CMS Measure ID/CMS QCDR ID: CAP 19

Measure Title: ROS 1 Biomarker Testing to Inform Clinical Management and Treatment Decisions in Patients with Non-small Cell Lung Cancer

Measure Specifications

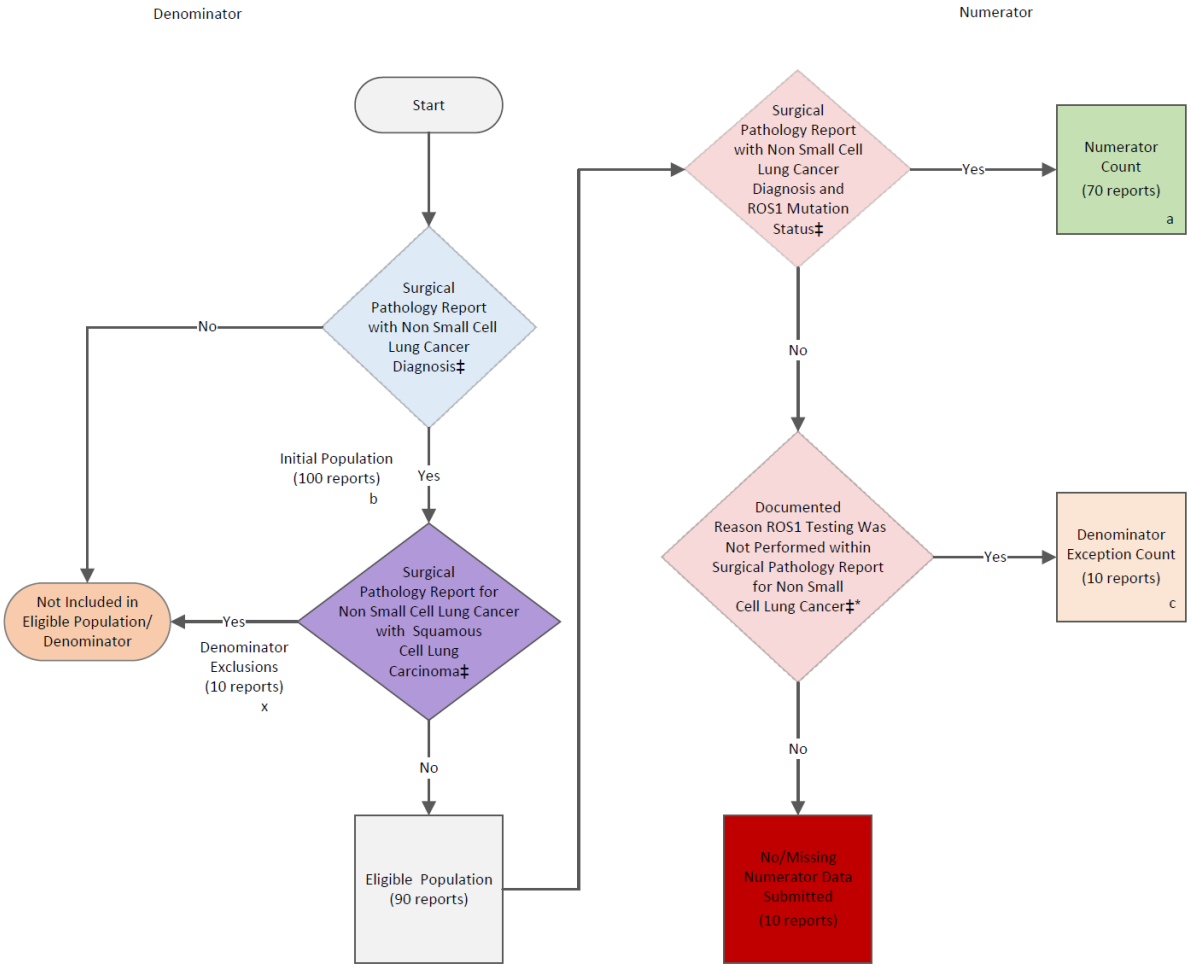
Measure Description	Percentage of non-small cell lung cancer (NSCLC) surgical pathology reports that include ROS1 mutation status. INSTRUCTIONS: This measure is to be reported each time a non-small cell lung cancer specimen pathology report is finalized during the performance period. This measure may 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 ROS1 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 ROS1 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) ROS1 testing was not performed (eg., payor-related limitations, patients receiving hospice)
Numerator Statement	Surgical pathology reports that contain impression or conclusion of, or recommendation for ROS1 mutation testing. Numerator guidance A short note on ROS1 mutation status can be made in the final report, such as: • ROS1 mutation(s) identified/positive • No ROS1 mutation(s) identified/ negative • ROS1 previously performed • ROS1 mutation testing recommended • ROS1 mutation cannot be determined ROS1 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 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 ROS1 rearrangement is thus necessary for appropriate clinical decision-making in advanced NSCLC. Alternative treatments are considered when ROS1 rearrangement is discovered before or during first-line chemotherapy. ROS1 rearrangement occurs in 1% to 2% of non-small cell lung carcinomas and predicts response to crizotinib and ceritinib therapy, which are first-line treatments. Response rates, including complete responses, approach 70% (2-4).

	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. Takeuchi K, Soda M, Togashi Y, et al. RET, ROS1 and ALK fusions in lung cancer. Nat Med. 2012;18(3):378-381. 4. Bergethon K, Shaw AT, Ou SH, et al. ROS1 rearrangements define a unique molecular class of lung cancers. J Clin Oncol. 2012;30(8):863-870.
Measure Type	Process
Data Source	Laboratory Information Systems; pathology reports
Summary of Performance Gap Evidence	Knowledge of ROS1 rearrangement is thus necessary for appropriate clinical decision-making in advanced NSCLC. Alternative treatments are considered when ROS1 rearrangement is discovered before or during first-line chemotherapy (1). ROS1 rearrangement occurs in 1% to 2% of non-small cell lung carcinomas and predicts response to crizotinib and ceritinib therapy, which are first-line treatments. Response rates, including complete responses, approach 70% (2-4). 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. Takeuchi K, Soda M, Togashi Y, et al. RET, ROS1 and ALK fusions in lung cancer. Nat Med. 2012;18(3):378-381. 4. Bergethon K, Shaw AT, Ou SH, et al. ROS1 rearrangements define a unique molecular class of lung cancers. J Clin Oncol. 2012;30(8):863-870.
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	ROS1 testing must be performed on all lung advanced-stage adenocarcinoma patients, irrespective of clinical characteristics (Strong Recommendation) (1). The NCCN guideline for non-small cell lung cancer recommends testing for ROS1 rearrangements for nonsquamous NSCLC or NSCLS NOS (Category 2A evidence) (2). 1. 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. 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



‡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.*