COLLEGE of AMERICAN PATHOLOGISTS

Center Guideline Insider

PATHOLOGY AND LABORATORY QUALITY CENTER FOR EVIDENCE-BASED GUIDELINES May 2024

PD-L1 and TMB Testing of Patients With Lung Cancer for Immunooncology Therapies

The "PD-L1 and TMB Testing of Patients With Lung Cancer for Immunooncology Therapies" guideline from the College of American Pathologists, Association for Molecular Pathology, International Association for the Study of Lung Cancer, Pulmonary Pathology Society, and LUNGevity Foundation was published on April 16, 2024, as an early online release in *Archives of Pathology & Laboratory Medicine* and the *Journal of Clinical Oncology.*

The guideline recommends using a validated PD-L1 immunohistochemistry (IHC) assay, along with other genomic biomarker assays, to optimize selection for immune checkpoint inhibitors (ICI) in advanced non-small cell lung cancer (NSCLC). It emphasizes proper validation of specimen types and fixatives, recommending clinically validated PD-L1 IHC assays when possible. Pathologists opting to use laboratory developed tests (LDTs) should validate them according to their accrediting body requirements. Furthermore, pathologists are advised to report PD-L1 IHC results using a percent expression score.

The guideline does not support clinicians' use of tumor mutational burden (TMB) alone to select patients with advanced NSCLC for ICI.

Visit the guideline webpage to review the guideline and additional resources and check out the PD-L1 Pathologist-to-Pathologist blog post by Guideline Chairs' Larissa Furtado, MD, FCAP and Lynette Sholl, MD, FCAP on CAP.org.

Center Mission

The CAP Pathology and Laboratory Quality Center for Evidence-based Guidelines (the Center), along with our professional partners, is advancing the specialty of pathology and laboratory medicine by bringing evidence-based medicine to the forefront of clinical decision making.

The Center helps pathologists and other clinicians make more informed decisions about diagnosis and optimal treatment, and places emphasis on the pathologist's role on the patient care team.

Advance the Specialty

Prepare pathologists for future roles

Strengthen the practice of pathology

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Workup of Amyloidosis: OPEN COMMENT PERIOD

The Workup of Amyloidosis Guideline draft recommendations were available for public comment from March 13 to April 3, 2024. 214 respondents reviewed the recommendations and submitted over 200 comments.

Guideline	Project Phase
Human Papillomavirus (HPV) Testing in Head & Neck Carcinomas (Updating 2017 publication)	Draft Manuscript
Workup of Amyloidosis	Open Comment Period
Molecular Testing Guideline for the Selection of Lung Cancer Patients for Treatment with TKI (Updating 2018 publication)	Draft Recommendations
Lower Anogenital Squamous Terminology for HPV-associated Lesions (Updating 2012 publication)	Research and Review
Interpretive Diagnostic Error Reduction: Guideline Update (Updating 2015 publication)	Research and Review
Gastroenteropancreatic Neuroendocrine Tumors and Ki-67	Research and Review
Evaluation of Measurable Residual Disease in Acute Lymphoblastic Leukemia	Determine Scope and Form Panel
Molecular Biomarkers for the Evaluation of Colorectal Carcinoma: Guideline Update (Updating 2017 publication)	Determine Scope and Form Panel – Submit an application
HER2 Testing and Clinical Decision Making in Gastroesophageal Adenocarcinoma: Guideline Update (Updating 2016 publication)	Determine Scope and Form Panel – Submit an application
Initial Diagnostic Workup of Acute Leukemia (Updating 2017 publication)	Determine Scope and Form Panel – Submit an application

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Did you know?

The CAP collaborates and partners with other medical societies such as the Association for Molecular Pathology (AMP) and the American Society of Clinical Oncology (ASCO) to develop select guidelines. These joint endeavors integrate diverse perspectives and expertise as well as facilitate endorsement and dissemination of guidelines to a broader audience.

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