CT Lung Screening in the Era of Expanded USPSTF Eligible to Screen Population

Rescue Lung Society 2021 Virtual Conference

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Director, Quality Screening and Program Initiatives

Disclosures:

- I have no financial relationships to disclose.

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U.S. Preventive Services TASK FORCE

Final Recommendation Statement

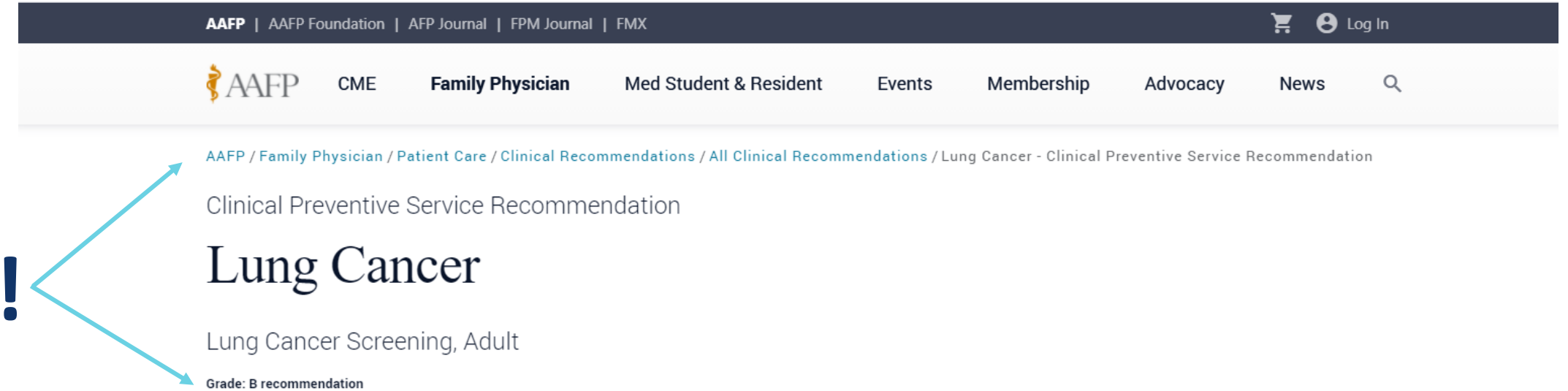
Lung Cancer: Screening

March 09, 2021

Recommendation Summary

Population	Recommendation	Grade
Adults aged 50 to 80 years who have a 20 pack-year smoking history and currently smoke or have quit within the past 15 years	The USPSTF recommends annual screening for lung cancer with low-dose computed tomography (LDCT) in adults aged 50 to 80 years who have a 20 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.	B

At Last!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Clinical Preventive Service Recommendation
Lung Cancer
Lung Cancer Screening, Adult
Grade: B recommendation
The AAFP supports the United States Preventive Services Task Force (USPSTF) recommendation for annual screening for lung cancer with low-dose computed tomography (LDCT) in adults aged 50 to 80 years who have a 20 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery.
The AAFP has reviewed the evidence and has determined there is sufficient evidence to support a B recommendation for lung cancer screening in adults at increased risk. However, the AAFP acknowledges that the harms from annual screening with LDCT are not well documented at this time and that there are considerable barriers to screening for lung cancer in the community setting. Future research is needed to determine the harms of annual screening with LDCT including overdiagnosis, unnecessary procedures due to incidental findings, and barriers to care among communities of color. (2021)
Grade Definition

Prior NCCN Group 2:

- Age ≥50 (no upper limit)
- Pack years ≥20
- Additional risk factor
- Note: No max limit on time since quit smoking

Latest NCCN Guidelines

- No longer a distinct Group 2
- Age ≥50 (no upper limit)
- Pack years ≥20
- No max limit on time since quit smoking

Key Gaps in New USPSTF Compared to NCCN:

- Upper age limit of 80
- 15 year max limit on time since quit smoking

National Comprehensive Cancer Network®

NCCN Guidelines Version 1.2021
Lung Cancer Screening

NCCN Guidelines Index
Table of Contents
Discussion

RISK ASSESSMENT[a,b] | **RISK STATUS** | **SCREENING**

- Smoking history[c]
- Radon exposure[d]
- Occupational exposure[e]
- Cancer history[f]
- Family history of lung cancer in first-degree relatives
- Disease history (COPD or pulmonary fibrosis)
- Smoking exposure[g] (second-hand smoke)

Patients not eligible for lung cancer screening
- Symptoms of lung cancer (see appropriate NCCN Guidelines)
- Previous lung cancer (see Surveillance in the NCCN Guidelines for Non-Small Cell Lung Cancer)
- Functional status and/or comorbidity that would prohibit curative intent treatment

High risk:[h,i,j]
- Age ≥50 y and
- ≥20 pack-year history of smoking (category 1)

→ In candidates for screening, shared patient/physician decision-making is recommended, including a discussion of benefits/risks[k] → Low-dose CT (LDCT)[l] (category 1) → See Screening Findings (LCS-2)

Low risk:
- Age <50 y and/or
- <20 pack-year history of smoking

→ Lung cancer screening not recommended

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any patient with cancer is in a clinical trial. Participation in clinical trials is especially encouraged.

Footnotes

LCS-1

Patient Protection and Affordable Care Act

Mandates preventive services coverage for **commercial plans** (unless grandfathered):

- Individual and small group market
- Large group market
- Self-Funded Plans (e.g., many employer-based plans, union plans)

And also for: **Medicaid Expansion Plans**

guideline for a recommended preventive service does not specify the frequency, method, treatment, or setting for the provision of that service, the plan or issuer can use reasonable medical management techniques to determine any coverage limitations. The use of reasonable medical management techniques allows plans and issuers to adapt these recommendations and guidelines to coverage of specific items and services where cost sharing must be waived. Thus, under these interim final regulations, a plan or issuer may rely on established techniques and the relevant evidence base to determine the frequency, method, treatment, or setting for which a recommended preventive service will be available without cost-sharing requirements to the extent not specified in a recommendation or guideline.

The statute and these interim final regulations clarify that a plan or issuer continues to have the option to cover preventive services in addition to those required to be covered by PHS Act section 2713. For such additional preventive services, a plan or issuer may impose cost-sharing requirements at its discretion. Moreover, a plan or issuer may impose cost-sharing requirements for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service.

The statute requires the Departments to establish an interval of not less than one year between when recommendations or guidelines under PHS Act section 2713(a)[4] are issued, and the plan year (in the individual market, policy year) for which coverage of the services addressed in such recommendations or guidelines must be in effect. These interim final regulations provide that such coverage must be provided for plan years (in the individual market, policy years) beginning on or after the later of September 23, 2010, or one year after the date the recommendation or guideline is issued. Thus, recommendations and guidelines issued prior to September 23, 2009 must be provided for plan years (in the individual market, policy years) beginning on or after September 23, 2010. For the purpose of these interim final regulations, a recommendation or guideline of the Task Force is considered to be issued on the last day of the month on which the Task Force publishes or otherwise releases the recommendation; a recommendation or guideline of the Advisory Committee is considered to be issued on the date on which it is adopted by the Director of the Centers for Disease Control and Prevention; and a recommendation or guideline in the comprehensive guidelines supported by HRSA is considered to be issued on the date on which it is accepted by the Administrator of HRSA or, if applicable, adopted by the Secretary of HHS. For recommendations and guidelines adopted after September 23, 2009, information at *http://www.HealthCare.gov/center/regulations/prevention.html* will be updated on an ongoing basis and will include the date on which the recommendation or guideline was accepted or adopted.

Finally, these interim final regulations make clear that a plan or issuer is not required to provide coverage or waive cost-sharing requirements for any item or service that has ceased to be a recommended preventive service.[5] Other requirements of Federal or State law may apply in connection with ceasing to provide coverage or changing cost-sharing requirements for any such item or service. For example, PHS Act section 2715(d)(4) requires a plan or issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

Recommendations or guidelines in effect as of July 13, 2010 are described in section V later in this preamble. Any change to a recommendation or guideline that has—at any point since September 23, 2009—been included in the recommended preventive services will be noted at *http://www.HealthCare.gov/center/regulations/prevention.html*. As described above, new recommendations and guidelines will also be noted at this site and plans and issuers need not make changes to coverage and cost-sharing requirements based on a new recommendation or guideline until the first plan year (in the individual market, policy year) beginning on or after the date that is one year after the new recommendation or guideline went into effect. Therefore, by visiting this site once per year, plans or issuers will have straightforward access to all the information necessary to determine any additional items or services that must be covered without cost-sharing requirements, or to determine any items or services that are no longer required to be covered.

The Affordable Care Act gives authority to the Departments to develop guidelines for group health plans and health insurance issuers offering group or individual health insurance coverage to utilize value-based insurance designs as part of their offering of preventive health services. Value-based insurance designs include the provision of information and incentives for consumers that promote access to and use of higher value providers, treatments, and services. The Departments recognize the important role that value-based insurance design can play in promoting the use of appropriate preventive services. These interim final regulations, for example, permit plans and issuers to implement designs that seek to foster better quality and efficiency by allowing cost-sharing for recommended preventive services delivered on an out-of-network basis while eliminating cost-sharing for recommended preventive health services delivered on an in-network basis. The Departments are developing additional guidelines regarding the utilization of value-based insurance designs by group health plans and health insurance issuers with respect to preventive benefits. The Departments are seeking comments related to the development of such guidelines for value-based insurance designs that promote consumer choice of providers or services that offer the best value and quality, while ensuring access to critical, evidence-based preventive services.

The requirements to cover recommended preventive services without any cost-sharing requirements do not apply to grandfathered health plans. *See* 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, and 45 CFR 147.140 (75 FR 34538, June 17, 2010).

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS

[4] Section 2713(b)(1) refers to an interval between "the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline." While the first part of this statement does not mention guidelines under subsection (a)(4), it would make no sense to treat the services covered under (a)(4) any differently than those in (a)(1), (a)(2), and (a)(3). First, the same sentence refers to "the requirement described in subsection (a)," which would include a requirement under (a)(4). Secondly, the guidelines under (a)(4) are from the same source as those under (a)(3), except with respect to women rather than infants, children and adolescents; and other preventive services involving women are addressed in (a)(1), so there is no plausible policy rationale for treating them differently. Third, without this clarification, it would be unclear when such services would have to be covered. These interim final regulations accordingly apply the intervals established therein to services under section 2713(a)(4).

[5] For example, if a recommendation of the United States Preventive Services Task Force is downgraded from a rating of A or B to a rating of C or D, or if a recommendation or guideline no longer includes a particular item or service.

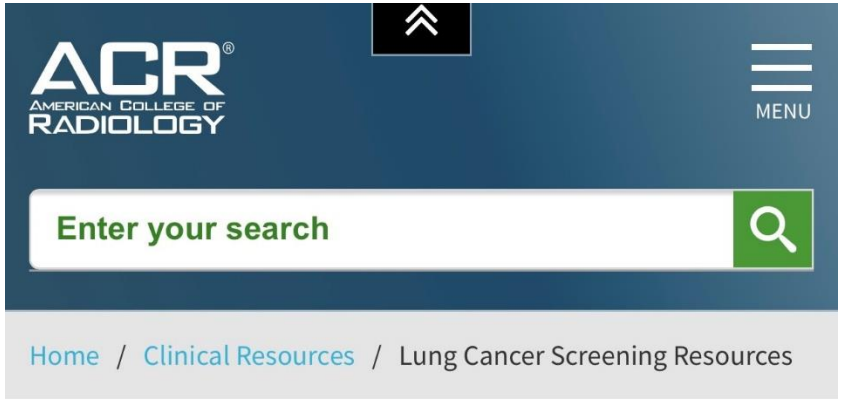
Coverage Timing: What Does the ACA Say?

Rules and Regulations 41729

site and plans and issuers need not make changes to coverage and cost-sharing requirements based on a new recommendation or guideline until the first plan year (in the individual market, policy year) beginning on or after the date that is one year after the new recommendation or guideline went into effect. Therefore, by visiting this site

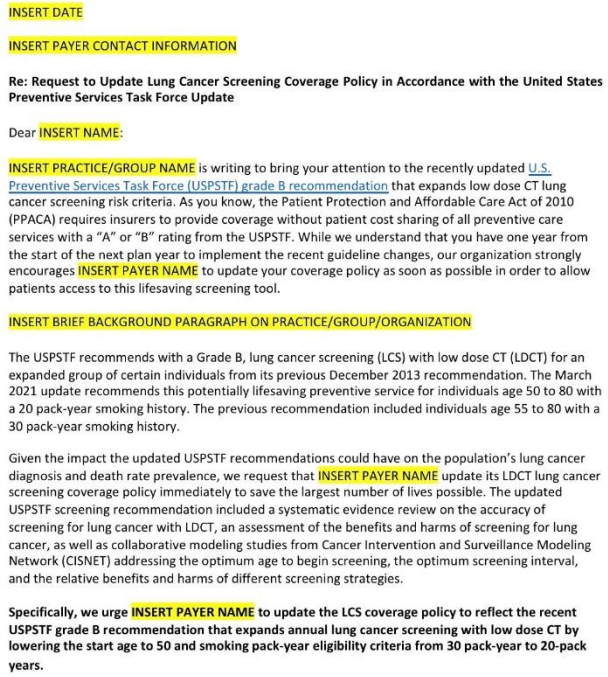
The statute and these interim final regulations clarify that a plan or issuer continues to have the option to cover preventive services in addition to those required to be covered by PHS Act section 2713. For such additional preventive services, a plan or issuer may impose cost-sharing requirements at its discretion. Moreover, a plan or issuer may impose cost-sharing requirements for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service.

ACR Form Letter to Request Private Payer Coverage



Resources for Front-Line Lung Cancer Screening Advocates

- Form Letter to Request Private Payer Coverage Policy Update in Accordance with Updated USPSTF Guidelines (Word doc)
- Expanded USPSTF Lung Cancer Screening Eligibility Thresholds Can Save Lives and Aid Health Equity Efforts
- ACR Lung Cancer Screening Economics & Billing Quick Reference Guide
- LuCa National Training Network Online Course



INSERT DATE

INSERT PAYER CONTACT INFORMATION

Re: Request to Update Lung Cancer Screening Coverage Policy in Accordance with the United States Preventive Services Task Force Update

Dear INSERT NAME:

INSERT PRACTICE/GROUP NAME is writing to bring your attention to the recently updated U.S. Preventive Services Task Force (USPSTF) grade B recommendation that expands low dose CT lung cancer screening risk criteria. As you know, the Patient Protection and Affordable Care Act of 2010 (PPACA) requires insurers to provide coverage without patient cost sharing of all preventive care services with a "A" or "B" rating from the USPSTF. While we understand that you have one year from the start of the next plan year to implement the recent guideline changes, our organization strongly encourages INSERT PAYER NAME to update your coverage policy as soon as possible in order to allow patients access to this lifesaving screening tool.

INSERT BRIEF BACKGROUND PARAGRAPH ON PRACTICE/GROUP/ORGANIZATION

The USPSTF recommends with a Grade B, lung cancer screening (LCS) with low dose CT (LDCT) for an expanded group of certain individuals from its previous December 2013 recommendation. The March 2021 update recommends this potentially lifesaving preventive service for individuals age 50 to 80 with a 20 pack-year smoking history. The previous recommendation included individuals age 55 to 80 with a 30 pack-year smoking history.

Given the impact the updated USPSTF recommendations could have on the population's lung cancer diagnosis and death rate prevalence, we request that INSERT PAYER NAME update its LDCT lung cancer screening coverage policy immediately to save the largest number of lives possible. The updated USPSTF screening recommendation included a systematic evidence review on the accuracy of screening for lung cancer with LDCT, an assessment of the benefits and harms of screening for lung cancer, as well as collaborative modeling studies from Cancer Intervention and Surveillance Modeling Network (CISNET) addressing the optimum age to begin screening, the optimum screening interval, and the relative benefits and harms of different screening strategies.

Specifically, we urge INSERT PAYER NAME to update the LCS coverage policy to reflect the recent USPSTF grade B recommendation that expands annual lung cancer screening with low dose CT by lowering the start age to 50 and smoking pack-year eligibility criteria from 30 pack-year to 20-pack years.

https://www.acr.org/Clinical-Resources/Lung-Cancer-Screening-Resources

What About Medicare?

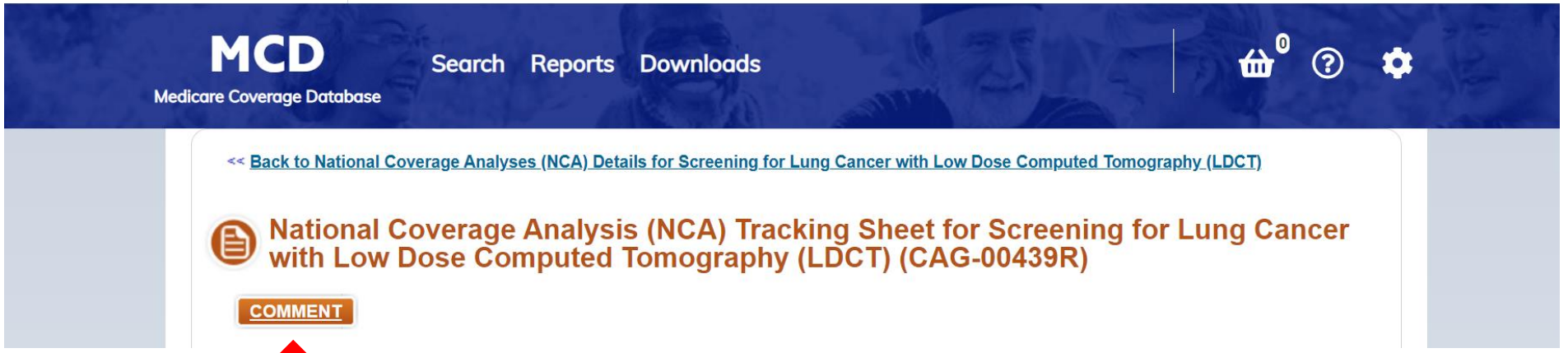
March 9, 2021

Tamara Syrek Jensen, JD, Director
Joseph Chin, MD, Deputy Director
Attn: Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Formal Reconsideration Request for National Coverage Determination on Screening for Lung Cancer with Low Dose CT - CAG-00439N

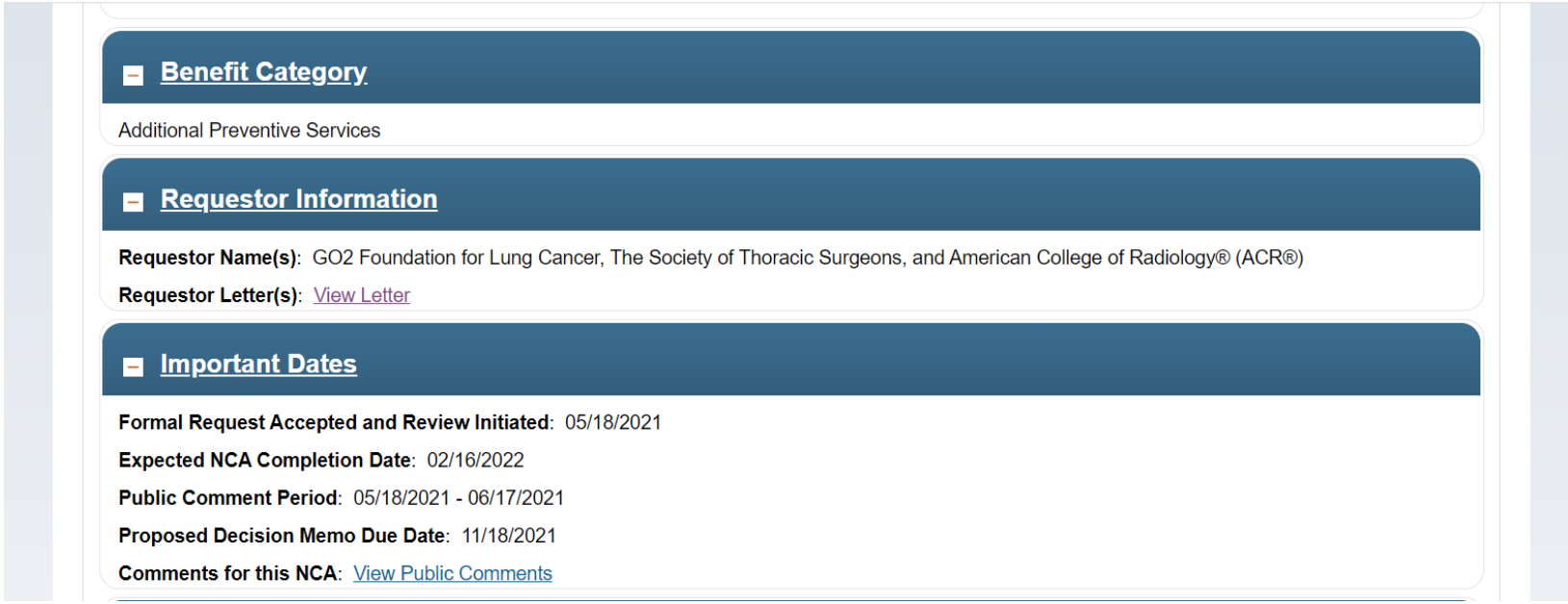
Dear Ms. Jensen and Dr. Chin:

The GO_2 Foundation for Lung Cancer, The Society of Thoracic Surgeons, and the American College of Radiology® (ACR®), formally request the Centers for Medicare and Medicaid Services (CMS) reconsider the existing Feb. 2015 National Coverage Determination (NCD) on Screening for Lung Cancer with Low Dose CT (CAG-00439N) in light of the updated U.S. Preventive Services Task Force (USPSTF) grade B recommendation that expands low dose CT lung cancer screening risk criteria. In addition, CMS should consider scientific evidence for this screening test relevant to the Medicare population that was not reviewed by CMS during the initial NCD and presented at a subsequent date.



30 Day Public Comment Period

Closed June 17, 2021

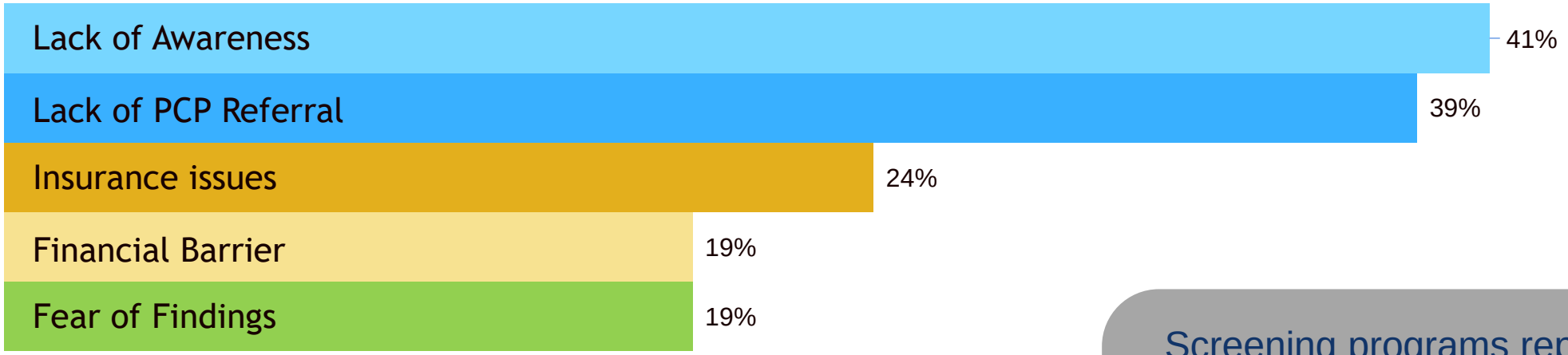


Joint Society Comment Submission—Key "Asks"

- **Lower the minimum age for lung cancer screening eligibility to age 50** and the **required smoking history to 20 pack/years**—aligning with new USPSTF Recommendation and NCCN LCS Guidelines.
- **Eliminate the maximum 15 years since quit limitation for screening eligibility among former smokers**--consistent with NCCN LCS Guidelines.
- **Eliminate the upper age limitation of 77 years for screening eligibility**—consistent with NCCN LCS Guidelines.
- **Remove Counseling and Shared Decision Making (SDM) as condition for lung cancer screening coverage and reimbursement**—to ensure intended patient-centered process does not act as barrier to screening uptake.
- **Clarify Radiology Imaging Facility criteria** to confirm LDCT lung cancer screening access as a covered benefit in all facilities including Independent Testing Facilities (IDTFs).

Wood DE et al. NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening, Version 1.2021.
Yang P, et al. Trends in Subpopulations at High Risk for Lung Cancer. J Thorac Oncol. 2016;11(2):194-202.
Tindle HA, et al. Lifetime Smoking History and Risk of Lung Cancer: Results from the Framingham Heart Study. JNCI. 2018;110(11);djy041
Reitsma M, Kendrick P, Anderson J, et al. Reexamining Rates of Decline in Lung Cancer Risk after Smoking Cessation: A meta-analsysis. ANNALSATS Articles in Press. 2020;10.1513/AnnalsATS.201909-6590C.

Barriers to Screening Uptake



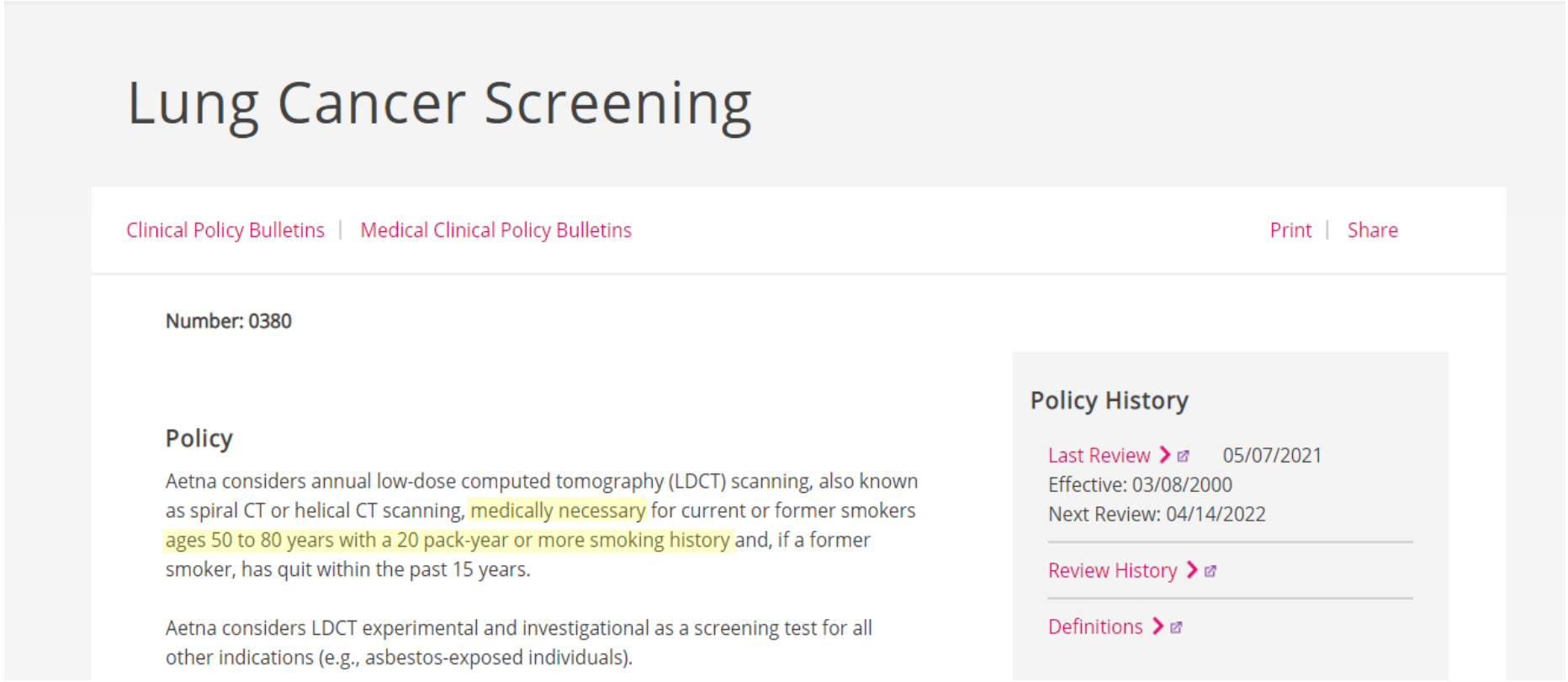
Barriers to Screening Adherence

Screening programs report that insurance issues and associated costs/financial barriers have a significant **impact on patient participation** in the screening process.

Source: GO_2 Foundation 2019 Screening Centers of Excellence Data Survey
N=99; unaided responses

Piecemeal Progress: Commercial Payers

aetna™



Lung Cancer Screening

Clinical Policy Bulletins | Medical Clinical Policy Bulletins Print | Share

Number: 0380

Policy

Aetna considers annual low-dose computed tomography (LDCT) scanning, also known as spiral CT or helical CT scanning, medically necessary for current or former smokers ages 50 to 80 years with a 20 pack-year or more smoking history and, if a former smoker, has quit within the past 15 years.

Aetna considers LDCT experimental and investigational as a screening test for all other indications (e.g., asbestos-exposed individuals).

Policy History

Last Review 05/07/2021
Effective: 03/08/2000
Next Review: 04/14/2022

Review History

Definitions

But…the fine print…

"The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered for a particular member."

Benefit plans must still be updated.

Many Programs Already Screen Additional Populations

In GO2 Foundation Screening Centers of Excellence Annual Survey 2020:

- 55% of programs report screening **only patients who meet CMS or USPSTF criteria**.
- 40% of programs also screened **NCCN Group 2 patients**.
- 10% reported screening patients with **occupational or environmental risk factors**.

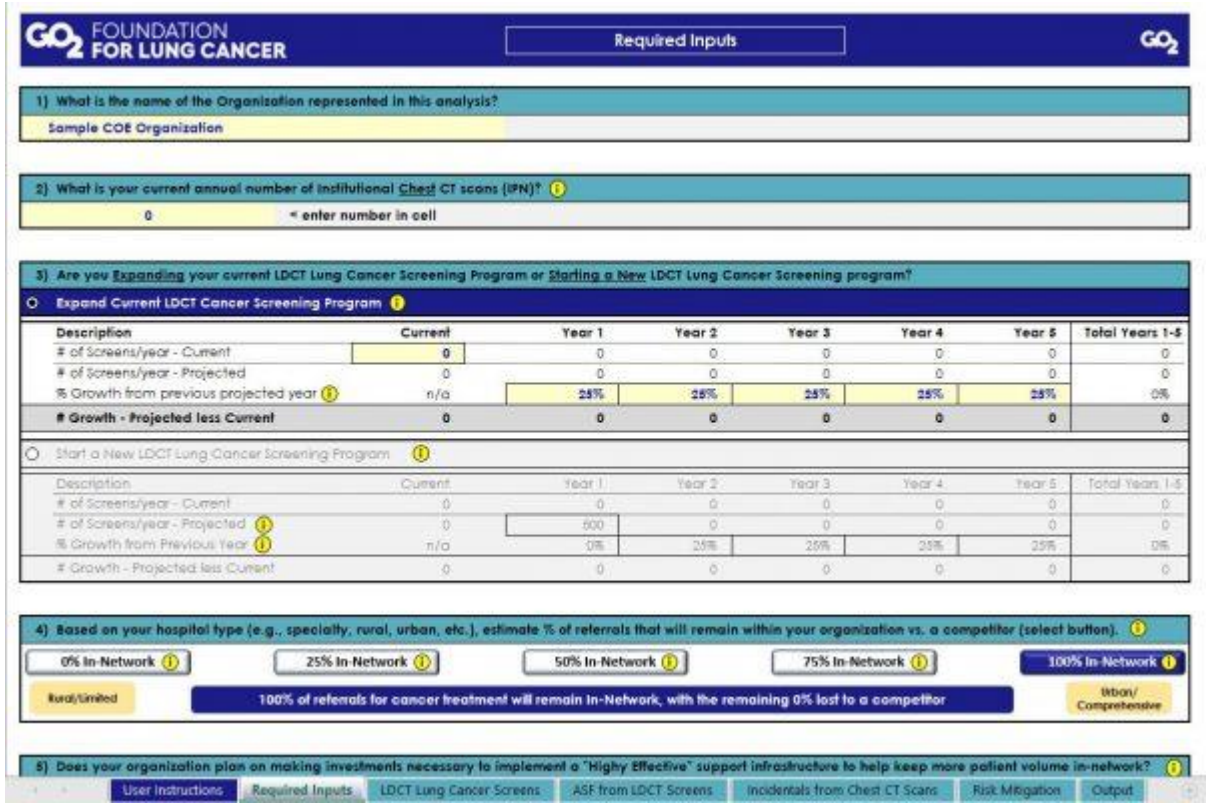
Billing for screenings outside criteria:

- Some obtain insurance authorization on ad-hoc basis via individualized program and patient advocacy
- Some have established low self-pay rates
- Some utilize grant or charity funds
- Some bill patient full cost

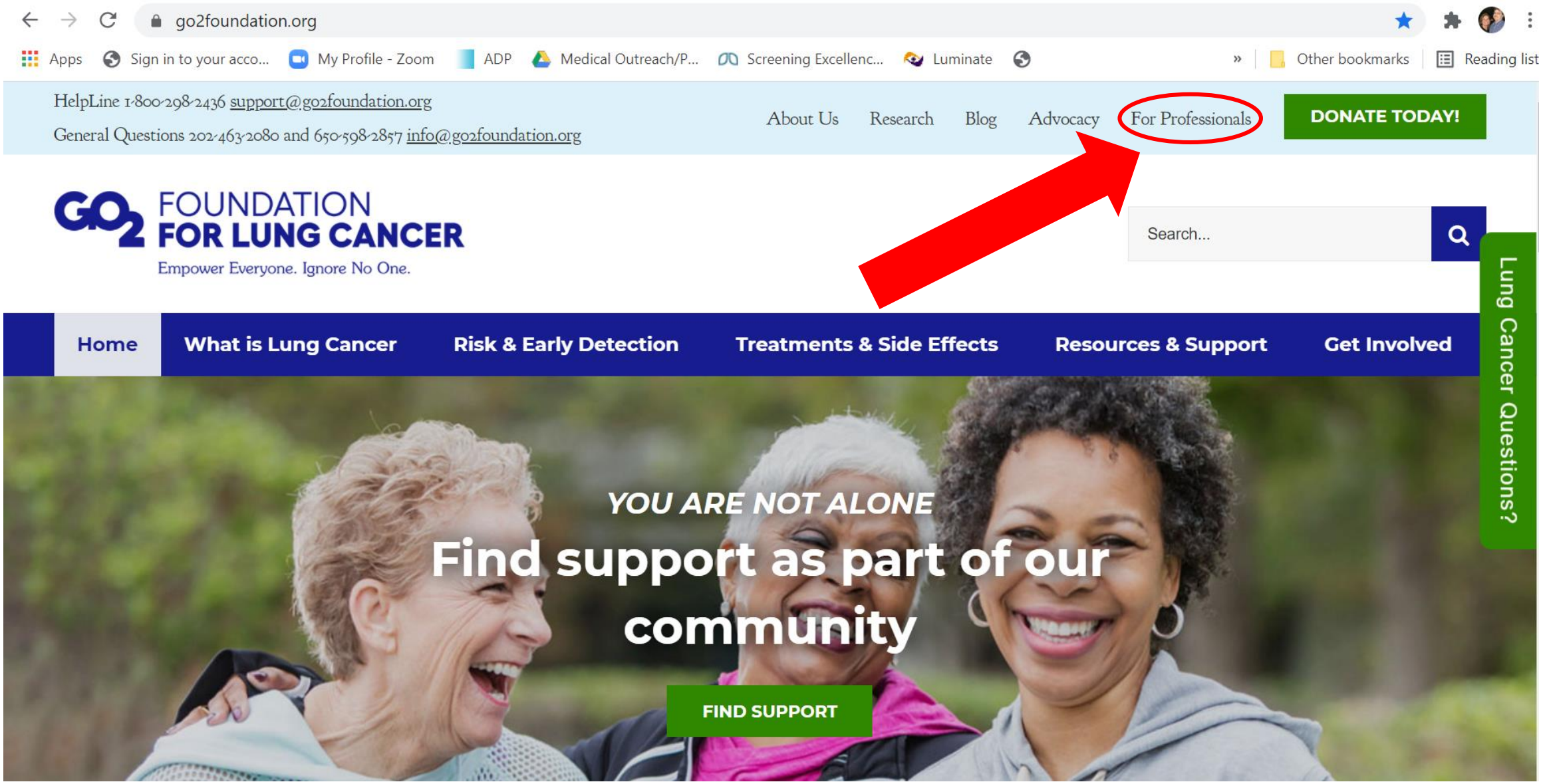
Tools to Build Capacity

Thoracic Oncology Business Model

- For teams building or growing their screening and incidental pulmonary nodule programs
- Will facilitate lung programs working directly with hospital administration to demonstrate a business case for supporting increased infrastructure and resources
- To save more lives and drive value.



For more information, contact Kim Parham,
kparham@go2foundation.org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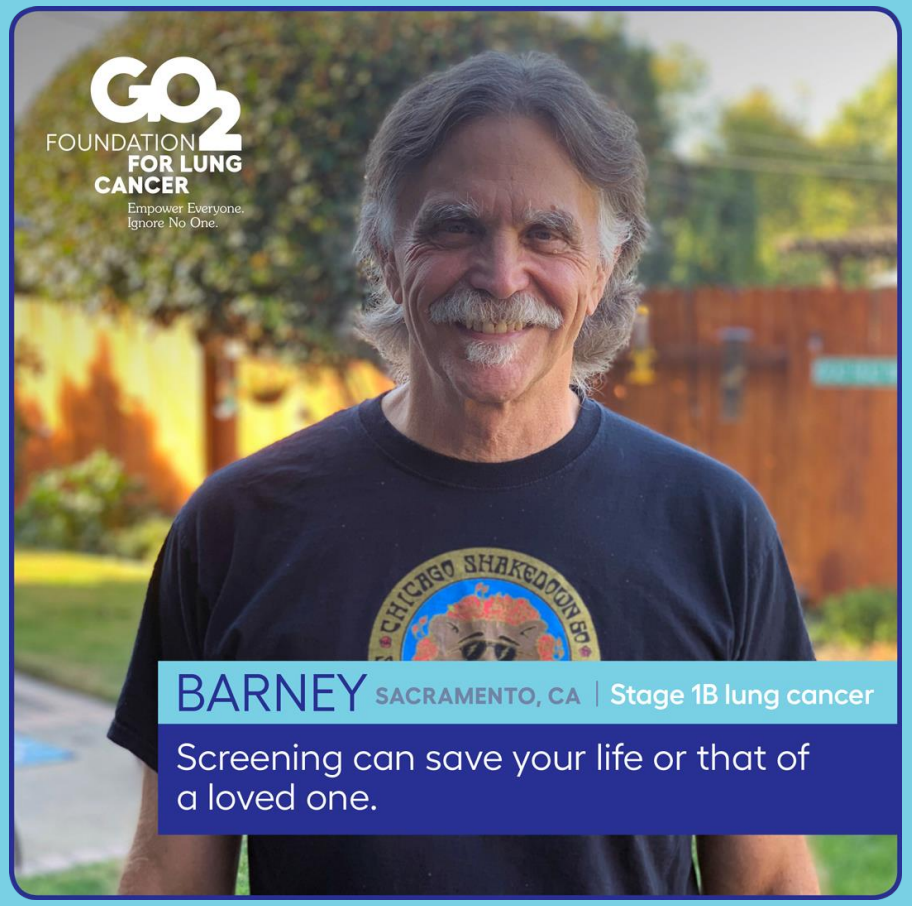

Thank You!

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