CMS Measure ID/CMS QCDR ID: CAP 16

Measure Title: Epidermal Growth Factor Receptor (EGFR) 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 epidermal growth factor receptor (EGFR) 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 EGFR 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 EGFR testing for that specimen. A significant number of patients with early-stage disease will progress to advanced disease in which EGFR mutation results can eventually guide their therapy. 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

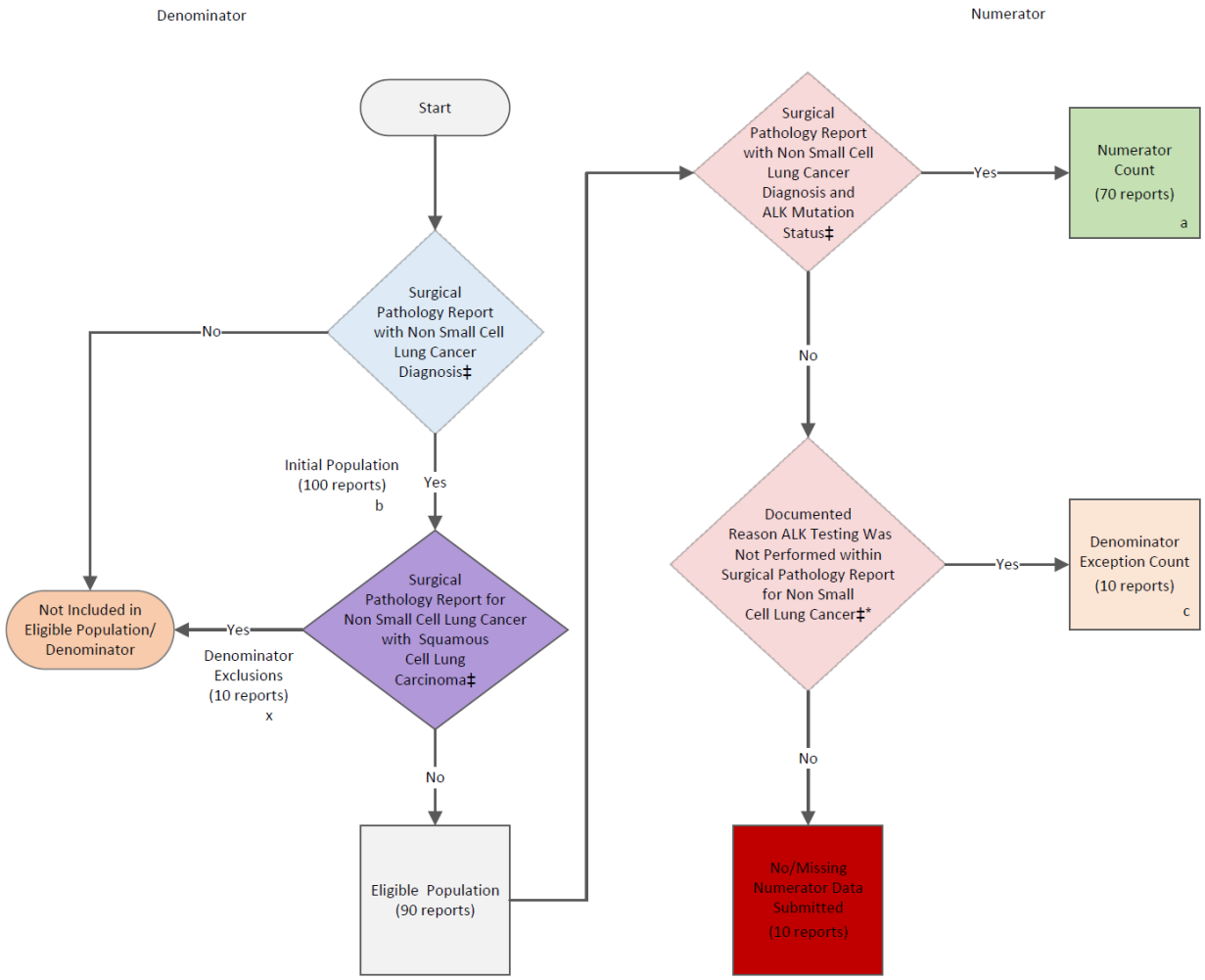
	and lung • C34.82: Malignant neoplasm of overlapping sites of left bronchus and lung • C34.90: Malignant neoplasm of unspecified part of unspecified bronchus or lung • C34.91: Malignant neoplasm of unspecified part of right bronchus or lung • C34.92: Malignant neoplasm of unspecified part of left bronchus or lung
Numerator Statement	Surgical pathology reports that contain impression or conclusion of, or recommendation for EGFR mutation testing. Numerator guidance: A short note on EGFR mutation status can be made in the final report, such as: • EGFR mutation(s) identified/positive • No EGFR mutation(s) identified/negative • EGFR previously performed • EGFR mutation testing recommended • EGFR mutation cannot be determined EGFR mutation status may be derived from either the primary or a reference laboratory.
Denominator Exclusions	Squamous cell carcinoma
Denominator Exceptions	Documentation of reason(s) EGFR testing was not performed (e.g., payor-related limitations, patients receiving hospice)
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 or 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 EGFR mutation is thus necessary for appropriate clinical decision-making in advanced NSCLC. Alternative treatments are considered when a characteristic EGFR mutation is discovered before or during first-line chemotherapy. In addition to identifying tumors that are likely to respond to

	targeted therapies, knowledge of EGFR mutation status typically predicts inferior response to immunotherapies. Approximately 20% of lung adenocarcinomas contain an EGFR activating mutation that predicts response to therapy with EGFR tyrosine kinase inhibitors such as erlotinib (2 – 7). 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. Maemondo M, Inoue A, Kobayashi K, et al. Gefitinib or chemotherapy for non-small-cell lung cancer with mutated EGFR. N Engl J Med. 2010;362(25):2380-2388. 4. Mitsudomi T, Morita S, Yatabe Y, et al. Gefitinib versus cisplatin plus docetaxel in patients with non-small-cell lung cancer harbouring mutations of the epidermal growth factor receptor (WJTOG3405): an open label, randomised phase 3 trial. Lancet Oncol. 2010;11(2):121-128. 5. Mok TS, Wu YL, Thongprasert S, et al. Gefitinib or carboplatin-paclitaxel in pulmonary adenocarcinoma. N Engl J Med. 2009;361(10):947-957. 6. Pao W, Miller V, Zakowski M, et al. EGF receptor gene mutations are common in lung cancers from "never smokers" and are associated with sensitivity of tumors to gefitinib and erlotinib. Proc Natl Acad Sci. 2004;101(36):13306-13311. 7. Rosell R, Carcereny E, Gervais R, et al. Erlotinib versus standard chemotherapy as first-line treatment for European patients with advanced EGFR mutation-positive non-small-cell lung cancer (EURTAC): a multicentre, open-label, randomised phase 3 trial. Lancet Oncol. 2012;13(3):239-246.
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 or 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 EGFR mutation is thus necessary for appropriate clinical decision-making in advanced NSCLC. Alternative treatments are considered when a characteristic EGFR mutation is discovered before or during first-line chemotherapy. In addition to identifying tumors that are likely to respond to targeted therapies, knowledge of EGFR mutation status typically predicts inferior response to immunotherapies. Approximately 20% of lung adenocarcinomas contain an EGFR activating mutation that predicts response to therapy with EGFR tyrosine kinase inhibitors such as erlotinib (3 – 8). 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. Maemondo M, Inoue A, Kobayashi K, et al. Gefitinib or chemotherapy for non-small-cell lung cancer with mutated EGFR. N Engl J Med. 2010;362(25):2380-2388.
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	EGFR molecular testing should be used to select patients for EGFR-targeted TKI therapy, and patients with lung adenocarcinoma should not be excluded from testing on the basis of clinical characteristics (Grade A Evidence) (1).

Measure is Derived From	EGFR mutation testing should be ordered at the time of diagnosis for patients presenting with advanced-stage disease (stage IV according to the 7th edition TNM staging system) who are suitable for therapy or at time of recurrence or progression in patients who originally presented with lower-stage disease but were not previously tested (Grade A Evidence) (1). Physicians may use molecular biomarker testing in tumors with histologies other than adenocarcinoma when clinical features indicate a higher probability of an oncogenic driver (Expert Consensus Opinion) (2). 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) (3). 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. 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. 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



‡Please refer to the specific section of the measure specification to identify the associated value sets or direct reference codes for use in submitting this measure, or to identify the Definition of the criteria associated with population criteria.

*Documented reasons include payor-related limitations and patients receiving hospice.

SAMPLE CALCULATION:

Performance Rate =

$$\frac{\text{Numerator (a = 70 reports)}}{\text{Denominator (b= 100 reports) – Denominator Exclusions (x= 10 reports) – Denominator Exceptions (c = 10 reports)}} = 87.5\%$$

DISCLAIMER: *Please refer to the measure specification for a complete listing of required data elements, value sets, direct reference codes, and logic definitions. The measure diagrams were developed as a supplement resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.*