

BUDGET IMPACT MODEL OF ENHANCED LUNG CANCER SCREENING WITH AI/ML TECH-BASED SOFTWARE AS A MEDICAL DEVICE (SAMD) ON A US COHORT AND PRIVATE PAYER PERSPECTIVE

OP9

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BACKGROUND

Lung cancer remains a leading cause cancer death worldwide.

Current standard of care, screening based on Low-Dose Computed Tomography (LDCT), has improved early detection, yet false positives and late-stage diagnoses persist.

There is a need for innovative, cost-effective screening approaches that improve diagnostic accuracy and optimize healthcare resource use and cost.

CADe/CADx are computer-aided tools that help radiologists detect and diagnose abnormalities in medical images.

OBJECTIVES

To evaluate the budget impact and resource use of implementing a CADe/CADx, an AI/ML tech-based Software as a Medical Device (SaMD), in lung cancer screening compared to standard LDCT-alone, from a US private payer perspective.

METHODS

A five-stage Markov model simulated lung cancer progression, comparing two screening strategies:

- LDCT + CADe/CADx SaMD (AI alone)
- LDCT-only (Radiologist alone)

Patient management followed Lung-RADS (Pinsky et al), incorporating real-world sensitivity and specificity inputs.

Disease progression was based on 1-year stage transitions (Pan) and 5-year mortality (Pan & Kay).

Cost elements included diagnostic procedures (LDCT, PET-CT, biopsies) based CPT codes tariffs 2024, treatments by cancer stage based on CMS tariff 2017 (Sheenan et al - excluding immunotherapy) and downstream clinical management.

Diagnostic accuracy & impact on Lung-RADS and disease stage were estimated relative to radiologist and SaMD performance

Outcomes were calculated Per Member Per Month (PMPM) over a 5-year horizon for a 1-million-member health plan

RESULTS

Lung cancer screening pathway and disease progression in the Markov model

1 Incorporation of a granular diagnostic pathway that accounts for the high costs associated with testing (i.e., biopsy, PET-CT etc.)

2 Differentiated screening program / timing / tests used according to the LUNG-RADS classification and guidelines

3 Creates a separate Markov Model for False Negative patients, as well as a differentiated pathways for subsequent True Positive / False Negative patients

4 False Negative patients enter into staging at a higher classification (Pan et al)

From population to diagnosis – Patient flow & performance: LDCT + SaMD alone vs LDCT only

Global population
i.e: 1 000 000 citizens

USPSTF
Eligible population
(4.29%)
50-80Y & >20P/Y
42 900 people

Henderson
Compliance rate
(16.4%)
7036 people

Average studies
1,12% Cancer rate
(1.12%)
79 cancers
6957 negative or benign

	LDCT	LDCT + SaMD
Sensitivity	80.30%	93.30%
Specificity	76.40%	92.40%

Jonas

True Positive (23.6%)	63 pts
False Positive (23.6%)	1642 pts
True Negative (76.4%)	5315 pts
False Negative (19.7%)	16 pts

Median

True Positive (93.3%)	74 pts
False Positive (7.6%)	529 pts
True Negative (92.4%)	6428 pts
False Negative (6.7%)	5 pts

LDCT + SaMD vs LDCT only	Change (%)
True Positive	+ 16%
False Negative	- 67%
True Negative	+ 21 %
False Positive	- 68%

CADe/CADx AI-based screening improves diagnostic accuracy, optimizes procedures & reduces costs for health insurers:

☐ - 67% false negatives & - 68% false positives

☐ - 16.5% CT-Scan, -89% PET-CT scans, -89% biopsies, -65% complications

☐ 5-year cumulative cost savings

☐ - \$1.55 PMPM savings in year 1 and - \$52.70M over 5 years, mainly from earlier detection & diagnosis and reduced late-stage treatment

☐ Biggest impact in Year 1 due to stage shift

☐ Cost savings diminish overtime as early cancer deaths accumulate whilst screening use, decision-making, and SaMD declines

Procedure rates per patient

Based on 7036 pts screened	LDCT + SaMD	LDCT Only	Variance
Procedure type	N/ patient	N/ patient	%
SaMD	1.11	0	NA
Screening	1.11	1.33	-16.5%
Shared decision making	1.11	1.33	-16.5%
Invasive diagnostic procedure (biopsy)	0.012	0.109	-89%
PET scan	0.018	0.166	-89%
Complications for biopsy	0.0016	0.0047	-65%

USPSTF: US Preventive Services Task Force - Screening for Lung Cancer: US Preventive Services Task Force Recommendation Statement - 2021 Mar 9;325(10):962-970.

Henderson: Prevalence of Lung Cancer Screening in the US, 2022. Henderson LM, et al. JAMA Netw Open. 2024.

Jonas: Screening for Lung Cancer With Low-Dose Computed Tomography: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force - 2021 Mar 9;325(10):971-987.

Pinsky: The National Lung Screening Trial: Results Stratified by Demographics, Smoking History and Lung Cancer Histology - Cancer. 2013 November 15; 119(22): 3976-3983.

Pan: Cost-effectiveness of volume computed tomography in lung cancer screening: a cohort simulation based on Nelson study outcomes - J Med Econ. 2024 Jan-Dec;27(1):27-38.

Kay: Revisions to the Tumor, Node, Metastasis staging of lung cancer (8th edition): Rationale, radiologic findings and clinical implications - World J Radiol. 2017 Jun 28;9(6):269-279.

Sheehan: Lung cancer costs by treatment strategy and phase of care among patients enrolled in Medicare. Cancer Med. 2019 Jan;8(1):94-103.

Median: Data-on-file, Median Technologies SA, 2025.

5-Year PMPM budget impact

PMPM
LDCT + SaMD vs no LDCT

Year	Cost saving (PMPM \$USD)
Year 1	-\$1.55
Year 2	-\$1.17
Year 3	-\$0.79
Year 4	-\$0.53
Year 5	-\$0.35

CONCLUSIONS

CADe/CADx SaMD enables earlier lung cancer detection & characterization, reduces invasive and useless procedures, and delivers meaningful cost savings for US payers. These findings advocate for integrating CADe/CADx SaMD into routine lung cancer screening programs.

DISCUSSION

Sensitivity and specificity were the most influential inputs. Over time, stage 3 and 4 to death transitions increasingly impacted outcomes. Findings show the technology is cost-effective, but real-world validation and research is needed to confirm these findings.