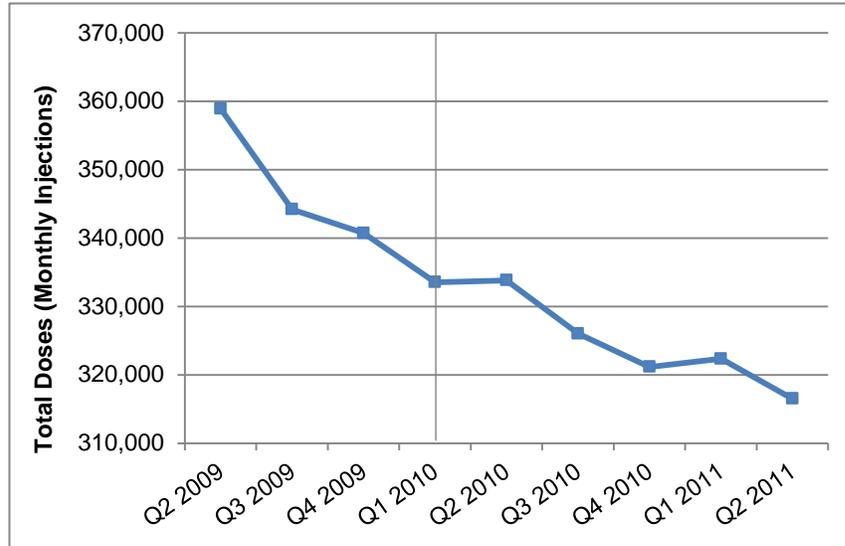
Although the administration of Zoladex decreased over the entire 27 months under review, utilization remained extremely low relative to utilization of Lupron; Eligard; and, to a lesser extent, Trelstar.

However, the overall utilization of LHRH agonists has been steadily decreasing

Despite variations in the administration of individual LHRH agonists, the number of doses of LHRH agonists administered overall for the treatment of prostate cancer began decreasing at least a year before CMS instructed contractors to rescind LCA policies and continued to fall for more than a

year afterward. This downward trend was evident not only for the more commonly administered monthly injections, but also for annual implants.

Figure 2: Decrease in Utilization of Monthly Injections To Treat Prostate Cancer



Note: Data points for each quarter represent the total utilization as of the end of that quarter. The vertical line distinguishes utilization under LCA policies from utilization after LCA policies were removed.
Source: OIG analysis of Medicare Part B claims data, 2012.

The number of monthly injections used to treat prostate cancer decreased about 7 percent during the year before elimination of LCA policies and continued to decrease another 5 percent in the 15 months after, resulting in an overall decrease of 12 percent from the second quarter of 2009 through the second quarter of 2011. (See Figure 2.)

The overall decrease in the administration of the annual Vantas implant was even more pronounced. The number of these implants used to treat prostate cancer fell by 23 percent in the year prior to elimination of LCA policies and continued to fall another 23 percent in the 15 months after, resulting in an overall decrease of 41 percent.

Although the use of LHRH agonists has been decreasing, we did not find a compensatory increase in another type of hormone therapy, the simple orchiectomy. The number of these procedures performed to treat prostate cancer declined 15 percent during the year before the elimination of LCA policies and continued to decline an additional 16 percent afterward.

A study published in 2009 in *The Journal of Urology* identified a similar reduction in the use of hormone therapy to treat prostate cancer. This study, which examined claims and payment data from 2003 to 2007, attributed the overall reduction in hormone therapy to a number of different factors, including a decrease in Medicare payment amounts following the implementation of the ASP-based reimbursement

methodology, the increased use of intermittent hormone therapy, and an increased recognition of the adverse effects associated with hormone therapy.^{31, 32} The study authors conclude that these factors, taken together, may have resulted in a more discriminating physician practice pattern and shrinking pool of appropriate candidates for LHRH agonists.

³¹ Steven L. Chang, Joseph C. Liao, and Rajesh Shinghal, “Decreasing Use of Luteinizing Hormone-Releasing Hormone Agonists in the United States is Independent of Reimbursement Changes: A Medicare and Veterans Health Administration Claims Analysis,” *The Journal of Urology* 182 (2009): 255.

³² As mentioned previously, increased health risks associated with hormone therapies may include anemia, loss of bone density, diabetes, vascular problems, and colorectal cancer.

CONCLUSION AND RECOMMENDATION

In 1995, Medicare contractors began using LCA policies to control the cost of LHRH agonists used to treat prostate cancer. However, CMS eliminated these policies in April 2010 as a result of a 2009 court ruling stating that Medicare law did not authorize the use of an LCA policy for an inhalation drug covered under Medicare Part B. Congressman Ken Calvert subsequently raised concerns that elimination of LCA policies for prostate cancer drugs may have provided physicians with an incentive to administer costlier drugs to patients.

Our results indicate that Medicare spending on clinically comparable LHRH agonists is higher in the absence of LCA policies, costing Medicare and its beneficiaries \$33 million in 1 year. Our results also confirm changes in utilization patterns for LHRH agonists, some of which appear to have occurred independently of LCA policies and some of which coincided with their removal. Specifically, the use of hormone therapy has been decreasing overall, which may be attributable in part to Medicare reimbursement but may also be influenced by clinical factors, such as an increased awareness of hormone therapy's health risks. In contrast, the shift in utilization patterns in favor of costlier products coincided directly with the removal of LCA policies.

LCA policies may be a useful tool for conserving taxpayer funds, provided that patients retain access to appropriate care; however, in light of the 2009 court ruling, LCA policies are not likely to be restored without legislative action. Therefore, we recommend that CMS:

Consider seeking legislative authority to implement LCA policies for Part B drugs under appropriate circumstances

By seeking a legislative change to amend the current statutory Medicare provisions applicable to Medicare Part B drugs, CMS could regain the flexibility to implement LCA policies for certain clinically comparable products under circumstances it deems appropriate.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred, in part, with the recommendation. CMS stated that it has evaluated its current authority in light of the court ruling and determined that further legislative action on this issue must occur before any LCA policies can be implemented. CMS additionally noted that any request for legislative authority for agency policies would be included in the annual President's Budget. However, CMS did not indicate whether it plans to seek such legislative authority consistent with our recommendation.

We did not make any changes to the report on the basis of CMS's comments. We ask that, in its final management decision, CMS more clearly indicate whether it concurs with our recommendation and what steps, if any, it will take to implement it.

For the full text of CMS's comments, see Appendix A.

APPENDIX A

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: SEP 28 2012

TO: Stuart Wright
Deputy Inspector General for Evaluations and Inspections

FROM: Marilyn Tavenner
Acting Administrator

SUBJECT: Office of Inspector General Draft Report: "Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare" (OEI-12-12-00210)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and respond to the Office of Inspector General (OIG) Draft Report entitled, "Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare." CMS appreciates OIG's effort to examine this issue.

In 1995, Medicare contractors began using least costly alternative (LCA) policies to control the cost of luteinizing hormone-releasing hormone agonists used in the treatment of prostate cancer. However, CMS eliminated these policies in April 2010 as a result of a 2009 court ruling that found that Medicare law did not authorize the use of an LCA policy for an inhalation drug covered under Medicare Part B. A member of Congress subsequently raised concerns that the elimination of LCA policies for prostate cancer drugs may have provided physicians with an incentive to administer costlier drugs to patients.

OIG Recommendation

Consider seeking legislative authority to implement LCA policies for Part B drugs under appropriate circumstances.

CMS Response

CMS concurs, in part, with the recommendation. CMS has completed evaluating its current authority in light of the December 2009 court ruling. CMS has determined that further legislative action on this issue must occur before it can implement any LCA policies. We note that any request for legislative authority for Agency policies would be included in the annual President's Budget.

CMS thanks the OIG for the opportunity to review and comment on this report.

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 David Tawes, Regional Inspector General for Evaluation and Inspections in the Baltimore regional office.

Lauren McNulty served as the team leader for this study. Central office staff who provided support include Althea Hosein, Meghan Kearns, Christine Moritz, and Tasha Trusty.

Office of Inspector General

<http://oig.hhs.gov>

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