Biomarker-Driven Cancer Care Is Not Reaching All Americans

BY PEGGY EASTMAN

As the targeted therapies of precision medicine continue to improve cancer outcomes, oncologists are increasingly basing treatments on specific biomarkers rooted in cancer biology, not site of origin.

"We're rapidly moving toward tissue-agnostic drug approvals based on the biology of the tumor," said William G. Cance, MD, Chief Medical and Scientific Officer of the American Cancer Society (ACS).

Speaking at the virtual National Forum on the Future of Health Care sponsored by the ACS Cancer Action Network (CAN)—the ACS nonprofit advocacy affiliate—Chance said that given this important paradigm shift it is vital to ensure equity in cancer care, so that all Americans can share in the progress and promise of precision medicine. But, he noted, that promise has yet to be realized.

Biomarker Statistics

According to statistics on cancer biomarker testing for 2019 released at the forum, targeted cancer therapies accounted for about 25 percent of the targeted drug approvals by the FDA; cancer therapies made up 30 percent of the late-stage development pipeline, primarily driven by targeted therapies; FDA approved the third tissue-agnostic targeted therapy for use in treating cancer types that have the same genetic biomarker regardless of where the cancer starts in the body; and FDA approved or cleared seven new diagnostics that help identify patients for targeted therapy.

Especially noteworthy was the June 2020 FDA accelerated approval of pembrolizumab for adults and children with unresectable or metastatic tumor mutational burden-high (TMB-H) solid tumors, as determined by an FDA-approved test. The drug is for patients with the TMB-high biomarker (10 or more mutations/megabase) who have progressed following prior treatment and have no other treatment alternatives. It is to be used with the FDA-approved companion diagnostic FoundationOne CDx assay.

But despite these advances in biomarker-driven cancer care, many cancer patients are not receiving the biomarker testing of their tumors indicated by professional guidelines. In a cohort of more than 3,000 cancer survivors, ACS CAN surveys (Survivor Views) found that:

- only 39 percent of respondents reported having their tumor tested;
- about one in eight respondents indicated that biomarker testing was not covered by their health insurer; and
- some 15 percent of respondents who received biomarker testing indicated that they had paid $500 or more out-of-pocket for their testing.

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Testing Advances & Issues

"The age of tissue-agnostic approvals is upon us," said David Fabrizio, PhD, Vice President of Translational Strategy at Foundation Medicine. It makes sense scientifically to define the cancer according to the biology of its origin, not where it occurs in the body, he said. But he also noted that most patients do not have health insurance that covers comprehensive genomic profiling.

"We remain optimistic that we are at a tipping point," said Fabrizio, stating that his company's goal is for every patient to have access to cancer biomarker testing.

"We see lung cancer as somewhat of a poster child for precision medicine," said Kristen Santiago, MS, Senior Director of Public Policy Initiatives at the LUNGevity Foundation. She noted that, while many lung cancer patients will have biomarker-driven cancers, most are treated in the community, and there is an access gap between the clinic and patients getting the appropriate testing, followed by therapy based on that testing.

"Patients are confused; they should not have to know what kind of testing they should have," she said. "People's access to genetic testing should not be dependent on where they live and what their insurance is."

"It is marvelous to see an increasing number of pan-cancer markers," said Phil Febbo, MD, Chief Medical Officer at Illumina, Inc. However, he believes much more professional and patient education on the role of biomarkers in improving diagnosis and treatment is needed.

While insurance coverage is "critical and necessary," he noted that it is not the only factor in ensuring access to biomarker testing. Many physicians in practice are not familiar with biomarker testing, and Febbo said "it seems like a bit of a black box." Physicians have very little time, so precision medicine reports and information in plain language need to be integrated into their decision-making, he stressed. Specific biomarkers may apply only to small groups of cancer patients, but Febbo also noted that "even though these are infrequent, they're very powerful and they need to be identified."

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>
> *—Kristen Santiago, MS, Senior Director at the LUNGevity Foundation*

The education gap in biomarker testing "has multiple layers," said Michelle Shiller, MD, Molecular Pathologist with PBM/PathGroup & Co. and Co-Medical Director for Genetics at Baylor Scott & White Health. She noted that such education—which includes knowing about biomarker testing availability—is especially needed at the community level. In addition to closing gaps in education, Shiller stressed the importance of improving insurance coverage of biomarker testing.

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"The reimbursement lags very far behind." She recommended that early on, when a new biomarker test is approved, there should be discussions on its use among health providers and payers so that "everyone is on the same page" as to what is best for patients.

Other speakers agreed with Shiller on the need for better reimbursement for biomarker testing so precision medicine therapies can be based on that testing and integrated into clinical practice.

"Too few people are receiving these therapies," said Krishna Komanduri, MD, Medical Director of the Adult Stem Cell Transplant Program at the University of Miami Health System. "We see remarkable differences in rates of utilization," said Komanduri, who is also inaugural Chief of the Division of Transplantation and Cellular Therapy. "Coverage does not equal reimbursement," such that many centers lose money on CAR T-cell therapy, for example. Komanduri said incentives are needed to develop innovative and transformative therapies in the field of precision medicine, and transparency is needed on their costs and benefits.

"Our system wasn't designed for one-time potentially curative therapies," said Vadim Lubarsky, MBA, Executive Director for CMS Policy and Reimbursement at Novartis. "That holistic viewpoint isn't generally appreciated. It's really hard being first. Our health care system really isn't designed to deal with firsts and unknowns."

Lubarsky advocated modernizing U.S. health care system reimbursement in a way that recognizes the coming pipeline of potentially transformative therapies and keeps Medicare Part B out-of-pocket costs predictable.

Agreeing was Kerry Weems, MBA, Executive Chairman of the Value-Based Healthcare Investors Alliance, as well as Chairman and CEO of Mycroft Bioanalytics. "How do you price a cure?" asked Weems. "We don't have the statutory means to price a cure. There a lot of people standing in line for coverage decisions" from CMS, but the agency has no way of setting priorities in its coverage queue. He noted that the coronavirus pandemic has focused attention on the need for modernization and constructive change in the U.S. health care system. "Now is the time for real change; this group [ACS CAN] should be part of it. Let's not waste an opportunity," Weems stressed.

From a payer's point of view, coding for molecular diagnostics is "very problematic," said Gabriel A. Bien-Willner, MD, PhD, FCAP, Medical Director and Chief Medical Officer for MolDX, Palmetto GBA, a Medicare administrative contractor. Noting that "Medicare is really run at a local level," he added that there are coding gaps in biomarker testing that can make it hard for payers to understand what services were provided and which gene tests were run. In addition, he said, the lack of uniformity in diagnostic tests creates another problem for payers considering reimbursement decisions.

Health providers need an understanding of what payers' evidentiary bars are, emphasized Bien-Willner, an anatomic pathologist and molecular genetic pathologist, adding that the outdated paradigm of "one gene, one drug" has hampered insurance coverage of biomarker testing. He noted that CMS coverage decisions are based on what is reasonable and necessary, and that for reimbursement a biomarker test needs to show analytical validity, clinical validity, and clinical utility.

Speakers predicted that cancer biomarker testing will become more routine as tissue-agnostic drug approvals based on cancer biology increase.

"Coverage will come if there's evidence for the benefit to the patient," stressed Febbo. He anticipates that such testing will become less and less expensive as its benefits become clear.

In closing remarks at the forum, ACS CAN President Lisa Lacasse, MBA, said that engaging all stakeholders in discussions on cancer biomarker testing, most especially patients, "is the only way to get better decision-making." OT

Peggy Eastman is a contributing writer.

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Learning Objectives for This Month's Activity:

After participating in this activity, readers should be better able to: 1. Describe the emerging targeted therapies of precision medicine available for cancer treatment. 2. Analyze the reimbursement and practice gap barriers hindering access to cancer biomarker testing. 3. Identify ways to narrow the access gap and ensure the equitable delivery of precision medicine to all Americans.

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