Revised Fleischner Society Guidelines - everything a practicing Respirologist needs to know

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University of Saskatchewan
Financial Interest Disclosure
(over the past 24 months)

<table>
<thead>
<tr>
<th>Company</th>
<th>Speaker</th>
<th>Advisory</th>
<th>Research</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>
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Chung-Chun Tyan

✓ I have no conflict of interest.
Objectives

• Review the revised Fleischer Society Guideline for the management of incidental pulmonary nodule
• Analyze the literature for which the recommendations are based upon
• Apply the new recommendations to clinical scenarios
Case 1

- 45 female, Caucasian
- Post trauma CT thorax
- Never smoker, no personal or family history of malignancy
- Solid nodule 5 mm
- Always worked in an office environment
- Next step in management?
Case 2

• 59 female, East Asian heritage
• CT thorax for investigation of chronic cough
• Never smoker, second hand smoke as a child
• Travels abroad frequently
• Ground glass nodule 14 mm, RUL
• Duration of recommended radiologic follow up? (assuming persistence)
Case 3

• 64 male, Caucasian
• CT abdo for abdominal pain followed up CT thorax
• Known COPD with 35 PYH
• Current smoker
• Retired heavy duty mechanic
• 13 mm nodule, 6 mm solid component
• Next step in management?
Fleischner Society

• International, multidisciplinary medical society for thoracic radiology
• Founded 1969 by eight radiologist
• Named in memory of Felix Fleischner
  • Clinician, educator and researcher
  • Pioneer in the use of chest radiograph to diagnosing lung disease

https://fleischnersociety.org/about-us/history/
Fleischer Guideline: Who is it for

- Incidental pulmonary nodules
  - Immunocompetent
  - Age 35 and above
  - Without pre-existing cancer
  - Not meant for lung cancer screening
  - The dimensions are average of long and short axes
## Fleischer Guideline: 2005 Solid Nodule

### Recommendations for Follow-up and Management of Nodules Smaller than 8 mm Detected Incidentally at Nonscreening CT

<table>
<thead>
<tr>
<th>Nodule Size (mm)*</th>
<th>Low-Risk Patient†</th>
<th>High-Risk Patient‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤4</td>
<td>No follow-up needed§</td>
<td>Follow-up CT at 12 mo; if unchanged, no further follow-up‖</td>
</tr>
<tr>
<td>&gt;4–6</td>
<td>Follow-up CT at 12 mo; if unchanged, no further follow-up‖</td>
<td>Initial follow-up CT at 6–12 mo then at 18–24 mo if no change‖</td>
</tr>
<tr>
<td>&gt;6–8</td>
<td>Initial follow-up CT at 6–12 mo then at 18–24 mo if no change</td>
<td>Initial follow-up CT at 3–6 mo then at 9–12 and 24 mo if no change</td>
</tr>
<tr>
<td>&gt;8</td>
<td>Follow-up CT at around 3, 9, and 24 mo, dynamic contrast-enhanced CT, PET, and/or biopsy</td>
<td>Same as for low-risk patient</td>
</tr>
</tbody>
</table>

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**Note.**—Newly detected indeterminate nodule in persons 35 years of age or older.

* Average of length and width.

† Minimal or absent history of smoking and of other known risk factors.

‡ History of smoking or of other known risk factors.

§ The risk of malignancy in this category (<1%) is substantially less than that in a baseline CT scan of an asymptomatic smoker.

‖ Nonsolid (ground-glass) or partly solid nodules may require longer follow-up to exclude indolent adenocarcinoma.
### Fleischer Guideline: 2013 Subsolid Nodule

#### Recommendations for the Management of Subsolid Pulmonary Nodules Detected at CT: A Statement from the Fleischner Society

<table>
<thead>
<tr>
<th>Nodule Type</th>
<th>Management Recommendations</th>
<th>Additional Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Solitary pure GGNs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤5 mm</td>
<td>No CT follow-up required</td>
<td>Obtain contiguous 1-mm-thick sections to confirm that nodule is truly a pure GGN</td>
</tr>
<tr>
<td>&gt;5 mm</td>
<td>Initial follow-up CT at 3 months to confirm persistence then annual surveillance CT for a minimum of 3 years</td>
<td>FDG PET is of limited value, potentially misleading, and therefore not recommended</td>
</tr>
<tr>
<td><strong>Solitary part-solid nodules</strong></td>
<td>Initial follow-up CT at 3 months to confirm persistence. If persistent and solid component &lt;5 mm, then yearly surveillance CT for a minimum of 3 years. If persistent and solid component ≥5 mm, then biopsy or surgical resection</td>
<td>Consider PET/CT for part-solid nodules &gt;10 mm</td>
</tr>
<tr>
<td><strong>Multiple subsolid nodules</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pure GGNs ≤5 mm</td>
<td>Obtain follow-up CT at 2 and 4 years</td>
<td>Consider alternate causes for multiple GGNs ≤5 mm</td>
</tr>
<tr>
<td>Pure GGNs &gt;5 mm without a dominant lesion(s)</td>
<td>Initial follow-up CT at 3 months to confirm persistence and then annual surveillance CT for a minimum of 3 years</td>
<td>FDG PET is of limited value, potentially misleading, and therefore not recommended</td>
</tr>
<tr>
<td>Dominant nodule(s) with part-solid or solid component</td>
<td>Initial follow-up CT at 3 months to confirm persistence. If persistent, biopsy or surgical resection is recommended, especially for lesions with &gt;5 mm solid component</td>
<td>Consider lung-sparing surgery for patients with dominant lesion(s) suspicious for lung cancer</td>
</tr>
</tbody>
</table>

**Note:** These guidelines assume meticulous evaluation, optimally with contiguous thin sections (1 mm) reconstructed with narrow and/or mediastinal windows to evaluate the solid component and wide and/or lung windows to evaluate the nonsolid component of nodules, if indicated. When electronic calipers are used, bidimensional measurements of both the solid and ground-glass components of lesions should be obtained as necessary. The use of a consistent low-dose technique is recommended, especially in cases for which prolonged follow-up is recommended, particularly in younger patients. With serial scans, always compare with the original baseline study to detect subtle indolent growth.

Radiology 2013; 266:304-317
Fleischer Guideline: 2017 Solid Nodule

<table>
<thead>
<tr>
<th>Nodule Type</th>
<th>Size</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low risk‡</td>
<td>&lt;6 mm (&lt;100 mm³)</td>
<td>No routine follow-up. CT at 6–12 months, then consider CT at 18–24 months. Consider CT at 3 months, PET/CT, or tissue sampling for low-risk patients (recommendation 1A). Nodules &lt;6 mm do not require routine follow-up in low-risk patients.</td>
</tr>
<tr>
<td>High risk‡</td>
<td>6–8 mm (100–250 mm³)</td>
<td>Optional CT at 12 months. CT at 6–12 months, then consider CT at 18–24 months. Consider CT at 3 months, PET/CT, or tissue sampling. Certain patients at high risk with suspicious nodule morphology, upper lobe location, or both may warrant 12-month follow-up (recommendation 1A).</td>
</tr>
<tr>
<td></td>
<td>&gt;8 mm (&gt;250 mm³)</td>
<td>Comments</td>
</tr>
<tr>
<td>Multiple</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low risk‡</td>
<td>&lt;6 mm (&lt;100 mm³)</td>
<td>No routine follow-up. CT at 3–6 months, then consider CT at 18–24 months. Use most suspicious nodule as guide to management. Follow-up intervals may vary according to size and risk (recommendation 2A).</td>
</tr>
<tr>
<td>High risk‡</td>
<td>6–8 mm (100–250 mm³)</td>
<td>Optional CT at 12 months. CT at 3–6 months, then consider CT at 18–24 months. Use most suspicious nodule as guide to management. Follow-up intervals may vary according to size and risk (recommendation 2A).</td>
</tr>
<tr>
<td></td>
<td>&gt;8 mm (&gt;250 mm³)</td>
<td>Comments</td>
</tr>
</tbody>
</table>

Initial follow-up CT at 3–6 mo then at 9–12 and 24 mo if no change

Radiology 2017; 284:228-243
### Fleischer Guideline: 2017 Subsolid Nodule

<table>
<thead>
<tr>
<th>Nodule Type</th>
<th>Size</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ground glass</td>
<td>&lt;6 mm (&lt;100 mm³)</td>
<td>CT at 6–12 months to confirm persistence, then CT every 2 years until 5 years.</td>
</tr>
<tr>
<td>Part solid</td>
<td>≥6 mm (≥100 mm³)</td>
<td>In certain suspicious nodules &lt; 6 mm, consider follow-up at 2 and 4 years. If solid component(s) or growth develops, consider resection. (Recommendations 3A and 4A).</td>
</tr>
<tr>
<td>Multiple</td>
<td>≤6 mm (&lt;100 mm³)</td>
<td>CT at 3–6 months. If stable, consider CT at 2 and 4 years.</td>
</tr>
<tr>
<td>Multiple</td>
<td>≥6 mm (≥100 mm³)</td>
<td>CT at 3–6 months. Subsequent management based on the most suspicious nodule(s). Multiple &lt;6 mm pure ground-glass nodules are usually benign, but consider follow-up in selected patients at high risk at 2 and 4 years (recommendation 5A).</td>
</tr>
</tbody>
</table>

*In practice, part-solid nodules cannot be defined as such until ≥6 mm, and nodules <6 mm do not usually require follow-up. Persistent part-solid nodules with solid components ≥6 mm should be considered highly suspicious (recommendations 4A–4C).*
General Recommendations: CT scan

- Reconstructed and archived with contiguous thin sections (≤1.5mm)
General Recommendations: CT scan

• Follow up CT should use a low-radiation technique
• The measurement should be the **average** of long and short axis
  • From the transverse, sagittal or coronal view with the **greatest** dimension
• Volumetric measurement can be used
  • More reproducible but software dependent
## Risk estimation: ACCP

<table>
<thead>
<tr>
<th>Assessment Criteria</th>
<th>Probability of Malignancy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low (&lt; 5%)</td>
</tr>
<tr>
<td>Clinical factors alone</td>
<td>Young, less smoking, no prior cancer, smaller nodule size,</td>
</tr>
<tr>
<td>(determined by clinical judgment and/or</td>
<td>regular margins, and/or non-upper-lobe location</td>
</tr>
<tr>
<td>use of validated model)(^a)</td>
<td></td>
</tr>
<tr>
<td>FDG-PET scan results</td>
<td>Low-moderate clinical probability and low FDG-PET activity</td>
</tr>
<tr>
<td>Nonsurgical biopsy results</td>
<td>Specific benign diagnosis</td>
</tr>
<tr>
<td>(bronchoscopy or TTNA)</td>
<td></td>
</tr>
<tr>
<td>CT scan surveillance</td>
<td>Resolution or near-complete resolution, progressive or persistent decrease in size,(^b) or no growth over (\geq 2) y (solid nodule) or (\geq 3-5) y (subsolid nodule)</td>
</tr>
</tbody>
</table>

\(^a\) Clinical factors alone: Young, less smoking, no prior cancer, smaller nodule size, regular margins, and/or non-upper-lobe location.

\(^b\) CT scan surveillance: Resolution or near-complete resolution, progressive or persistent decrease in size, or no growth over \(\geq 2\) y (solid nodule) or \(\geq 3-5\) y (subsolid nodule).

Chest 2013;143(5 Suppl):e93S–e120S.
Lung cancer screening studies

• National Lung Screening Trial (NLST)
• Dutch–Belgian lung cancer screening trial (NELSON)
• International Early Lung Cancer Action Program (iELCAP)
• Pan-Canadian Early Detection of Lung Cancer Study (PanCan) and British Columbia Cancer Agency (BCCA) cancer screening trials
Solid nodules
Recommendation for Solid Lung Nodules <6 mm

- *Single solid noncalcified nodules.* Solid nodules smaller than 6 mm do not require routine follow-up in patients at low risk (1C)

- Some nodules smaller than 6 mm with suspicious morphology, upper lobe location, or both may warrant follow up at 12 month (2A)

Case courtesy of Dr Usman Bashir, Radiopaedia.org, rID: 18318
Solid Lung Nodules <6 mm: Low clinical risk

- In NELSON, baseline negative scan has 1% risk of lung cancer in 5.5 years\(^1\)

Solid Lung Nodules <6 mm: High clinical risk
Recommendation for Solid Lung Nodules 6-8 mm

• Patients with low clinical risk are recommended to undergo initial follow-up at 6–12 months depending on size, morphology, and patient preference (1C)

• Patients with high clinical risk are recommended to undergo initial follow up at 6-12 months and again at 18-24 month (1B)
Solid Lung Nodules 6-8 mm: Low clinical risk

Lancet Oncol 2014; 15: 1332–41

Respirology (2014) 19, 921–928
Solid Lung Nodules 6-8 mm: high clinical risk


Lancet Oncol 2014; 15: 1332–41
Recommendation for Solid Lung Nodules >8 mm

- Consider 3-month follow up, work-up with combined positron emission tomography (PET) and CT (PET/CT), tissue sampling, or a combination thereof (1A)
Solid Lung Nodules >8 mm

Radiology 2017; 284:228-243
Recommendation for multiple solid noncalcified nodules: <6 mm

• For multiple solid noncalcified nodules smaller 6 mm in diameter, **no routine follow-up is recommended** (2B)
  • In patients at high risk, a 12 month follow-up examination may be considered
Recommendation for multiple solid noncalcified nodules: ≥6 mm

- For multiple solid noncalcified nodules with at least one nodule 6 mm or larger in diameter, follow-up is recommended at approximately 3-6 months followed by an optional second scan at 18-24 months that will depend on estimate risk. (1B)
Multiple solid noncalcified nodules: >6 mm

Part-solid nodule
Recommendation for pure ground-glass nodules <6 mm

• For pure ground-glass nodules smaller than 6 mm, **no routine follow-up is recommended** (1B)
  • 2 and 4 year follow-up in selected subjects at high risk.
Pure ground-glass nodule <6mm
Recommendation for pure ground-glass nodules ≥6 mm

• For pure ground-glass nodules 6 mm or larger, follow-up scanning is recommended at 6-12 months and then every 2 years thereafter until 5 years (1B)

Radiology 2015 Nov;277(2):555-64
Pure ground-glass nodule ≥6mm

<table>
<thead>
<tr>
<th>Investigator</th>
<th>Total GGO</th>
<th>Frequency of growth</th>
<th>Take away message</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change et al. ¹</td>
<td>122</td>
<td>9.8% (12/122)</td>
<td>Median volume doubling time 769 days</td>
</tr>
<tr>
<td>Matsuguma et al. ²</td>
<td>98</td>
<td>14.2% (14/98)</td>
<td>The time to 2-mm growth curves at 2-year and 5-year cumulative percentages of growing nodules were 13% and 23%</td>
</tr>
<tr>
<td>Kobayashi et al. ³</td>
<td>82</td>
<td>25.6% (21/82)</td>
<td>All growing GGNs began to grow within 3 years</td>
</tr>
<tr>
<td>Lee et al. ⁴</td>
<td>143</td>
<td>19.6% (28/143)</td>
<td>The appearance of solid component should trigger consideration for resection</td>
</tr>
</tbody>
</table>


Radiology 2012;263:578–83
Pure ground-glass nodule ≥6mm

<table>
<thead>
<tr>
<th>Parameter</th>
<th>&lt;6 mm</th>
<th>6–9 mm</th>
<th>10–14 mm</th>
<th>15–30 mm</th>
<th>≥31 mm</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resolved or decreased</td>
<td>341</td>
<td>177</td>
<td>70</td>
<td>39</td>
<td>1</td>
<td>628</td>
</tr>
<tr>
<td>Lung cancer</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Stable or growth</td>
<td>1063</td>
<td>439</td>
<td>164</td>
<td>92</td>
<td>6</td>
<td>1764</td>
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<tr>
<td>Pathologic diagnosis</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Lung cancer</td>
<td>9</td>
<td>20</td>
<td>27</td>
<td>15</td>
<td>2</td>
<td>73</td>
</tr>
<tr>
<td>AAH, ABP*</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Nonmalignant diagnosis</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>1404</td>
<td>616</td>
<td>234</td>
<td>131</td>
<td>7</td>
<td>2392</td>
</tr>
</tbody>
</table>

0.6%  3.2%  11.5%  11.5%  28.6

Recommendation for part-solid nodules <6 mm

• For solitary part-solid nodules smaller than 6 mm, no routine follow-up is recommended (1C)
Recommendation for part-solid nodules $\geq 6$ mm solid component $< 6$ mm

- For solitary part-solid nodules 6 mm or larger with a solid component less than 6 mm in diameter, **follow up** is recommended at **3-6 months** and then annually for **minimum of 5 years**.
Part-solid nodule ≥6 mm solid component <6 mm

Part-solid nodule ≥6 mm and solid component <6 mm
Recommendation for part-solid nodules ≥6 mm solid component ≥6 mm

• For solitary part-solid nodules with a solid component 6 mm or larger, a short-term follow-up CT scan at 3-6 months should be considered. For nodules with particularly suspicious morphology, a growing solid component, or a solid component larger than 8mm, PET/CT, biopsy or resection are recommended (1B)
Part-solid nodules ≥6 mm solid component ≥6 mm

Recommendation for multiple subsolid lung nodules <6 mm

• In patients with multiple subsolid nodules smaller than 6 mm, one must consider infectious causes.

• If lesions remain persistent after an initial follow-up scan at 3-6 months, consider follow-up at approximately 2 and 4 years to confirm stability. (1C)
Recommendation for multiple subsolid lung nodules ≥6 mm

• In patients with multiple subsolid nodules with at least one nodule that is 6 mm or larger, management decision should be based on the most suspicious nodule (1C)

Radiology 2017; 284:228-243
Risk factors for malignancy

- General considerations
  - Location
  - Multiplicity
  - Interobserver variability
  - Underlying lung disease
- Pleural retraction
- Margin
- Age, sex and race
Observer variability for classification of pulmonary nodules

Statistically favored to be malignant pulmonary nodule

- Spiculated & ragged
  - Odds ratio (OR) 2.2-2.5
- Eccentric & dystrophic calcification
- Pleural retraction

Acta Radiologica 2011; 52: 401–409
Statistically favored to be malignant pulmonary nodule: Location location location...

- In general
  - Upper lobes\(^1\)
  - Odds ratio 2.0\(^2\)
- Adenocarcinoma
  - Peripheral\(^3\)
- Squamous
  - hila\(^3\)

Nodule multiplicity

• PanCan trial\(^1\)
  • Multiplicity of nodules was associated with a reduced risk of Cancer

1. Lung Cancer 2015 Jul;89(1):27-30
Emphysema and fibrosis


Age, sex and race

- For each additional decade of lung, lung cancer incidence increases steadily\(^1\)

- Female sex found to be a risk factor in PanCan trial\(^2\)

- US study, black and men and native Hawaiian men have higher incidence of lung cancer\(^3\)

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1. Canadian Cancer Society, Canadian Cancer Statistics 2017
Case 1

- 45 female, Caucasian
- Post trauma CT thorax
- Never smoker, no personal or family history of malignancy
- Solid nodule 5 mm
- Always worked in an office environment
- Next step in management?
Case 1

• Next step in management?

1. Repeat LDCT in 3-6 month
2. Repeat LDCT in 12-16 month
3. Repeat LDCT in 2 years
4. No further imaging recommended
Case 2

• 59 female, East Asian heritage
• CT thorax for investigation of chronic cough
• Never smoker, second hand smoking as a child
• Travels abroad frequently
• Ground glass nodule 14 mm, RUL
• Duration of recommended follow up? (assuming persistence)
Case 2

• Duration of recommended radiologic follow up? (assuming persistence)

1. 3 years
2. 5 years
3. 10 years
4. No required
Case 3

- 64 male, Caucasian
- CT abdo for abdominal pain followed up CT thorax
- Known COPD with 35 PYH
- Current smoker
- Retired heavy duty mechanic
- 13 mm nodule, 8 mm solid component
- Next step in management?
Case 3

• Next step in management?

1. LDCT in 3 month
2. PET/CT
3. CT guided biopsy
4. Lobar resection
### A: Solid Nodules

<table>
<thead>
<tr>
<th>Nodule Type</th>
<th>Size</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low risk¹</td>
<td>&lt;6 mm (&lt;100 mm³)</td>
<td>No routine follow-up</td>
</tr>
<tr>
<td></td>
<td>6–8 mm (100–250 mm³)</td>
<td>CT at 6–12 months, then consider CT at 18–24 months</td>
</tr>
<tr>
<td></td>
<td>&gt;8 mm (&gt;250 mm³)</td>
<td>Consider CT at 3 months, PET/CT, or tissue sampling</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nodules &lt;6 mm do not require routine follow-up in low-risk patients (recommendation 1A).</td>
</tr>
<tr>
<td>High risk¹</td>
<td>Optional CT at 12 months</td>
<td>CT at 6–12 months, then CT at 18–24 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Consider CT at 3 months, PET/CT, or tissue sampling</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Certain patients at high risk with suspicious nodule morphology, upper lobe location, or both may warrant 12-month follow-up (recommendation 1A).</td>
</tr>
<tr>
<td>Multiple</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low risk¹</td>
<td>No routine follow-up</td>
<td>CT at 3–6 months, then consider CT at 18–24 months</td>
</tr>
<tr>
<td>High risk¹</td>
<td>Optional CT at 12 months</td>
<td>CT at 3–6 months, then at 18–24 months</td>
</tr>
</tbody>
</table>

### B: Subsolid Nodules

<table>
<thead>
<tr>
<th>Nodule Type</th>
<th>Size</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ground glass</td>
<td>&lt;6 mm (&lt;100 mm³)</td>
<td>No routine follow-up</td>
</tr>
<tr>
<td></td>
<td>≥6 mm (≥100 mm³)</td>
<td>CT at 6–12 months to confirm persistence, then CT every 2 years until 5 years</td>
</tr>
<tr>
<td>Part solid</td>
<td>No routine follow-up</td>
<td>CT at 3–6 months to confirm persistence. If unchanged and solid component remains &lt;6 mm, annual CT should be performed for 5 years.</td>
</tr>
<tr>
<td>Multiple</td>
<td>CT at 3–6 months. If stable, consider CT at 2 and 4 years.</td>
<td>CT at 3–6 months. Subsequent management based on the most suspicious nodule(s).</td>
</tr>
<tr>
<td></td>
<td>Multiple &lt;6 mm pure ground-glass nodules are usually benign, but consider follow-up in selected patients at high risk at 2 and 4 years (recommendation 5A).</td>
<td></td>
</tr>
</tbody>
</table>