CMS Measure ID/CMS QCDR ID: CAP 13

Measure Title: Anaplastic Lymphoma Kinase (ALK) Biomarker Testing to Inform Clinical Management and Treatment Decisions in Patients with Non-small Cell Lung Cancer

Measure Specifications

Measure Description	Percentage of non-small cell lung cancer (NSCLC) surgical pathology reports that include anaplastic lymphoma kinase (ALK) mutation status. INSTRUCTIONS: This measure is to be reported each time a non-small cell lung cancer specimen pathology report is finalized during the performance period. This measure may be submitted by eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. The results of ALK testing of a specimen are frequently needed at some point during a patient's treatment. Pathologists are uniquely well positioned at the time of signing out the surgical pathology report to detail the disposition of ALK testing for that specimen. Referring physicians depend on both the pathologists' interpretations of and any recommendations for tests in order to provide quality patient care. If the status is not indicated in each pathology report for the patient, unnecessary repeat testing may be performed delaying treatment and increasing cost. This measure monitors the success of pathologists in effectively communicating this important information for the purpose of care coordination and efficient use of resources.
Denominator Statement	All surgical pathology reports with a diagnosis of NSCLC. CPT®: 88305, 88307, 88309 **AND** • C34.00: Malignant neoplasm of unspecified main bronchus • C34.01: Malignant neoplasm of right main bronchus • C34.02: Malignant neoplasm of left main bronchus • C34.10: Malignant neoplasm of upper lobe, unspecified bronchus or lung • C34.11: Malignant neoplasm of upper lobe, right bronchus or lung • C34.12: Malignant neoplasm of upper lobe, left bronchus or lung • C34.2: Malignant neoplasm of middle lobe, bronchus or lung • C34.30: Malignant neoplasm of lower lobe, unspecified bronchus or lung • C34.31: Malignant neoplasm of lower lobe, right bronchus or lung • C34.32: Malignant neoplasm of lower lobe, left bronchus or lung • C34.80: Malignant neoplasm of overlapping sites of unspecified bronchus and lung • C34.81: Malignant neoplasm of overlapping sites of right bronchus and lung • C34.82: Malignant neoplasm of overlapping sites of left bronchus and

	lung • C34.90: Malignant neoplasm of unspecified part of unspecified bronchus or lung • C34.91: Malignant neoplasm of unspecified part of right bronchus or lung • C34.92: Malignant neoplasm of unspecified part of left bronchus or lung
Denominator Exclusions	Squamous cell carcinoma
Denominator Exceptions	Documentation of reason(s) ALK testing was not performed (e.g., payor-related limitations, patients receiving hospice)
Numerator Statement	Surgical pathology reports that contain impression or conclusion of, or recommendation for ALK mutation testing. Numerator guidance A short note on ALK mutation status can be made in the final report, such as: • ALK mutation(s) identified / positive • No ALK mutation(s) identified / negative • ALK previously performed • ALK mutation testing recommended • ALK mutation cannot be determined ALK mutation status may be derived from either the primary or a reference laboratory.
Numerator Exclusions	None
Measure Information	
NQS Domain	Communication and Care Coordination
Meaningful Measures Area(s)	Transfer of Health Information and Interoperability
Meaningful Measure Rationale	Various gene alterations have been identified as oncogenic drivers for NSCLC, including mutations of EGFR, ALK and ROS1. The Lung Cancer Mutation Consortium found that two thirds of NSCLC patients have an oncogenic driver and that overall survival improves if patients receive matched targeted therapy (1). Knowledge of ALK rearrangement is thus necessary for appropriate clinical decision-making in advanced NSCLC. Alternative treatments are considered when ALK rearrangement is discovered before or during first-line therapy. In addition to identifying tumors that are likely to respond to targeted therapies, knowledge of ALK rearrangement status typically predicts inferior response to immunotherapies. Approximately 5% of lung adenocarcinomas have a chromosomal rearrangement involving the ALK gene and associated with

	ALK protein overexpression. Patients with such tumors this tumor respond to therapy with ALK tyrosine kinase inhibitors, such as crizotinib (2, 3). 1. Kris MG, Johnson B, Berry LD, et al. Using multiplexed assays of oncogenic drivers in lung cancers to select targeted drugs. JAMA. 2014;311:1998–2006. 2. Lindeman NI, Cagle PT, Aisner DL, Arcila ME, Beasley MB, Bernicker EH, et al. Updated molecular testing guideline for the selection of lung cancer patients for treatment with targeted tyrosine kinase inhibitors: Guideline From the College of American Pathologists, the International Association for the Study of Lung Cancer, and the Association for Molecular Pathology. J Thorac Oncol. 2018 Mar;13(3):323-358. 3. Shaw AT, Kim DW, Nakagawa K, et al. Crizotinib versus chemotherapy in advanced ALK-positive lung cancer. N Engl J Med. 2013;368(25):2385-2394.
Measure Type	Process
Data Source	Laboratory Information Systems; pathology reports
Summary of Performance Gap Evidence	Lung cancer is among the cancers with highest incidence and represents a leading cause of cancer-related mortality in the US (1). Non-small cell lung cancer (NSCLC) accounts for 84% of all lung cancers (1). Various gene alterations have been identified as oncogenic drivers for NSCLC, including mutations of EGFR, ALK and ROS1. The Lung Cancer Mutation Consortium found that two thirds of NSCLC patients have an oncogenic driver and that overall survival improves if patients receive matched targeted therapy (2). Knowledge of ALK rearrangement is thus necessary for appropriate clinical decision-making in advanced NSCLC. Alternative treatments are considered when ALK rearrangement is discovered before or during first-line therapy. In addition to identifying tumors that are likely to respond to targeted therapies, knowledge of ALK rearrangement status typically predicts inferior response to immunotherapies. Approximately 5% of lung adenocarcinomas have a chromosomal rearrangement involving the ALK gene and associated with ALK protein overexpression. Patients with such tumors this tumor respond to therapy with ALK tyrosine kinase inhibitors, such as crizotinib (3, 4). 1. American Cancer Society. Cancer facts & figures 2018. Atlanta: American Cancer Society, 2018. 2. Kris MG, Johnson B, Berry LD, et al. Using multiplexed assays of oncogenic drivers in lung cancers to select targeted drugs. JAMA. 2014;311:1998–2006. 3. Lindeman NI, Cagle PT, Aisner DL, Arcila ME, Beasley MB, Bernicker EH, et al. Updated molecular testing guideline for the selection of lung cancer patients for treatment with targeted tyrosine kinase inhibitors: Guideline From the College of American Pathologists, the International Association for the Study of Lung Cancer, and the Association for Molecular Pathology. J Thorac Oncol. 2018 Mar;13(3):323-358.

	4. Shaw AT, Kim DW, Nakagawa K, et al. Crizotinib versus chemotherapy in advanced ALK-positive lung cancer. N Engl J Med. 2013;368(25):2385-2394.
Measure Owner	College of American Pathologists
NQF ID	N/A
Number of Performance Rates	1
Overall Performance Rate	1st Performance Rate
High-priority	Yes
Improvement Notation	Inverse Measure: No **Proportional Measure: Yes (Higher score indicates better quality)** Continuous Variable Measure: No Ratio Measure: No Risk-adjusted: No
Specialty	Pathology
Current Clinical Guideline the Measure is Derived From	ALK molecular testing should be used to select patients for ALK-targeted TKI therapy, and patients with lung adenocarcinoma should not be excluded from testing on the basis of clinical characteristics (Grade B evidence) (1). Testing for ALK gene rearrangements and EGFR gene mutations is recommended in the NSCLC algorithm for patients with nonsquamous NSCLC or NSCLC NOS so that patients with these genetic abnormalities can receive effective treatment with targeted agents (Category 1 evidence) (2). 1. Lindeman NI, Cagle PT, Beasley MB, Chitale DA, Dacic S, Giaccone G, et al. Molecular testing guideline for selection of lung cancer patients for EGFR and ALK tyrosine kinase inhibitors: guideline from the College of American Pathologists, International Association for the Study of Lung Cancer, and Association for Molecular Pathology. Arch Pathol Lab Med. 2013 Jun;137(6):828-60. 2. Ettinger DS, Wood DE, Aisner DL, Akerley W, Bauman J, Chang JY, et al. NCCN clinical practice guidelines in oncology: non-small cell lung cancer, version 5.2018. National Comprehensive Cancer Network. Available at https://www.nccn.org/professionals/physician_gls/recently_updated.aspx

Measure Flow