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The 'Least Costly Alternative' Approach for Payment of Medicare Part B Drugs

How different reimbursement models could affect drug prices

Overview

From 1995 to 2010, the Centers for Medicare & Medicaid Services (CMS) applied a “least costly alternative” (LCA) approach to set payment for some drugs in Medicare Part B, which pays providers for the use of physician-administered drugs. Reimbursement for Part B drugs that were determined to be clinically comparable was based on the payment rate for the least costly product. However, CMS discontinued the LCA policy in 2010 after the U.S. Court of Appeals for the District of Columbia Circuit ruled that it was not authorized under Medicare law,¹ which requires that providers be reimbursed at 106 percent of the average sales price (ASP) of a drug.² Of this payable total, Medicare covers 80 percent of the cost, and beneficiaries pay the remaining 20 percent.³

The U.S. Department of Health and Human Services' Office of Inspector General has recommended that CMS consider seeking legislative authority to implement LCA policies for Part B drugs.⁴

Past use of the LCA policy in Medicare Part B

The LCA policy has previously been used to pay for drugs to treat prostate cancer, respiratory disease, and chronic renal failure.⁵ Under the LCA policy, Medicare would not pay the additional cost of a more expensive drug when a clinically comparable, lower-cost drug was available; however, a beneficiary could continue treatment with a higher-priced drug by choosing to pay the additional cost.

An LCA policy was used to control the cost of luteinizing hormone-releasing hormone (LHRH) agonists to treat patients with prostate cancer. In 2003, the cost of one LHRH agonist, goserelin, was 27 percent less than that of leuprolide, a different LHRH drug (\$446.49 per dose of goserelin compared with \$611.56 per dose of leuprolide).⁶ Under the LCA approach, the Medicare payment amount for leuprolide—the higher-cost drug—was set at the price of goserelin, with patients paying the difference in price.

How LCA could work

Under an LCA policy, the amount that Medicare pays for any drug would be based on the price of the least costly drug among clinically comparable products grouped into an LCA category. However, different policy choices would affect the total payment that providers receive for administering Part B drugs:

Unique ASP approach: Total payment (Medicare and a beneficiary's share combined) for any drug in an LCA category would be 106 percent of the unique ASP for that drug. Medicare's share of the payment would be limited to 80 percent of the cost of the least expensive drug in the category, with beneficiaries paying the remaining amount. This would mean that beneficiaries treated with the least expensive drug would pay 20 percent of the payment to providers. However, patients treated with higher-priced drugs would be required to pay the difference between the least costly and more expensive products. Requiring patients to pay more for high-cost drugs will result in a decrease in their use and an increase in the use of clinically comparable, lower-cost alternatives.⁷

Under this approach, some patients would bear substantially higher out-of-pocket costs compared with the current payment system, while providers would be at no increased financial risk for selecting a higher-cost product within an LCA category. There would also be an indirect incentive for manufacturers to reduce prices, because minimizing the price differential between the LCA drug and others in that category would presumably increase market share for the other drugs.

Common ASP approach: All drugs in an LCA category would have the same payment, set at 106 percent of ASP for the least costly drug. Medicare would pay 80 percent of this cost, and beneficiaries would pay 20 percent. This would effectively reduce provider payment for higher-cost drugs in an LCA category. Under this approach, providers would have less financial incentive to prescribe high-cost medications, because they would potentially be reimbursed less than what they originally paid for the drug. As above, there is also an indirect financial incentive to the manufacturer to lower prices: By converging on the price of the least costly product in a category, a manufacturer would increase its market share.

A Hypothetical Example of Different LCA Approaches

Evidence suggests that two drugs covered under Part B—Drug 1 and Drug 2—have the same effect on a patient’s psoriasis when administered weekly. However, the drugs have different prices. The current Medicare payment rate to providers, which is set at ASP+6%, is \$100 per treatment for Drug 1 and \$80 per treatment for Drug 2.

Under the current Part B payment policy, beneficiaries pay 20 percent of the cost of either drug, and Medicare pays the remaining 80 percent.

Under an LCA policy, Medicare would reimburse providers 80 percent of the cost of the cheaper drug, or \$64, regardless of which was administered.

Under the unique ASP approach, provider payment for either drug would not change—\$100 for Drug 1 and \$80 for Drug 2—although Medicare’s contribution would be \$64 for either drug. Medicare beneficiaries would pay the remaining cost, either \$36 (for Drug 1) or \$16 (for Drug 2).

Under the common ASP approach, provider payment for either drug would be set at the cost of the cheaper drug, or \$80. Regardless of whether they are treated with Drug 1 or Drug 2, beneficiaries would be required to pay 20 percent of the payment total, or \$16.

Table 1
Examples of Payment Approaches

		Drug 1	Drug 2
Current approach	Total provider reimbursement (ASP+6%)	\$100	\$80
	Medicare payment (80% of total provider reimbursement)	\$80	\$64
	Beneficiary payment (20% of total provider reimbursement)	\$20	\$16
Unique ASP approach	Total provider reimbursement (ASP+6%)	\$100	\$80
	Medicare payment (80% of total provider reimbursement for lowest-cost drug)	\$64	\$64
	Beneficiary payment (total provider reimbursement minus Medicare payment)	\$36	\$16
Common ASP approach	Total provider reimbursement (ASP+6% of lowest-cost drug)	\$80	\$80
	Medicare payment (80% of total provider reimbursement)	\$64	\$64
	Beneficiary payment (20% of total provider reimbursement)	\$16	\$16

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These two approaches would reduce the financial incentive to use higher-cost drugs, albeit in different ways. The unique ASP approach shifts the cost of expensive drugs in an LCA category to patients, whereas the common ASP approach reduces provider incentives to prescribe high-cost medications. In either case, spending on Part B drugs would be reduced if patients and their providers shifted from using high-cost drugs to ones that are clinically comparable but lower in price.

Barriers to implementation

Medicare is required by law to pay providers for Part B medications at 106 percent of the ASP. Therefore, Congress would need to pass legislation to give CMS the authority to use an LCA approach for setting new Part B drug payment rates.

If Congress authorized an LCA approach, CMS would then need to develop a transparent, public process to determine whether different pharmaceutical products are clinically comparable. Evidence submitted by pharmaceutical manufacturers for FDA approval, and data from other clinical studies, likely would be part of the review.

Medicare could draw on several sources of information to evaluate whether different drugs are equally effective. The Coverage and Analysis Group at CMS currently assesses clinical evidence for Medicare coverage policies. LCA policies could also be informed by the Medicare Evidence Development and Coverage Advisory Committee, which provides CMS with independent, expert advice on a variety of clinical topics. Finally, CMS could use the Evidence-based Practice Centers (EPCs), funded through the Agency for Healthcare Research and Quality, to assess the clinical evidence on different drugs. The EPCs are a network of research institutions with expertise in conducting comparative effectiveness reviews to inform providers and policymakers.

Effects on drug spending

Studies have estimated cost savings for Medicare if LCA policies were applied to drugs covered under Part B, and the examples below help to illustrate how these savings would occur. The Pew Charitable Trusts takes no position on the benefits or risks associated with these specific drugs.

Osteoarthritis of the knee

In 2008, the Congressional Budget Office (CBO) estimated the impact an LCA approach could have on viscosupplements, which are medications used to treat patients with osteoarthritis. Medicare spent approximately \$180 million on these drugs in 2007. CBO concluded that with an LCA approach, Medicare would save approximately \$200 million from 2010 to 2014 and almost \$500 million from 2010 to 2019.⁸

Prostate cancer

In 1995, as noted above, Medicare began applying an LCA policy to LHRH agonists, which are used to treat patients with prostate cancer. In 2011, Medicare and its beneficiaries spent approximately \$289 million on these drugs, representing about 2 percent of Part B drug spending. The Department of Health and Human Services' Office of Inspector General (HHS OIG) found that if LCA policies had not been rescinded in 2010, Medicare costs would have been reduced by \$33.3 million over one year, from \$264.6 million to \$231.3 million, or approximately 13 percent.⁹

Stakeholder perspectives

In addition to the HHS OIG recommendation that CMS consider seeking legislative authority to implement LCA policies, members of the Medicare Payment Advisory Commission (MedPAC)—an independent congressional agency advising Congress on matters affecting Medicare—have supported their use.¹⁰ However, MedPAC has not issued a formal recommendation to Congress on the topic.

Critics have raised several concerns about the LCA approach, stating that these policies create significant access barriers to important new treatment options.¹¹ Concerns have also been raised that LCA policies discourage medical progress and that it would be difficult for the government to set appropriate payment rules because patients respond differently to drug therapies.¹² Others have called LCA policies inappropriate and unfair to patients because they substitute Medicare’s determination that certain drugs are interchangeable for a physician’s professional judgement.¹³

Conclusion

Evidence suggests that using an LCA policy for some medications would significantly reduce pharmaceutical costs in Medicare Part B. If Congress gave Medicare the authority to pay for drugs based on the price of the LCA, then CMS would need to adopt a transparent process to ensure that high-quality evidence is used to inform pricing policies. An LCA approach is not appropriate for all health conditions and patient populations. The right balance between managing health care costs and safeguarding patient access to medically appropriate therapies needs to be found before such a policy could be effectively administered.

Endnotes

- 1 Hays v. Sebelius, [https://www.cadc.uscourts.gov/internet/opinions.nsf/7ED0A2CCC27AD83085257807005999C4/\\$file/08-5508-1221815.pdf](https://www.cadc.uscourts.gov/internet/opinions.nsf/7ED0A2CCC27AD83085257807005999C4/$file/08-5508-1221815.pdf).
- 2 The average sales price (ASP) of a drug is the weighted average of all nonfederal sales to drug wholesalers net of rebates and other discounts. Additional information on ASP can be found in Section 1847A of the Social Security Act: http://www.ssa.gov/OP_Home/ssact/title18/1847A.htm. It should also be noted that the Budget Control Act of 2011, which is also known as the sequester, reduced the amount that Medicare pays for all services, including Part B drugs, by 2 percent through 2021. The sequester has no effect on the beneficiary share of payment to providers.
- 3 Medicare Part B uses a buy-and-bill system to pay for drugs. Providers purchase drugs from drug companies and/or wholesalers and then bill Medicare after treating patients. Furthermore, in 2016, Medicare beneficiaries are charged the 20 percent Part B co-insurance after paying a \$166 deductible.
- 4 Department of Health and Human Services, "Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare Part B" (2012), <http://oig.hhs.gov/oei/reports/oei-12-12-00210.pdf>.
- 5 Technically, the policy was implemented by Medicare contractors, who administer the Medicare program on behalf of CMS, including the development of payment and coverage policies for Part B drugs.
- 6 Department of Health and Human Services, "Medicare Reimbursement for Lupron" (2004), <http://www.oig.hhs.gov/oei/reports/oei-03-03-00250.pdf>.
- 7 Dana P. Goldman et al., "Prescription Drug Cost Sharing: Associations With Medication and Medical Utilization and Spending and Health," *Journal of the American Medical Association* 298, no. 1 (2007): 61-69, <http://jama.jamanetwork.com/article.aspx?articleid=207805>.
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- 10 Medicare Payment Advisory Commission, public meeting proceedings (2015), <http://www.medpac.gov/documents/october-2015-meeting-transcript.pdf?sfvrsn=0>; Medicare Payment Advisory Commission, public meeting proceedings (2014), http://www.medpac.gov/documents/092014-medpac_transcript.pdf?sfvrsn=0.
- 11 Kerry Young, "MedPAC Stirs Talk of Cost-Based Approach on Some Drugs," *CQ Healthbeat*, Sept. 11, 2014, <http://www.commonwealthfund.org/publications/newsletters/washington-health-policy-in-review/2014/sep/sep-15-2014/medpac-stirs-talk-of-cost-based-approach-on-some-drugs>.
- 12 Peter Whoriskey and Dan Keating, "An Effective Eye Drug Is Available for \$50. But Many Doctors Choose a \$2,000 Alternative," *The Washington Post*, Dec. 7, 2013, http://www.washingtonpost.com/business/economy/an-effective-eye-drug-is-available-for-50-but-many-doctors-choose-a-2000-alternative/2013/12/07/1a96628e-55e7-11e3-8304-caf30787c0a9_story.html.
- 13 "Coalition Urges CMS to Drop LCA Policy for Prostate Cancer Drugs," *Urology Times*, Nov. 16, 2006, <http://urologytimes.modernmedicine.com/urology-times/news/modernmedicine/modern-medicine-feature-articles/coalition-urges-cms-drop-lca-poli?page=full>; Kenneth Thorpe, "MedPAC Recommendations Miss the Mark," *The Hill*, April 22, 2014, <http://thehill.com/blogs/congress-blog/healthcare/203976-medpac-recommendations-miss-the-mark>.

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