



Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Lung Cancer Screening with Low Dose Computed Tomography (LDCT)		
MNG #: 088	<input checked="" type="checkbox"/> SCO <input checked="" type="checkbox"/> One Care <input checked="" type="checkbox"/> MAPD-MA Medicare Preferred <input checked="" type="checkbox"/> MAPD-MA Medicare Value <input checked="" type="checkbox"/> MAPD-RI Medicare Preferred <input checked="" type="checkbox"/> MAPD-RI Medicare Value <input checked="" type="checkbox"/> DSNP-RI Medicare Maximus	Prior Authorization Needed? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Clinical: <input checked="" type="checkbox"/>	Operational: <input type="checkbox"/>	Informational: <input type="checkbox"/>
Medicare Benefit: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Approval Date: 10/14/2021;	Effective Date: 2/06/2022;
Last Revised Date:	Next Annual Review Date: 10/14/2022;	Retire Date:

OVERVIEW:

In the United States, *lung cancer* is the leading cause of cancer death and second most common cancer. The National Cancer Institute estimates that there are about 235,760 new cases of lung cancer and about 131,880 deaths from this disease in 2021. As such, screening may be important for further clinical evaluation, timely diagnosis, and appropriate treatment to prevent a substantial number of lung cancer-related deaths. The goal of screening is to benefit individuals by decreasing lung cancer mortality, improving quality of life, maintaining a low rate of false-positive results, and preventing additional unnecessary testing.

The United States Preventive Services Task Force (USPSTF) recommends the use of *low-dose computed tomography scan (LDCT)* for lung cancer screening. LDCT is a procedure that uses a computer connected to an x-ray machine that gives off a low dose of radiation to make a series of detailed pictures of the body. These pictures are taken from different angles and used to re-create three-dimensional views of one’s internal tissues and organs. There is demonstrated moderate net benefit in persons at *high risk of lung cancer* based on age, total cumulative exposure to tobacco smoke, and years since quitting smoking.

DEFINITIONS:

Computed Tomography (CT): Imaging procedure that uses specialized x-ray equipment to create scans of areas inside the body. The x-ray source produces a fan shaped beam that passes through the section of the patient’s body to obtain snapshots at various angles. The image data is sent to a computer to reconstruct all of the individual snapshots into cross-sectional images of the internal organs and tissues.

Low-dose Computed Tomography (LDCT): Imaging procedure (similar to the standard dose CT) that produces cross-sectional images of the patient’s internal organs and tissues using a low-dose of radiation.

Lung Cancer: Refers to the proliferation of malignant cells that originate in the airways and pulmonary parenchyma. There are two types of lung cancers: *non-small cell lung cancer* and *small cell lung cancer*.



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Non-Small Cell Lung Cancer (NSCLC): Malignant tumor of the lung that is characterized by genetic mutations (in oncogenes, tumor suppressor genes, and chromatin modifying genes), gene rearrangements, gene amplifications, gene deletions, and epigenetic changes. NSCLC accounts for approximately 85% to 90% of lung cancer cases. The subtypes include non-squamous cell carcinoma (adenocarcinoma and large cell carcinoma) and squamous cell carcinoma.

Pack-years (in the context of smoking history): Method of calculating how much a person has smoked in their lifetime. It is defined as the number of cigarette packs smoked everyday multiplied by the number of years of smoking. For example, one pack-year is equivalent to smoking to an average of 20 cigarettes (or one pack) per day for one year.

Small Cell Lung Cancer (SCLC): Malignant tumor of the lung that is characterized by mutations that cause autocrine growth loops, activation of proto-oncogenes, and the loss or inactivation of tumor-suppressor genes. SCLC is described as having a rapid doubling time, high growth fraction, and can result in widespread metastases early in the disease. The subtypes include neuroendocrine tumor, pure small cell lung cancer, and combined small cell lung cancer.

DECISION GUIDELINES:

Clinical Coverage Criteria:

Commonwealth Care Alliance may cover lung cancer screening with low-dose computed tomography (LDCT) if all of the following criteria are met:

- The member is age 50 to 80 years old,
- The member has ≥ 20 pack-year smoking history,
- The member has quit smoking within the past 15 years or currently smokes,
- The member does not have signs or symptoms of lung cancer,
 - The signs or symptoms of lung cancer include but are not limited to: new onset of cough, hemoptysis, dyspnea, chest pain, and signs and symptoms or laboratory abnormalities of distant metastases or paraneoplastic syndromes in a current or former smoker.
- The member has received a written order for lung cancer screening with LDCT,
 - The order should contain the following information: member's date of birth, pack-year smoking history, current smoking status, statement that the member is asymptomatic (without the signs or symptoms of lung cancer), and the national provider identifier of the ordering practitioner
- This is the initial LDCT screen for lung cancer or follow-up has been \geq one year since the prior LDCT screen,
 - Before the beneficiary's first lung cancer LDCT screening, the beneficiary must receive a counselling and shared decision-making visit that meets all of the following criteria, and is appropriately documented in the beneficiary's medical records:
 - Must be furnished by a physician (as defined in Section 1861(r)(1) of the Social Security Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in § 1861(aa)(5) of the Social Security Act), AND
 - Must include all of the following elements:

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- Determination of beneficiary 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;
 - Shared decision-making, including the use of one or more decision aids, to include benefits and harms of screening, 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; AND
 - 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
- The lung cancer screening must be furnished in a radiology imaging facility that meets the following requirements, AND
 - Performs LDCT with volumetric CT dose index (CTDIvol) of ≤ 3.0 mGy (milligray) for standard size patients, and with appropriate reductions and increases for smaller and larger patients, accordingly,
 - For reference, a standard size patient measures five feet seven inches, and approximately 155 pounds.
 - Utilizes a standardized lung nodule identification, classification, and reporting system,
 - Collects and submits data to a CMS-approved registry for each LDCT lung cancer screen performed, AND
 - Makes smoking cessation interventions available for current smokers
 - The lung cancer screening result is read by a qualified radiologist. The radiologist must meet all of the following eligibility criteria:
 - Board certification or board eligibility with the American Board of Radiology or equivalent organization,
 - Documented training in diagnostic radiology and radiation safety,
 - Involvement in the supervision and interpretation of at least 300 chest computed tomography acquisitions in the past 3 years, AND
 - Documented participation in continuing medical education in accordance with current American College of Radiology standards

LIMITATIONS/EXCLUSIONS:

Commonwealth Care Alliance will limit lung cancer screening with low-dose computed tomography to one (1) screen per year for those who meet the clinical coverage criteria. For subsequent annual lung cancer LDCT screenings, the beneficiary must receive a written order for lung cancer LDCT screening.



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AUTHORIZATION:

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not signify that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider’s agreement with the Plan (including complying with Plan’s Provider Manual specifications).

CPT Code	Description
71271	Computed tomography, thorax, low dose for lung cancer screening, without contrast material
HCPCS Code	Description
G0296	Counseling visit to discuss the need for lung cancer screening using low dose computed tomography (LDCT)

REGULATORY NOTES:

Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the servicearea who are medical experts in the appropriate field, review of FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions. If at any time a CMS Local or National Coverage Determination (LCD or NCD) is published that conflicts with the criteria set forth herein, the NCD or LCD criteria shall supersede these criteria.

Disclaimer:

This Medical Necessity Guideline is not a rigid rule. As with all of CCA’s criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member’s unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member’s unique clinical circumstances will generally be required.



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RELATED REFERENCES:

1. Center for Medicare and Medicaid Services. (2021). *Billing and coding: IDTFs and low dose CT scan for lung cancer screening for CPT code 71271*. Retrieved from <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58641>
2. Center for Medicare and Medicaid Services. (2016). *National coverage analysis (NCA): Lung cancer screening with low computed tomography (LDCT)*. Retrieved from <https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=274>
3. Center for Medicare and Medicaid Services. (2016). *National coverage determination (NCD): Lung cancer screening with low computed tomography (LDCT)*. Retrieved from <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=364>
4. InterQual. (2021). *Imaging, chest, noncardiac: Low-dose computed tomography (LDCT), chest*. Retrieved from <https://cca-trn.guidingcare.com/InterQualConnect//home/index?authNO=18285&staffID=71978&module=UM&episodeID=&patientID=16204&decisionID=26971&decisionDiagCodes=R53.81,S5170&UN=mzhang&FN=Mary&LN=Zhang>
5. Midthun, D. (2021). *Overview of the initial treatment and prognosis of lung cancer*. Retrieved from https://www.uptodate.com/contents/overview-of-the-initial-treatment-and-prognosis-of-lung-cancer?search=non-small%20cell%20lung%20cancer&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1
6. National Cancer Institute. (2021). *NCI dictionaries: Low-dose computed tomography*. Retrieved from <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/low-dose-computed-tomography>
7. National Cancer Institute. (2021). *Surveillance, epidemiology, and end results program: Lung and bronchus cancer*. Retrieved from <https://seer.cancer.gov/statfacts/html/lungb.html>
8. Sher, T., Dy, G. & Adjei, A. (2008). Small cell lung cancer. *Mayo Clinic Proceedings*, 83(3): 355-367.
9. Swanton, C. & Govindan, R. (2016). Clinical implications of genomic discoveries in lung cancer. *New England Journal of Medicine*, 374(19): 1864-1873.
10. Thomas, K. & Gould, M. (2021). *Overview of the initial evaluation, diagnosis, and staging of patients with suspected lung cancer*. Retrieved from https://www.uptodate.com/contents/overview-of-the-initial-evaluation-diagnosis-and-staging-of-patients-with-suspected-lung-cancer?search=lung%20cancer&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1
11. U.S. Preventive Services Task Force. (2021). *Lung cancer: Screening*. Retrieved from <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening>
12. Weiss, K. & Jolanda van Zuuren, E. (2021). *Lung cancer screening*. Retrieved from <https://www.dynamed-com.ahs.idm.oclc.org/prevention/lung-cancer-screening>
13. Zheng, M. (2016). Classification and pathology of lung cancer. *Surgical Oncology Clinics of North America*, 25(3): 447-468.
14. Weiss, K. & Shaughnessy, A. (2021). *Non-small cell lung cancer*. Retrieved from <https://www.dynamed-com.ahs.idm.oclc.org/condition/non-small-cell-lung-cancer>

ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	



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REVISION LOG:

REVISION DATE	DESCRIPTION

APPROVALS:

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Title [Print]

10/14/2021

Signature

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