Lack of Pathology–Driven Reflexive Molecular Testing

Potential Action Items

- Develop and implement a reflexive molecular testing pathway
- Update process and policy to include:
  - — Simultaneous testing for EGFR & ALK
  - — Documentation of why EGFR & ALK were not completed
  - — Create process and tools for monitoring

Ideas for Process Improvement

Centers agreed that the use of a routine, upfront pathology-driven molecular testing pathway reduces delays and ensures that a greater percentage of appropriate biopsy samples will undergo molecular testing. The definition of "reflexive molecular testing" is evolving with the changing landscape of oncology treatment. (Note: reflex testing is a testing policy that does not require a separate clinician order for each case, is appropriate if agreed on by the lung cancer care team, and may help ensure expedited and consistent routing of specimens for molecular testing.)

Although some centers may use a sequential approach to reflexive testing for mutation markers (e.g., test for mutation #1, and if that is negative, then test for mutation #2, etc.), this approach may add unnecessary delays to the process. Hence, many centers are moving to a simultaneous testing approach (e.g., simultaneously test for mutation #1 and mutation #2) to minimize delays in obtaining potentially actionable test results. Some centers considered modeling similar pathways from their practice of reflexively testing for estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) status in breast cancer patients.

Most centers agreed that a lung needle biopsy sample that has an adenocarcinoma component should undergo EGFR and ALK testing at a minimum. Some felt that additional mutation markers could be actionable based on the 2014 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer.[1] Cancer centers also felt that the pathologist should not wait for disease staging information before sending the sample for molecular testing because this may add unnecessary delays.

Centers that developed and implemented a pathology-driven reflexive pathway formed an interdisciplinary task force to evaluate options and make recommendations to their leadership team. Centers that already had a reflexive molecular testing pathway agreed that they needed to further refine the process to ensure that biopsies were not being missed. These centers established an ongoing monthly process to track and measure how well their team of pathologists were following their reflexive pathway. Each time they discovered deviations from the pathway, they spent time discussing the reasons for those changes to explore whether additional refinements were necessary to their processes.

References

[1]Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer V.4.2014. ©2014 National Comprehensive Cancer Network, Inc. All rights reserved. Accessed October 29, 2014. To view the most recent and complete version of the guideline, go to www.nccn.org.