وزارة الصحة
Ministry of Health

Lung Cancer Screening Protocol

VERSION 1.0

2026

وزارة الصحة
Ministry of Health

Prepared by	
Prof. Dr. Mushbab Alassiri	
Dr. Abdulaziz Almosabihi	
Dr. Shaya Ahmed Alshaya	
Dr. Wael Althagafi	
R.T. Salma Aldossary	
Dr. Khlood Sagor	
Dr. Khaled Klis	
Dr. Fahad Alghamdi	
Reviewed by	
Prof. Dr. Hamdan Aljahdali	
Approved by	
Prof. Dr. Salim Alawi Baharoon	

وزارة الصحة
Ministry of Health

Table of Contents

1. **Introduction**

Lung cancer remains the leading cause of cancer-related mortality worldwide. Early detection through systematic screening has demonstrated significant potential to reduce mortality rates. This protocol delineates a structured, evidence-based approach to lung cancer screening aimed at high-risk populations, emphasizing standardized procedures, patient safety, and follow-up strategies.

2. **Objectives**

a) Identify high-risk individuals for lung cancer through targeted screening using a specific screening criterion
b) Facilitate early detection of lung malignancies to increase the survival rate, decrease mortality, and improve prognosis.
c) Minimize false-positive and false-negative results by employing standardized imaging protocols and expert interpretation.
d) Establish clear pathways for diagnostic confirmation, multidisciplinary management, and patient navigation support.

3. **Target Population**

a) **Inclusion Criteria:**
   i. Age: 50–80 years
   ii. Smoking history: ≥20 pack-years
   iii. Current smokers or those who have quit within the past 15 years

b) **Exclusion Criteria:**
   i. Symptomatic patients suspected of lung cancer (refer for diagnostic workup according to the standards of practice).
   ii. Previous diagnosis of lung cancer
   iii. Severe comorbidities limiting life expectancy <5 years (e.g., advanced liver disease, respiratory failure, NYHA class IV heart failure)
   iv. Severe comorbidities limiting curative treatment for lung cancer.
   v. Inability to undergo low-dose computed tomography (LDCT)
   vi. Quit more than 15 years ago
   vii. age below 50 and more than 80 years

4. **Stakeholder Engagement & Infrastructure Planning**

a) **Leadership & Policy:**
   i. **Resource allocation**
      - MOH, Health Holding Company, Non-MOH Government health sectors, Private Hospital.

ii. **Policy:**
- The Saudi Health Council, through its National Committee, will lead policy development, resource allocation, and program oversight

iii. **Enablers:**
- National Insurance Authority, National Health Insurance Council

5. Healthcare Facilities and implementation stages

I. Active screening for early lung cancer using low-dose computed tomography (LDCT) should be initiated in primary care settings, community clinics, as well as internal medicine and pulmonary clinics.

c) **Multidisciplinary Teams (MDT):**
i. Comprises pulmonologists, thoracic surgeons, oncologists, thoracic radiologists, pathologists, and patient coordinators.
ii. Regular MDT meetings for case reviews and management planning

d) **Data Management:**
i. Develop a secure, interoperable national registry integrated with electronic health records (EHR) for patient tracking, automated eligibility flagging, and outcome monitoring.
ii. Implement continuous quality assurance and audit processes.

6. Program Initiation and Planning

The program should be started at primary and community medicine clinics and in any clinics where the patient is followed (e.g., Internal medicine and pulmonary) as per Figure 1. Patients with lung cancer RADS 4A and B should be referred to a tertiary care hospital within the cluster or to the nearest facilities where the following facilities are available:

a) **Clinical Experience for establishing a Multidisciplinary Team (MDT):**
i. Pulmonologists
ii. Thoracic surgeons
iii. Oncologists
iv. Radiologists specialized in thoracic imaging
v. Liaison personnel to coordinate the patient care and journey

b) **Infrastructure and Resources:**
i. Virtual and or physical lung cancer clinics for the first visit and follow-up
ii. Access to low-dose CT (LDCT) imaging facilities
iii. Standardized reporting systems (e.g., Lung-RADS)
iv. Secure data registry for tracking outcomes

v. Prepare patient education materials and decision aids supporting shared decision-making and smoking cessation counselling

7. **Patient Identification and Referral**

a) **Starting Point: (Pathway Appendix 1)**

i. Identify high-risk individuals primarily in pulmonary clinics, internal medicine, primary care clinics, and smoking cessation programs.
ii. Utilize existing electronic health records (EHR) to flag eligible patients based on age and smoking history.
iii. Refer patients meeting the criteria to lung cancer screening clinics
iv. **Each cluster** should establish a clear pathway for referral of patients to lung cancer screening clinics

b) **Referral Process:**

i. **Primary care providers (PCPs)** or smoking cessation clinics refer eligible patients to the screening clinic within primary or secondary care via referral forms or direct scheduling.
ii. Referring physicians with the authorization to order a Low Dose CT (LDCT) chest scan should place the order in the system and follow up on the result.
iii. In case of unavailability of specific facility or tests, the PCP, based on the location, will refer to a higher centre within the cluster or to the nearest available facilities within MOH.
iv. Each cluster will create its referral pathways within its own facilities

c) **Patient Outreach and Education:**

i. Distribute screening criteria to family physicians, internal medicine, pulmonary, and smoking cessation clinics
ii. Through community outreach
iii. Conduct counselling sessions emphasizing the importance of participation and smoking cessation

8. **Smoking cessation clinic**

a) All current smokers enrolled in the lung cancer Screening program will be offered referral to the Smoking cessation clinics.
b) Smoking cessation clinic within each cluster, and the MOH will receive referrals for all smokers enrolled in the lung cancer program.

9. Pre-Test Evaluation and Preparation

a) First clinic Visit and clinical Assessment:

i. Confirm eligibility based on criteria
ii. Evaluate comorbidities that might influence test safety or follow-up
iii. Review medications and contraindications
iv. Provide comprehensive counselling on screening benefits, risks, and alternatives
v. Engage the patient in shared decision-making and obtain the verbal consent of the patient
vi. Schedule LDCT with clear patient instructions (no fasting required).

10. Conducting the LDCT Test

a) Test Procedure:

i. Position the patient supine with arms raised above the head.
ii. Use standardized low-dose protocols (radiation dose 1.5–2.0 mSv).
iii. Capture thin-section axial images (1–1.25 mm slice thickness) from lung apices to adrenal glands during deep inspiration.
iv. No contrast required.

b) Imaging Protocol: Technical Specifications:

Imaging protocol	
Parameter	**Details**
Scanner Type	Multi-slice CT (preferably ≥64-slice)
Radiation Dose	1.5-2.0 mSv (low-dose protocol)
Slice Thickness	1-1.25 mm
Acquisition Range	From lung apices to adrenal glands
Breath-hold	Deep inspiration (full lung inflation)
Contrast	Not required for screening (non-contrast protocol)

c) Quality Control:

i. Calibrate scanners regularly.
ii. Maintain consistent imaging parameters.
iii. Store images in DICOM format for standardized interpretation.
iv. Ensure adherence to technical standards for dose and image quality
v. Radiology technicians document patient positioning and technical parameters

11. Image Reporting and Interpretation

a) Radiological Assessment:

i. Images reviewed by experienced thoracic radiologists
ii. Apply Lung-RADS classification:

Lung RADS assessment category – Appendix 2		
Category	**Description**	**Management Recommendations**
1	Negative: No nodules or benign findings	Continue annual screening
2	Benign findings: non-cancerous nodules	Continue annual screening
3	Possibly benign; short-term follow-up (6 months)	Repeat LDCT in 6 months
4A	Suspicious; warrants further diagnostic evaluation	Refer to the pulmonary clinic for Diagnostic work-up (biopsy, PET-CT)
4B	Highly suspicious; likely malignancy	Urgent referral to the pulmonary clinic

b) Structuring the Report:

i. Include measurement of nodules (size, volume, solidity). location,
ii. Describe location and density, and morphological characteristics.
iii. Assign Lung-RADS category clearly
iv. Recommendations for follow-up or intervention.

12. Communicating Results and Next Steps

a) Reporting to the Referring Physician:

i. Deliver detailed reports to referring providers and lung cancer clinics promptly.
ii. Summarize findings and recommended management steps as per LRADS criteria

b) Follow-Up Actions:

I. **Lung-RADS 1–2:**
- Continue routine annual screening

II. **Lung-RADS 3:**
- Schedule a follow-up LDCT at 6 months
    1. Reassess the need for further diagnostic procedures

c) Lung-RADS 4A–4B:

i. Immediate referral to pulmonology or thoracic oncology for further evaluation

ii. Diagnostic procedures may include:
- Tissue biopsy (percutaneous, bronchoscopy, or surgical)
- Multidisciplinary team discussion for staging and management

13. Management of Detected Abnormalities

a) Confirmatory Diagnostics:

i. Confirm diagnosis with histopathology using minimally invasive biopsy techniques where feasible.

b) Treatment Planning:

i. For confirmed malignancies, staging is performed to guide treatment options

ii. Multidisciplinary tumor board reviews each case to formulate individualized management plans (surgery, chemotherapy, radiotherapy, targeted therapies)

iii. Incorporate patient preferences and comorbidities in decision-making.

14. Data Tracking, Quality Assurance, and Program Evaluation

a) Maintain a comprehensive electronic registry to track screened individuals, imaging results, and follow-up schedules.
b) Use automated alerts for timely follow-up, LDCT, and clinical reviews
c) Monitor key performance indicators: detection rates, false positives, interval cancers, and patient outcomes.
d) Conduct regular audits and update protocols based on emerging evidence.
e) Provide ongoing training for radiologists, clinicians, and support staff
f) Employ emerging imaging technologies and AI tools for enhanced nodule characterization as they become validated and available.

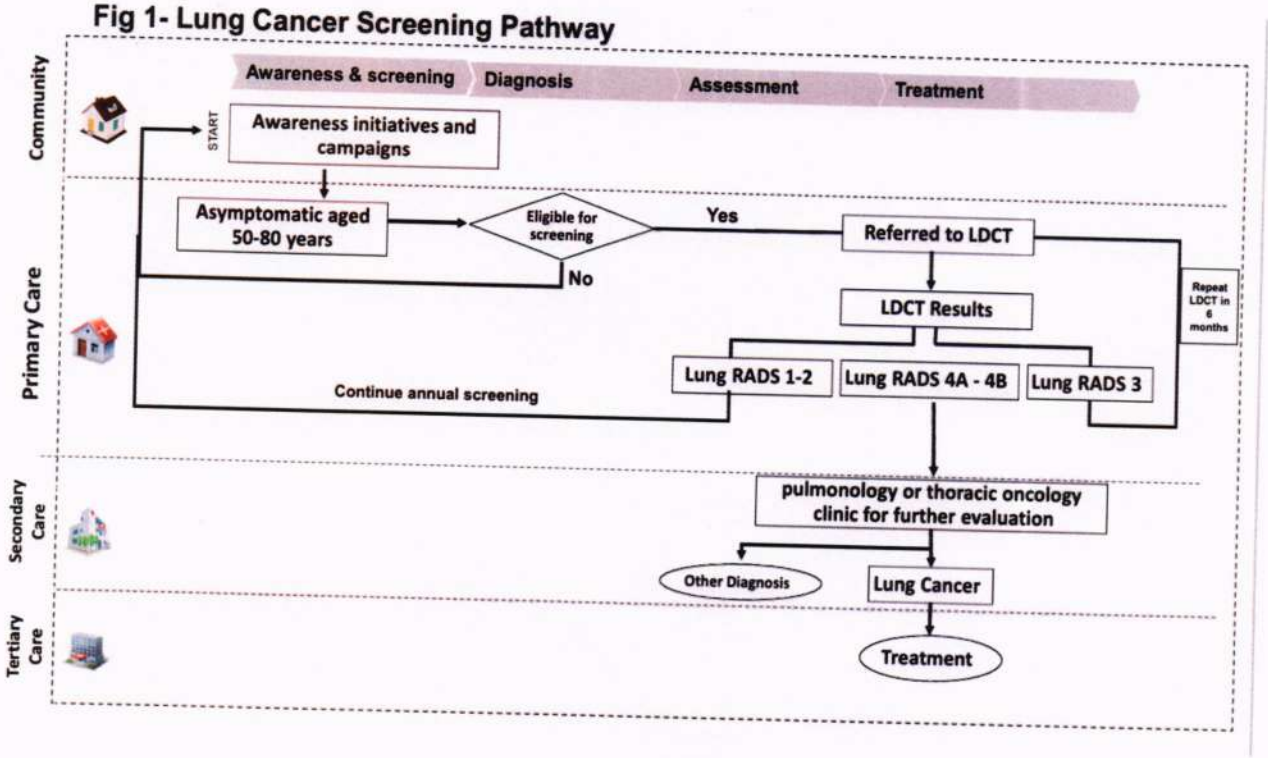
15. Key performance indicator (KPI)

a) Number of patients referred to the program
b) Number of patients seen in the program
c) The duration from the physician's order for the LDCT until the patient is booked for an appointment.
d) Number of screening CT scans done annually
e) Number of lung nodules/masses detected and went for procedures
f) Number of confirmed Lung cancers detected
g) The turnaround time from the LDCT scan performance to the treating physician's receipt of the final radiology report
h) Number of patients referred to smoking cessation clinic
i) Percentage of patients screened within 30 days of referral from Primary Health Care

16. Appendixes

Appendix 1

Fig 1- Lung Cancer Screening Pathway



وزارة الصحة
Ministry of Health

Appendix 2

ACR AMERICAN COLLEGE OF RADIOLOGY

Lung-RADS® 2022

Release Date: November 2022

Lung-RADS	Category Descriptor	Findings	Management
0	**Incomplete** Estimated Population Prevalence: ~ 1%	Prior chest CT examination being located for comparison (see note 9)	Comparison to prior chest CT;
		Part or all of lungs cannot be evaluated	Additional lung cancer screening CT imaging needed;
		Findings suggestive of an inflammatory or infectious process (see note 10)	1-3 month LDCT
1	**Negative** Estimated Population Prevalence: 39%	**No lung nodules OR**	12-month screening LDCT
		Nodule with benign features: • Complete, central, popcorn, or concentric ring calcifications **OR** • Fat-containing	
2	**Benign** Based on imaging features or indolent behavior Estimated Population Prevalence: 45%	**Juxtapleural nodule:** • < 10 mm (524 mm^3) mean diameter at baseline or new **AND** • Solid; smooth margins; and oval, lentiform, or triangular shape	
		Solid nodule: • < 6 mm (< 113 mm^3) at baseline **OR** • New < 4 mm (< 34 mm^3)	
		Part-solid nodule: • < 6 mm total mean diameter (< 113 mm^3) at baseline	
		Non-solid nodule (GGN): • < 30 mm (< 14,137 mm^3) at baseline, new, or growing **OR** • ≥ 30 mm (≥ 14,137 mm^3) stable or slow-growing (see note 7)	
		Airway nodule, subsegmental at baseline, new, or stable (see note 11)	
		Category 3 nodule that is stable or decreased in size at 6-month follow-up CT, **OR** Category 3 or 4A nodules that resolve on follow-up, **OR** Category 4B findings proven to be benign in etiology following appropriate diagnostic workup	
3	**Probably Benign** Based on imaging features or behavior Estimated Population Prevalence: 9%	**Solid nodule:** • ≥ 6 to < 8 mm (≥ 113 to < 268 mm^3) at baseline **OR** • New 4 mm to < 6 mm (34 to < 113 mm^3)	6-month LDCT
		Part-solid nodule: • ≥ 6 mm total mean diameter (≥ 113 mm^3) with solid component < 6 mm (< 113 mm^3) at baseline **OR** • New < 6 mm total mean diameter (< 113 mm^3)	
		Non-solid nodule (GGN): • ≥ 30 mm (≥ 14,137 mm^3) at baseline or new	
		Atypical pulmonary cyst: (see note 12) • Growing cystic component (mean diameter) of a thick-walled cyst	
		Category 4A nodule that is stable or decreased in size at 3-month follow-up CT (excluding airway nodules)	
4A	**Suspicious** Estimated Population Prevalence: 4%	**Solid nodule:** • ≥ 8 to < 15 mm (≥ 268 to < 1,767 mm^3) at baseline **OR** • Growing < 8 mm (< 268 mm^3) **OR** • New 6 to < 8 mm (113 to < 268 mm^3)	3-month LDCT; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm^3) solid nodule or solid component
		Part-solid nodule: • ≥ 6 mm total mean diameter (≥ 113 mm^3) with solid component ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm^3) at baseline **OR** • New or growing < 4 mm (< 34 mm^3) solid component	
		Airway nodule, segmental or more proximal at baseline or new (see note 11)	
		Atypical pulmonary cyst: (see note 12) • Thick-walled cyst **OR** • Multilocular cyst at baseline **OR** • Thin- or thick-walled cyst that becomes multilocular	
4B	**Very Suspicious** Estimated Population Prevalence: 2%	**Airway nodule**, segmental or more proximal, and stable or growing (see note 11)	Referral for further clinical evaluation
		Solid nodule: • ≥ 15 mm (≥ 1767 mm^3) at baseline **OR** • New or growing ≥ 8 mm (≥ 268 mm^3)	Diagnostic chest CT with or without contrast; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm^3) solid nodule or solid component; tissue sampling; and/or referral for further clinical evaluation Management depends on clinical evaluation, patient preference, and the probability of malignancy (see note 13)
		Part-solid nodule: • Solid component ≥ 8 mm (≥ 268 mm^3) at baseline **OR** • New or growing ≥ 4 mm (≥ 34 mm^3) solid component	
		Atypical pulmonary cyst: (see note 12) • Thick-walled cyst with growing wall thickness/nodularity **OR** • Growing multilocular cyst (mean diameter) **OR** • Multilocular cyst with increased loculation or new/increased opacity (nodular, ground glass, or consolidation)	
		Slow-growing solid or part-solid nodule that demonstrates growth over multiple screening exams (see note 8)	
4X	Estimated Population Prevalence: < 1%	Category 3 or 4 nodules with additional features or imaging findings that increase suspicion for lung cancer (see note 14)	
S	**Significant or Potentially Significant** Estimated Population Prevalence: 10%	**Modifier:** May add to category 0-4 for clinically significant or potentially clinically significant findings unrelated to lung cancer (see note 15)	As appropriate to the specific finding

وزارة الصحة
Ministry of Health

NOTES

1. **Lung-RADS Category:** Each exam should be coded 0-4 based on the nodule with the highest degree of suspicion.
2. **Lung-RADS Management:** The timing of follow-up imaging is from the date of the exam being interpreted. For example, 12-month screening LDCT for Lung-RADS 2 is from the date of the current exam. Also note that management of category 3 and 4A nodules follows a stepped approach based on follow-up stability or decrease in size. If nodules resolve on follow-up, reclassify according to the most concerning finding.
3. **Practice Audit Definitions:** A negative screen is defined as categories 1 and 2; a positive screen is defined as categories 3 and 4. A negative screen does not mean that an individual does not have lung cancer.
4. **Nodule Measurement:** To calculate nodule mean diameter, measure both the long and short axis to one decimal point in mm, and report mean nodule diameter to one decimal point. The long and short axis measurements may be in any plane to reflect the true size of the nodule. Volumes, if obtained, should be reported to the nearest whole number in mm^3.
5. **Size Thresholds:** Apply to nodules at first detection and that enlarge, reaching a higher size category. When a nodule crosses a new size threshold for other Lung-RADS categories, even if not meeting the definition of growth, the nodule should be reclassified based on size and managed accordingly.
6. **Growth:** An increase in mean diameter size of > 1.5 mm (> 2 mm^3) within a 12-month interval.
7. **Slow-Growing–Non-Solid (Ground-Glass) Nodules:** A ground-glass nodule (GGN) that demonstrates growth over multiple screening exams but does not meet the > 1.5 mm threshold increase in size for any 12-month interval may be classified as Lung-RADS 2 until the nodule meets findings criteria of another category, such as developing a solid component (then manage per part-solid nodule criteria).
8. **Slow-Growing-Solid or Part-Solid Nodules:** A solid or part-solid nodule that demonstrates growth over multiple screening exams but does not meet the > 1.5 mm threshold increase in size for any 12-month interval is suspicious and may be classified as a Lung-RADS 4B. Slow-growing nodules may not have increased metabolic activity on PET/CT; therefore, biopsy, if feasible, or surgical evaluation may be the most appropriate management recommendation.
9. **Prior Exams:** If waiting on prior exams (either a prior screening or diagnostic CT), the Lung-RADS 0 category is temporary until the comparison study is available and a new Lung-RADS category is assigned.
10. **Suspected Infectious or Inflammatory Findings:**
    a. Lung-RADS 0 with 1-3 month follow-up LDCT may be recommended for pulmonary findings suggesting an indeterminate infectious or inflammatory process. Such findings may include segmental or lobar consolidation, multiple new nodules (more than six), large solid nodules (≥ 8 mm) appearing in a short interval, and new nodules in certain clinical contexts (eg, immunocompromised patient). At 1-3 month follow-up, a new Lung-RADS classification and management recommendation should be provided based on the most suspicious nodule.
    b. New solid or part-solid nodules with imaging features more concerning for malignancy than an infectious or inflammatory process meeting Lung-RADS 4B size criteria may be classified as such with appropriate diagnostic and/or clinical evaluation.
    c. Some findings indicative of an infectious or infectious process may not warrant short-term follow-up (eg, tree-in-bud nodules or new < 3 cm ground glass nodules). These nodules may be evaluated using existing size criteria with a Lung-RADS classification and management recommendation based on the most suspicious finding.
11. **Airway Nodules:**
    a. Endotracheal or endobronchial abnormalities that are segmental or more proximal are classified as Lung-RADS 4A.
    b. Subsegmental and/or multiple tubular endobronchial abnormalities favor an infectious process; if no underlying obstructive nodule is identified, these findings may be classified as Lung-RADS 0 (likely infectious or inflammatory) or 2 (benign).
    c. The presence of air in segmental or more proximal airway abnormalities often favors secretions; if no underlying soft tissue nodule is identified, these findings may be classified as Lung-RADS 2.
    d. Segmental or more proximal airway nodules that are stable or growing on 3-month follow-up CT are upgraded to Lung-RADS 4B with management recommendation for further clinical evaluation (typically bronchoscopy).
12. **Atypical Pulmonary Cysts:**
    a. Thin-walled Cyst: Unilocular with uniform wall thickness < 2 mm. Thin-walled cysts are considered benign and are not classified or managed in Lung-RADS.
    b. Thick-walled Cyst: Unilocular with uniform wall thickness, asymmetric wall thickening, or nodular wall thickening ≥ 2 mm (cystic component is the dominant feature); manage as an atypical pulmonary cyst.
    c. Multilocular Cyst: Thick- or thin-walled cyst with internal septations. Manage as an atypical pulmonary cyst.
    d. Cavitary Nodule: Wall thickening is the dominant feature; manage as a solid nodule (total mean diameter).
    e. Cyst with an Associated Nodule: Any cyst with adjacent internal (endophytic) or external (exophytic) nodule (solid, part-solid, or ground-glass). Management is based upon Lung-RADS criteria for the most concerning feature.
    f. Growth: > 1.5 mm increase in nodule size (mean diameter), wall thickness, and/or size of the cystic component (mean diameter) occurring within a 12-month interval.
    g. Fluid-containing cysts may represent an infectious process and are not classified in Lung-RADS unless other concerning features are identified.
    h. Multiple cysts may indicate an alternative diagnosis such as Langerhans cell histiocytosis (LCH) or lymphangioleiomyomatosis (LAM) and are not classified in Lung-RADS unless other concerning features are identified. (Reference: Seaman DM, Meyer CA, Gilman MD, McCormack FX. Diffuse Cystic Lung Disease at High-Resolution CT. AJR 2011;196: 1305-1311)
13. **Category 4B:** Management is predicated on clinical evaluation (comorbidities), patient preference, and risk of malignancy. Radiologists are encouraged to use the McWilliams, et al Assessment Tool when making recommendations (https://brocku.ca/lung-cancer-screening-and-risk-prediction/risk-calculators/).
14. **Category 4X:** Category 3 or 4 nodules with additional imaging findings that increase the suspicion of lung cancer, such as spiculation, lymphadenopathy, frank metastatic disease, a GGN that doubles in size in 1 year, etc. 4X is a distinct Lung-RADS category; X should not be used as a modifier.
15. **Exam Modifier:** An S modifier may be added to Lung-RADS categories 0-4 for clinically significant or potentially clinically significant findings unrelated to lung cancer.
    a. Management should adhere to available ACR Incidental Findings management recommendations (https://www.acr.org/Clinical-Resources/Incidental-Findings). The ACR Lung Cancer Screening CT Incidental Findings Quick Reference Guide summarizes common findings and management (https://www.acr.org/-/media/ACR/Files/Lung-Cancer-Screening-Resources/LCS-Incidental-Findings-Quick-Guide.pdf).
    b. Findings that are already known, and have been or are in the process of clinical evaluation DO NOT require an S modifier. Any evidence of a concerning change in a known significant or potentially significant finding that is unexpected warrants renewed use of the S modifier.
16. **Lung Cancer Diagnosis:** Once a patient is diagnosed with lung cancer, further management (including additional imaging, such as PET/CT) may be performed for purposes of lung cancer staging; this is no longer considered screening.

Abbreviations: LDCT: low-dose chest CT; GGN: ground-glass nodule

Additional resources available at: https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads