



Access to Comprehensive Genomic Profiling (ACGP) Coalition

An interview with Maude Champagne, Co-Founder and Treasurer of ACGP

Introduction

Cancer is a disease of the genome. Comprehensive genome profiling (CGP) testing allows for better understanding of the genomic drivers of a tumor and recommends appropriate treatment specific to each patient. While quality CGP assays are offered by academic medical centers and many commercial providers across the country, these assays are not readily accessible for advanced cancer patients, due to reimbursement issues.

A group of like-minded reimbursement experts noted this discrepancy in coverage and came together to form Access to Comprehensive Genomic Profiling, a non-profit organization that has brought together diagnostic and therapeutic companies as a coalition with a singular goal – making CGP accessible to US cancer patients (see <https://accesstocgp.com/>). Their mission is laudable for many reasons, not the least of which

is addressing inequities in the health care system and reducing overall net healthcare costs. Of equal value, but perhaps more subtle, is the effort to generate strong evidence, across subpopulations, regarding the clinical utility and economic benefits for the healthcare system of using CGP. In the end, we all benefit.

In the following, Maude Champagne (Illumina, one of ACGP's founders) makes the case for ACGP's mission, goals, and plans. We invite you to read and learn more about this organization.

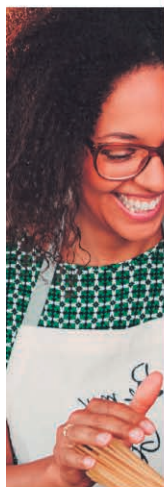
Q. What is Comprehensive Genomic Profiling?

A. Since cancer is a disease of the genome, optimal cancer treatment starts with understanding the variants in the DNA that are driving tumor growth. Comprehensive Genomic Profiling (CGP) is a laboratory test that examines the tumor sample

to identify unique genomic variants, which could then be used as biomarkers to indicate the likelihood of a cancer patient to respond to a targeted therapy or immuno-oncology therapy. CGP is the driving force behind precision medicine, where the treatment selection is optimized to each patient's tumor.

Q. Why is CGP (and access to it) so crucial for cancer patients?

A. CGP is a precision medicine approach that enables providers to understand what is happening “genomically” with an individual's cancer and, potentially, identify the therapies most likely to benefit the patient. CGP offers the benefits of improving outcomes for patients, saving time to reach diagnosis and treatment options, and reducing harm. To the last point, CGP can avoid a diagnostic and therapeutic odyssey early in the



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patient's treatment journey and thereby reduce the likelihood of adverse events that take a toll on the individual. It can also shorten the time to treatment, avoid the need to repeat a biopsy, which is invasive, and decrease waste across the entire health system.

Q. Can you provide background on the mission, make-up, and goals of the ACGP coalition?

A. ACGP was formed in the Fall of 2020 from a conversation between Illumina and two other founding members (see About ACGP inset). Our companies were experiencing the same major hurdles related to national coverage of CGP and realized how much we had in common. The idea was formed to tackle those access hurdles together by educating stakeholders about the value of CGP, using a single voice to accelerate access for patients. The group has grown to be comprised of 13 full member companies, all of which are diagnostic manufacturers and laboratory service providers of CGP for advanced cancer patients. About a year ago, we expanded our organization to include another tier of associate members. This group is comprised of pharmaceutical companies with a product in their pipeline for which a CGP assay will help in identifying patients that will benefit from the therapy.

Our overarching mission is to raise awareness about the clinical utility and economic benefit of CGP for advanced cancer patients. We are currently laser-focused on commercial payers, especially those who still lack policies to cover CGP tests across tumor types. We are working to educate them about why CGP is so crucial for cancer care and their members. We offer a couple of case studies as examples of engagement with these commercial payers (see Case Study insets).

Q. Why do you think a coalition approach will be more successful at improving access to CGP versus individual companies making their respective case?

A. Although each of our member companies has their own unique experience with enabling access to CGP, the overall goals and strategies that we share are remarkably similar. Without a doubt, our message is stronger to our audience when it comes from all 17 of ACGP's participating companies especially given the breadth, depth, and collective experience of the participants (see <https://accesscogp.com/member-companies/> and <https://accesscogp.com/member-companies/associate-members/>). We felt that our message as a coalition carries a lot more weight than any one voice alone. ACGP is supported by advocacy

and other healthcare stakeholders to represent the broader clinical ecosystems.

We keep our messaging concise but meaningful, emphasizing the impact that access restrictions can and are having across the entire field of oncology care. Joining forces also gives us the opportunity to maintain a regular exchange with each other about how coverage is evolving and how to be the most effective in improving patient access to CGP. By taking lessons learned and harmonizing our message, we can approach each payer with a unified voice and clearly articulate the need for expanded coverage of CGP for cancer patients.

"Insurance companies need to realize that it's very expensive to treat a patient incorrectly. And so not only are we doing the right thing by treating a patient correctly, sometimes you also have to argue that the right thing to do can be economical as well."

Rachel Sanborn, MD
Medical Oncologist
Earle A. Chiles Research Institute
Providence Cancer Institute

"Reimbursement has to change. That's the big barrier."

David Bartlett, MD
Chair, Allegheny Health
Network (AHN) Cancer Institute

"My view is that all patients should have their tumors sequenced at least once."

Sandip Patel, MD
Associate Professor of Medicine,
University of California, San Diego

Q. With that kind of structure, how are the coalition's aspirational goals balanced with the various offerings and needs of its members?

A. It is an ongoing process. We recognize there are different barriers to CGP access, and we want to tackle them all, but we also want to work where we can be most effective. We try to categorize ideas from members by ranking which types of barriers are having the most influence on our ability to achieve the ACGP coalition goals, and then prioritize the associated activities accordingly. This means engaging in a lot of open discussions about the issues our members and the patients

we serve are facing and how best to move the needle effectively.

Remaining focused on the overarching goals outlined by our members is imperative as multiple ideas arise. Member companies are encouraged to provide feedback and suggestions, and we are constantly exploring any adjustments to our strategy that could move us towards our goal. It is an iterative process that requires input from all involved, which is what makes the open discussion in this coalition so valuable.

Q. Who are the stakeholders the coalition is most interested in engaging?

A. As I mentioned previously, right now we're focused on commercial payers as our key stakeholders. We've held meetings with a range of national and regional payers and have had meaningful discussions that have led to coverage improvement for cancer patients (as well as better outcomes!). We also use payer's feedback to continually refine our messaging and guide our strategic objectives. Additionally, we engage with laboratory benefit managers to discuss updating their policies.

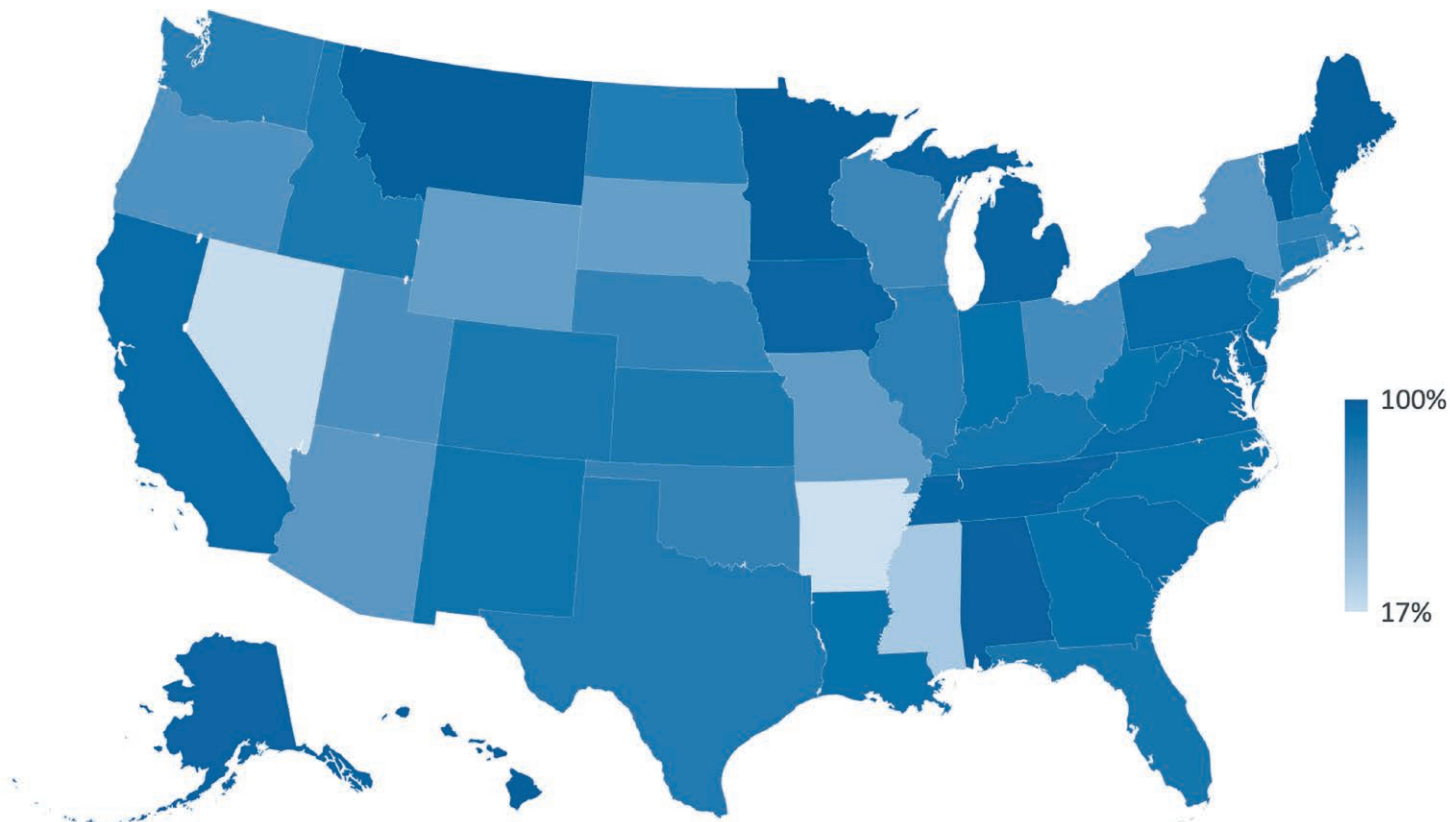
We also have a committee within ACGP that reaches out to other types of key stakeholders that can advocate for access to CGP. This includes entities like providers and patient advocacy organizations. We've held listening sessions with these groups for our members to engage and discuss alignment between our goals and theirs. Our membership has such a vast network in this space and it's important to capitalize on these relationships to promote a dialogue that breaks down access barriers for patients.

Q. Medicare patients have broad access to CGP. Given the issues with disparities in healthcare access in the U.S., how does ACGP address equitable insurance coverage?

A. Increasing coverage for CGP across commercial payers is crucial for improving access to care and advancing health equity for patients. Expanded coverage offers the opportunity to provide a precision medicine treatment approach to advanced cancer patients, reducing harm and improving outcomes. Our coalition also engages in Medicaid-focused work related to coding in an effort to combat disparities in access related to CGP.

Q. Does ACGP participate in government working groups?

A. There are several trade associations and medical associations that are actively engaged in policy making and working in Washington D.C. to ensure clinical diagnostic laboratories



Coverage for comprehensive genomic profiling in at least one tumor type in percentage of US lives covered by commercial insurance (depicted by state).

interests are represented. ACGP, as a coalition, does not participate in government working groups since our goal is to focus our effort in the space of CGP reimbursement where no other such organization exists.

Q. What are the most common concerns you hear from members? From stakeholders?

A. Our members' concerns, first and foremost, are related to expanding narrow medical policies that are limiting CGP access today.

"While we see payers as stakeholders, we want payers to see themselves as stakeholders, too."

Second, the medical coding ecosystem is in constant evolution in the U.S. and our members are actively engaged to ensure the appropriate framework is in place for CGP billing, removing hurdles such as pre-authorization.

While we see payers as stakeholders, we want

payers to see themselves as stakeholders, too. We know that payers are open to learning about CGP and how genomic testing brings value in the healthcare system. These are complex, innovative assays that were not taught in medical schools even 10 years ago. Education is key in ensuring that payers recognize the benefits for patients.

Payers are concerned that CGP results alone may not translate into changing the way oncologists provide treatment. However, this does not match what we are seeing in practice. In fact, oncologists are embracing CGP to guide them into optimal

CASE STUDIES

ACGP has successfully engaged with several commercial insurers in the U.S. to discuss their restrictive coverage policy regarding CGP, better understand their concerns, and spark change.

Case Study #1: Payer not covering CGP but covering a drug that requires the presence of a complex mutational signature that can only be identified using CGP to be eligible for treatment.

ACGP highlighted the discrepancy in coverage if a drug is approved but the biomarker test necessary to be eligible for that drug is not covered. The payer agreed and is now covering CGP for advanced cancer patients.

Case Study #2: Payer with concerns over assessing the quality of the results coming from a CGP test, therefore denying coverage.

Since CGP is a class of assay and ACGP members are offering different assays with different attributes and different regulatory approvals, we were able to highlight to the payer the many different quality certification programs and regulatory bodies that guarantee the high performance of CGP assays. That payer opened coverage selectively for assays that meet regulatory criteria that are preferred by the payer institution. This is an example where ACGP was able to recognize that U.S. payers differ in their preferences and, thus, sought areas of consensus to increase access for cancer patients.

treatment selection for their patients. Therefore, uptake of CGP is an important message to communicate back to payers: CGP is considered by oncologists as an innovative approach that benefits patients with improved outcomes and longer survival times.

Q. Have you faced any major hurdles in your work to increase access? How have you overcome these hurdles?

A. Some payers have expressed concerns over the lack of data linking CGP to improved patient survival in prospective randomized trials. While this type of evidence is commonly generated for cancer treatments, it is complex to link a diagnostic assay, especially with as many potential outcomes as CGP has, to a single survival metric. CGP can detect hundreds of biomarkers, linked to tens of targeted treatment and immunology drugs, or hundreds of clinical trials across advanced solid cancers. Even a negative result by CGP, meaning no actionable biomarker found in a tumor, can lead to better treatment by considering palliative care instead of other treatments that may not benefit the patient but cause unnecessary burden.

We are exploring funding our very own Health Economics and Outcomes Research (HEOR) study to increase evidence of the medical utility of CGP. Our HEOR experts from each of our member companies have mapped out study designs that would impactfully improve the body of evidence around the benefits of using a CGP approach for patients living with advanced cancer.

Q. Have you recruited pharma companies to join ACGP? Or otherwise as affiliate members?

A. Yes, as noted above, we now have four associate biopharma member companies that all have a product in their pipeline for which the use of a CGP assay will help in identifying patients that will benefit from the therapy. The pharmaceutical industry is a key stakeholder in the CGP ecosystem since the innovative therapeutics that are developed today stand to benefit patients that show specific biomarkers in their tumor. High-quality,

comprehensive biomarker testing availability is essential for those novel drugs to reach the patient population that they can help.

“We are a young organization with the opportunity to educate many stakeholders (beyond commercial payers) about the value of CGP and promote access for cancer patients.”

Q. What does ACGP see as the future of the coalition – for example, will ACGP eventually integrate other omics technologies? Or have an impact beyond diagnostics to include drug development?

A. We are a young organization with the opportunity to educate many stakeholders (beyond commercial payers) about the value of CGP and promote access for cancer patients. We continually seek to align our goals to the changing needs of the industry, adapting to tackle existing and new barriers related to CGP and the understanding of its clinical utility. For example, we’ve had requests to consider getting involved in provider education. Raising awareness about CGP is an ongoing process that requires input from stakeholders across the entire healthcare ecosystem.

CGP is currently the most advanced test for clinical use to profile a patient’s tumor. Advances in genomics are happening at an unparalleled speed, allowing us to better understand and characterize cancer as never before. These are exciting times in cancer research, and we hope to see the fruit of academic advances continue into routine clinical practice in years to come. There may come a day where CGP is no longer the gold standard and becomes replaced by whole genome sequencing, or is complemented with epigenomics, proteomics, or other tools. ACGP continually adapts to the latest scientific knowledge to promote our core mission of enabling U.S. cancer patients access to innovative, lifesaving diagnostic assays. ^{16,17}

Key Points

- Comprehensive Genomic Profiling (CGP) is a laboratory test that provides a precision medicine approach to optimize treatment selection for advanced cancer patients, improving outcomes and reducing harm.
- Formed in the fall of 2020, Access to Comprehensive Genomic Profiling (ACGP) is a collaborative coalition of 17 leading molecular diagnostics companies, laboratories, and biopharma companies that aims to share the clinical utility and economic value of CGP with healthcare stakeholders, thereby increasing access to this innovative technology in the United States.
- ACGP’s current mission is highly focused on meeting with commercial payers within the U.S. to discuss their coverage policy regarding CGP. ACGP has successfully held meetings with a range of national and regional payers over the past year, leading to coverage improvement for cancer patients.
- ACGP uses open dialogue between members and engagement with stakeholders across the entire healthcare system to continually adapt to the changing landscape and latest scientific knowledge, focusing on promoting its core mission of enabling patient access to these innovative, lifechanging diagnostic assays for cancer patients in the U.S.



Maude Champagne

Co-Founder and Treasurer, ACGP

Maude currently serves as the Director of Market Access Strategy and Operations at Illumina, Inc. She is responsible for building a global roadmap

for reimbursement and access for Illumina’s oncology genomic diagnostic testing portfolio. In this role, she establishes the framework for the economically viable introduction of innovative molecular diagnostic tests into clinical practice, including considerations around availability of appropriate coding, value-based rate setting, and establishing coverage for patient access. Ms. Champagne has over 15 years of experience commercializing companion diagnostics, including reimbursement and access, product management, marketing, and sales. She currently sits on various workgroups including the American Clinical Laboratory Association’s Reimbursement Workgroup, the Association for Molecular Pathology’s Economic Affairs Committee, and co-chairs the BloodPAC Reimbursement Work Group. Ms. Champagne holds a Bachelor of Pharmacology from Université de Sherbrooke in Quebec, Canada, and an International Executive MBA in Business Integration from Julius-Maximilians-University in Würzburg, Germany.

About ACGP

Access to Comprehensive Genomic Profiling (ACGP) is a collaborative coalition of leading molecular diagnostics companies and laboratories that aims to raise awareness about CGP for advanced cancer patients. Founded in 2020, the coalition seeks to educate stakeholders about the value of CGP tests in all tumor types; to assure appropriate use in the patient journey; and to inform medical management on the potential to improve clinical outcomes. The organization’s membership is dedicated to sharing the clinical utility and economic value of CGP with healthcare stakeholders, thereby increasing access to this innovative technology in the United States.

For further information, visit: <https://accesstocgp.com>