

ORIGINAL RESEARCH

Offering Lung Cancer Screening to High-Risk Medicare Beneficiaries Saves Lives and Is Cost-Effective: An Actuarial Analysis

Bruce S. Pyenson, FSA, MAAA; Claudia I. Henschke, PhD, MD; David F. Yankelevitz, MD; Rowena Yip, MPH; Ellyne Dec, FSA, MAAA

Stakeholder Perspective,
page 281

BACKGROUND: By a wide margin, lung cancer is the most significant cause of cancer death in the United States and worldwide. The incidence of lung cancer increases with age, and Medicare beneficiaries are often at increased risk. Because of its demonstrated effectiveness in reducing mortality, lung cancer screening with low-dose computed tomography (LDCT) imaging will be covered without cost-sharing starting January 1, 2015, by nongrandfathered commercial plans. Medicare is considering coverage for lung cancer screening.

OBJECTIVE: To estimate the cost and cost-effectiveness (ie, cost per life-year saved) of LDCT lung cancer screening of the Medicare population at high risk for lung cancer.

METHODS: Medicare costs, enrollment, and demographics were used for this study; they were derived from the 2012 Centers for Medicare & Medicaid Services (CMS) beneficiary files and were forecast to 2014 based on CMS and US Census Bureau projections. Standard life and health actuarial techniques were used to calculate the cost and cost-effectiveness of lung cancer screening. The cost, incidence rates, mortality rates, and other parameters chosen by the authors were taken from actual Medicare data, and the modeled screenings are consistent with Medicare processes and procedures.

RESULTS: Approximately 4.9 million high-risk Medicare beneficiaries would meet criteria for lung cancer screening in 2014. Without screening, Medicare patients newly diagnosed with lung cancer have an average life expectancy of approximately 3 years. Based on our analysis, the average annual cost of LDCT lung cancer screening in Medicare is estimated to be \$241 per person screened. LDCT screening for lung cancer in Medicare beneficiaries aged 55 to 80 years with a history of ≥ 30 pack-years of smoking and who had smoked within 15 years is low cost, at approximately \$1 per member per month. This assumes that 50% of these patients were screened. Such screening is also highly cost-effective, at $< \$19,000$ per life-year saved.

CONCLUSION: If all eligible Medicare beneficiaries had been screened and treated consistently from age 55 years, approximately 358,134 additional individuals with current or past lung cancer would be alive in 2014. LDCT screening is a low-cost and cost-effective strategy that fits well within the standard Medicare benefit, including its claims payment and quality monitoring.

Am Health Drug Benefits.
2014;7(5):272-282
www.AHDBonline.com

Received July 7, 2014.
Accepted in final form July 16, 2014.

Disclosures are at end of text

Lung cancer is a lethal disease that claims the lives of more people in the United States annually than the next 4 most lethal cancers combined, which are, in order, colon, breast, pancreas, and prostate cancers.^{1,2} In the United States, an estimated 224,210 people will be diagnosed with lung cancer, and an estimated 159,260 people will die of the disease in 2014.³ The in-

cidence of lung cancer increases with age,⁴ and the risk increases with the cumulative effects of past smoking. Millions of Medicare beneficiaries are at significant risk.⁵

On December 31, 2013, lung cancer screening using low-dose computed tomography (LDCT) was rated as a level "B" recommendation by the US Preventive Services Task Force (USPSTF),⁶ a panel of independent experts convened by the Agency for Healthcare Research and Quality to evaluate the strength of evidence and the balance of benefits and harms of preventive services.⁷ The USPSTF recommendation applies to people aged 55 to 80 years with a history of heavy smoking.⁶ LDCT is an imaging technology that enables 3-dimensional visualization of internal body structures, including the lungs, using low doses of radiation.

Mr Pyenson is Principal & Consulting Actuary, Milliman, Inc, New York; Dr Henschke is Clinical Professor, Radiology, Icahn School of Medicine at Mount Sinai; Dr Yankelevitz is Professor, Radiology, Icahn School of Medicine at Mount Sinai; Ms Yip is Senior Biostatistician, Icahn School of Medicine at Mount Sinai, New York; Ms Dec is Actuary, Milliman, Inc, New York.

Under the Affordable Care Act, the “B” recommendation means that LDCT lung cancer screening must be covered without cost-sharing by qualified health plans starting January 1, 2015.^{6,8} Qualified health plans include commercial insurance and self-insured benefit plans, with the exclusion of grandfathered plans. Several private insurers have initiated LDCT screening coverage in advance of the 2015 requirement.⁹ Furthermore, versions of the USPSTF recommendations have been adopted essentially by every major academic body with an interest in lung cancer, including the National Comprehensive Cancer Network, American Association for Thoracic Surgery, American College of Radiology, Society of Thoracic Surgeons, International Association for the Study of Lung Cancer, American College of Chest Physicians, and the American Cancer Society.

Medicare has begun a national coverage analysis to determine whether LDCT lung cancer screening meets its criteria for coverage, which includes whether screening is reasonable and necessary for early detection, whether the service has an “A” or a “B” recommendation by the USPSTF, and whether screening is appropriate for Medicare beneficiaries.

High doses of radiation can be harmful. LDCT can be performed at very low doses of <0.7 mSv per procedure¹⁰ by comparison, the annual natural background radiation in New York City (sea level) is 3 mSv. LDCT technology refinements and protocol optimization have translated into patient benefits, supporting the detection of ever-smaller lung cancers, reducing the rate of surgical procedures, and providing higher cure rates.¹¹⁻¹⁴

Advances in LDCT technology, promising results from nonrandomized trials,¹⁴ and unchanged survival statistics over the previous 30 years, led to the implementation of the National Lung Screening Trial (NLST), the most expensive and one of the largest randomized screening trials ever sponsored by the National Cancer Institute.¹³ The trial of 53,454 people aged 55 to 74 years at high risk for lung cancer was conducted to determine whether LDCT screening could reduce mortality from lung cancer. Participants in this 2-arm US study received 3 annual screenings with either an LDCT or a chest x-ray. Based on the study protocol, the trial was stopped when findings demonstrated a relative reduction of 20% in lung cancer mortality in the LDCT arm versus the chest x-ray arm.¹³

Observational data and epidemiologic arguments for breast cancer also suggest that additional rounds of screening would reduce lung cancer mortality by much more than 20%.¹⁵⁻²² Other large studies have shown that computed tomography (CT) screening is associated with a high proportion (much higher than 70%) of the lung cancer diagnoses being early stage^{15-17,21} compared with 15% in the national data.²³ Long-term survival rates of

KEY POINTS

- Lung cancer is the leading cause of cancer death in the United States and worldwide.
- Because the risk increases with age and with a history of smoking, some Medicare beneficiaries are at high risk for this type of cancer.
- Low-dose computed tomography (LDCT) has been shown to reduce mortality from lung cancer by more than 20%.
- Under healthcare reform, LDCT must be covered without cost-sharing by nongrandfathered commercial health plans beginning in 2015.
- Based on this new analysis, LDCT screening of high-risk Medicare beneficiaries is cost-effective and will cost approximately \$1 per member per month.
- The average annual cost of such a screening policy is estimated to be \$241 for a Medicare beneficiary screened.
- Given all causes of mortality, without screening, Medicare patients newly diagnosed with lung cancer have an average of 3 years life expectancy.
- With screening, these patients would have an additional 4 years of additional life expectancy incremental to the life expectancy without screening.
- If all eligible beneficiaries had been screened and treated consistently from age 55 years, approximately 358,134 additional individuals with current or past lung cancer would be alive in 2014.

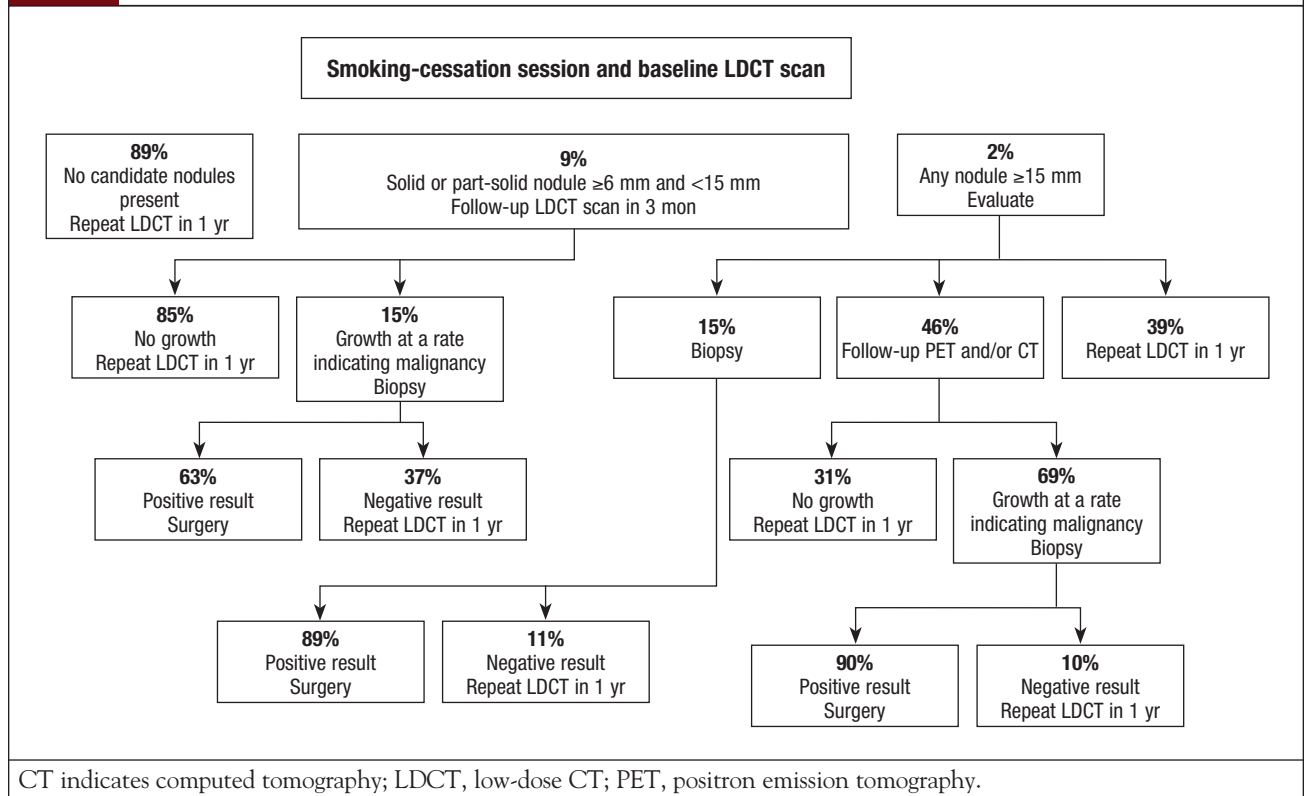
approximately 80% have been reported for patients with lung cancer who are diagnosed by CT screening^{12,15,16} compared with a 16.8% 5-year survival rate from the national data.²³

One of the coauthors of this article was the lead author of an actuarial analysis of LDCT lung cancer screening for the commercially insured population.²⁴ This report used similar methodology, types of structures, and data to examine lung cancer screening for the Medicare program. The Medicare program faces significant budget limitations, and any new coverage benefit will face scrutiny regarding its costs and benefits.

The purpose of the present study was to estimate the hypothetical 2014 costs and benefits associated with the responsible implementation of widespread lung cancer screening in the high-risk US population covered by Medicare.

Study Data and Methods

Our study had 2 phases. First, we determined Medicare’s cost of screening, assuming a 50% uptake rate for the por-

Figure 1 Decision Tree for Initial Baseline Screening

tion of eligible individuals who would use the screening. Then, we determined Medicare's cost per life-year saved.

Screening-Eligible Populations

The Medicare enrollment and demographics were derived from the 2012 Centers for Medicare & Medicaid Services (CMS) beneficiary files and were forecast to 2014 based on US Census Bureau projections.²⁵ Screening-eligible patients with Medicare coverage were defined as smokers and former smokers aged 55 to 80 years who had a ≥ 30 pack-year smoking history and had smoked within the previous 15 years. These criteria reflect key elements of the USPSTF recommendation.⁶ Pack-years represent the product of the number of years an individual has smoked and the average number of packs of cigarettes daily. The group eligible for lung cancer screening was estimated to comprise approximately 4.9 million people, or approximately 10% of Medicare beneficiaries, based on actuarially adjusted (to 2014) populations reported by Ma and colleagues for 2010.⁵

Data Sources and Methods for Cost of Screening

We estimated the cost of LDCT lung cancer screening and follow-up components of the screening process using 2014 Medicare fees. We analyzed medical claims in the Medicare 5% sample to determine the cost and dis-

tribution of biopsy types (fine-needle aspiration, bronchoscopy, and video-assisted thoracic surgery). We applied these costs to the established screening protocols and the observed distribution of outcomes in lung cancer screening trials, such as those used in the NLST¹³ and the International Early Lung Cancer Action Program (I-ELCAP).^{18,26} Each screening included a 30-minute smoking-cessation session.

Observational studies have determined that the initial baseline and annual repeat LDCT screenings are likely to find nodules with different characteristics,²⁷ and we followed the various standard protocols for each. The initial baseline protocol is shown in **Figure 1**, and the annual repeat protocol is described in the **Appendix** (see www.AHDBonline.com). All data were from HIPAA-compliant studies with Institutional Review Board-approved protocol.

The services performed after LDCT lung screening, if any, depend on the round of screening (ie, baseline or repeated annually), nodule size and morphology, and other clinical considerations.^{28,29} These services could potentially include an additional LDCT scan, a course of antibiotics, or in <3% of baseline or <1% of annual screenings, a biopsy of a lung nodule. Evidence shows that 13% of patients who undergo baseline LDCT screening require diagnostic evaluation before their next annual

screening, whereas only 5% of patients who undergo repeated annual screening require such an evaluation.^{12,28}

The I-ELCAP investigators reported that lung cancers are diagnosed in 1.3% and 0.3% of Medicare-age individuals based on the I-ELCAP protocol for initial and repeat screenings, respectively.¹² Clearly, most screenings do not detect lung cancer, and 97% of initial screenings and 99% of follow-up screenings do not lead to an invasive procedure. Published probabilities reflect the investigators' populations. To better match the Medicare population, similar (yet distinct) follow-up probabilities were developed based on the population aged ≥65 years in a large observational trial, which are specified in the Appendix (online).

To determine costs, we applied the 2014 national Medicare fee schedule³⁰ for the prices of CT scanning and a 30-minute smoking-cessation program. The screening and smoking-cessation program had no patient cost-sharing, as required of Medicare-covered preventive benefits. A patient cost-sharing of 30%, which reflects the actual patient experience in the authors' database analysis, was applied to follow-up outpatient diagnostic services. Details of the codes and the costs that were used are provided in the Appendix (online).

Because systematic screening for lung cancer had not been used in the past, we assumed that the 2014 Medicare enrollment demographics reflected the accrued lung cancer incidence and mortality exposure of an unscreened population. We constructed an alternative 2014 population assuming the mortality experience in a screened population. The alternative 2014 population included the patient cohort that was newly diagnosed in 2014 and patients diagnosed in previous years who have survived to 2014, assuming that screening had started 25 years earlier.

Half of the high-risk Medicare population aged 55 to 80 years, or approximately 2.4 million people, were assumed to participate in lung cancer screening, based on comparisons with other types of screening. This is lower than the 75.2% adherence rate in 2010 to colorectal cancer screening for the Medicare population aged ≥65 years, which took many years of promotion to achieve.³¹ We spread the annual cost of screening across all 50 million Medicare beneficiaries, and divided it by 12 to produce the per-member per-month (PMPM) cost; PMPM units are often used by Medicare and other health insurance programs.

Methods and Data Sources for the Cost-Benefit Analysis

In our model, stage shifting, in which screening identifies cancers at earlier stages, is fundamental to the ability of lung cancer screening to reduce mortality. LDCT screening results in a greater number of lung cancers being

Table 1 Approximate Mapping of TNM Lung Cancer Stages to Modeled Stages

TNM stages	IA, IB	IIA, IIB, IIIA	IIIB, IV
Modeled stages	A	B	C

detected at an earlier stage,¹³ which leads to earlier treatment and lower treatment costs and to more people living after having been diagnosed with lung cancer.

We analyzed the Medicare 5% sample data by disease stage at diagnosis to determine treatment cost for the years after diagnosis. The treatment cost for lung cancer reflects clinical treatment decisions that depend in part on the disease stage at diagnosis. The *International Classification of Diseases, Ninth Revision* diagnosis codes on claims data do not explicitly identify the cancer stage; therefore, we established 3 stage designations—A, B, and C—based on treatment patterns for patients in the 9-month period after diagnosis.

We grouped TNM cancer stages into 3 categories that we believe corresponds approximately to early or localized lung cancer, regionally advanced lung cancer, or metastatic disease, which were denoted as stages A, B, and C, respectively (Table 1). Our 3 stages represent tumors similar to those classified as local, regional, and distant cancer, respectively, in the Surveillance, Epidemiology, and End Results (SEER) registry.³² This methodology allowed the use of claims histories to assign patients to these 3 categories. The Appendix (see online) contains details of our stage designation methodology and results.

We created several screening scenarios—status quo (ie, no screening), base-case screening, and other scenarios—to analyze how varying key model assumptions would change the cost-benefit results. The status quo scenario assumes that LDCT screening was not performed. The differences in costs and life-years lived between the status quo and the base-case scenarios provide the net cost of screening and the number of life-years saved as a result of screening.

In the status quo scenario, lung cancers were categorized by stage at diagnosis (from the SEER cancer registry using SEER*Stat software), with corresponding treatment costs and mortality. In the screening scenarios for the cost-benefit analyses, we assumed that the entire target population was screened annually and that the screening-eligible population would generate 80% of the population's cases of cancer, slightly lower than the 90% of lung cancers attributed to smoking by the Centers for Disease Control and Prevention.³³

Because LDCT can detect nodules before a cancer becomes symptomatic, the incidence of screening-detected cancers at a given age was taken from the SEER

Table 2 Expected Number of US Lung Cancer Survivors in Medicare in 2014: Base-Case Scenario

Age, yrs	Lung cancer survivors at end of year (diagnosed at age ≥55 yrs)				
	People screened in 2014, N	Without screening, N	With screening (excludes lead-time yrs), N	Additional patients with lung cancer in 2014, N	Patients with lung cancer within 3 yrs of diagnosis (not included in additional patient count), N
55-59	201,786	1595	2794	1199	2374
60-64	284,117	4917	9777	4859	4433
65-69	1,879,943	40,169	70,421	30,252	18,988
70-74	1,489,434	69,882	145,128	75,246	28,745
75-80	1,039,049	88,278	209,037	120,759	27,237
81-100	N/A	49,356	175,176	125,819	2058
Total, 55-110	4,894,329	254,197	612,333	358,138	83,835

Source: Authors' analysis.

incidence for an age 3 years older, but with earlier stages. For example, a cancer diagnosed through screening in a patient aged 67 years represents an earlier stage of the same cancer that would have been diagnosed 3 years later, when that person would have been age 70 years. This is consistent with the time for a 6-mm cancer detected in screening to grow from stage I to stage III, with a diameter of >7 cm, assuming a volume doubling time (ie, measure of the tumor growth rate) of 98 days.³⁴

For all scenarios in the cost-benefit analyses, we assumed 100% uptake to allow direct comparisons to alternative protocols and to other studies of lung cancer screening and screening for other cancers. In 2014, the surviving 65-year-old patients would have received annual screenings since 2004, when they were age 55 years, but the 55-year-old patients would have been screened only once. In contrast, we assumed a 50% uptake rate for the PMPM cost of screening, because our goal for the price of screening analysis was to develop a realistic PMPM Medicare cost.

We compiled historical cohorts of high-risk Medicare beneficiaries starting at age 55 years to actuarially match the 2014 population of high-risk patients aged 55 to 80 years. In each model year and scenario, we applied SEER cancer incidence rates by age, sex, and stage to identify the incidence at status quo. We reduced the number of lives in each cohort annually with an all-cause mortality rate that is appropriate for smokers.³⁵ For screened patients with lung cancer, we applied stage-specific lung cancer mortality rates, and we tracked patients with lung cancer who would have been survivors.

Because the USPSTF recommendation means that lung cancer screening must be covered without cost-sharing in qualified health plans (commercial coverage), we assumed that any Medicare beneficiaries initiating coverage after the age of 55 years would have had the benefit

of screening under their previous form of coverage. For example, all high-risk individuals aged 65 years in 2014 were assumed to have been screened for 10 years. For Medicare, most of the screenings of patients aged <65 years were assumed to have occurred through commercial insurance, because Medicare beneficiaries represent only a small proportion of people aged 55 to 64 years.

Earlier cancer detection produces longer apparent cancer survival in diagnosed patients (ie, both younger age when diagnosed and at an earlier stage). This is known as “lead time bias.” To avoid attributing additional survival time because of lead-time bias, we calculated life-years saved based on the impact of the disease stage shift only. As a result, although we included costs that are associated with longer treatment of patients with lung cancer resulting from lead-time (ie, earlier) detection, we assumed no lead time in calculating the life-years survival benefit.

We used 2014 cost levels throughout our analysis to eliminate the need for discounting or trending (other than trending historical data to 2014), a strategy that is more straightforward than forecasting future healthcare costs over 20 years and discounting them to the present time.

Study Results

Cost of Screening

We estimated the average annual cost of lung cancer screening to be \$241 per person screened, assuming that 75% of the screenings were annual repeat screenings (see Appendix online). Our assumption is consistent with the ratio reported in a large collaborative study of LDCT screening.¹²

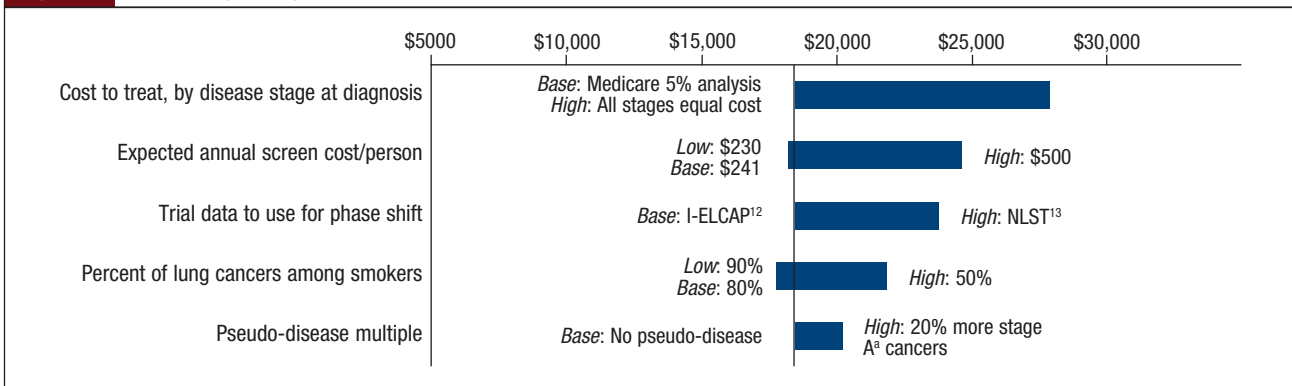
The cost to Medicare for an annual LDCT screening plus follow-up is approximately 11% lower than that for baseline screening, because of the lower rate of new nodules requiring near-term diagnostic evaluation relative to

Table 3 Estimated Impact of Lung Cancer Screening on Life-Years Saved and Cost per Life-Year Saved,^a Using Base-Case (I-ELCAP Data for Screening Results)

Impact of screening	Total	Male	Female
Cumulative life-years saved, yrs	2,825,652	1,313,423	1,512,229
Lead-time correction, yrs	568,599	276,563	292,036
True life-years saved (0-yr lead time life-year saved), yrs	2,257,053	1,036,860	1,220,193
Cumulative extra cost, \$	41,647,811,614	23,241,454,701	18,406,356,913
Cost per additional life-year, \$	18,452	22,415	15,085
Patients diagnosed with lung cancer in 2014			
Average life expectancy without screening, yrs	3.07	2.81	3.36
Average life expectancy with screening (with no lead time), yrs	7.01	6.30	7.83
Average increased life span because of screening, yrs	3.94	3.49	4.47

^aLife-years saved and cost are for patients with cancer aged 55-110 years. I-ELCAP indicates International Early Lung Cancer Action Program. Source: Authors' analysis.

Figure 2 Sensitivity Analysis: Cost per Additional Life-Year Saved



^aFor this cost analysis, cancer stage was designated as A, B, or C based on treatment patterns for patients in the 9-month period after diagnosis.

I-ELCAP indicates International Early Lung Cancer Action Program; NLST, National Lung Screening Trial.

the initial baseline screening. Assuming that 50% of the patients aged 55 to 80 years with ≥ 30 pack-years of smoking were screened, the Medicare cost spread across the Medicare population would be \$1.02 PMPM, assuming no cost-sharing for the initial or annual screening LDCT or smoking-cessation session. This cost is lower than the Medicare cost for screening mammography (see Appendix online). By comparison, in 2012, the average monthly cost of Medicare benefits was approximately \$672 per beneficiary for Medicare Part A and Part B; the total monthly spending for Part D (including enrollee spending) was approximately \$235.³⁶

Cost-Benefit Analysis

Approximately 4.9 million high-risk Medicare beneficiaries would meet the USPSTF criteria for lung cancer

screening in 2014. If all had been screened and treated consistently from age 55 years, approximately 358,134 additional individuals with current or past lung cancer would be alive in 2014 (Table 2).

The additional number of 358,134 individuals does not include patients who were cured of lung cancer but who died of other causes, or the estimated 83,835 “lead-time” cases—that is, additional patients living with lung cancer (generally at a less-advanced stage) because their cancer was detected earlier through LDCT screening. The “lead-time” patients were not counted as “lung cancer survivors” until they have reached the age when they would have been diagnosed with lung cancer in the absence of screening.

Table 3 shows the total life-years saved by early treatment as the sum of all years of additional life for all screening-eligible Medicare patients with lung cancer who are

Table 4 Key Assumptions and Sensitivity Results

Key cost-benefits model component	Base-case assumption	Sensitivity assumption and impact on cost per life-year saved
Annual treatment cost, by stage ^a at diagnosis	The 5-year cost to treat a patient diagnosed at stage A ^a is approximately 73% of the 5-year cost to treat if the patient was diagnosed at stage C ^a	If 5-year treatment costs were the same, regardless of stage at diagnosis, the cost per life-year saved would be higher, at approximately \$28,000
Cost of screening	The expected cost of annual screening and follow-up is \$241 for each screened patient	If annual screening cost per person was \$500, the cost per life-year saved would be approximately \$25,000
Stage ^a at diagnosis	Distribution of stage at diagnosis is consistent with the I-ELCAP experience, ¹² with 78% at stage A ^a	If diagnosed patients exhibit the stage distribution reported in NLST (63% at local early-stage disease), ¹³ the cost per life-year saved would be approximately \$24,000
Lung cancers inside/outside screened population	Of lung cancer in patients aged 55-80 years, 80% occur in the population eligible for screening, and 20% of lung cancers occur among those lower-risk patients outside of the target population	If lower-risk females (not eligible for screening) account for patients with lung cancer at twice the rate as males (40% and 20%, respectively), females would cost approximately \$16,000 per life-year saved, and the overall cost per life-year saved would be approximately \$20,000. If only 50% of all lung cancers occur among the screening-eligible population, the cost per life-year saved would be approximately \$22,000
Overdiagnosis/pseudo-disease	No pseudo-disease	If 20% more patients are identified with stage A ^a cancer, without any reduction in the number of patients with stage B ^a or C ^a cancers, the cost per life-year saved would be \$20,000

^aFor this cost analysis, cancer stage was designated as A, B, or C based on treatment patterns for patients in the 9-month period after diagnosis.
I-ELCAP indicates International Early Lung Cancer Action Program; NLST, National Lung Screening Trial.

alive in 2014, until their death or until age 110 years, if earlier. Consistent with Table 1, “true life-years saved” does not include the life-years associated with lead time.

The cumulative extra cost reflects the expected cost of annual screening and follow-up (\$241) for all eligible Medicare patients for every year. It includes offsets for the reduced cost associated with earlier stage treatment and is increased by extra costs of treatment for additional years (see Appendix online). This cost is useful only in the context of the model’s calculation of cost per life-year saved, because it is not necessarily calculated to be consistent with Medicare’s own multiyear financial projections.

Overall, we estimated that 1 life-year is saved at a cost of approximately \$18,452. The earlier treatment of lung cancer enabled by early diagnosis through screening increases the average life expectancy of people who are screened, as well as that of the entire Medicare population. Without screening, patients newly diagnosed with lung cancer who are covered by Medicare have an average life expectancy of approximately 3 years. Screening results in an additional life expectancy of approximately 4 years for patients incremental to the life expectancy without screening, and with a greater improvement for younger patients.

Women with late-stage lung cancer lose more life expectancy than do men. As a result, systematic screening and earlier treatment can save relatively more life-years for screening-eligible women than for screening-eligible men. The cost of 1 life-year saved for a woman is approximately \$15,085.

The costs and benefits of screening differed according to our sensitivity scenarios (Figure 2). Figure 2 illustrates various sensitivity analyses of cost per 1 life-year saved, based on changes in key assumptions. The base-case scenario shows that 1 life-year is saved at a cost of approximately \$18,452. The main base-case and sensitivity assumptions for the key model components are outlined in Table 4.

Lung and Other Cancer Screenings

The published estimates for the cost per life-year saved for the screening of breast, cervical, and colorectal cancers, trended to 2012 dollars, are reported elsewhere.²⁴ The cost per life-year saved figures reported here for LDCT lung cancer screening in the Medicare population are comparable with or lower than the estimates for the other cancer screenings.³⁷ From the standpoint of

cost per life-year saved, lung cancer with LDCT meets or exceeds the value of these other screenings. It is worth noting that the cost per life-year saved figures for other cancers cited above were performed when screening and treatment costs were much lower than today's costs, and when practices and therapies might have been different.

Discussion

The Medicare program is one of the world's largest health insurers, and using life and health actuarial techniques and actual Medicare data to model financial and mortality outcomes helps to make our forecasts more realistic and relevant to Medicare practices and procedures. Important assumptions in this present study, such as the types of biopsies, the cost of treatment, and the mortality rates, reflect real-world "community practice" rather than assumptions from clinical trials.

Lung cancer screening is cost-effective for several reasons. First, suspicious nodules can be assessed for changes in nodule volume without biopsy between LDCT screenings. Second, the high-risk, 4.9 million Medicare population that is the target for lung cancer screening is smaller than the target population for other cancer screenings. Third, lung cancer detected in symptomatic patients is much more often rapidly fatal than is the case in other cancers; thus, the number of life-years saved by screening for lung cancer is greater than the number in other cancer screenings.

Our estimates related to the cost of lung cancer screening are more favorable than the NLST findings because (1) the NLST design required trial termination if the difference in mortality between the 2 study arms was >20%,¹³ and (2) the assumptions based on improved screening strategies, notably what have become established protocols for follow-up, were not part of the NLST. In particular, "volume change analysis," which measures the volume growth rate of a suspicious clinical nodule in serial LDCT scans across a defined time interval, reduces the need for biopsies.^{38,39}

Given the benefits of lung cancer screening, adherence to screening in the target Medicare population should be encouraged. Full adherence is ideal, but we believe that our assumption of 50% uptake to estimate the PMPM cost to Medicare in an average year will still require substantial efforts to inform primary care physicians and high-risk individuals.

Medicare uses numerous tools to police the quality of services provided to beneficiaries. These include retrospective audits to detect billing errors, fraud (ie, making false statements or misrepresenting the facts to obtain payment or benefit), and abuse (eg, misusing codes on a claim, overcharging for services or supplies, and billing for services that were not medically necessary).⁴⁰ We

believe that these tools can be used to ensure the efficient and safe rollout of LDCT screening across the entire Medicare population. Medicare may choose to implement quality programs in different ways by region to determine which work best. In addition, the assignment of a separate *Current Procedural Terminology*® (CPT®) code for LDCT lung cancer screening would help to distinguish screening from nonscreening diagnostics, help to avoid the use of high-dose CTs, and make it easier to track other quality metrics (eg, appropriate follow-up and the portion of cancers detected by screening).

We note that in its June 30, 2014, update of procedure codes (effective October 2014), CMS has assigned a new CPT code, S8032, for LDCT for lung cancer screening.⁴¹ National professional organizations have or are developing certification standards that will allow widespread lung cancer screening with appropriate quality controls, such as those of the American College of Radiology Lung Imaging Reporting and Data System.⁴²

Follow-up on nodules depends on the size of the nodule and whether it appears on the initial baseline screening or a subsequent annual screening. Most nodules requiring follow-up are resolved without biopsy through subsequent LDCT scans. Even so, biopsy complications have declined over time with minimally invasive surgical techniques. Our cost of screening assumes that nodules ≥ 6 mm are followed up after the initial LDCT scan.²⁹

Although we did not explicitly examine the benefits of smoking cessation in our model, adding smoking-cessation programs to a commercial population LDCT screening program improved the program's cost-effectiveness by between 20% and 45%.^{43,44} A recent retrospective analysis of the NLST data showed that patients with suspicious findings on LDCT scans quit smoking at high rates, regardless of whether the finding was cancerous, thus supporting the view that lung cancer screening offers a "teachable moment."⁴⁵

Limitations

We acknowledge several limitations in our study design. First, we appreciate that no one source can provide all of the necessary data⁴⁶; however, using multiple sources can produce confounding results. The trial populations on which we based our stage-shift assumptions could have had different characteristics than those in the larger population.

We understand that screening costs could be higher and that benefits could be lower than those shown in our findings under different conditions (eg, if the screening population includes individuals other than the high-risk population, or if follow-up care differs from that in the clinical trial settings). Alternatively, the costs could be lower and the benefits of screening might be higher. The

costs to treat early stage lung cancer could decrease with the identification of very early stage lung cancers, more emphasis on minimally invasive surgery, and other treatment innovations.

In addition, our cost per life-year saved results are the differences in costs and life-years between the status quo and the screening scenarios, and some potential biases in assumptions (eg, excessively high smoker mortality or systemically too-low costs of treatment for cancer) would apply to both scenarios. Nonetheless, we believe that our calculations of the cost per life-year saved of screening offer reliable comparisons with respect to the cost of other services, because such calculations are often based on assumptions from clinical trials.

Finally, we did not take into account the likely positive effects of the smoking-cessation counseling built into each screening session or effects on productivity, taxes, disability, life insurance costs, or the likely additional costs incurred by Social Security programs because of survivorship from lung cancer.

Conclusions

If all eligible Medicare beneficiaries had been screened and treated consistently from age 55 years, approximately 358,134 additional individuals with current or past lung cancer would be alive in 2014. Our study demonstrates that for the high-risk Medicare population of smokers and former smokers, LDCT screening for lung cancer is low cost, as well as cost-effective. The cost, incidence rates, mortality rates, and other parameters presented in this study represent real-world, community practice data and are consistent with Medicare processes and procedures. LDCT screening for lung cancer fits well within the current standard Medicare benefit. The widespread LDCT screening of Medicare beneficiaries would allow the use of Medicare claims data to identify key outcomes within months, and this information could be used to further refine actual practice. Designing and establishing systems to immediately track these data and to quickly identify best practices would be an exemplar of a rapid, patient-centered system change.

Furthermore, LDCT screening has the ability to identify other disease states that are prevalent in the screened age-group and among smokers and former smokers, such as coronary artery disease, aortic aneurysms, other thoracic tumors, and upper abdominal tumors. ■

Acknowledgment

The authors would like to thank Kathleen Wildasin for her editorial support.

Funding Source

The study was funded by the Early Diagnosis and Treat-

ment Research Foundation, whose main source of funding for this project came from a grant from the Medical Imaging & Technology Alliance, a division of the National Electrical Manufacturers Association.

Author Disclosure Statement

Mr Pyenson provides actuarial consulting services to General Electric and Covidien, and is an employee of Milliman, Inc, which provides actuarial consulting services to numerous health insurance organizations, pharmaceutical and device manufacturers, and advocacy groups. Dr Henschke has received grants from Flight Attendant Medical Research Institute and the American Legacy Foundation during and outside of this study and is the President of the Early Diagnosis and Treatment Research Foundation. Dr Yankelevitz is a named inventor on several patents and patent applications relating to the evaluation of diseases of the chest, including measurement of nodules, some of which are owned by Cornell Research Foundation and are nonexclusively licensed to General Electric, and for which Dr Yankelevitz is entitled to a share of any compensation which Cornell Research Foundation may receive from its commercialization of these patents. Ms Yip reported no conflicts of interest. Ms Dec provides actuarial consulting services to General Electric and Covidien, and is an employee of Milliman, Inc. Milliman Inc. was paid for their work on this project.

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STAKEHOLDER PERSPECTIVE

Cost-Effectiveness and the Medicare Budget

By Joseph R. Antos, PhD

Wilson H. Taylor Scholar in Health Care and Retirement Policy, American Enterprise Institute, Washington, DC

PAYERS/RESEARCHERS: How should Medicare decide whether to expand coverage to its beneficiaries to include a new medical technology, or a new application of an existing technology? According to the Centers for Medicare & Medicaid Services (CMS), Medicare coverage is “limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury.”¹ Millions of lives and billions of dollars can be at stake, depending on how CMS determines whether a technology is reasonable and necessary.

Although the effectiveness of a technology in diagnosing or treating a disease is an important factor in a coverage decision, cost-effectiveness analysis is not formally considered by CMS, despite the long-standing concern that Medicare spending is growing at an unsustainable rate. The concerns range from skepticism about the methods used in cost-effectiveness analyses to fears that such analyses could be used to ration care.

Perhaps the best-known critique of cost-effectiveness methodology was delivered by Kassirer and Angell in a

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STAKEHOLDER PERSPECTIVE *Continued*

1994 editorial in the *New England Journal of Medicine*.² They pointed out that cost-effectiveness analysis is a modeling exercise that depends critically on the data and the assumption used. Consequently, there can be ambiguity in the results, and various studies could yield different conclusions about the cost-effectiveness of a particular technology.²

That is certainly true, but hardly a disqualification. The study by Pyenson and colleagues in this issue of *American Health & Drug Benefits* is a case in point.³ Their meticulous analysis depends critically on assumptions regarding the incidence of disease, the rate at which high-risk individuals would use low-dose computed tomography (LDCT) screening for lung cancer, the rate of subsequent treatment, the cost of such screening and subsequent treatment, and other factors. Different assumptions—such as those regarding the rate of overdiagnosis⁴ and subsequent testing and treatment that could have been avoided—could result in higher estimated costs than these investigators find.

The present study by Pyenson and colleagues, which is focused on patients with lengthy histories of heavy smoking who are most likely to develop lung cancer, demonstrates the need for Medicare coverage to pair the LDCT technology with the population most likely to benefit from it.

Clinical trials are not immune to such uncertainty, despite their methodologic purity. Actual patient populations and providers who care for them cannot be counted on to do everything according to the research protocol. Any analysis of the costs and benefits of a technology before its general adoption is a prediction, not a certainty.

POLICYMAKERS: The real issue is how the results of a cost-effectiveness analysis are used. Policymakers have distanced themselves from any hint of government rationing of healthcare. In establishing the Patient-Centered Outcomes Research Institute, Congress prohibited the US Secretary of Health & Human Services from

using a cost-effectiveness standard to determine coverage or payment by Medicare.⁵ Nonetheless, there remains a concern that budgetary pressures could increasingly favor technologies with low estimated costs per quality-adjusted life-year, without sufficient flexibility to account for variations in the health needs of patients.

Ironically, cost-effectiveness analyses may not lead to reductions in Medicare spending.⁶ The coverage process is like an iceberg: it focuses on new technologies, which are likely to account for a small fraction of Medicare spending, while largely ignoring services that are already covered and account for the bulk of its spending. It is simply not feasible to do a full review of all past coverage decisions. As a result, there is a built-in bias toward more—not less—spending, regardless of the analytic tools used to drive coverage decisions.

The best strategy is the obvious one. Medicare should use all of the information that is available in its coverage decisions, including cost-effectiveness analysis. For technologies that offer great potential benefits but also great potential cost, coverage with evidence development—temporary coverage targeted at specific patient populations, which allows detailed data collection on all aspects of the treatment—could be a useful approach.

The present study by Pyenson and colleagues, which is focused on patients with lengthy histories of heavy smoking who are most likely to develop lung cancer, demonstrates the need for Medicare coverage to pair the LDCT technology with the population most likely to benefit from it. The coverage decision takes us only part of the way to that goal. Both patients and the Medicare program rely on the physician to make that judgment at the point of service. ■

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