

Ensuring Access to Evidence-based Biomarker Testing for Patients with Cancer

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Objectives for Today's Presentation

- Orientation to the role of clinical practice guidelines
- Overview of guideline adherence as a cost-saving and quality improvement tool
- Overview of mechanisms to navigate the evidence in biomarker testing
- Overview of NCCN Biomarker Compendium as a health policy tool to ensure policy stays evergreen

NCCN Mission and Vision

Who We Are

An alliance of leading cancer centers devoted to patient care, research, and education

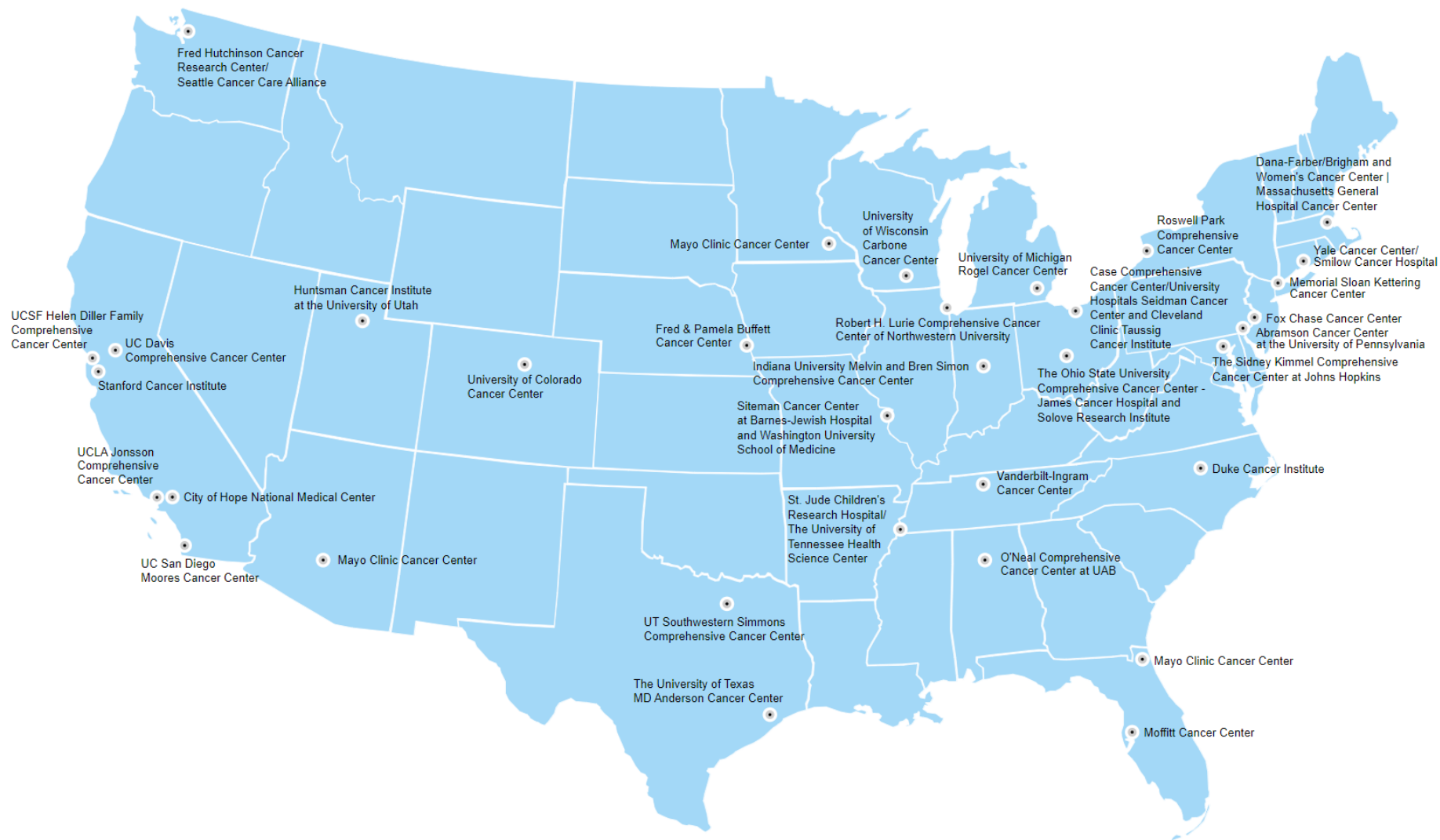
Our Mission

To improve and facilitate quality, effective, equitable, and accessible cancer care so all patients can live better lives

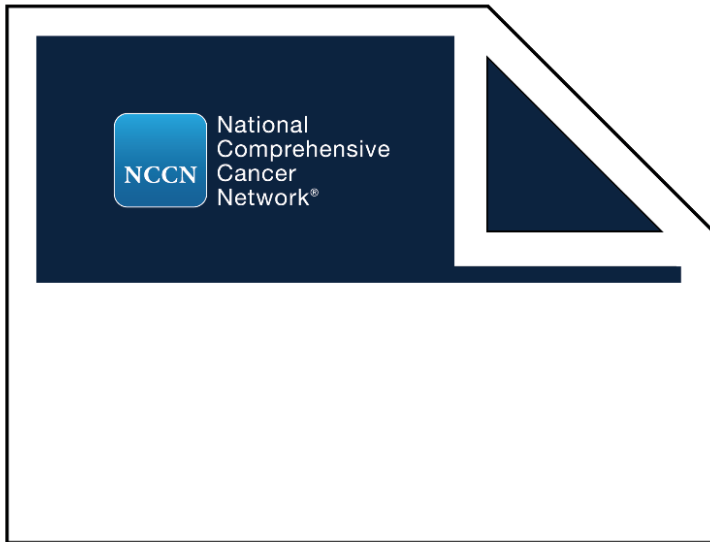
Our Vision

To define and advance high-quality, high-value, patient-centered cancer care globally

NCCN Member Institutions



NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)



- 84 NCCN Guidelines® apply to 97% of cancer cases in the United States
- 13 million downloads across web-based and mobile applications in 2021
- The most thorough and most **frequently updated** clinical practice guidelines available in any area of medicine
- Widely available free of charge for non-commercial use

NCCN Guidelines® Expertise

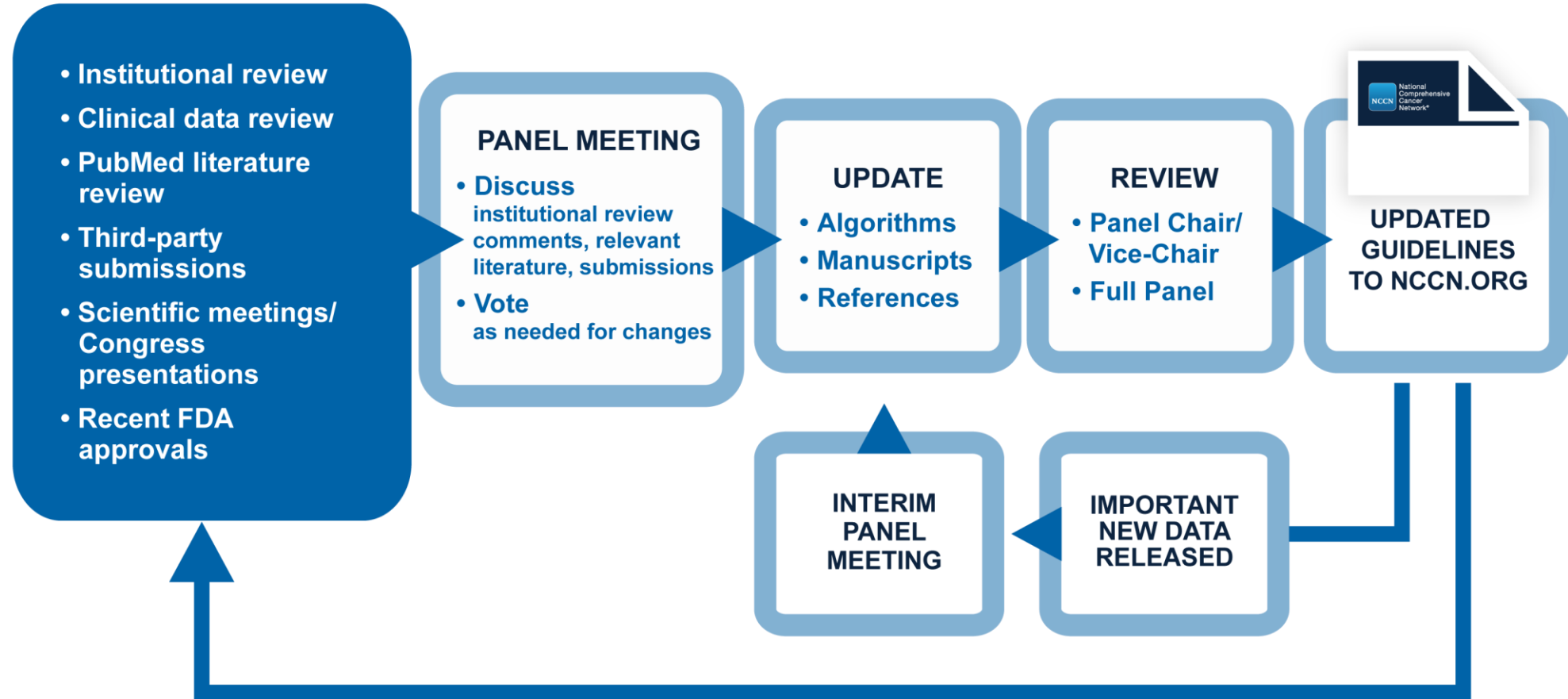


- Each of 61 NCCN Guidelines Panels has 32 to 35 experts.
- More than 1,700 Panel Members participate in developing and updating NCCN Guidelines.
- It is estimated that NCCN Guidelines Panel Members contributed more than 40,000 hours in 2021.

NCCN Guidelines[®] Multidisciplinary Panels

- Medical oncology
- Surgery/Surgical oncology
- Radiation oncology
- Hematology/Hematology oncology
- Bone Marrow Transplantation
- Urology
- Neurology/Neuro-oncology
- Gynecologic oncology
- Otolaryngology
- Orthopedics/Orthopedic oncology
- Pathology
- Dermatology
- Internal medicine
- Gastroenterology
- Endocrinology
- Diagnostic Radiology
- Interventional Radiology
- Nursing
- Cancer genetics
- Psychiatry, psychology
- Pulmonary medicine
- Pharmacology/Pharmacy
- Infectious diseases
- Allergy/Immunology
- Anesthesiology
- Cardiology
- Geriatric medicine
- Epidemiology
- Patient advocacy
- Palliative, Pain management
- Pastoral care
- Oncology social work

NCCN Guidelines® Development



Concurrent development and production of NCCN Guidelines derivative products

NCCN Guidelines[®] Firewall

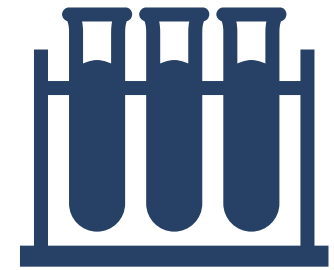
- NCCN imposes strict policies to shield the guidelines development processes from external influences
- The “firewall” surrounding the NCCN Guidelines processes includes:
 - financial support policies
 - panel participation and communication policies
 - guidelines disclosure policies
 - and policies regarding relationships to NCCN’s other business development activities
- NCCN does not accept any form of industry or other external financial support for the guidelines development program.
- The guidelines development is supported exclusively by the Member Institutions’ dues.

Public and Private Payer Use of NCCN Content

- NCCN content is used by payers representing more than 85% of covered lives in the United States
- CMS has recognized the NCCN Drugs and Biologics Compendium[®] since 2008
- Medicare Administrative Contractor (MAC) use of NCCN Biomarker Compendium
 - National Government Services, Inc.: LCD Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms
 - Novitas and First Coast: Proposed LCD Genetic Testing for Oncology
- CVS Transform Oncology Care Model
- Referencing NCCN as an evidence base ensures the coverage remains evergreen

Navigating the Evidence: Analytic Validity vs. Clinical Utility

- **Analytical validity:** How well does the test predict the presence or absence of a particular biomarker? Does the test accurately test what it says it tests for?
- **Clinical Utility:** Does the biomarker you are testing for provide information that will or guide treatment or risk-reducing interventions? In other words, **does testing for this biomarker matter?**



NCCN Biomarkers Compendium®

- Contains information designed to support decision-making around the use of biomarker testing in patients with cancer.
- Updated in conjunction with the [NCCN Guidelines](#) on a continual basis.
- Includes tests that measure changes in genes or gene products and which are used for the following :
 - Diagnosis
 - Screening
 - Monitoring
 - Surveillance
 - Prediction
 - Prognostication

NCCN Biomarkers Compendium Results (1)

Options

Use the drop-down menus to search the database:

Guideline:
 Disease:
 Gene Symbol:
 Gene Alias:
 Molecular Abnormality:



Fields to display/hide:

- Specific Indication
- Test
- Test Detects
- Methodology
- Chromosome
- Test Purpose
- When to Test
- Guideline Page
- Notes
- Specimen Type
- Display All

Reset Filters 0 Ready to Print

Filters: Non-Small Cell Lung Cancer v.1.2022 > Non-Small Cell Lung Cancer > ALK

NCCN Biomarkers Compendium® Table of Contents

Default Sort Showing 1 to 2 of 2 entries

Guideline - Disease	Specific Indication	Molecular Abnormality	Gene Symbol	Test Detects	Methodology	NCCN Category	NCCN Recommendation	Test Purpose	When to Test	Guideline Page	Notes
Non-Small Cell Lung Cancer	Adenocarcinoma, Large cell, NSCLC NOS	ALK gene rearrangement	ALK	Gene rearrangement	FISH, IHC, RT-PCR, Next generation sequencing	1	Stage IVA, M1a: pleural or pericardial effusion; M1b Advanced or metastatic disease: Adenocarcinoma, Large Cell, NSCLC not otherwise specified (NOS) Molecular testing, including: <ul style="list-style-type: none"> EGFR mutation (category 1), ALK (category 1), KRAS, ROS1, BRAF, NTRK1/2/3, MET ex14 skipping, RET Testing should be conducted as part of broad molecular profiling read less	Predictive	Workup for Metastatic Disease	NSCL-13 NSCL-14 NSCL-18 NSCL-H 4 of 7	The NCCN NSCLC Guideline panel strongly advises broader molecular profiling with the goal of identifying rare driver mutations for which effective drugs may already be available, or to appropriately counsel patients regarding the availability of clinical trials. Broad molecular profiling is defined as molecular testing that identifies all biomarkers identified in NSCL-19, in either a single assay or a combination of a limited number of assays, and optimally also identifies emerging biomarkers (NSCL-I). Tiered approaches based on low prevalence of co-occurring biomarkers are acceptable. Broad molecular profiling is a key component of the improvement of care of patients with NSCLC. The presence of an ALK rearrangement is associated with responsiveness to oral ALK TKIs. read less
Non-Small Cell Lung Cancer	Squamous cell carcinoma	ALK gene rearrangement	ALK	Gene rearrangement	FISH, IHC, RT-PCR, Next generation sequencing	2A	Stage IVA, M1a: pleural or pericardial effusion; M1b Advanced or metastatic disease: Squamous cell carcinoma. Consider molecular testing, including: <ul style="list-style-type: none"> EGFR mutation, ALK, KRAS, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping, RET Testing should be conducted as part of broad molecular profiling read less	Predictive	Workup for Metastatic Disease	NSCL-13 NSCL-14 NSCL-18 NSCL-H 4 of 7	The NCCN NSCLC Guideline panel strongly advises broader molecular profiling with the goal of identifying rare driver mutations for which effective drugs may already be available, or to appropriately counsel patients regarding the availability of clinical trials. Broad molecular profiling is defined as molecular testing that identifies all biomarkers identified in NSCL-19, in either a single assay or a combination of a limited number of assays, and optimally also identifies emerging biomarkers (NSCL-I). Tiered approaches based on low prevalence of co-occurring biomarkers are acceptable. Broad molecular profiling is a key component of the improvement of care of patients with NSCLC. The presence of an ALK rearrangement is associated with responsiveness to oral ALK TKIs. read less

Study Finds Majority of Coverage Policies More Restrictive than Guidelines

- A 2022 study by Sapotka et al evaluated commercial payer coverage policies of multi-gene panel tests and compared the policies with NCCN Guideline recommended testing in NSCLC, Metastatic Breast, Metastatic Colon, and Advanced Melanoma.
- Evaluated publicly available coverage policies for cancer somatic testing among the largest payers in each state from July 2021 to November of 2021
- The authors conclude 71% of plans/policies were classified as 'more restrictive' than the guidelines.

State-level distribution of fully insured commercial lives by alignment of coverage policies to guidelines.

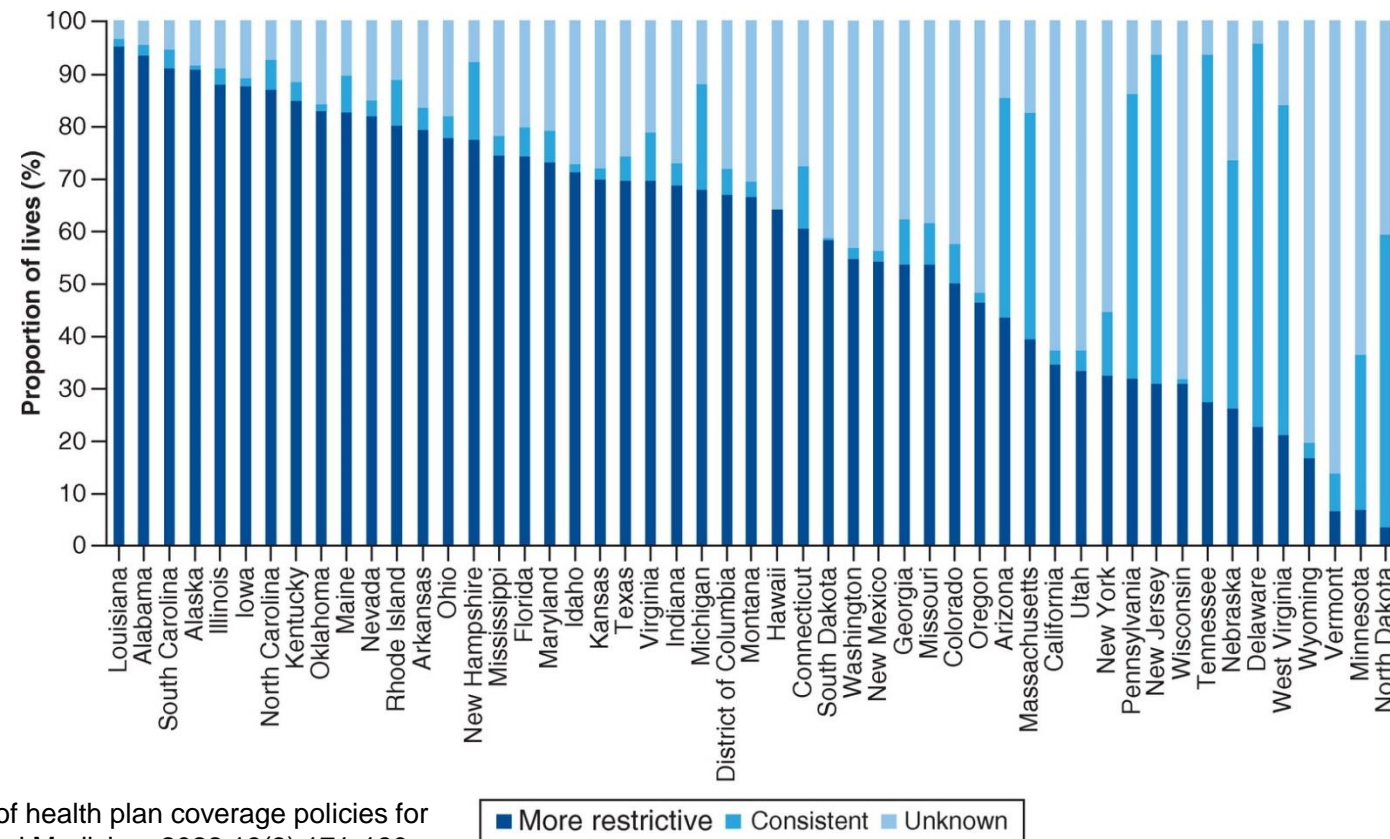


Chart and information derived from: Wong WB, Anina D, Lin CW, Adams DV. Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors. *Personalized Medicine*. 2022;19(3):171-180.

doi:10.2217/pme-2021-0174

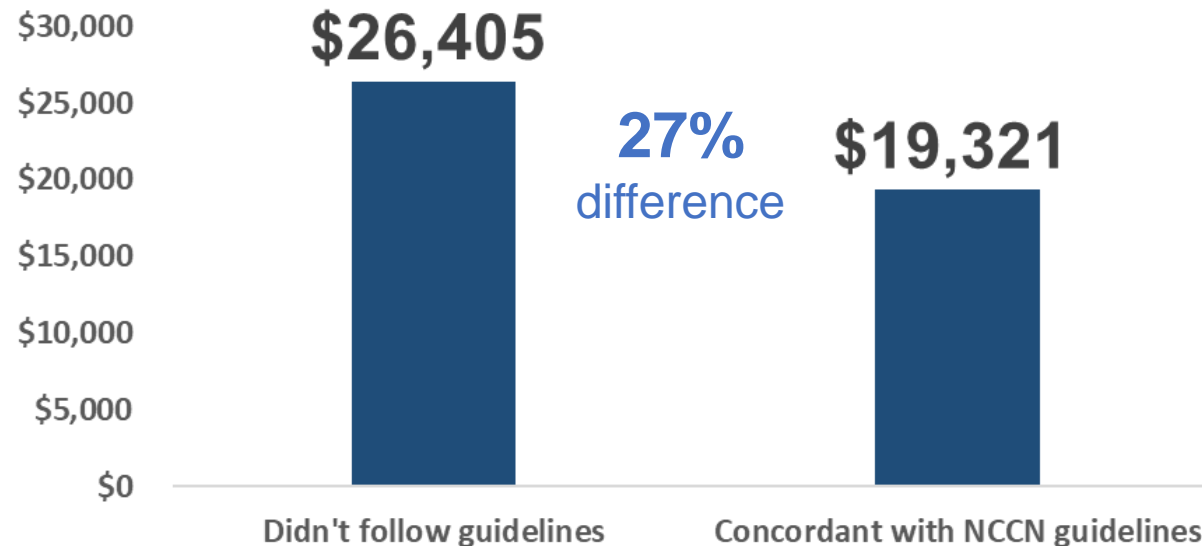
Study: Guideline Adherence Reduces Costs in NSCLC

Study evaluated 2,690 members of a Medicare Advantage plan who were NSCLC patients during the first half of 2020. (CVS Health)

Novologix decision support technology (CVS Health) improved treatment concordance with NCCN guidelines from **60% to 81%**

Brito, Managed Healthcare Executive, May 21, 2021

Total cost of care for NSCLC

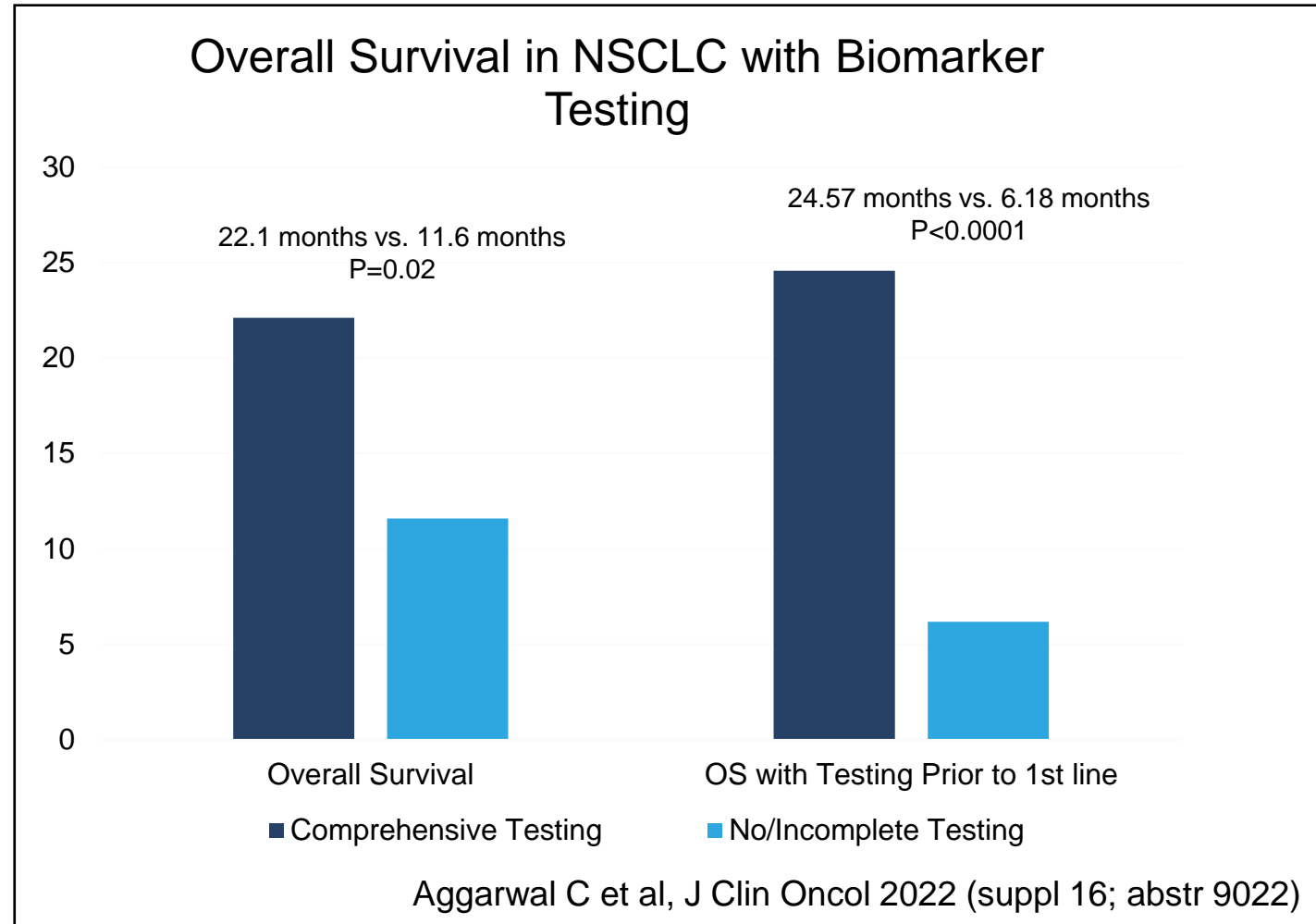


81% of Medicare Advantage plan members were “NCCN concordant”

Yeon et al. J Clin Oncol 39(15):s1522, 2021 <https://meetings.asco.org/abstracts-presentations/200123>

Guideline-Concordant Biomarker Testing and Survival in NSCLC

- Single institution retrospective cohort study
 - Newly diagnosed stage IV NSCLC patients 12/2019-12/2020
- Comprehensive testing
 - All recommended biomarkers per NCCN Clinical Practice Guidelines
- Median survival increased with guideline-concordant testing
 - Difference likely mediated by delivery of targeted therapy
- Hypothesis-generating



Summary

- Adherence to clinical practice guidelines has been proven to improve quality of care, overall survival, and quality of life, while also reducing costs to payers and patients.
- Coverage of biomarker testing is variable across payers and the science is rapidly evolving.
- Health policies should cite sources of evidence that are continuously updated to ensure the policy stays evergreen as the science advances.
- There are tools available to ensure patients are accessing biomarker testing that offers clinical utility to meaningfully guide and improve their treatment and care outcomes.