Maryland
DEPARTMENT OF HEALTH
Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

May 25, 2021

Dear Participating Provider:

Thank you for participating in the Maryland Cigarette Restitution Fund Cancer Prevention, Education, Screening and Treatment (CRF CPEST) Program to provide no cost lung cancer screening. The CRF CPEST Program was established to reduce cancer incidence and mortality in Maryland. As lung cancer is one of the seven targeted cancers under the CRF CPEST Program, the Lung Cancer Program seeks to increase lung cancer screening rates among uninsured or underinsured, low income individuals statewide and, in some instances, to also provide diagnostic and treatment services. When further diagnostic or treatment services for eligible clients screened through CRF CPEST Program are not available, clients will be linked to appropriate programs for funding.

We are pleased to enclose the updated "Minimal Clinical Elements for Lung Cancer Detection and Diagnosis." The updates include:

- Removal of High Risk-Group 2 individuals for determining eligibility into the lung cancer screening module.
- Update to High Risk criteria (age and pack-year) for enrollment into the lung cancer screening module to align with the 2021 United States Preventive Services Task Force (USPSTF) and the National Comprehensive Cancer Network's (NCCN) definition of High Risk.
- Update to when individuals should discontinue screenings to exclude those who are no longer eligible for curative lung surgery but are eligible for radiotherapy.
- Update NCCN algorithms for attachments, titled, "Management of Findings of Initial Low-Dose Computed Tomography in the CRF CPEST Lung Cancer Screening Program," labeled as Attachment C, and "Management of Follow-up or Annual Low-dose Computed Tomography (LDCT) Results in CRF CPEST Lung Cancer Screening Program," labeled as Attachment D, to utilize the most current versions from the NCCN Clinical Practice Guidelines

in Oncology (NCCN Guidelines®): Lung Cancer Screening, Version 1.2021- December 17, 2020.

We appreciate your cooperation in using the new guidelines during your care of CRF CPEST patients. If you have any questions regarding the new "Minimal Clinical Elements for Lung Cancer Detection and Diagnosis" for the Maryland CRF CPEST Program, please contact Ken Lin Tai, M.D., M.P.H., Director of the Center for Cancer Prevention and Control (CCPC) at 410-767-2036 or kenlin.tai@maryland.gov.

Sincerely,

Stanley Watkins, M.D.
Chairman, Medical Advisory Committee

Enclosure

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Local CRF CPEST Coordinators

Maryland Department of Health (MDH) Center for Cancer Prevention and Control
Cigarette Restitution Fund Cancer Prevention, Education, Screening and Treatment (CRF CPEST) Program
Minimal Clinical Elements for Lung Cancer Detection and Diagnosis
Revised May 2021

Goal: The goal of the Minimal Clinical Elements for Lung Cancer Detection and Diagnosis is to provide clients of the Maryland Cigarette Restitution Fund Cancer Prevention, Education, Screening and Treatment Program with optimal care during lung cancer detection and diagnosis.

Objective: To provide clinical guidelines for lung cancer screening and diagnostic testing including the interpretation and management of results of low-dose computed tomography (LDCT).

Maryland Department of Health (MDH) Center for Cancer Prevention and Control
Cigarette Restitution Fund Cancer Prevention, Education, Screening and Treatment (CRF CPEST) Program
Minimal Clinical Elements for Lung Cancer Detection and Diagnosis
Revised May 2021

I. Maryland Cigarette Restitution Fund Cancer Prevention, Education, Screening and Treatment (CRF CPEST) Program- Client Eligibility Criteria

A. Client Eligibility Criteria for Enrollment into CRF CPEST Program-Lung Cancer Screening Module (including additional work-up following an abnormal screening within the program):

An individual that meets the criteria listed below will be enrolled in the CRF CPEST Lung Cancer Screening Module.

Individuals who are at High Risk[1] for lung cancer:

- Anyone, age 50 to 80 years, and;
- ≥ 20 pack-year smoking history (*See Attachment A: Calculating Pack Years*), and;
- Currently smokes or quit smoking in the past 15 years.

Note: 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; however, those who are no longer eligible for curative lung surgery but are eligible for radiotherapy may continue annual lung cancer screening. If a person is program eligible and has a prior history of lung cancer, annual lung cancer screening with LDCT may resume 5 years after diagnosis of lung cancer at the discretion of the provider and client *(refer to 'special situations' on page 4).*

B. Client Eligibility Criteria for an Annual Low Dose Computed Tomography (LDCT) Lung Cancer Screening:[2]

A client enrolled in the CRF CPEST Lung Cancer Screening Module must receive the following services before receiving an annual LDCT lung cancer screening.

1. Client must receive counseling on the importance of maintaining cigarette smoking abstinence if former smoker; or the importance of smoking cessation if current smoker and must be furnished with information about tobacco cessation interventions.
2. Client must receive a written order for LDCT lung cancer screening which is appropriately documented in the client's medical records and meets the following criteria:
   - For initial LDCT lung cancer screening services, the client must receive a written order for LDCT lung cancer screening during a lung cancer screening counseling and shared decision making visit, furnished by a physician or qualified non-physician practitioner (meaning a physician assistant or nurse practitioner).
     - A lung cancer screening counseling and shared decision making visit includes the following elements:
       - Determining client's eligibility including age, absence of signs or symptoms of lung cancer, a specific calculation of cigarette smoking pack-years; and if a former smoker, the number of years since quitting;
       - Making a shared decision, including the use of one or more decision aids, to include benefits and harms of screening[3] (see LCS-B), follow-up diagnostic testing, over-diagnosis, false positive rate and total radiation exposure;
       - Counseling on the importance of adherence to annual lung cancer LDCT screening, impact of comorbidities and ability or willingness to undergo diagnosis and treatment;
       - Counseling on the importance of maintaining cigarette smoking abstinence if former smoker; or the importance of smoking cessation if current smoker and, if appropriate, furnishing of information about tobacco cessation interventions; and a written order for lung cancer screening with LDCT.

- For subsequent LDCT lung cancer screenings, the client must receive a written order for LDCT lung cancer screening, which may be furnished during **any** appropriate visit with a physician or qualified non-physician practitioner. If a physician or qualified non-physician practitioner elects to provide a lung cancer screening counseling and shared decision making visit for subsequent lung cancer screenings with LDCT, the visit must meet the criteria described above for a counseling and shared decision making visit.
- Written orders for both initial and subsequent LDCT lung cancer screenings must contain the following information, which must also be appropriately documented in the client's medical records:
  - Client's date of birth;
  - Actual number of pack-year smoking history (*See Attachment A: Calculating Pack Years*);
  - Current smoking status, and for former smokers, the number of years since quitting smoking;
  - Statement that the client is asymptomatic for lung cancer, though they may have signs or symptoms of other diseases [chronic obstructive pulmonary disease (emphysema and chronic bronchitis) and pulmonary fibrosis];
  - Statement verifying client has been furnished with a counseling and shared decision making visit, as described above;
  - National Provider Identifier (NPI) of the ordering practitioner.

C. Client Eligibility Criteria for Enrollment into CRF CPEST Program- Lung Cancer Post-Screening Module for Individuals Screened Outside of the Program Requiring CRF Funded Diagnostic Services:

- Anyone, age 50 to 80 years, and;
- Provides local CRF CPEST Program with documentation of abnormal finding(s) from lung cancer screening LDCT and recommended diagnostic work up to rule out lung cancer.

II. Findings, Reporting, Management of Results, Additional Procedures and Program Coverage

A. Results and Reports

1. LDCT findings should be reported using the American College of Radiology Lung CT Screening Reporting & Data System (Lung-RADS^{tm}), Version 1.1 Assessment Categories.[4] *(See Attachment B: Lung-RADS® Version 1.1 Assessment Categories Release date: 2019)*
2. **CT reports should be structured to include the following information:**[5]
   - **Indication**: with language suggesting 'lung cancer screening' or 'surveillance of lung nodules to rule out lung cancer.'
   - For each indeterminate nodule, the size shape, morphology and lobar/segmental location should be reported.
   - The series and slice number should also be reported for each nodule to facilitate comparison on future examinations.
   - Examinations should always be compared directly with previous ones, and not simply with prior reports, and any change in nodule size, shape or composition should be determined.
   - The CT reports should include standard Lung-RADS guidelines for further evaluation of positive test results.

B. Management of Findings of Initial Low-Dose Computed Tomography

1. **See Attachment C:** *Management of Findings of Initial Low-Dose Computed Tomography in the CRF CPEST Lung Cancer Screening Program*

[NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines ®): Lung Cancer Screening, Version 1.2021- December 17, 2020 algorithms][3]

2. **Lung-RADS category 0 result:** If a radiologist recommends obtaining results or copies of prior LDCT following a Lung-RADS category 0 result, local CRF CPEST program should assist in obtaining the results or copies.
3. **Lung-RADS category 1 or 2 result:** Local CRF CPEST program ensures a copy of results is forwarded to ordering provider for management of findings per Radiologist's recommendation in accordance with Lung Cancer MCE, Attachment C.
   - Continue annual screening with LDCT in 12 months.
4. **Lung-RADS category 3 result:**
   - Local CRF CPEST program ensures a copy of results is forwarded to ordering provider.
   - Local CRF CPEST program obtains ordering provider's recommendation for follow-up, in accordance with Lung Cancer MCE, Attachment C.
   - Short term follow-up LDCT in 6 months.
   - Ordering provider may refer to the appropriate Specialist (e.g. Pulmonologist or Thoracic Surgeon) for evaluation and/or possible presentation to the multidisciplinary team.
5. **Lung-RADS category 4 result:**
   - Local CRF CPEST program ensures a copy of results is forwarded to ordering provider for management of findings per Radiologist's recommendation in accordance with Lung Cancer MCE, Attachment C.
   - Local CRF CPEST program obtains ordering provider's recommendation for follow-up and/or referral to specialist, in accordance with Lung Cancer MCE, Attachment C.
   - The evaluation for the suspicion of lung cancer requires a multidisciplinary approach with expertise in lung nodule management (thoracic radiology, pulmonary medicine and thoracic surgery) (see LCS-3 and LCS-4, footnote s).[3]

C. Management of Findings of <u>Follow-up</u> or <u>Annual</u> Low-dose Computed Tomography

1. **See Attachment D:** *Management of <u>Follow-up</u> or <u>Annual</u> Low-dose Computed Tomography (LDCT) Results in CRF CPEST Lung Cancer Screening Program*
   [NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines ®): Lung Cancer Screening, Version 1.2021- December 17, 2020 algorithms][3]
2. **Lung-RADS category 0 result:** If a radiologist recommends obtaining results or copies of prior LDCT following a Lung-RADS category 0 result, local CRF CPEST program should assist in obtaining the results or copies.
3. **Lung-RADS category 1 or 2 result:**
   - Local CRF CPEST program ensures a copy of results is forwarded to ordering provider for management of findings per Radiologist's recommendation in accordance with Lung Cancer MCE, Attachment D.
   - Continue annual screening with LDCT in 12 months
4. **Lung-RADS category 3 result:**
   - Local CRF CPEST program ensures a copy of results is forwarded to ordering provider.
   - Local CRF CPEST program obtains ordering provider's recommendation for follow-up, in accordance with Lung Cancer MCE, Attachment D.
   - Short term follow-up LDCT in 6 months.
   - Ordering provider may refer to the appropriate Specialist (e.g. Pulmonologist or Thoracic Surgeon) for evaluation and/or possible presentation to the multidisciplinary team.

5. **Lung-RADS category 4 result:**
   - Local CRF CPEST program ensures a copy of results is forwarded to ordering provider for management of findings per Radiologist's recommendation in accordance with Lung Cancer MCE, Attachment D.
   - Local CRF CPEST program obtains ordering provider's recommendation for follow-up and/or referral to specialist, in accordance with Lung Cancer MCE, Attachment D.
   - The evaluation for the suspicion of lung cancer requires a multidisciplinary approach with expertise in lung nodule management (thoracic radiology, pulmonary medicine and thoracic surgery) (see LCS-7 and LCS-8, footnote s).[3]

D. Management of Findings requiring follow-up for diseases other than lung cancer (e.g. suspicious for other cancers, chronic obstructive pulmonary disease, moderate to severe coronary artery calcification or aortic aneurysm)

1. **If client has a Primary Care Provider (PCP**): Local CRF CPEST program forwards copies of reports and refers client to his/her PCP for follow-up of finding(s).
2. **If client does not have a PCP:** Local CRF CPEST program links client to a primary care provider and forwards copies of reports for the management of findings and determination of appropriate follow-up of findings other than lung cancer.

E. Additional Procedures and Program Coverage

Note: *Providers should consult with the local CRF CPEST Program for questions about coverage for payment of procedures.* Reimbursement is based on client eligibility and availability of local CRF CPEST Program funds.

Special Situations: If an individual is program eligible and has a prior history of lung cancer, annual lung cancer screening with LDCT may resume 5 years after diagnosis of lung cancer at the discretion of the provider and client. Enrollment into the Lung Cancer Screening Module is on a case-by-case basis. Prior to enrollment, programs must first contact the MDH Nurse Consultant for guidance.

Reimbursement for Additional Screening or Diagnostic Procedures: Only procedures recommended in the Algorithms (as Attachments C and D), based on imaging or histologic findings, will be CRF funded. Additional or alternative procedures are usually not paid for by the CRF CPEST Program. Please contact your local CRF CPEST Program for more information.

Reimbursement for Treatment Procedures: Please contact your local CRF CPEST Program for more information.

- Surgical or oncology consult visits
- Follow-up surgical or oncology visits
- Chemotherapy
- Radiation Therapy
- Surgery
- Complications related to a CRF CPEST funded diagnostic procedure or treatment
- Palliative care

References:

1. *Final Update Summary: Lung Cancer: Screening*. U.S. Preventive Services Task Force, 2021. https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening
2. *Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT).* Centers for Medicare & Medicaid Services, February 2015. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274
3. Referenced with permission from the NCCN Guidelines® for Lung Cancer Screening V.1.2021 © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed April 26, 2020. Available online at www.NCCN.org (NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.)
4. Lung Imaging Reporting and Data System (Lung-RADS®) by American College of Radiology is licensed under a Creative Commons Attribution-NoDerivatives 4.0 International License. Based on a work at https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads
5. Arenberg D, Kazerooni EA., "Setting Up a Lung Cancer Screening Program", *J Natl Comp Cancer Network* 2012; 10; 277-285.

Lung Cancer Medical Advisory Committee

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Attachment A: *Calculating Pack Years*

Pack Years[1]**:** The amount an individual has smoked over a period of time. One Pack Year is equal to smoking one pack per day for one year. To calculate an individual's pack years, multiply the number of packs of cigarettes they smoked per day by the number of years they smoked.

How to calculate number of pack years:
Ask the client, "Have you ever smoked tobacco?"
Ask the client, "At what age did you start smoking?"
Ask the client, "Do you currently smoke?"
If they are a *current smoker*, subtract the age when they started smoking from their current age.
If they are a *former smoker*, ask "At what age did you quit?" and subtract the age when they started smoking from the age they were when they quit.
Ask the client, "On average, how many cigarettes did/do you smoke per day?" *20 cigarettes= 1 pack
Multiply the number of packs smoked per day by the number of years smoked.

#packs per day smoked X **#years smoking** = **Pack Years**

Example #1: Client is a 62 year old current smoker who started smoking at age 15. She smoked a pack a day until her 60th birthday and then cut back to a half a pack per day (PPD).

Step 1. Calculate number of years of smoking.
62 (current age) – 15 (age started smoking) = **47** total years smoking 1 PPD, but the last 2yrs at 0.5 PPD
Therefore, **45 years at 1 PPD** and **2 years at 0.5 PPD**

Step 2. Calculate pack years. Remember, one Pack Year is equal to smoking 1 PPD for 1 year.

45 years smoking 1 PPD = **45** Pack Years
(45 years X 1 PPD)
2 year smoking 0.5 PPD = **+ 1** Pack Years
(2 years X 0.5 PPD) **46** Total Pack Years

Example #2: Client is a 70 year old former smoker who quit 7 years ago. On average, he smoked 2 packs per day. He started smoking at 12 years old.

Step 1. Calculate number of years of smoking.
70 (current age) – **12** (age started smoking) = **58** – 7 (years ago he quit) = **51** total years smoking

Step 2. Calculate pack years (one Pack Year is equal to smoking 1 PPD for 1 year).
51 years smoking 2 PPD = (51 years X 2 PPD) = **102** Total Pack Years

[1] https://www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=306510

Attachment B: *Lung-RADS® Version 1.1 Assessment Categories*

Category Descriptor	Lung-RADS Score	Findings	Management	Risk of Malignancy	Est. Population Prevalence
Incomplete	**0**	Prior chest CT examination(s) being located for comparison Part or all of lungs cannot be evaluated	Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed	n/a	1%
Negative No nodules and definitely benign nodules	**1**	No lung nodules Nodule(s) with specific calcifications: complete, central, popcorn, concentric rings and fat containing nodules	Continue annual screening with LDCT in 12 months	< 1%	90%
Benign Appearance or Behavior Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	**2**	**Perifissural nodule(s)** *(See Footnote 11)* < 10 mm (524 mm^3) **Solid nodule(s):** < 6 mm (< 113 mm^3) new < 4 mm (< 34 mm^3) **Part solid nodule(s):** < 6 mm total diameter (< 113 mm^3) on baseline screening **Non solid nodule(s) (GGN):** <30 mm (<14137 mm^3) **OR** ≥ 30 mm (≥ 14137 mm^3) and unchanged or slowly growing **Category 3 or 4 nodules unchanged for ≥ 3 months**			
Probably Benign Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer	**3**	**Solid nodule(s):** ≥ 6 to < 8 mm (≥ 113 to < 268 mm^3) at baseline **OR** new 4 mm to < 6 mm (34 to < 113 mm^3) **Part solid nodule(s)** ≥ 6 mm total diameter (≥ 113 mm^3) with solid component < 6 mm (< 113 mm^3) **OR** new < 6 mm total diameter (< 113 mm^3) **Non solid nodule(s)** (GGN) ≥ 30 mm (≥ 14137 mm^3) on baseline CT or new	6 month LDCT	1-2%	5%
Suspicious Findings for which additional diagnostic testing is recommended	**4A**	**Solid nodule(s):** ≥ 8 to < 15 mm (≥ 268 to < 1767 mm^3) at baseline **OR** growing < 8 mm (< 268 mm^3) **OR** new 6 to < 8 mm (113 to < 268 mm^3) **Part solid nodule(s):** ≥ 6 mm (≥ 113 mm^3) with solid component ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm^3) **OR** with a new or growing < 4 mm (< 34 mm^3) solid component **Endobronchial nodule**	3 month LDCT; PET/CT may be used when there is a ≥ 8 mm (≥ 268 mm^3) solid component	5-15%	2%
Very Suspicious Findings for which additional diagnostic testing and/or tissue sampling is recommended	**4B**	**Solid nodule(s)** ≥ 15 mm (≥ 1767 mm^3) **OR** new or growing, and ≥ 8 mm (≥ 268 mm^3) **Part solid nodule(s) with:** a solid component ≥ 8 mm (≥ 268 mm^3) **OR** a new or growing ≥ 4 mm (≥ 34 mm^3) solid component	Chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm (≥ 268 mm^3) solid component. *For new large nodules that develop on an annual repeat screening CT, a 1 month LDCT may be recommended to address potentially infectious or inflammatory conditions*	> 15%	2%
	4X	Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy			
Other Clinically Significant or Potentially Clinically Significant Findings (non lung cancer)	**S**	**Modifier - may add on to category 0-4 coding**	As appropriate to the specific finding	n/a	10%

Attachment B: *Lung-RADS® Version 1.1 Assessment Categories*

IMPORTANT NOTES FOR USE:

1. **Negative screen:** does not mean that an individual does not have lung cancer
2. **Size:** To calculate nodule mean diameter, measure both the long and short axis to one decimal point, and report mean nodule diameter to one decimal point
3. **Size Thresholds:** apply to nodules at first detection, and that grow and reach a higher size category
4. **Growth:** an increase in size of > 1.5 mm (> 2 mm^3)
5. **Exam Category:** each exam should be coded 0-4 based on the nodule(s) with the highest degree of suspicion
6. **Exam Modifiers:** S modifier may be added to the 0-4 category
7. **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 screening
8. **Practice audit definitions:** a negative screen is defined as categories 1 and 2; a positive screen is defined as categories 3 and 4
9. **Category 4B Management:** this is predicated on the probability of malignancy based on patient evaluation, patient preference and risk of malignancy; radiologists are encouraged to use the McWilliams et al assessment tool when making recommendations
10. **Category 4X:** nodules with additional imaging findings that increase the suspicion of lung cancer, such as spiculation, GGN that doubles in size in 1 year, enlarged lymph nodes etc.
11. Solid nodules with smooth margins, an oval, lentiform or triangular shape, and maximum diameter less than 10 mm or 524 mm^3 (perifissural nodules) should be classified as category 2
12. **Category 3 and 4A nodules that are unchanged on interval CT should be coded as category 2, and individuals returned to screening in 12 months**
13. **LDCT:** low dose chest CT

*Additional resources available at - https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads
*Link to Lung-RADS calculator - https://brocku.ca/lung-cancer-screening-and-risk-prediction/risk-calculators/

Attachment C: *Management of Findings of Initial Low-dose Computed Tomography (LDCT) in the CRF CPEST Program-Lung Module*

NCCN algorithms:

- LCS-B Risks/Benefits of Lung Cancer Screening
- LCS-2 & 2A Screening Findings
- LCS-3 & 3A Solid Nodule on Initial Screening LCDT
- LCS-4 & 4A Part-solid Nodule on Initial Screening LCDT
- LCS-5 Nonsolid Nodule on Initial Screening LCDT
- LCS-A Low-Dose Computed Tomography Acquisition, Storage, Interpretation and Nodule Reporting

RISKS/BENEFITS OF LUNG CANCER SCREENING[1]

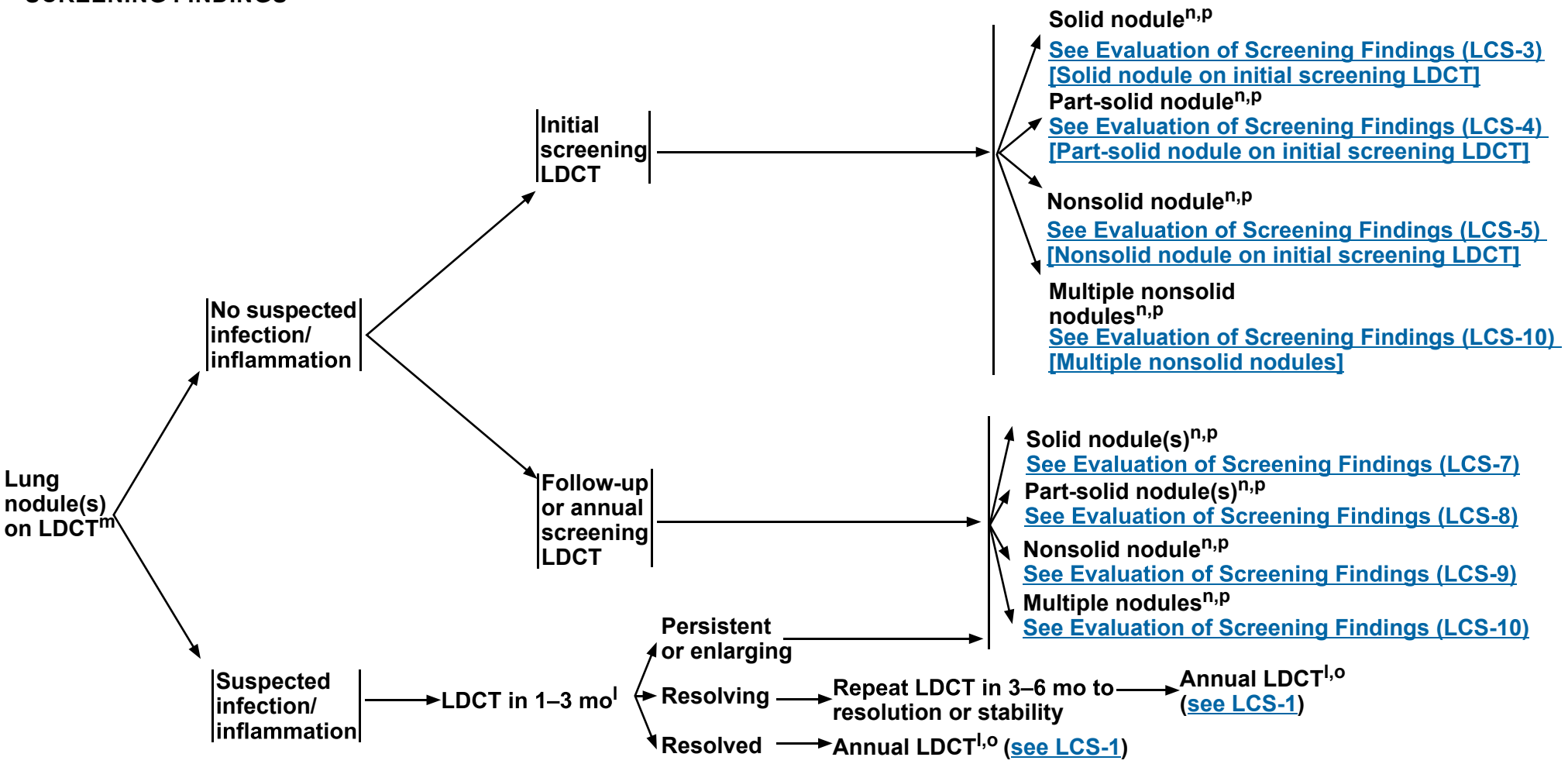
RISKS
- Futile detection of small aggressive tumors or indolent disease
- Quality of life
  - Anxiety of test findings
- Physical complications from diagnostic workup
- False-positive results
- False-negative results
- Unnecessary testing and procedures
- Radiation exposure
- Cost
- Incidental lesions

BENEFITS
- Decreased lung cancer mortality[2-4]
- Quality of life
  - Reduction in disease-related morbidity
  - Reduction in treatment-related morbidity
  - Improvement in healthy lifestyles
  - Reduction in anxiety/psychosocial burden
- Discovery of other significant occult health risks (eg, thyroid nodule, severe but silent coronary artery disease, early renal cancer in upper pole of kidney, aortic aneurysm, breast cancer)

[1] See Discussion for more detailed information.
[2] National Lung Screening Trial Research Team, Aberle DR, et al. N Engl J Med 2011;365:395-409.
[3] Ru Zhao Y, et al. Cancer Imaging 2011;11 Spec No A:S79-S84.
[4] De Koning H, et al. N Engl J Med 2020;382:503-513; Pastorino U, et al. Ann Oncol 2019;30:1162-1169; Becker N, et al. Int J Cancer 2020;146:1503-1513.

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.

SCREENING FINDINGS



Findings requiring follow-up for diseases other than lung cancer (eg, suspicious for other cancers, COPD, moderate to severe coronary artery calcification, aortic aneurysm)

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

Footnotes

[l] All screening and follow-up chest CT scans should be performed at low dose (100–120 kVp and 40–60 mAs or less), unless evaluating mediastinal abnormalities or lymph nodes, where standard-dose CT with IV contrast might be appropriate (see LCS-A). There should be a systematic process for appropriate follow-up.

[m] The NCCN Guidelines for Lung Cancer Screening are harmonized with Lung-RADS with rounding of measurement to the nearest whole number (mm). https://www.acr.org/-/media/ACR/Files/RADS/Lung-RADS/LungRADSAssessmentCategoriesv1-1.pdf.

[n] Without benign pattern of calcification, fat in nodule suggestive of hamartoma, or features suggesting inflammatory etiology. When multiple nodules or other findings are present that suggest occult infection or inflammation is a possibility, suggest follow-up LDCT in 1–3 months.

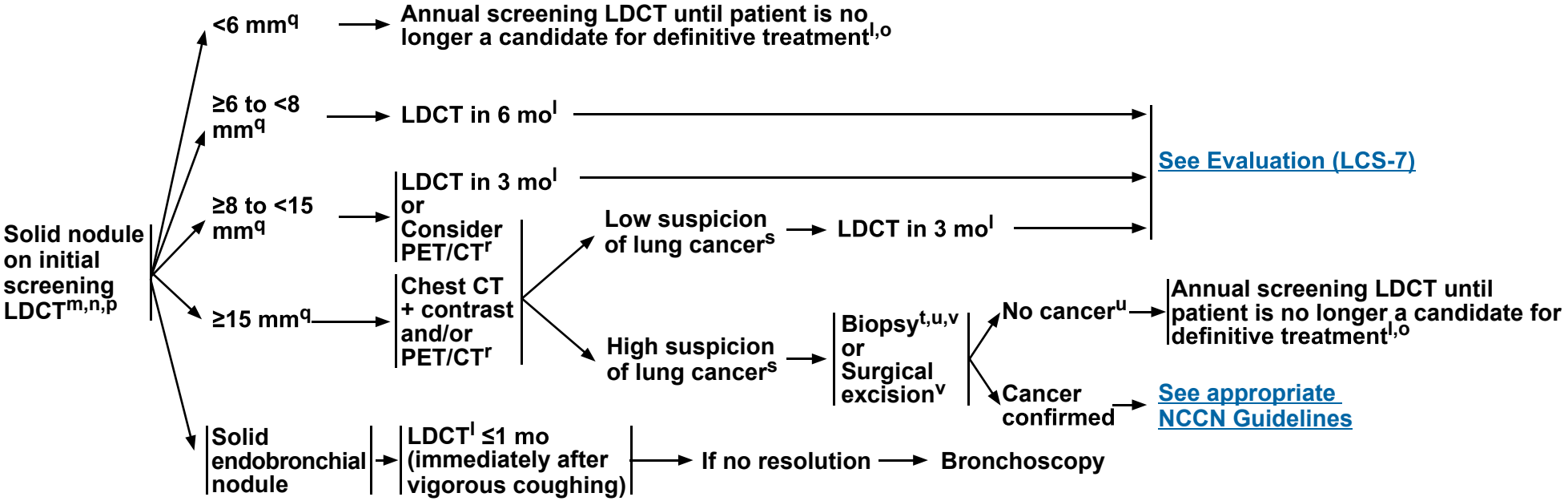
[o] There is uncertainty about the appropriate duration of screening and the age at which screening is no longer appropriate.

[p] A nodule is a rounded opacity, measuring up to 3 cm in diameter. A solid nodule has a homogeneous soft-tissue attenuation, a ground-glass nodule (also known as a nonsolid nodule) has hazy increased attenuation that does not obliterate bronchial and vascular margins, and a part-solid nodule has elements of both solid and ground-glass nodules. Nodules should be evaluated and measured on CT using lung windows. The size of all nodules is underestimated when viewed on lung windows, and some nodules may not even be visible, particularly ground-glass nodules and small nodules. Hansell DM, et al. Radiology 2008;246:697-722.

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.

EVALUATION OF SCREENING FINDINGS

FOLLOW-UP OF SCREENING FINDINGS



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[m] The NCCN Guidelines for Lung Cancer Screening are harmonized with Lung-RADS with rounding of measurement to the nearest whole number (mm). https://www.acr.org/-/media/ACR/Files/RADS/Lung-RADS/LungRADSAssessmentCategoriesv1-1.pdf

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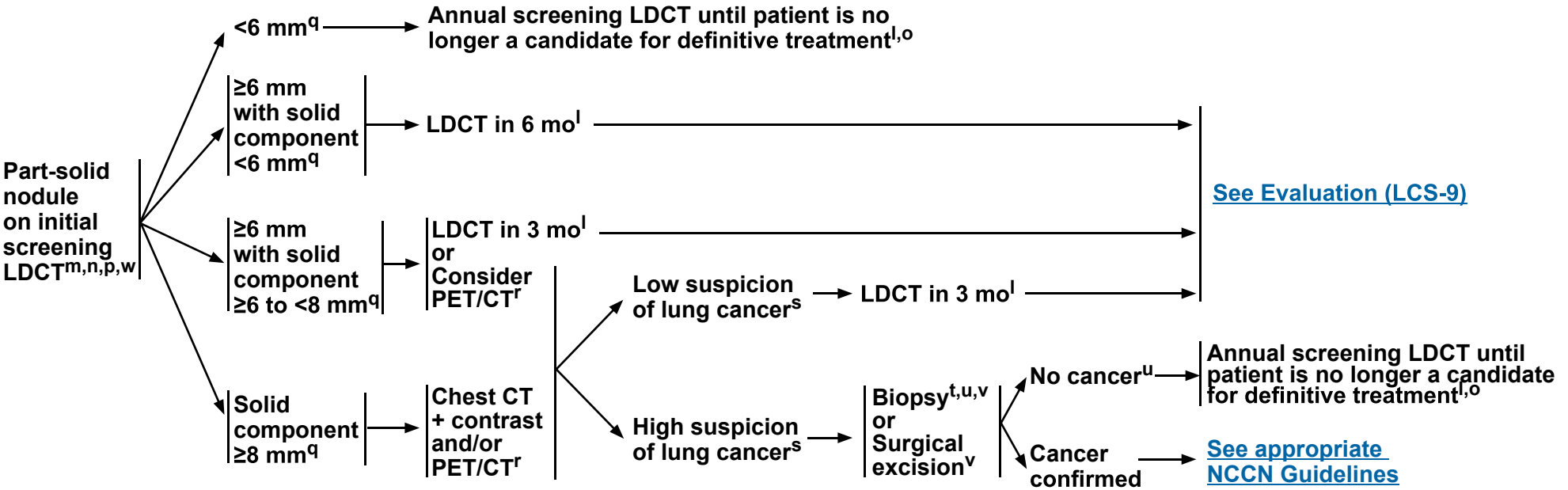

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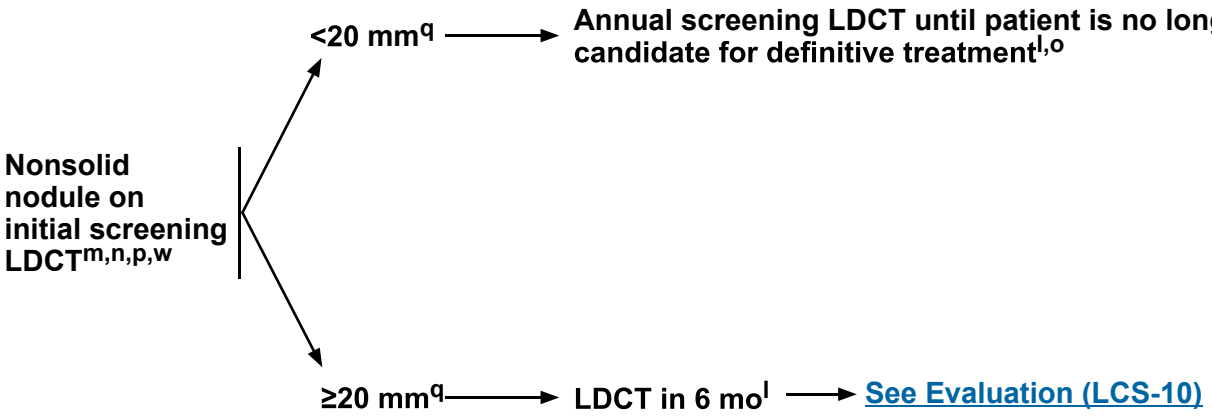

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LOW-DOSE COMPUTED TOMOGRAPHY ACQUISITION, STORAGE, INTERPRETATION, AND NODULE REPORTING (Lung-RADS)[1-4]

Acquisition	Small Patient (BMI ≤30)	Large Patient (BMI >30)
Total radiation exposure	≤3 mSv	≤5 mSv
kVp	100–120	120
mAs	≤40	≤60
	All Patients	
Gantry rotation speed	≤0.5	
Detector collimation	≤1.5 mm	
Slice width	≤2.5 mm; ≤1.0 mm preferred for characterization of nodule consistency, particularly for small nodules[5]	
Slice interval	≤slice width; 50% overlap preferred for 3D and CAD applications	
Scan acquisition time	≤10 seconds (single breath hold)	
Breathing	Maximum inspiration	
Contrast	No oral or intravenous contrast	
CT scanner detectors	≥16	
Storage	All acquired images, including thin sections; MIPs and CAD renderings if used	
Interpretation Tools		
Platform	Computer workstation review	
Image type	Standard and MIP images	
Comparison studies	Comparison with prior chest CT images (not reports) is essential to evaluate change in size, morphology, and density of nodules; review of serial chest CT exams is important to detect slow growth	
Nodule Parameters		
Size	Largest mean diameter on a single image (mean of the longest diameter of the nodule and its perpendicular diameter, when compared to the baseline scan)	
Density	Solid, ground-glass, or mixed (mixed; otherwise referred to as part solid)	
Calcification	Present/absent; if present: solid, central vs. eccentric, concentric rings, popcorn, stippled, amorphous	
Fat	Report if present	
Shape/Margin	Round/ovoid, triangular/smooth, lobulated, spiculated	
Lung location	By lobe of the lung, preferably by segment, and if subpleural	
Location in dataset	Specify series and image number for future comparison	
Temporal comparison	If unchanged, include the longest duration of no change as directly viewed by the interpreter on the images (not by report); if changed, report current and prior size	

See Footnotes and References LCS-A 2 of 2

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Footnotes and References

[1] Protocol information: http://www.aapm.org/pubs/CTProtocols/documents/LungCancerScreeningCT.pdf
[2] The LDCT acquisition parameters should be used both for annual screening LDCT exams and for interim LDCTs recommended to evaluate positive screens. The former are considered screening CTs by CPT code, and the latter are considered diagnostic CTs by CPT code.
[3] Pinsky PFF, et al. Ann Intern Med 2015;162:485-491.
[4] Reporting the presence or absence of coronary arterial calcification (CAC) detected on chest CT may be useful to the referring clinician and patient as a marker of atherosclerosis. CAC may be reported using either a visual score (none, mild, moderate, severe) or quantitative score (such as the Agatston score). Further evaluation is recommended if CAC is severe. Munden RF, et al. J Am Coll Radiol 2018;15:1087-1096; Hecht HS, et al. J Thorac Imaging 2017;32:W54-W66.
[5] It is crucial that all nonsolid lesions be reviewed at thin (<1.5 mm) slices to exclude any solid components. Any solid component in the nodule requires management of the lesion with the part-solid recommendations (see LCS-4 or LCS-8).

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Attachment D: *Management of Findings of Follow-up or Annual Low-dose Computed Tomography (LDCT) in the CRF CPEST Program-Lung Module*

NCCN algorithms:

- LCS-B Risks/Benefits of Lung Cancer Screening
- LCS-2 & 2A Screening Findings
- LCS-6 New Nodule on Follow-up or Annual LCDT
- LCS-7 Solid Nodule (unchanged) on Follow-up or Annual LCDT
- LCS-8 & 8A Solid Nodule (new or growing) on Follow-up or Annual LCDT
- LCS-9 & 9A Part-solid Nodule on Follow-up or Annual LCDT
- LCS-10 & 10A Nonsolid Nodule on Follow-up or Annual LCDT
- LCS-11 Multiple Nonsolid Nodules LCDT
- LCS-A Low-Dose Computed Tomography, Acquisition, Storage, Interpretation and Nodule Reporting

RISKS/BENEFITS OF LUNG CANCER SCREENING[1]

RISKS
- Futile detection of small aggressive tumors or indolent disease
- Quality of life
  - Anxiety of test findings
- Physical complications from diagnostic workup
- False-positive results
- False-negative results
- Unnecessary testing and procedures
- Radiation exposure
- Cost
- Incidental lesions

BENEFITS
- Decreased lung cancer mortality[2-4]
- Quality of life
  - Reduction in disease-related morbidity
  - Reduction in treatment-related morbidity
  - Improvement in healthy lifestyles
  - Reduction in anxiety/psychosocial burden
- Discovery of other significant occult health risks (eg, thyroid nodule, severe but silent coronary artery disease, early renal cancer in upper pole of kidney, aortic aneurysm, breast cancer)

[1] See Discussion for more detailed information.
[2] National Lung Screening Trial Research Team, Aberle DR, et al. N Engl J Med 2011;365:395-409.
[3] Ru Zhao Y, et al. Cancer Imaging 2011;11 Spec No A:S79-S84.
[4] De Koning H, et al. N Engl J Med 2020;382:503-513; Pastorino U, et al. Ann Oncol 2019;30:1162-1169; Becker N, et al. Int J Cancer 2020;146:1503-1513.

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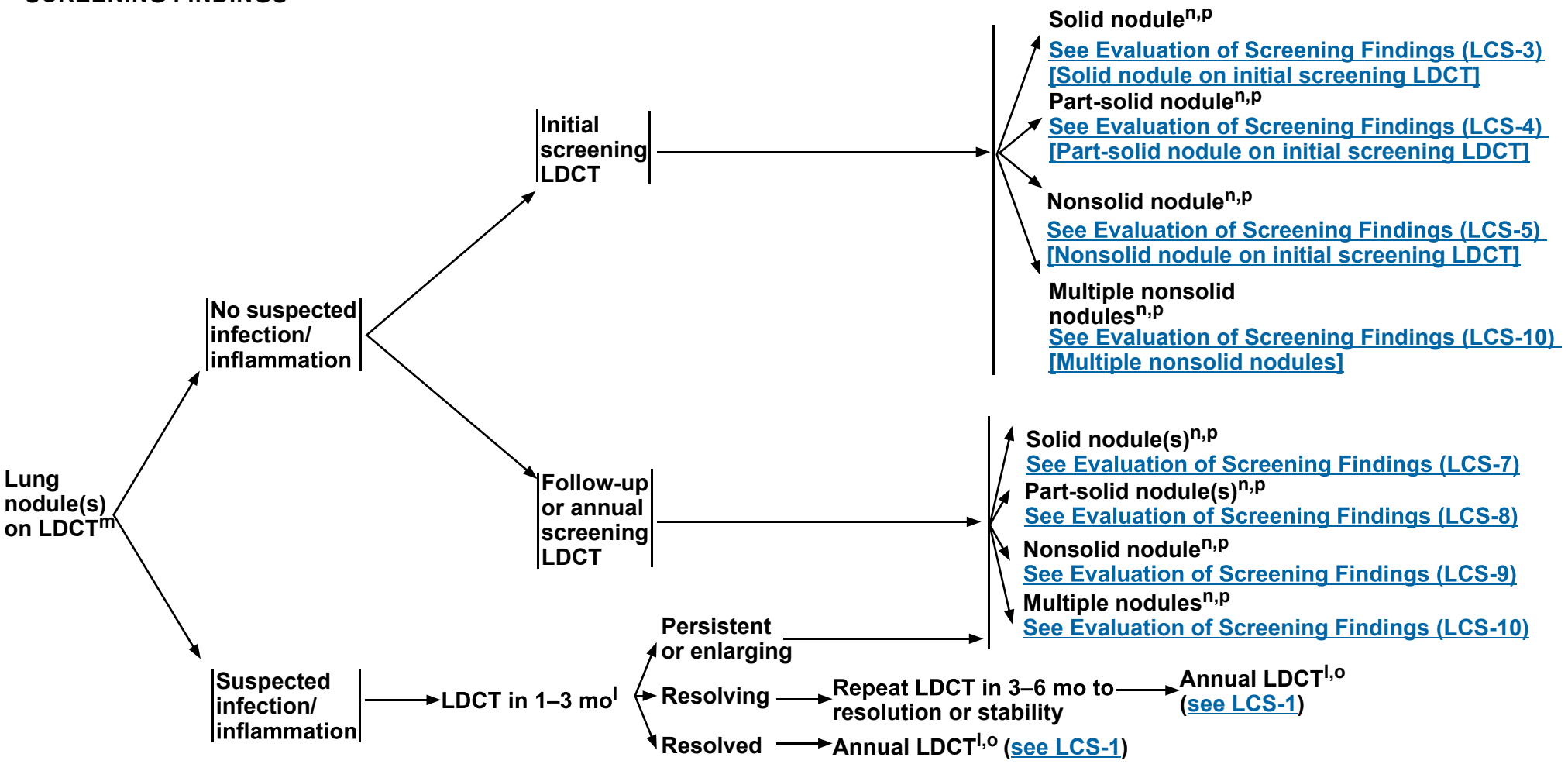

Findings requiring follow-up for diseases other than lung cancer (eg, suspicious for other cancers, COPD, moderate to severe coronary artery calcification, aortic aneurysm)

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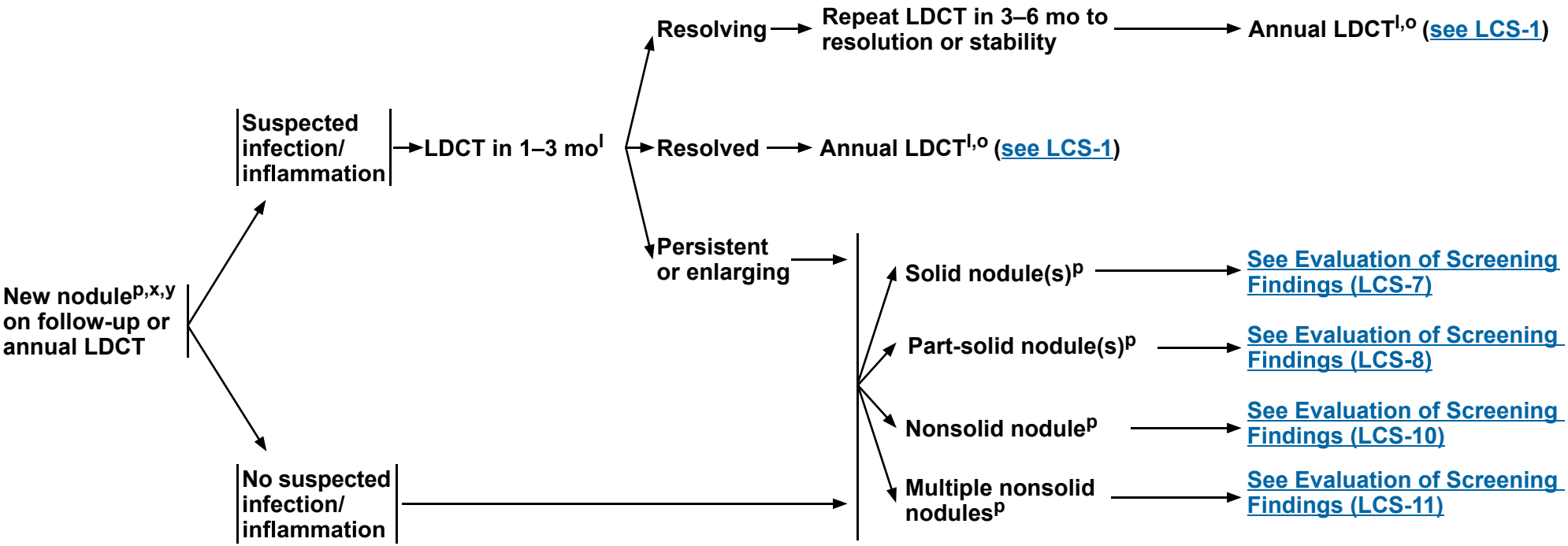

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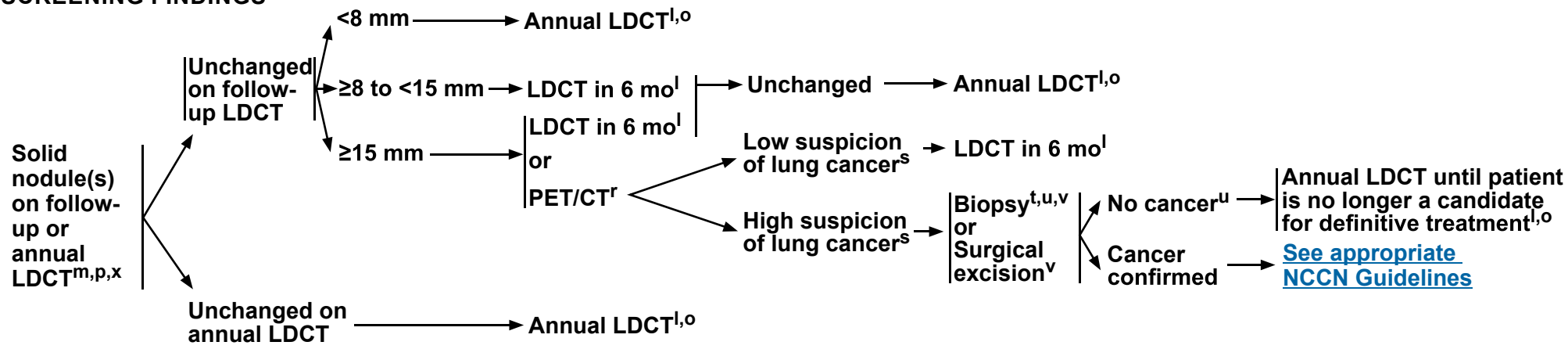

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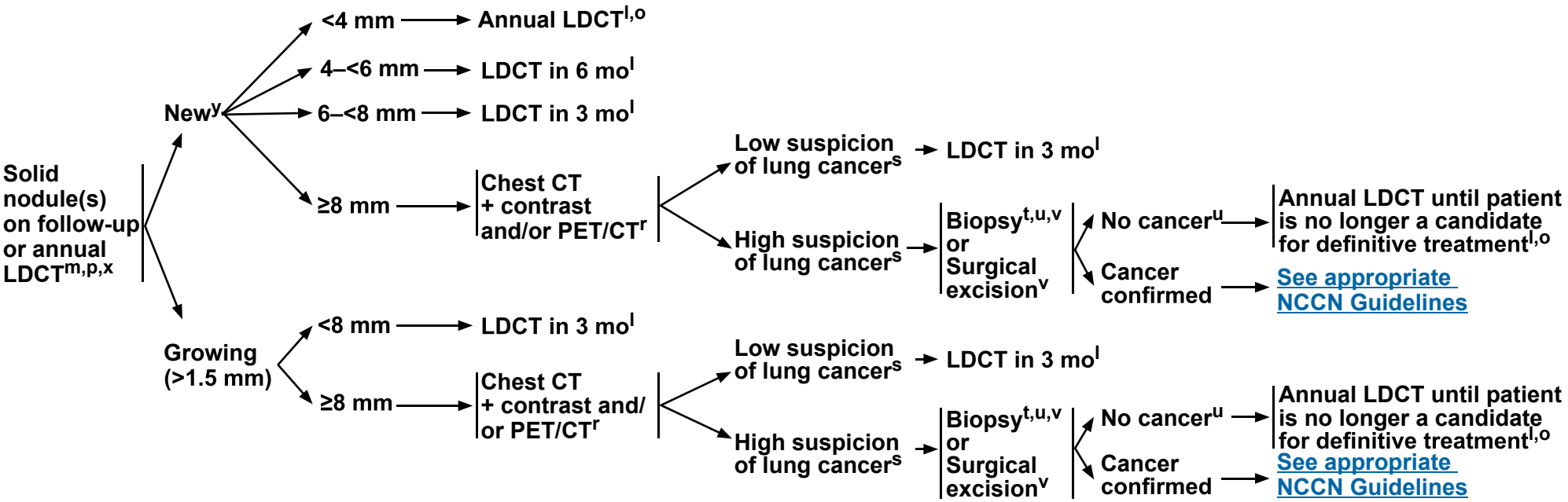

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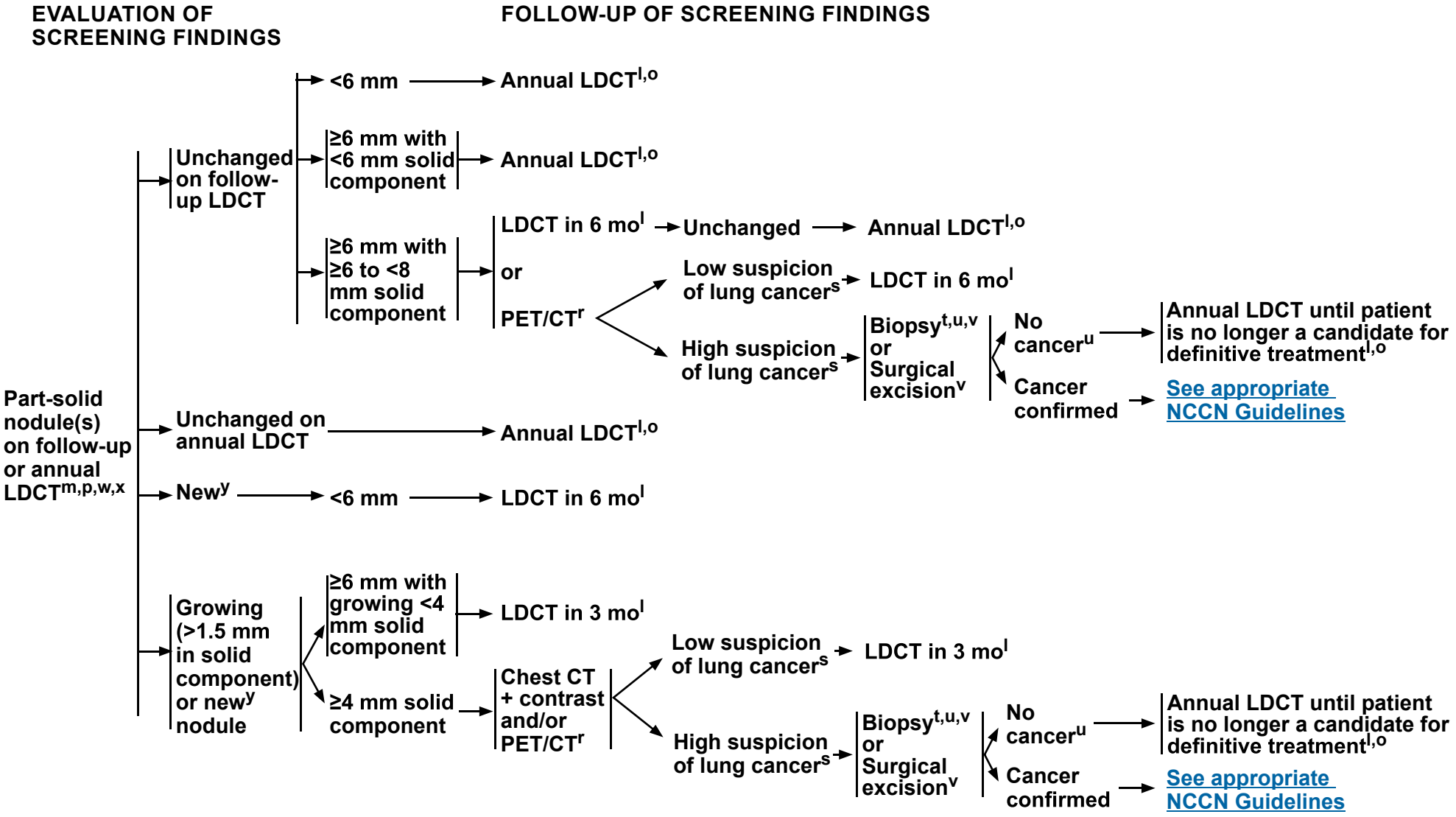

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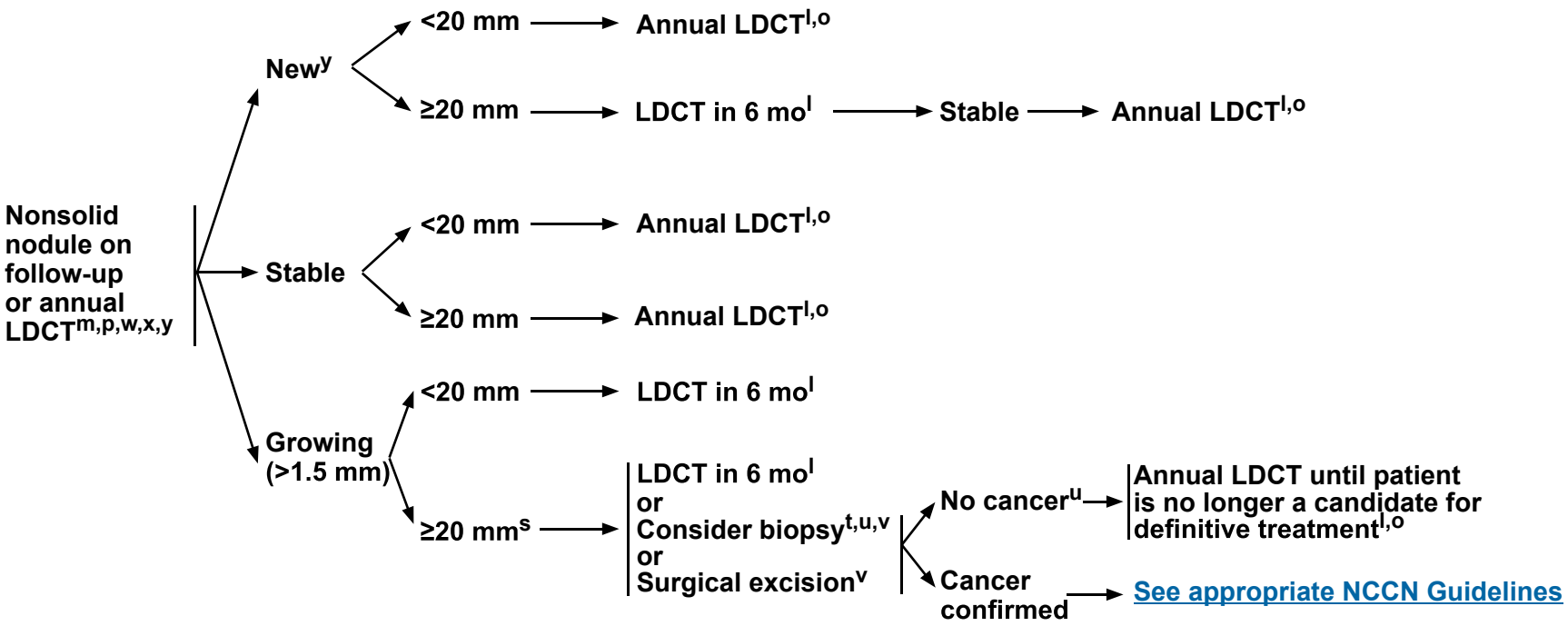

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[l] All screening and follow-up chest CT scans should be performed at low dose (100–120 kVp and 40–60 mAs or less), unless evaluating mediastinal abnormalities or lymph nodes, where standard-dose CT with IV contrast might be appropriate (see LCS-A). There should be a systematic process for appropriate follow-up.

[m] The NCCN Guidelines for Lung Cancer Screening are harmonized with Lung-RADS with rounding of measurement to the nearest whole number (mm). https://www.acr.org/-/media/ACR/Files/RADS/Lung-RADS/LungRADSAssessmentCategoriesv1-1.pdf

[o] There is uncertainty about the appropriate duration of screening and the age at which screening is no longer appropriate.

[p] A nodule is a rounded opacity, measuring up to 3 cm in diameter. A solid nodule has a homogeneous soft-tissue attenuation, a ground-glass nodule (also known as a nonsolid nodule) has hazy increased attenuation that does not obliterate bronchial and vascular margins, and a part-solid nodule has elements of both solid and ground-glass nodules. Nodules should be evaluated and measured on CT using lung windows. The size of all nodules is underestimated when viewed on lung windows, and some nodules may not even be visible, particularly ground-glass nodules and small nodules. Hansell DM, et al. Radiology 2008;246:697-722.

[s] The evaluation for the suspicion of lung cancer requires a multidisciplinary approach with expertise in lung nodule management (thoracic radiology, pulmonary medicine, and thoracic surgery). This may include use of a lung nodule risk calculator to assist with probability determination. Examples of lung nodule risk calculators: Mayo risk model; Brock university model; model by Herder, GJ et al. Chest 2005;128:2490-2496. The use of risk calculators does not replace multidisciplinary nodule management. Geographic and other factors can substantially influence the accuracy of nodule calculators.

[t] Tissue samples need to be adequate for both histology and molecular testing. Travis WD, et al. In, WHO Classification of Tumours of the Lung, Pleura, Thymus and Heart, 4th Ed. Lyon:International Agency for Research on Cancer;2015:16-17.

[u] If biopsy is non-diagnostic and a strong suspicion for cancer persists, suggest repeat biopsy or surgical excision or short-interval follow-up (3 months).

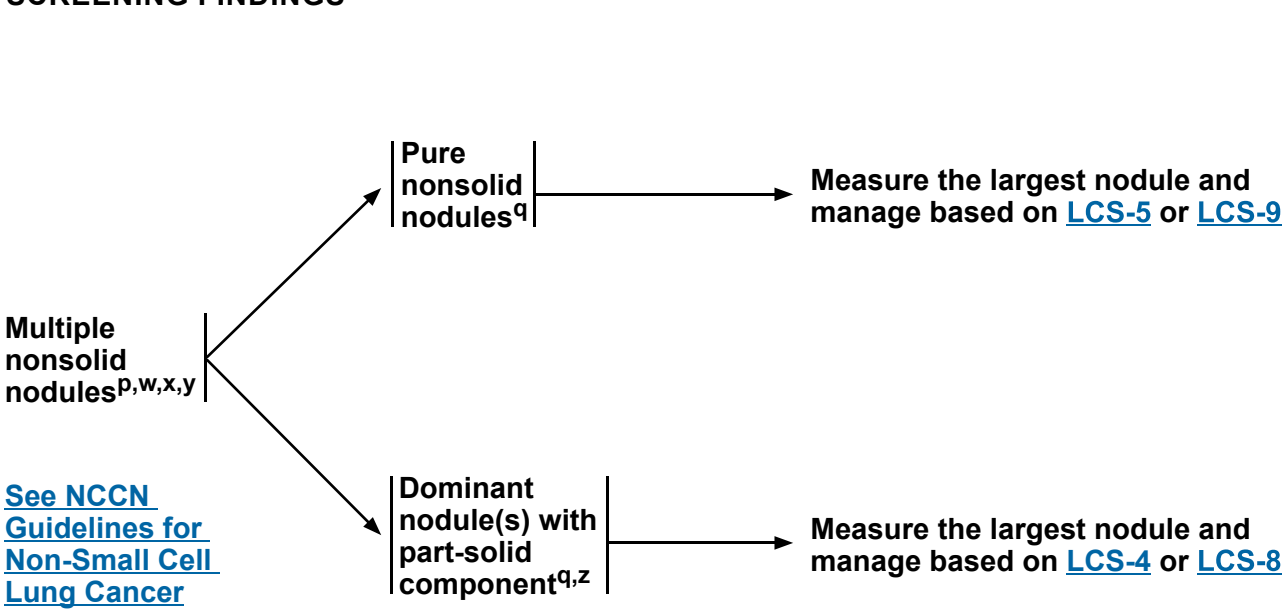
[v] See the diagnostic evaluation of a lung nodule (DIAG-1 through DIAG-A) in the NCCN Guidelines for Non-Small Cell Lung Cancer.

[w] It is crucial that all nonsolid lesions be reviewed at thin (<1.5 mm) slices to exclude any solid components. Any solid component in the nodule requires management of the lesion with the part-solid recommendations (see LCS-4 or LCS-8).

[x] Rapid increase in size should raise suspicion of inflammatory etiology or malignancy other than non-small cell lung cancer (see LCS-6).

[y] New nodule is defined as ≥4 mm in mean diameter.

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.



[p] A nodule is a rounded opacity, measuring up to 3 cm in diameter. A solid nodule has a homogeneous soft-tissue attenuation, a ground-glass nodule (also known as a nonsolid nodule) has hazy increased attenuation that does not obliterate bronchial and vascular margins, and a part-solid nodule has elements of both solid and ground-glass nodules. Nodules should be evaluated and measured on CT using lung windows. The size of all nodules is underestimated when viewed on lung windows, and some nodules may not even be visible, particularly ground-glass nodules and small nodules. Hansell DM, et al. Radiology 2008;246:697-722.

[q] Nodules should be measured on lung windows and reported as the average diameter rounded to the nearest whole number; for round nodules only a single diameter measurement is necessary. Mean diameter is the mean of the longest diameter of the nodule and its perpendicular diameter.

[w] It is crucial that all nonsolid lesions be reviewed at thin (<1.5 mm) slices to exclude any solid components. Any solid component in the nodule requires management of the lesion with the part-solid recommendations (see LCS-4 or LCS-8).

[x] Rapid increase in size should raise suspicion of inflammatory etiology or malignancy other than non-small cell lung cancer. (see LCS-6).

[y] New nodule is defined as ≥4 mm in mean diameter.

[z] All part-solid nodules ≥6 mm should be identified and solid areas should be measured.

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LOW-DOSE COMPUTED TOMOGRAPHY ACQUISITION, STORAGE, INTERPRETATION, AND NODULE REPORTING (Lung-RADS)[1-4]

Acquisition	Small Patient (BMI ≤30)	Large Patient (BMI >30)
Total radiation exposure	≤3 mSv	≤5 mSv
kVp	100–120	120
mAs	≤40	≤60
	All Patients	
Gantry rotation speed	≤0.5	
Detector collimation	≤1.5 mm	
Slice width	≤2.5 mm; ≤1.0 mm preferred for characterization of nodule consistency, particularly for small nodules[5]	
Slice interval	≤slice width; 50% overlap preferred for 3D and CAD applications	
Scan acquisition time	≤10 seconds (single breath hold)	
Breathing	Maximum inspiration	
Contrast	No oral or intravenous contrast	
CT scanner detectors	≥16	
Storage	All acquired images, including thin sections; MIPs and CAD renderings if used	
Interpretation Tools		
Platform	Computer workstation review	
Image type	Standard and MIP images	
Comparison studies	Comparison with prior chest CT images (not reports) is essential to evaluate change in size, morphology, and density of nodules; review of serial chest CT exams is important to detect slow growth	
Nodule Parameters		
Size	Largest mean diameter on a single image (mean of the longest diameter of the nodule and its perpendicular diameter, when compared to the baseline scan)	
Density	Solid, ground-glass, or mixed (mixed; otherwise referred to as part solid)	
Calcification	Present/absent; if present: solid, central vs. eccentric, concentric rings, popcorn, stippled, amorphous	
Fat	Report if present	
Shape/Margin	Round/ovoid, triangular/smooth, lobulated, spiculated	
Lung location	By lobe of the lung, preferably by segment, and if subpleural	
Location in dataset	Specify series and image number for future comparison	
Temporal comparison	If unchanged, include the longest duration of no change as directly viewed by the interpreter on the images (not by report); if changed, report current and prior size	

See Footnotes and References LCS-A 2 of 2

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Footnotes and References

[1] Protocol information: http://www.aapm.org/pubs/CTProtocols/documents/LungCancerScreeningCT.pdf
[2] The LDCT acquisition parameters should be used both for annual screening LDCT exams and for interim LDCTs recommended to evaluate positive screens. The former are considered screening CTs by CPT code, and the latter are considered diagnostic CTs by CPT code.
[3] Pinsky PFF, et al. Ann Intern Med 2015;162:485-491.
[4] Reporting the presence or absence of coronary arterial calcification (CAC) detected on chest CT may be useful to the referring clinician and patient as a marker of atherosclerosis. CAC may be reported using either a visual score (none, mild, moderate, severe) or quantitative score (such as the Agatston score). Further evaluation is recommended if CAC is severe. Munden RF, et al. J Am Coll Radiol 2018;15:1087-1096; Hecht HS, et al. J Thorac Imaging 2017;32:W54-W66.
[5] It is crucial that all nonsolid lesions be reviewed at thin (<1.5 mm) slices to exclude any solid components. Any solid component in the nodule requires management of the lesion with the part-solid recommendations (see LCS-4 or LCS-8).

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