THE CANCER LETTER

ACS CAN wages state-by-state battle to expand access to biomarker testing

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With growing evidence that molecular characterization of a tumor helps predict a patient's prognosis and response to specific treatments, biomarker testing has been required or recommended for more than half of the 62 oncology drugs introduced over the past five years. However, health insurance policies don't always cover tests, thus denying their clients access to precision medicine.

"This incredible innovation that we're so excited about with these new therapeutics—it's not being equally accessed," Lisa Lacasse, president of the American Cancer Society Cancer Action Network, said to *The Cancer Letter*.

According to a 2020 ACS CAN survey of 933 cancer patients, out of the 44% of patients who reported out-of-pocket costs for biomarker testing, about a third paid over $500. These costs were prohibitive—29% of patients who discussed treatment plans with their providers and decided to forgo biomarker testing did so because of limited insurance coverage.

Barriers to biomarker testing appear to fall along racial, ethnic, and socioeconomic lines. ACS CAN reported in May 2021 that NSCLC patients who were Black, older, or on Medicaid were less likely to receive next-gen sequencing biomarker testing. These disparities were visible across cancer types and there were lower rates of testing in community oncology vs. academic medicine settings.

"Biomarker testing is going to have an ever-increasing role in cancer treatment going forward," Devon Adams, senior analyst for policy and legislative support at ACS CAN, said to *The Cancer Letter*. "We want to make sure that we address any kind of disparities that may be popping up now so that they aren't exacerbated in the future as these therapies take off in the future."

Advocacy groups are working to update healthcare legislation to expand access to testing.

In late July, Illinois Gov. JB Pritzker approved HB 1779, which amended the Illinois Insurance Code so that state-regulated health insurance plans amended, delivered, issued, or renewed on or after Jan. 1, 2022, will be required to cover biomarker testing.

ACS CAN officials said they worked closely with Rep. Mary Flowers (D-31st), who introduced the bill in the House. HB 1779 garnered bipartisan support, with 50 Democrats and 10 Republicans sponsoring or co-sponsoring the bill. It passed unanimously in the Illinois House and Senate.

"We approached Mary Flowers and worked with her to make sure that the language was something that could support and cover both Medicaid and the state-regulated market," Shana Crews, ACS CAN Illinois government relations director, said to *The Cancer Letter*. "That was something we felt was really important to make sure that we're pulling as many people into this coverage model that we can, because health care is regulated by so many different layers of government."

Coverage under the new Illinois law isn't limited to cancer. According to HB 1779, payment is to be provided for biomarker testing "for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition" when the test is supported by evidence, including but not limited to:

- Labeled indications for an FDA-approved test or indicated tests for an FDA-approved drug;
- Centers for Medicare and Medicaid Services National Coverage Determinations;
- Nationally recognized clinical practice guidelines;
- Consensus statements;

criteria of the National Institutes of Health's National Library of Medicine for indexing in Index Medicus, Excerpta Medicus, Medline, and MEDLARS database of Health Services Technology Assessment Research; and

- Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

By the definition provided in the legislation, biomarker testing includes but is not limited to single-analyte tests, multiplex panel tests, and partial or whole genome sequencing.

The law also stipulates that biomarker testing must be provided efficiently, without disruptions to patient care—and if a provider limits access to testing, "the patient and prescribing practitioner shall have access to a clear, readily accessible, and convenient processes to request an exception."

Louisiana, too, approved legislation in June that expanded access to genetic testing and biomarker testing specifically for cancer, and in October, California barred insurers from requiring prior authorization for biomarker testing in late-stage cancer. As of 2018, Medicare beneficiaries with advanced cancer have coverage for next-generation sequencing.

Also in 2018, a plan by the Oregon Health Authority to deny Medicaid coverage for next-generation sequencing in the state was swiftly quashed (*The Cancer Letter*, Sept. 28, 2018).

"Right now, we're doing all of our legislative planning for 2023 sessions, but it looks like we'll have either specific campaigns and/or education and awareness work in probably about 12 states in 2022," Lacasse said.

Lacasse said the network's efforts are best spent on state-level legislation, particularly because tackling state healthcare policy may pave the way for federal-level changes. ACS CAN has advocacy operations in 50 states.

"Passing legislation at the federal level is proving to be complicated, to say the least, and there is all this regulation that happens at the state," Lacasse said. "We'll be pulling levers at all levels of government, but right now, state governments seem to be the place where we can have the fastest impact."

The Illinois bill ties coverage to national compendia and guidelines—and this means the legislation can adapt to the evolving science on biomarker testing.

"Once you have coverage, you have coverage, and it should continue to grow, which hopefully

for 50 genes or more.

A 2020 report commissioned by ACS CAN and the LUNGevity Foundation found that payers hesitate to provide coverage for such multi-gene panels, citing uncertain clinical utility. Insurance coverage of multi-gene panels is often specific to a tumor site.

Most indications for biomarker testing are for late-stage disease, but Adams said he would "hope and assume that one day that's going to change."

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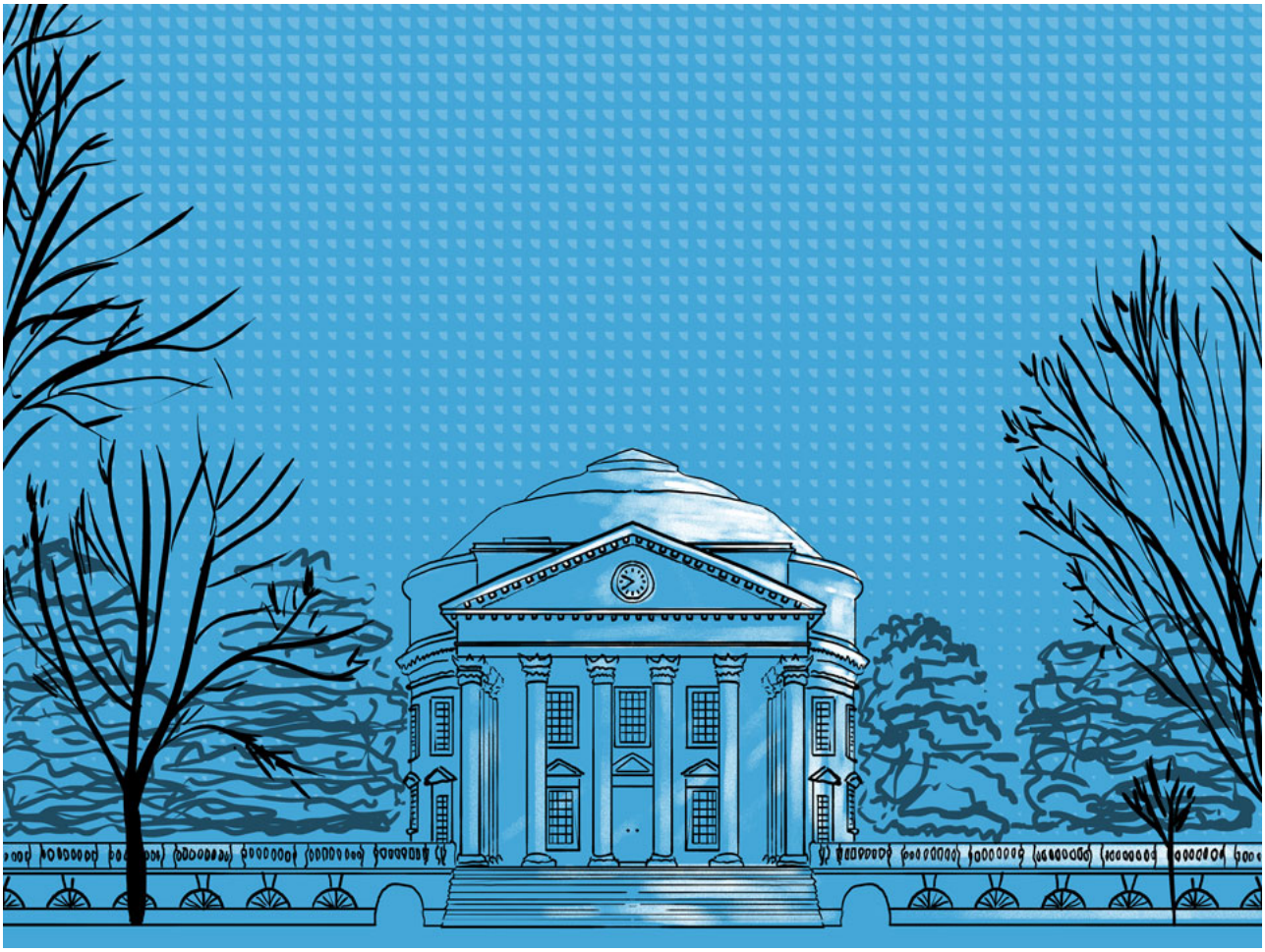

CONVERSATION WITH THE CANCER LETTER

Tom Loughran tells us how he got UVA over the hump to comprehensive designation

The University of Virginia has taken a long, circuitous path to NCI comprehensive cancer center designation, but it got there.

November 19, 2021 | *Vol.47 No.43*

By Paul Goldberg

GUEST EDITORIAL HEALTH EQUITY

To make clinical trials equitable, cancer groups evaluate restrictive eligibility criteria

Emergent public-private partnerships (PPPs) have risen to the occasion to streamline and coordinate severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines. With these monumental efforts have come important public discussions about equitable access and representation in clinical trials (CTs).

November 19, 2021 | *Vol.47 No.43*

By Julia Beaver, Thomas S. Uldrick, Gwynn Ison, Suanna S. Bruinooge, Caroline Schenkel and Edward S. Kim

CANCER HISTORY PROJECT CONVERSATION WITH THE CANCER LETTER

Patricia Ganz on how survivorship went from being an outlier to the mainstream

The National Coalition for Cancer Survivorship began in 1986 with 23 people at a hotel in Albuquerque and a $100 contribution from Patricia A. Ganz, who recalls thinking: "I don't think I've ever invested in anything that was so good."

November 19, 2021 | *Vol.47 No.43*

By Alexandria Carolan

IN THE ARCHIVES

Cancer researchers, including Nobel laureates, center directors, gather at Nixon Library to mark 50th anniversary of the National Cancer Act

The Richard Nixon Foundation will host the Nixon National Cancer Conference at the Richard Nixon Presidential Library and Museum in Yorba Linda, CA, on Dec. 1-2.

November 19, 2021 | *Vol.47 No.43*

IN BRIEF

Bridget Oppong named deputy director of Ohio State's Center for Cancer Health Equity

Bridget Oppong was named deputy director of the Center for Cancer Health Equity at The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (OSUCCC – James).

November 19, 2021 | *Vol.47 No.43*

IN BRIEF

Mitchell Schnall to continue as ECOG-ACRIN Cancer Research Group co-chair

Mitchell D. Schnall was re-elected co-chair of the ECOG-ACRIN Cancer Research Group by the Principal Investigator Committee.

November 19, 2021 | *Vol.47 No.43*

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