

#### **Overview:**

The American Cancer Society Cancer Action Network (ACS CAN) conducted this nationwide survey of providers who have a role in the screening, diagnosis, and treatment of cancers to better understand their experiences and challenges with biomarker testing. The survey was conducted online July 22 to October 8, 2021 among 315 oncology providers. The survey findings provide important insights into the experiences of providers regarding the use of biomarker testing and illuminate key areas for improvement to optimize the potential of biomarker testing to impact patient care.

Respondents are primarily oncologists (81%), but to fully capture the range of experiences related to biomarker testing, other providers with direct involvement in decisions related to ordering, interpreting, or applying the results are also included. Registered nurses and advanced practice providers comprise 10% of the sample, surgeons another 5%, pathologists 2%, with other specialists such as urologists and pulmonologists completing the sample. Forty-one percent practice in an academic setting while 59% practice primarily within a community site. The margin of error for a sample of this size is +/-5.5%.

## **Key Findings:**

Key findings from the survey include:

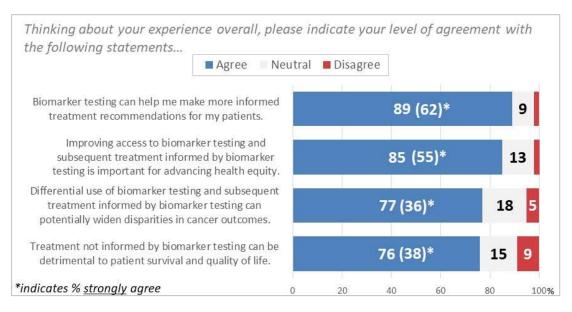
- **Providers agree biomarker testing offers important benefits.** In addition to enabling better informed treatment recommendations, majorities further agree that improving access to biomarker testing can reduce disparities and advance health equity.
- The majority of patients who need a biomarker test are getting one. While 68% say over threequarters of appropriate patients receive the tests, this leaves room for expanded use of biomarker testing.
- Patient concerns about cost and coverage are seen as key barriers, along with the availability of adequate samples. Two-thirds report that patient insurer coverage for a desired biomarker test is a significant or moderate barrier.
- Lab turnaround time is seen as a significant barrier to optimal use of biomarker testing. Addressing insurance-related delays could shorten the time between ordering tests and receiving actionable results.
- Insurance obstacles are the most frequently mentioned concern in an open-ended question, followed by the need for provider education and support. Additionally, enacting better coverage policies is seen as one of the most important ways to improve providers' ability to test patients for biomarkers.



# **Detailed Survey Findings:**

## Providers Agree Biomarker Testing Offers Important Benefits

The idea that biomarker testing can help providers make more informed treatment recommendations is met with resounding agreement. Nearly nine-in-ten providers agree with this statement and 62% *strongly* agree. Furthermore, 85% agree that improving access to biomarker testing and subsequent treatment informed by biomarker testing is important for advancing health equity. Over three-quarters of providers also recognize that differential use of biomarker testing can potentially widen disparities, and that treatment not informed by biomarker testing can be detrimental to patient survival and quality of life.



# Figure 1: Biomarker Testing Offers Important Benefits

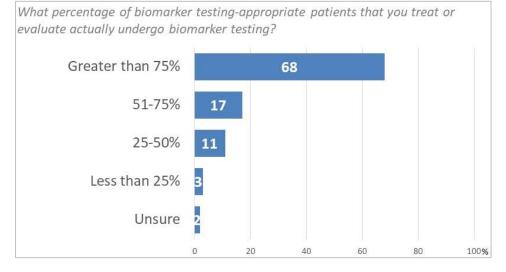
# Majority of Patients Who Need a Biomarker Test Get One, With Potential for Expanded Use

A majority of providers say that over 75% of their patients who are appropriate for biomarker testing receive one. However, 14% say that only half or fewer of appropriate patients are tested and another 17% of providers estimate the number to be 51-75%, demonstrating greater potential for more patients' care to be informed by biomarker testing.

Providers report that multi-marker panel testing is the most frequently used test type (90%), while many use multiple additional test types as well. Nearly two-thirds report using staining for protein expression, while single-analyte (48%), whole genome (39%) and whole exome (33%) are used less frequently. While a majority (52%) use a combination of in-house and outsourced labs for analysis, there are some differences between those practicing in academic versus community sites. Academic sites are almost twice as likely to rely solely on an in-house lab than community-based providers (15% compared to 8% of community sites), while community sites are more likely to rely solely on outsourcing (43% vs. 22% of academic sites). However, the plurality of both groups use some combination of in-house and outsourced analysis (62% academic, 47% community).



# Figure 2: Majorities of Appropriate Patients Receive Biomarker Tests



Most often, the oncologist or provider who is primarily responsible for the patients' treatment orders biomarker testing (92%), but often there may be additional roles involved as well. Thirty-seven percent say pathologists order biomarker testing at their practice, while 32% cite a surgeon or surgical oncologist. One-in-five (20%) say testing is initiated reflexively. Those who cite 'informing clinical trial eligibility' as a reason for conducting biomarker testing (further discussed below) are most likely to report that tests are completed reflexively or automatically at their practice (23% versus 16% of those who don't mention trial participation).

Biomarker testing is more often conducted at the initial diagnosis of or progression to advanced/metastatic disease (88%). Nearly all (94%) practicing at academic sites initiate biomarker testing at this point. Additionally, most identify several other points at which biomarker testing may also be ordered, including at initial diagnosis of local disease (71%), at progression of metastatic disease after first line treatment (62%), at recurrence of local disease (56%), and during monitoring and therapeutic drug response (34%).

This timing aligns with the primary reason cited for biomarker testing, which is to inform the immediate line of therapy (86%). Many providers cite multiple additional reasons for ordering biomarker testing, such as to inform future lines of therapy (74%), and to inform avoidance of therapies less likely to be effective or to which the tumor may be resistant. As mentioned above, informing clinical trial eligibility is also seen as a reason to conduct biomarker testing, cited by 52% of providers. Unsurprisingly, clinical trial participation is a bigger driver at academic sites, where 55% of providers point to identifying trial eligibility as a reason for conducting biomarker testing, compared to 33% of community-based providers.

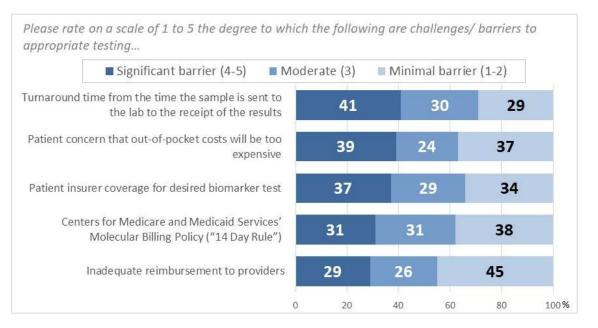
Clinical practice guidelines are the most frequently consulted resource in deciding whether to recommend or order testing, cited by 91%, but peer-reviewed literature (66%) and guidelines or protocols established by the providers' practice, health system, or institution are also important (49%). National Comprehensive Cancer Network (NCCN) (87%) and American Society of Clinical Oncology (ASCO) (72%) are the most



heavily relied-upon clinical practice guidelines for this audience. When it comes to keeping up with the latest information and recommendations for biomarker testing, Peer reviewed publications/journals are the top source (79%), followed by medical conferences (70%), continuing education (64%), and professional societies (50%).

## Lab Turn-Around Time, Cost and Coverage Issues, and Sample Requirements Are Top Barriers

The survey assessed fifteen potential barriers or challenges to optimal use of biomarker testing, and the turnaround time to receive results from the lab was ranked as the most significant barrier, with 71% saying the timeline is at least a moderate barrier to appropriate testing and 41% a significant barrier. Fifty-six percent report that they have initiated non-targeted systemic therapy while awaiting results from the lab performing the test. Several cost and coverage issues were also seen as significant barriers, including patient concerns about out-of-pocket costs (39%), patient insurer coverage for desired biomarker testing (37%), the "14 Day Rule" (31%), and inadequate reimbursement to providers (29%).



## Figure 3: Top Barriers

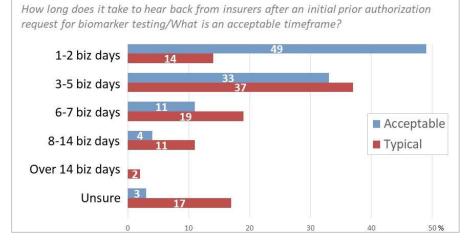
Concerns related to the samples needed for biomarker testing are also important, with 37% ranking tissue *quantity* as a significant barrier (70% moderate or greater barrier), and 30% saying tissue *quality* is a significant barrier (66% moderate or greater barrier). Also noteworthy, more than half of providers (53%) ranked staying current with the latest guidelines in biomarker testing for the cancers they treat as at least a moderate barrier (26% significant), and 55% said assessing the quality of different biomarker tests is a barrier (20% consider this a significant barrier).

## Insurance Delays Offer Potential to Reduce Timeline Barrier

Seventy-eight percent of providers report that prior authorization is required at least some of the time with the insurers they interact with, and a plurality of 46% say it is required most of the time or always.



Just 13% say it is rarely or never required. While 37% say they typically receive a response to their initial prior authorization request within three to five business days, 49% say that one to two days is the acceptable timeframe to hear back from insurers (just 14% report a typical response time of 1-2 days). Nearly a third (32%) report that it typically takes six to fourteen days or more to receive the insurer's response to the initial prior authorization request.



#### Figure 4: Response Time

Half of those surveyed report that they have initiated non-targeted systemic therapy due to prior authorization obstacles. While 29% have done so because it took too long to hear back from an insurer, another 21% initiated non-targeted therapy because their prior authorization request for biomarker testing was denied. Fortunately, a majority (57%) report that fewer than 25% of their prior authorization requests are denied, however 15% say at least a quarter up to half of their requests are denied and another 10% say that more than half of their prior authorization requests are denied, demonstrating the need for better coverage of biomarker testing.

#### Provider Wish List: Better Tissue Sampling, Automatic Ordering, and Better Coverage of Tests

When asked to select the top three things that would best improve their ability to test patients for biomarkers, the top responses reflect the key barriers identified above. Better sampling of tissue and the ability to have testing ordered reflexively or automatically, potentially reducing the provider burden of keeping current with the latest guidelines, are each cited by 46% as the best improvements from a list of options. Better coverage policies for the tests that are needed is similarly important, selected by 43%. Six other options were chosen as a top improvement by at least one out of five providers, with better awareness of which tests to use (30%) and better/more consistent reimbursement of tests to the provider or practice (29%) next most important.

Echoing the cost and coverage concerns identified as barriers and top areas for improvement, when given the opportunity to report the top issues or challenges related to biomarker testing in an open-ended question, insurance concerns top the list with 18% of verbatim comments mentioning insurance obstacles. Provider education, support, and ease of information is the second most frequently mentioned category



of comments at 12%, with nearly as many (11%) mentioning the turnaround time or delays to receive results before they can be applied to patient care.

#### Representative comments regarding insurance obstacles (18% of open-ended responses):

"I think the current situation is that the budget for reimbursing test expenses is somewhat insufficient."

*"Insurance providers need a better understanding of the literature justifying using biomarkers."* 

"Insurance coverage is formidable."

#### Representative comments regarding provider education & support (12% of open-ended responses):

"Better provider education necessary."

"Difficult to keep up to date with advancing biomarkers."

*"I need better clinical decision support and infrastructure optimization, which can improve my work confidence and efficiency."* 

#### Representative comments regarding turnaround time (11% of open-ended responses):

"The delays for test results seem long."

"Ensure a quick turnaround time so there are no delays in care."

"The technology needs improvement to make results more readily available for testing to become more feasible at the point of care."

# About ACS CAN

The American Cancer Society Cancer Action Network (ACS CAN) is making cancer a top priority for public officials and candidates at the federal, state and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is critical to the fight for a world without cancer. For more information, visit www.fightcancer.org.

ACS CAN worked with ACS colleagues to distribute the survey to ACS health system partners, the ACS Lung Cancer Biomarker Testing ECHO Series, the National Lung Cancer Roundtable, and cancer center directors, as well as with the Association of Community Cancer Centers (ACCC). Funding for the survey was provided by Amgen, Bayer, EMD Serono, Foundation Medicine, NeoGenomics, and Pfizer.