CAP 34: Biomarker Status to Inform Clinical Management and Treatment Decisions in Patients with Non-small Cell Lung Cancer

1. **I have seen lung FNA (Fine Needle Aspiration) coded as 88305. Are these cases included in the measure?**

   No. We do not want FNAs for this measure even if they are coded as 88305. Per the specification, it is only lung biopsies and resections only. CPT code 88305 covers a lot of things that we do not include in this measure.

2. **Are metastatic liver cases, where the cancer originated in the lung and then metastasized to the liver, included in the measure?**

   This depends on the sample. The case would only be included in the measure if the sample in question was a lung sample. That is, if the sample was liver but they traced the cancer back to the lung, we do not want it. If they found it in the liver, then went back and took a lung sample, that is fine as long as they coded that lung sample as the primary. We do want to include all lung cancer patients, including advanced stage patients whose cancer has metastasized, but we can only accept lung samples that are coded as the primary tumor.

3. **I have a lung, wedge resection case with two lesions: the first lesion is squamous cell carcinoma (Denominator Exclusion) and the second lesion is invasive adenocarcinoma with documentation that ALK, EGFR, and ROS1 tests were previously done. Which lesion counts? Both?**

   Since the first lesion is considered a Denominator Exclusion and the second lesion is considered Met, then the overall case would fall into the Performance Met category. The relevant specimens had the proper documentation and so the overall case is Met.

4. **I have seen several path reports that say, “See previous path report”. Does this count as “previously performed”?**

   It is fine to attest that the biomarker test was previously performed (if it actually was performed). However, if those cases were to be audited, you would need to come up with the previous pathology report showing that the tests were done. If for some reason those path reports are not available, or there is not a specific documentation of the three biomarkers in the original report, it should be marked as Not Met to protect yourself in case of an audit. As long as you know where the previous reports are and are confident that they document the status of all three biomarkers, that is fine.

5. **If a provider states “EGFR, ROS-1, ALK-1 and PDL-1 testing may be clinically indicated and are available upon request.”, would that be sufficient to code 'performance met'? Or would it be unacceptable since the provide isn't explicitly stating that they recommend the testing?**

   For this measure, it needs to be documented that they did the test, previously performed, recommended the biomarker testing, or sent the sample for testing. We can accept the statement as Met because it leans toward the “recommendation” end of things. Although the statement isn’t really firm, it implies that the pathologists knows that the tests may be needed.

6. **If I perform/send out cases to a reference laboratory for ROS1 testing only, can I document that testing is recommended for the other two biomarkers?**

   If your institution does not support ALK or EGFR testing, then you could write a note that says, “ALK and EGFR recommended where appropriate” or “additional biomarker testing including ALK, and EGFR recommended per guidelines” or something of that nature.

   If there isn’t a reason why the institution has not been doing ALK and EGFR testing: if they are not doing it because the institution does not support it or they have to the tests sequentially, or it is only recommended on

certain samples, that is fine. You can make a generic statement about recommended where and when appropriate.

However, if the institution is simply not doing the testing, then we cannot accept documentation that the tests were "recommended". Essentially, there needs to be a reason why the institution is not in compliance with the guideline, and it would be considered as Not Met.

7. **Do I have to provide documentation on the status of all three biomarkers?**

   Yes. Information must be provided about each biomarker. A non-specific note about "biomarker testing" or other documentation that does not conclusively identify each biomarker by name does not meet the measure. However, the status does NOT have to be the same for all three biomarkers as long as each is recorded.

8. **Should I be including squamous cell carcinoma (denominator exclusion) cases?**

   Yes, squamous cell carcinoma cases should be included. You should enter data for all cases whether they are exclusions, exceptions, met, and not met cases.

9. **The reason the biomarker test was not ordered is not always listed in the pathology report, as the clinician waits to assimilate all information and then calls us to order the biomarker test. Is that okay? How do we enter this in the Webtool/Manual Data Entry tool?**

   In the Webtool/Manual Data Entry tool, you can select the test that will be ordered, then on the question about the results (Please select the (ALK/EGFR/ROS1) mutation result documented in the pathology report), select Biomarker test recommended. The choice of which test and what the result is do not affect the calculation of the score as long as something is selected.

10. **Sometimes clinicians do not order a lung biomarker test for various reasons, such as the tumor is inoperable, the sample size is too small, etc. Is this considered a denominator exception? Is it okay to include these cases? How do I record these options in the Webtool/Manual Data Entry tool since the choices are Financial Reasons and Comfort Measures?**

    Yes, the reasons that you listed are considered exceptions because any medical reason for not performing the test is acceptable.

    We do not have the responses for all possible reasons the test was not performed. However, "insufficient tumor" is a new option that we have added. If none of the options listed do not apply to the medical reason, then please select the option that most closely relates to it or you can select "Financial Reason". (The answer to the exception questions does not affect the calculation of the measure).

11. **Our practice does ALK/ EGFR/ROS1 testing as part of panel of tests. Does that meet the measure?**

    Yes, as long as information about each biomarker (ALK, EGFR, and ROS1) is documented in the report, it does not matter whether it was done on its own or as part of a panel.

12. **We send out non-small cell lung cancer cases for biomarker testing at a reference lab. Do I have to separately document the results provided by the reference lab to meet this measure?**

    No. A statement that ALK, EGFR, and ROS1 testing was recommended or sent out is sufficient to meet the measure. Actual results from the reference lab are strongly encouraged but not required.

13. **The ordering clinician noted in the order that this patient will not be receiving treatment. Normally, we do not do biomarker testing for patients who will not be receiving treatment. Should I perform the tests in order to meet the measure?**

    No. This case is an exception, meaning that it will not be part of the performance rate calculation. Patients in hospice or otherwise noted as not receiving treatment are an exception, as are patients who decline testing, payor-related limitations on testing, and other medical reasons that testing was not done. This is indicated in the Webtool/Manual Data Entry version of this measure as “Patient Reasons”.

14. **Why are there so many options in the Webtool for the question about which tests were done? Which of these tests meet the measure?**

    All of the listed tests meet the measure. The list of tests is primarily informational for the clinician. This information is not used for any other purpose and does not affect the performance score.

15. **Is my performance score affected if ALK, EGFR, or ROS1 was not identified?**

    No. The result of the test does not affect the score. Multiple options are available to help clinicians accurately meet the measure. This encourages thorough review of each case rather than the assumption that the case meets the measure. However, a statement regarding the status of all three biomarkers must be documented in the pathology report to meet the measure.

16. **The biomarkers are typically performed at the request of our oncologist. When we are entering data in the Webtool, should we select “No test performed” or “Test recommended”?**

    In this case, you should select the type of test that would be performed (the type of test is not a factor in the calculation of the measure) and then select “Biomarker test recommended” for the questions, “Please select the (ALK/EGFR/ROS1) mutation result documented in the pathology report”.