Quality ID #395: Lung Cancer Reporting (Biopsy/Cytology Specimens)
– National Quality Strategy Domain: Communication and Care Coordination
– Meaningful Measure Area: Transfer of Health Information and Interoperability

2022 COLLECTION TYPE: MEDICARE PART B CLAIMS

MEASURE TYPE:
Process – High Priority

DESCRIPTION:
Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following The International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.

INSTRUCTIONS:
This measure is to be submitted each time a patient’s pathology report addresses specimens with a diagnosis of non-small cell lung cancer; however, only one quality data code (QDC) per date of service for a patient is required. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

Measure Submission Type:
Measure data may be submitted by individual MIPS eligible clinicians using Medicare Part B claims. The listed denominator criteria are used to identify the intended patient population. The numerator quality data codes included in this specification are used to submit the quality actions allowed by the measure on the claim form(s). All measure-specific coding should be submitted on the claim(s) representing the denominator eligible encounter and selected numerator option.

DENOMINATOR:
Lung biopsy and cytology specimen reports with a diagnosis of primary non-small cell lung cancer

**Denominator Criteria (Eligible Cases):**
Patients ≥ 18 years of age on date of service

AND
**Diagnosis for lung cancer (ICD-10-CM):** C34.00, C34.01, C34.02, C34.10, C34.11, C34.12, C34.2, C34.30, C34.31, C34.32, C34.80, C34.81, C34.82, C34.90, C34.91, C34.92

AND
**Patient encounter during performance period (CPT):** 88104, 88108, 88112, 88173, 88305
**WITHOUT**
Telehealth Modifier: GQ, GT, 95, POS 02

NUMERATOR:
Lung biopsy and cytology specimen reports with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following IASLC guidance (see below) (including but not limited to squamous cell carcinoma, or adenocarcinoma) OR classified as NSCLC-NOS with an explanation included in the pathology report

**IASLC Guidance:** The IASLC recommends the following regarding terminology for small biopsy and cytology specimens:
1. Do not use the term “large cell carcinoma”
2. Do not use the term “AIS (adenocarcinoma in situ)” or “MIA (minimally invasive adenocarcinoma)” if a noninvasive pattern is present in a small biopsy, the term “lepidic growth” should be used instead
3. Do not use the term “BAC (bronchioloalveolar carcinoma)”

All three recommendations must be followed in order for a case to be considered Met (ie if any one of these terms is
present, the case is Not Met)

Numerator Quality Data Coding Options:
If Patient is not Eligible for this Measure because the Specimen is not of Lung Origin or is not Classified as Non-Small Cell Lung Cancer Report

Denominator Exclusion: G9420:
Specimen site other than anatomic location of lung or is not classified as primary non-small cell lung cancer

OR

Non-Small Cell Lung Cancer Biopsy and Cytology Specimen Reports Classified

Performance Met: G9418:
Primary non-small cell lung cancer biopsy and cytology specimen report documents classification into specific histologic type following IASLC guidance OR classified as NSCLC-NOS with an explanation

OR

Non-Small Cell Lung Cancer Biopsy and Cytology Specimen Reports not Classified for a Medical Reason

Denominator Exception: G9419:
Documentation of medical reason(s) for not including the histological type OR NSCLC-NOS classification with an explanation (e.g., Specimen insufficient or non-diagnostic, specimen does not contain cancer, or other documented medical reasons)

OR

Non-Small Cell Lung Cancer Biopsy and Cytology Specimen Reports not Classified, Reason not Given

Performance Not Met: G9421:
Primary non-small cell lung cancer biopsy and cytology specimen report does not document classification into specific histologic type OR histologic type does not follow IASLC guidance OR is classified as NSCLC-NOS but without an explanation

RATIONALE:
Lung cancer is the most frequent cause of major cancer incidence and mortality worldwide. The classifications of lung cancer published by the World Health Organization (WHO) in 1967, 1981, and 1999 were written primarily by pathologists for pathologists. Only in the 2004 revision, relevant genetics and clinical information were introduced. Nevertheless, because of remarkable advances over the last 6 years in our understanding of lung adenocarcinoma, particularly in the area of medical oncology, molecular biology, and radiology, there is a pressing need for a revised classification, based not on pathology alone, but rather on an integrated multidisciplinary platform.

For the first time, this classification addresses an approach to small biopsies and cytology in lung cancer diagnosis. Recent data regarding epidermal growth factor receptor (EGFR) mutation predicting responsiveness to epidermal growth factor receptor tyrosine kinase inhibitors (EGFR-TKIs), toxicities, and therapeutic efficacy have established the importance of distinguishing squamous cell carcinoma from adenocarcinoma and non-small cell lung carcinoma (NSCLC) not otherwise specified (NOS) in patients with advanced lung cancer. Approximately 70% of lung cancers are diagnosed and staged by small biopsies or cytology rather than surgical resection specimens, with increasing use of transbronchial needle aspiration (TBNA), endobronchial ultrasound-guided TBNA and esophageal ultrasound-guided needle aspiration. Within the NSCLC group, most pathologists can identify well- or moderately-differentiated squamous cell carcinomas or adenocarcinomas, but specific diagnoses are more difficult with poorly differentiated tumors. Nevertheless, in small biopsies and/or cytology specimens, upwards of 30% of specimens continue to be diagnosed as NSCLC-NOS. The most recent recommendations from WHO are that pathologists “reduce the use of the term NSCLC NOS as much as possible and classify tumors according to their specific histologic subtype” (WHO, 2015).

CLINICAL RECOMMENDATION STATEMENTS:
To address advances in oncology, molecular biology, pathology, radiology, and surgery of lung adenocarcinoma, an
international multidisciplinary classification was sponsored by the International Association for the Study of Lung Cancer, American Thoracic Society, and European Respiratory Society. This new adenocarcinoma classification is needed to provide uniform terminology and diagnostic criteria, especially for bronchioloalveolar carcinoma (BAC), the overall approach to small non-resection cancer specimens, and for multidisciplinary strategic management of tissue for molecular and immunohistochemical studies.

For small biopsies and cytology, we recommend that NSCLC be further classified into a more specific histologic type, such as adenocarcinoma or squamous cell carcinoma, whenever possible (strong recommendation, moderate quality evidence).

The terms AIS or MIA should not be used in small biopsies or cytology specimens. If a noninvasive pattern is present in a small biopsy, it should be referred to as lepidic growth.

The term large cell carcinoma should not be used for diagnosis in small biopsy or cytology specimens and should be restricted to resection specimens where the tumor is thoroughly sampled to exclude a differentiated component.

We recommend discontinuing the use of the term “BAC”

We recommend that the term NSCLC-NOS be used as little as possible and we recommend it be applied only when a more specific diagnosis is not possible by morphology and/or special stains (strong recommendation, moderate quality evidence).

The above strategy for classification of adenocarcinoma versus other histologies and the terminology should be used in routine diagnosis and future research and clinical trials so that there is uniform classification of disease cohorts in relationship to tumor subtypes.


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### SAMPLE CALCULATIONS

**Data Completeness**

\[
\text{Denominator Exclusion}(x=0 \text{ procedures}) + \text{Performance Met}(a=40 \text{ procedures}) + \text{Denominator Exception}(b=10 \text{ procedures}) + \text{Performance Not Met}(c=20 \text{ procedures}) = \frac{70 \text{ procedures}}{80 \text{ procedures}} = 87.50\%
\]

**Performance Rate**

\[
\text{Performance Met}(a=40 \text{ procedures}) = \frac{40 \text{ procedures}}{80 \text{ procedures}} = 66.67\%
\]

\[
\text{Data Completeness Numerator}(70 \text{ procedures}) - \text{Denominator Exclusion}(x=0 \text{ procedures}) - \text{Denominator Exception}(b=10 \text{ procedures}) = 60 \text{ procedures}
\]

*See the posted measure specification for specific coding and instructions to submit this measure.*

NOTE: Submission Frequency: Procedure

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The measure diagrams were developed by CMS as a supplemental resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.
2022 Medicare Part B Claims Flow Narrative for Quality ID #395:
Lung Cancer Reporting (Biopsy/Cytology Specimens)

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1. Start with Denominator

2. Check Patients greater than or equal to 18 years of age on date of service:
   a. If Patients greater than or equal to 18 years of age on date of service equals No, do not include in Eligible Population/Denominator. Stop processing.
   b. If Patients greater than or equal to 18 years of age on date of service equals Yes, proceed to check Diagnosis for lung cancer as listed in Denominator*.

3. Check Diagnosis for lung cancer as listed in Denominator*:
   a. If Diagnosis for lung cancer as listed in Denominator* equals No, do not include in Eligible Population/Denominator. Stop processing.
   b. If Diagnosis for lung cancer as listed in Denominator* equals Yes, proceed to check Patient encounter during performance period as listed in Denominator*.

4. Check Patient encounter during performance period as listed in Denominator*:
   a. If Patient encounter during performance period as listed in Denominator* equals No, do not include in Eligible Population/Denominator. Stop processing.
   b. If Patient encounter during performance period as listed in Denominator* equals Yes, proceed to check Telehealth Modifier.

5. Check Telehealth Modifier:
   a. If Telehealth Modifier equals Yes, do not include in Eligible Population/Denominator. Stop processing.
   b. If Telehealth Modifier equals No, include in Eligible Population/Denominator.

6. Denominator Population:
   - Denominator Population is all Eligible Procedures in the Denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d equals 80 procedures in the Sample Calculation.

7. Start Numerator

8. Check Specimen site other than anatomic location of lung or is not classified as primary non-small cell lung cancer:
   a. If Specimen site other than anatomic location of lung or is not classified as primary non-small cell lung cancer equals Yes, include in the Data Completeness Met and Denominator Exclusion.
      • Data Completeness Met and Denominator Exclusion letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter x equals 0 procedures in the Sample Calculation.
   b. If Specimen site other than anatomic location of lung or is not classified as primary non-small cell lung cancer equals No, do not include in Eligible Population/Denominator. Stop processing.
cancer equals No, proceed to check Primary non-small cell lung cancer biopsy and cytology specimen report documents classification into specific histologic type following IASLC guidance OR classified as NSCLC-NOS with an explanation.

9. Check Primary non-small cell lung cancer biopsy and cytology specimen report documents classification into specific histologic type following IASLC guidance OR classified as NSCLC-NOS with an explanation:

   a. If Primary non-small cell lung cancer biopsy and cytology specimen report documents classification into specific histologic type following IASLC guidance OR classified as NSCLC-NOS with an explanation equals Yes, include in Data Completeness Met and Performance Met.
      • Data Completeness Met and Performance Met letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 40 procedures in Sample Calculation.

   b. If Primary non-small cell lung cancer biopsy and cytology specimen report documents classification into specific histologic type following IASLC guidance OR classified as NSCLC-NOS with an explanation equals No, proceed to check Documentation of medical reason(s) for not including the histological type OR NSCLC-NOS classification with an explanation.

10. Check Documentation of medical reason(s) for not including the histological type OR NSCLC-NOS classification with an explanation:

   a. If Documentation of medical reason(s) for not including the histological type OR NSCLC-NOS classification with an explanation equals Yes, include in the Data Completeness Met and Denominator Exception.
      • Data Completeness Met and Denominator Exception letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b equals 10 procedures in the Sample Calculation.

   b. If Documentation of medical reason(s) for not including the histological type OR NSCLC-NOS classification with an explanation equals No, proceed to check Primary non-small cell lung cancer biopsy and cytology specimen report does not document classification into specific histologic type OR histologic type does not follow IASLC guidance OR is classified as NSCLC-NOS but without an explanation.

11. Check Primary non-small cell lung cancer biopsy and cytology specimen report does not document classification into specific histologic type OR histologic type does not follow IASLC guidance OR is classified as NSCLC-NOS but without an explanation:

   a. If Primary non-small cell lung cancer biopsy and cytology specimen report does not document classification into specific histologic type OR histologic type does not follow IASLC guidance OR is classified as NSCLC-NOS but without an explanation equals Yes, include in Data Completeness Met and Performance Not Met.
      • Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c equals 20 procedures in the Sample Calculation.

   b. If Primary non-small cell lung cancer biopsy and cytology specimen report does not document classification into specific histologic type OR histologic type does not follow IASLC guidance OR is classified as NSCLC-NOS but without an explanation equals No, proceed to check Data Completeness Not Met.

12. Check Data Completeness Not Met:
a. If Data Completeness Not Met, the Quality Data Code was not submitted. 10 procedures have been subtracted from the Date Completeness Numerator in the Sample Calculation.

**Sample Calculations**

Data Completeness equals Denominator Exclusion (x equals 0 procedures) plus Performance Met (a equals 40 procedures) plus Denominator Exception (b equals 10 procedures) plus Performance Not Met (c equals 20 procedures) divided by Eligible Population/Denominator (d equals 80 procedures). All equals 70 procedures divided by 80 procedures. All equals 87.50 percent.

Performance Rate equals Performance Met equals Performance Met (a equals 40 procedures) divided by Data Completeness Numerator (70 procedures) minus Denominator Exclusion (x equals 0 procedures) minus Denominator Exception (b equals 10 procedures). All equals 40 procedures divided by 60 procedures. All equals 66.67 percent.

*See the posted measure specification for specific coding and instructions to submit this measure.

NOTE: Submission Frequency: Procedure

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