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International Lung Cancer Experts Seek Public Comments on Updated Molecular Testing Guideline to Improve Patient Selection and Targeted Therapies

ROCKVILLE, MD — August 22, 2024 — The College of American Pathologists (CAP), the International Association for the Study of Lung Cancer (IASLC), and the Association for Molecular Pathology (AMP) announced today the open comment period for the revised 2018 evidence-based guideline, "Updated Molecular Testing Guideline for the Selection of Lung Cancer Patients for Treatment With Targeted Tyrosine Kinase Inhibitors."

"Rapid advancements in adjuvant and neoadjuvant therapy for patients with early-stage non-small cell lung carcinoma make this revision essential to guide optimal patient care," said guideline update co-chair Sinchita Roy-Chowdhuri, MD, PhD, FCAP, Professor of Pathology at The University of Texas MD Anderson Cancer Center. "This revised guideline provides a clear framework based on evidence from recently published clinical literature."

The open comment period begins today and will close on September 12, 2024. The online format provides an opportunity for public review of new draft recommendations for several key topics, as well as recommendation statements that have been reaffirmed since the initial guideline was jointly published in 2013 and updated in 2018 online by *Archives of Pathology & Laboratory Medicine, The Journal of Thoracic Oncology,* and *The Journal of Molecular Diagnostics.* For more information and to provide comments, visit https://www.amp.org/opencomment/.

The guideline revisions are designed to provide state-of-the-art molecular testing of lung cancer recommendations for pathologists, oncologists, patient advocacy groups, and cancer and molecular diagnostic laboratory professionals. The revisions are all based on evidence from an unbiased review of published experimental literature since 2018 and include the recommendations from an expert panel of renowned worldwide leaders in the field. The final recommendations will be approved and jointly published after consideration of the public comments, further panel discussion, and a complete evidence analysis.

"The revised guideline addresses next-generation sequencing and expanded biomarker testing for patients with non-squamous non-small cell lung carcinoma participating in other clinical trials," said guideline update co-chair Sanja Dacic, MD, PhD, FCAP, Professor of Pathology at Yale School of Medicine. "We strongly encourage our peers to provide feedback to ensure our draft recommendations are sound, practical, and implementable, supporting best clinical practices and optimal patient care."

"The final manuscript will serve as both an update and extension of the 2013 and 2018 practice guidelines that established evidence-based best practices for molecular biomarker testing for patients diagnosed with lung adenocarcinoma," said Neal I. Lindeman, MD, guideline update co-chair, the Faculty Distinguished Professor of Pathology and Laboratory Medicine II at Weill Cornell Medicine. "We will continue to update this guideline as appropriate, and we will add guidelines for other biomarkers associated with lung cancer as medical knowledge and clinical practice continue to advance."

Together with a multi-disciplinary expert panel, co-chair Drs. Roy-Chowdhuri, Dacic, and Lindeman formulated new draft recommendations addressing the following key questions:

- In patients with NSCLC being considered for molecularly targeted therapies, does biomarker testing improve treatment response rates and survival rates?
- In patients with NSCLC being considered for molecularly targeted therapies, what histopathologic and clinical characteristics should be used to select patients for molecular testing?
- In patients diagnosed with lung cancer without an adenocarcinoma component or NSCLC NOS and being considered for molecularly targeted therapies, does biomarker testing improve treatment response rates, survival rates, or diagnostic accuracy?
- When conducting lung biomarkers testing, what are the diagnostic test characteristics of the available assays?
- In patients with NSCLC who have progressed while undergoing treatment with molecularly targeted therapies, should biomarker testing be utilized to guide the next line of therapy?
- In patients with NSCLC who have progressed while undergoing treatment with molecularly targeted therapies, what are the preferred resistance mutation detection assays?
- In patients with NSCLC undergoing treatment with molecularly targeted therapies, should molecular testing be used to monitor for progression?

In conjunction with updating the guideline, CAP, IASLC, and AMP will develop clinical tools and resources for pathologists and oncologists that summarize the findings and recommendations. The organizations expect to develop a patient guide for further understanding, including questions for patients to ask their physicians.

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About the College of American Pathologists (CAP)

As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. For more information, visit the CAP Newsroom, CAP.org and yourpathologist.org to watch pathologists at work and see the stories of the patients who trust them with their care.

About the International Association for the Study of Lung Cancer (IASLC)

The International Association for the Study of Lung Cancer (IASLC) is the only global organization dedicated to studying lung cancer and other thoracic malignancies. Founded in 1974, the association's membership includes more than 11,000 lung cancer specialists across all disciplines in over 100 countries, forming a global network working together to conquer lung and thoracic cancers worldwide. The association also publishes the *Journal of Thoracic Oncology*, the primary educational and informational publication for topics relevant to preventing, detecting, diagnosing, and treating all thoracic malignancies. Membership is open to any physician, scientist, nurse or allied health professional interested in lung cancer and other thoracic malignancies, including patients, survivors, caregivers, and advocates. Visit www.iaslc.org for more information and follow us on X @IASLC.

About the Association for Molecular Pathology (AMP)

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,900+ members practice various disciplines of molecular diagnostics, including bioinformatics, infectious diseases, inherited conditions, and oncology. Members are pathologists, clinical laboratory directors, basic and translational scientists, technologists, and trainees who practice in various settings, including academic and community medical centers, government, and industry. Through the efforts of its Board of Directors, Committees, Working Groups, and Members, AMP is the primary resource for expertise, education, and collaboration in one of the fastest-growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high-quality, appropriate testing. For more information, visit www.amp.org and follow AMP on X: @AMPath.