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Cohere Medicare Advantage Policy -**Computed Tomography (CT), Chest** *Clinical Guidelines for Medical Necessity Review*

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Medical Necessity Criteria

Service: Cohere Medicare Advantage Policy - Computed Tomography (CT), Chest

Benefit Category

Diagnostic Services in Outpatient Hospital Diagnostic Tests (other)

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Related CMS Documents

Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage.¹⁻³

- <u>National Coverage Determination (NCD). Computed tomography</u> (220.1)
- Local Coverage Determination (LCD). Computerized Axial Tomography (CT), Thorax (L33459)
- Local Coverage Determination (LCD). Multiple Imaging in Oncology
 L35391
- <u>Billing and Coding: Computerized Axial Tomography (CT), Thorax</u> (A56580)
- <u>Billing and Coding: Multiple Imaging in Oncology (A56848)</u>

Recommended Clinical Approach

Computed tomography (CT) of the chest can be performed as a screening examination in high-risk patients and to diagnose and evaluate a myriad of thoracic processes involving the lungs, mediastinum/hilum, pleura, and chest wall. Contrast usage is guided by the clinical scenario being investigated.⁴

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of Computed Tomography (CT), Chest. This process helps to prevent both incorrect denials and inappropriate approvals

of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Inherent risk of procedure: There are inherent risks of imaging, including cumulative radiation exposure, contrast, allergy, nephrotoxicity, and contrast extravasation into surrounding tissues.¹⁻⁴
- Potential danger to pregnancy: CT imaging completed during pregnancy confers a dose of ionizing radiation to the fetus and is generally only utilized when the potential benefits of this specific imaging modality outweigh the risks to the pregnancy. Fetal risk includes fetal demise, intrauterine growth restriction, microcephaly, delayed intellectual development, risk of childhood cancer, and fetal thyroid injury.⁵
- Compared to adults, children are more sensitive to radiation. CT exposure among children may increase their risk of leukemia and brain cancer.⁶
- Increased healthcare costs and complications from the inappropriate use of additional interventions.²

The clinical benefits of using these criteria include:

- Low-dose CT scans are essential for screening survivors of head and neck cancer, a population at high risk for secondary cancers, including lung cancer.⁸
- CT can provide timely diagnosis of early-stage lung cancer and reduce lung cancer-related mortality among high-risk individuals.⁸
- When examining for penetrating injuries in the thoraco-abdominal region, multidetector computed tomography (MDCT) is a less invasive alternative to procedures such as diagnostic laparoscopy.⁹
- MCDT can provide scans of the chest within an interval of breath, thereby reducing imaging time and keeping the artifacts of respiratory movement to a minimum.¹⁰
- Computed tomography is effective in diagnosing diaphragmatic injuries caused by penetrating trauma, particularly in patients with good blood circulation and stable heart rates.¹⁰

• Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials and ensure that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Fleischner Society 2017 Guidelines for Management of Incidentally Detected Pulmonary Nodules in Adults¹¹

Solid Nodules*				
	Size			
Nodule Type	<6mm (<100 mm³)	6–8 mm (100–250 mm ³)	>8 mm (>250 mm³)	Comments
Single				
Low Risk**	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	Nodules <6 mm do not require routine follow-up in low-risk patients (recommendation 1A).
High Risk**	Optional CT at 12 months	CT at 6–12 months, then 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 a 12-month follow-up (recommendation 1A).
Multiple				
Low Risk**	No routine follow-up	CT at 3–6 months, then	CT at 3–6 months, then	Use most suspicious nodule as guide to

		consider CT at 18–24 months	consider CT at 18–24 months	management. Follow-up intervals may vary according to size and risk (recommendation 2A).
High Risk**	Optional CT at 12 months	CT at 3–6 months, then at 18–24 months	CT at 3–6 months, then at 18–24 months	Use most suspicious nodule as guide to management. Follow-up intervals may vary according to size and risk (recommendation 2A).
Subsolid Nodul	 PS*			
	si	ze		
Nodule Type	<6mm (<100 mm³)	≥ 6 mm (>100 mm3)	Comments	
Single				
Ground Glass	No routine follow-up	CT at 6–12 months to confirm persistence, then CT every 2 years until 5 years	In certain suspicious nodules <6 mm, consider follow-up at 2 and 4 years. If solid component(s)or growth develops, consider resection. (Recommendations 3A and 4A).	
Part Solid	No routine follow-up	CT at 3–6 months to confirm persistence. If unchanged and solid component remain <6 mm, annual CT should be performed for 5 years.	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 6mm should be considered highly suspicious (recommendations 4A-4C).	
Multiple	CT at 3–6 months. If stable, consider CT at 2 and 4 years	CT at 3–6 months. Subsequent management based on the most suspicious	Multiple <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).	

	nodule(s)	
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Lung-RADS® (2022) ²				
Lung- RADS	Category Descriptor	Findings	Management	
		Prior chest CT examination being located for comparison (see note 9)	Comparison to prior chest CT	
0	Incomplete Estimated Population Prevalence: ~1%	Part of all of the 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	
	Negative	No lung nodules; OR		
1	Estimated Population Prevalence: 39%	 Nodule with benign features: Complete, central, popcorn, or concentric ring calcifications; OR Fat-containing 		
		 Juxtapleural Nodule < 10 mm (524 mm³) mean diameter at baseline or new; AND Solid; smooth margins; and oval, lentiform, or triangular shape 		
2	Benign Based on	 Solid Nodule < 6 mm (< 113 mm³) at baseline; OR New <4 mm (< 34 mm³) 	12-month	
	imaging features or indolent behavior	 Part Solid Nodule < 6 mm (< 113 mm³) total mean diameter at baseline 		
	Estimated Population Prevalence: 45%	 Non-Solid Nodule (GGN) <30 mm (< 14,137 mm³) at baseline, new or growing; OR ≥30 mm (≥ 14,137 mm³) stable or slowly growing (see note 7) 		
		Airway nodule, subsegmental - at baseline, new, or stable (see note 11)		
		Category 3 lesion that is stable or decreased in size at 6-month follow-up		

		 CT; OR Category 4B lesion proven to be benign in etiology following appropriate diagnostic workup 	
		 Solid Nodule ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm³) at baseline; OR New 4 mm to <6 mm (34 to < 113 mm³) 	
3	Probably Benign Based on imaging features or bebayior	 Part Solid Nodule ≥ 6 mm (≥ 113 mm³) total mean diameter with solid component < 6 mm (< 113 mm³) at baseline New < 6 mm (< 113 mm³) total mean diameter 	6-month LDCT
	Estimated	 Non-Solid Nodule (GGN) ≥ 30 mm (≥ 14,137 mm³) at baseline or new 	
	Prevalence: 9%	 Atypical Pulmonary Cyst (see note 12) Growing cystic component (mean diameter) of a thick-walled cyst 	
		Category 4A lesion that is stable or decreased in size at 3-month follow-up CT (excluding airway nodules)	
		 Solid Nodule ≥ 8 mm to < 15 mm (≥ 268 to < 1767 mm³) at baseline; OR Growing < 8 mm (< 268 mm³) New 6 to < 8 mm (113 to < 268 mm³) 	
4A	Suspicious Estimated Population Prevalence:	 Part Solid Nodule ≥ 6 mm (≥ 113 mm³) total mean diameter with solid component ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm³) at baseline; OR New or growing <4 mm (< 34 mm³) solid component 	3-month LDCT; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm ³) solid podulo
	4% Airway Nodule, segmental or more pr - at baseline (see note 11) Atypical Pulmonary Cyst (see note 12 • Thick-walled cyst; OR • Multilocular cyst at baseline; OR • Thin- or thick-walled cyst that becomultilocular	Airway Nodule, segmental or more proximal - at baseline (see note 11)	or solid component
		 Atypical Pulmonary Cyst (see note 12) Thick-walled cyst; OR Multilocular cyst at baseline; OR Thin- or thick-walled cyst that becomes multilocular 	
		Airway Nodule, segmental or more proximal - stable or growing (see note 11)	Referral for further clinical evaluation

4В	Very Suspicious Estimated Population Prevalence: 2%	 Solid Nodule ≥ 15 mm (≥ 1767 mm³) at baseline; OR New or growing ≥ 8 mm (≥ 268 mm³) Part Solid Nodule Solid component ≥ 8 mm (≥ 268 mm³) at baseline; OR New or growing ≥ 4 mm (≥ 34 mm³) 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, 	Diagnostic chest CT with or without contrast; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm ³) solid nodules or solid component; Tissue sampling; and/or referral for further clinical
		Slow-growing solid or part-solid nodule that demonstrates growth over multiple screening exams (see note 8)	evaluation; Management depends on clinical evaluation,
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)	patient preference, and the probability of malignancy (see note 13)
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

Medical Necessity Criteria

Indications

- → Computed tomography (CT), chest is considered appropriate if ANY of the following is TRUE:
 - Chest radiograph and physical examination have been performed and are indeterminate, or findings require further evaluation AND any of the following:

- Evaluation of pulmonary, mediastinal, pleural or chest wall infections and their complications; **OR**
- Neoplastic or hematologic conditions with involvement or potential involvement of the thorax¹ for ANY of the following:
 - Diagnosis and management of mediastinal neoplasms and other processes, including but not limited to thymoma mediastinal adenopathy.
 - Initial staging; OR
 - Treatment planning; **OR**
 - Response assessment; **OR**
 - Surveillance, and **ANY** of the following is **TRUE**¹²⁻¹⁶:
 - The patient is assumed to have either no known disease or disease that is stable or clinically insignificant (every 6-12 months for an overall duration [e.g., 5 years]); OR
 - Suspected recurrence/progression; **OR**
- For the evaluation of cardiopulmonary failure or insufficiency (e.g. unexplained shortness of breath, heart failure); OR
- Cardiovascular abnormalities, known or suspected, including ANY of the following⁴:
 - Aneurysm; **OR**
 - Embolism; **OR**
 - Thrombosis; **OR**
 - Congenital anomalies; **OR**
 - Postoperative complications; **OR**
 - Sequelae of atherosclerotic disease; OR
- For diagnosis and management of pulmonary or pleural fluid collections, including but not limited to **ANY** of the following:
 - Abscess; **OR**
 - Empyema; **OR**
 - Effusion; OR
 - Pneumothorax; **OR**
- For diagnosis and management of interstitial and alveolar lung disease, including but not limited to idiopathic, allergic, collagen-vascular, environmental or other causes⁴; OR
- For the evaluation of thoracic sequelae of remote processes, including but not limited to ANY of the following:

- Pancreatitis; **OR**
- Gastrointestinal perforation; OR
- For the assessment of injury or complications due to ANY of the following:
 - Trauma; **OR**
 - Burns; **OR**
 - Surgery; **OR**
 - Organ transplantation; **OR**
 - Radiation therapy; OR
 - Chemotherapy⁴; **OR**
 - Invasive procedure, including but not limited to **ANY** of the following:
 - Pacemaker placement; OR
 - Chest tube placement; **OR**
 - Mechanical ventilation; **OR**
- For the evaluation of symptoms that may be arising from the chest or be referred to the chest, including but not limited to ANY of the following:
 - Cough; OR
 - Hemoptysis; **OR**
 - Chest pain; **OR**
 - Abdominal pain; OR
- For the evaluation of a patient with myasthenia gravis to rule out thymic tumors; OR
- For guidance for interventional procedures¹¹; **OR**
- Concern for aortic dissection due to symptoms or imaging including but not limited to ANY of the following:
 - Sudden excruciating back or chest pain; OR
 - Sudden neurologic episode; OR
- Repeat imaging (defined as repeat request following recent imaging of the same anatomic region with the same modality), in the absence of established guidelines, will be considered reasonable and necessary if ANY of the following is TRUE:
 - New or worsening symptoms, such that repeat imaging would influence treatment; OR
 - One-time clarifying follow-up of a prior indeterminate finding; **OR**

• In the absence of change in symptoms, there is an established need for monitoring which would influence management.

Non-Indications

- → Computed tomography (CT), chest with contrast is not considered appropriate if ANY of the following is TRUE:
 - History of anaphylactic allergic reaction to iodinated contrast media.

*NOTE: The referring professional and radiologist should discuss the risks and benefits of contrast media administration, including possible prophylaxis, in patients with chronic or worsening kidney disease or severe renal failure. **NOTE: CT in pregnant patients should be requested at the discretion of the ordering provider and obstetric care provider.

***NOTE: CT in patients with claustrophobia should be requested at the discretion of the ordering provider.

Disclaimer on Radiation Exposure in Pediatric Population

Due to the heightened sensitivity of pediatric patients to ionizing radiation, minimizing exposure is paramount. At Cohere, we are dedicated to ensuring that every patient, including the pediatric population, has access to appropriate imaging following accepted guidelines. Radiation risk is dependent mainly on the patient's age at exposure, the organs exposed, and the patient's sex, though there are other variables. The following technical guidelines are provided to ensure safe and effective imaging practices:

Radiation Dose Optimization: Adhere to the lowest effective dose principle for pediatric imaging. Ensure that imaging protocols are specifically tailored for pediatric patients to limit radiation exposure.¹⁷⁻¹⁸

Alternative Modalities: Prioritize non-ionizing imaging options such as ultrasound or MRI when clinically feasible, as they are less likely to expose the patient to ionizing radiation. For instance, MRI or ultrasound should be considered if they are more likely to provide an accurate diagnosis than CT, fluoroscopy, or radiography.¹⁷⁻¹⁸

Cumulative Dose Monitoring: Implement systems to track cumulative

radiation exposure in pediatric patients, particularly for those requiring multiple imaging studies. Regularly reassess the necessity of repeat imaging based on clinical evaluation.¹⁷⁻¹⁸

CT Imaging Considerations: When CT is deemed the best method for achieving a correct diagnosis, use the lowest possible radiation dose that still yields reliable diagnostic images.¹⁷⁻¹⁸

Cohere Imaging Gently Guideline

The purpose of this guideline is to act as a potential override when clinically indicated to adhere to Imaging Gently and Imaging Wisely guidelines and As Low As Reasonably Possible (ALARA) principles.

Level of Care Criteria

Inpatient or Outpatient

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
71250	Computed tomography (CT), thorax; without contrast material
71260	Computed tomography (CT), thorax; with contrast material(s)
71270	Computed tomography (CT), thorax; without contrast material, followed by contrast material(s) and further sections
76380	Computed tomography, limited or localized follow-up study

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Hassankhani et al. (2023) conducted a systematic review and meta-analysis of the diagnostic utility of multidetector computed tomography (MDCT) scans in penetrating diaphragmatic injuries. The study investigates the diagnostic efficacy of MDCT in detecting diaphragmatic injuries caused by penetrating trauma, with a focus on the potential risks of missed injuries and complications in cases managed nonoperatively despite the recognized value of CT scans for stable patients. The progression of CT technology, notably with the emergence of MDCT, has significantly improved the capacity to identify and assess diaphragmatic injuries caused by penetrating trauma. Although CT has solidified its role in evaluating blunt abdominal trauma patients who are hemodynamically stable, becoming the preferred imaging method in this regard, utilization in cases of penetrating thoracoabdominal trauma remains an ongoing subject of investigation. The study underscores the efficacy of MDCT in identifying diaphragmatic injury resulting from penetrating trauma with moderate to high diagnostic accuracy.^[0]

Cramer et al. (2021) provide a secondary analysis of a randomized control trial (RCT) on the incidence of second primary lung cancer after low-dose CT versus chest X-ray screening in head and neck cancer survivors. A total of 53,452 participants were enrolled in the study; 171 survivors of head and neck cancer were identified (82 had screening via low-dose CT of the chest and 89 via chest X-ray. The average age of participants was 61 years, with 132 being male (77%). The incidence of lung cancer was notably higher among head and neck cancer survivors compared to those without. In head and neck cancer survivors, the incidence of second primary lung cancer was 2610 cases per 100,000 person-years in the low-dose CT group versus 1594 cases per 100,000 person-years in the chest X-ray group. Overall survival in head and neck cancer survivors was 7.07 years with low-dose CT compared to 6.66 years with chest X-ray. The secondary analysis of the RCT indicates that head and neck cancer survivors face a heightened risk of developing second primary lung cancer. Low-dose CT screening is essential for such survivors, particularly individuals with a significant history of cigarette smoking who are deemed suitable for curative treatment.⁸

Oldroyd et al. (2021) performed a systematic review and meta-analysis to determine the clinical factors linked with cancer susceptibility in idiopathic inflammatory myopathies (IIMs) and conduct a comprehensive review of the available evidence concerning cancer screening within this context. The meta-analysis assessed the cancer risk linked with numerous clinical risk factors and myositis-specific autoantibodies (MSAs), providing insights for cancer screening strategies among IIM patients. The authors note that findings can collectively contribute to refining cancer screening guidelines, potentially facilitating earlier cancer detection and enhancing patient outcomes.¹⁹

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