# Programmatic/Institutional Checklist:
# BIOMARKER TESTING IN LUNG CANCER

CHEST

Establishing a systematic biomarker testing program for eligible patients takes both time and collaboration across specialties. This programmatic/institutional checklist details key objectives for multidisciplinary teams, enabling clear expectations and processes across hand-offs to aid in the testing process.

The following requires sustained interdisciplinary coordination by relevant stakeholders over time.

- ☐ **Identify relevant stakeholders:** Include medical oncologists, pathologists, and proceduralists acquiring tissue (ie, pulmonology, interventional radiology, pathology, thoracic surgery) and the locations/staff where procedures take place.
- ☐ **Define the current state:** Describe the local process of biomarker testing and what the goal or ideal state would be.
- ☐ **Define eligible patients:** Discuss and define which stages and histology of lung cancer should receive biomarker testing (and any differences in the panel needed). Ensure these decisions are known by all stakeholders.
  - ☐ Several guidelines exist to aid in assessing patient eligibility.[1, 2] In general, all patients with advanced/metastatic non-squamous histology (ie, adenocarcinoma, large cell, and NSCLC NOS) should receive comprehensive biomarker testing, including PD-L1. For those with advanced/metastatic squamous histology, PD-L1 should be assessed, and comprehensive biomarker testing should be considered, with the decision left to local treating physicians.[2]
  - ☐ Biomarker testing in early-stage NSCLC is indicated but quickly evolving. Practice-changing clinical trials have used biomarker testing (esp. EGFR, ALK, and PD-L1) to direct treatment (eg, with adjuvant osimertinib) or as inclusion/exclusion criteria (eg, for the use of neoadjuvant chemo-immunotherapy).[3-5]
- ☐ **Prioritize tissue-based comprehensive biomarker testing for advanced/metastatic NSCLC:** Ensure assay(s) are capable of comprehensive molecular testing for all biomarkers with FDA-approved therapies.
  - ☐ Comprehensive biomarker testing is generally defined as testing for all FDA-approved precision medicine treatments for which a patient is eligible.
  - ☐ Weigh factors such as local testing capacity/expertise, turnaround time, specimen transportation, and comprehensiveness of results in determining the testing laboratory (ie, in-house, outsourced) and assay(s).
  - ☐ Serum-based biomarker testing is establishing its role in directing the use of precision medicine therapies, and guidance on their use is also evolving. For instances in which tissue-based testing is incomplete or not feasible, serum-based testing should be strongly considered.[2] Notable weaknesses include the inability to assess PD-L1 score and lower sensitivity (ie, a negative serum biomarker testing would not adequately preclude an actionable mutation in comparison to a negative tissue biomarker panel).[2]
- ☐ **Communicate tissue requirements:** Ensure proceduralists, pathologists, and oncologists are aware of the laboratory and assay tissue quantity requirements and specimen handling.
  - ☐ In general, most labs have a description of the number and percentage of tumor cells required. Most labs accept formalin-fixed paraffin-embedded (FFPE) tissue samples, but a discussion about sample preparation will help optimize tissue use.[6]
- ☐ **Establish a collaborative ordering plan:** Establish a multidisciplinary plan to prevent ordering delays. You may want to consider identifying the responsible party, reflex testing, designating ordering providers, and electronic health record prompts. Compliance obstacles exist for pathologists to order biomarker testing, so care should be taken to manage these concerns if pathologist ordering is planned.[7, 8]
- ☐ **Ensure visibility of biomarker test results:** Results should reside in a uniform and easily visible place in the patient's health record.
- ☐ **Identify measurable metrics of biomarker testing:** Measuring metrics will enable the multidisciplinary team to evaluate and perform process improvements. Examples of metrics may include turnaround time intervals, number of unsuccessful or "quantity not sufficient" (QNS) specimens, number of eligible patients who receive testing, and measures of precision medicine therapies delivered to patients.
- ☐ **Create a multidisciplinary plan for process improvement and addressing barriers:** Plan to review measurable metrics and to discuss and troubleshoot any other obstacles experienced (eg, insurance, procedural availability, other causes of delay) in a multidisciplinary manner.
- ☐ **Establish a multidisciplinary communication process for updates:** With the recent pace of advances in lung cancer biomarkers and therapies, a communication plan to discuss how to incorporate changes in treatments (eg, new biomarkers, therapies, or indications) for patients is essential.

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**REFERENCES**