Evolving Conversations with U.S. Payers about Comprehensive Genomic Profiling

May 2023

Key Takeaways

- **Evaluating the clinical utility of comprehensive genomic profiling is essential to enabling medically necessary cancer care, a longstanding priority for payers.** Building shared definitions and frameworks to assess clinical utility is a known need and there is energy to move this forward.
- **Considering the medical necessity of CGP on a gene-by-gene basis is not sustainable.** Coverage and policies are moving toward considering CGP as a whole, but challenged by a rising number of included genes and a dynamic evidence base.
- **The value of CGP lies within a rising number of inputs,** such as: quality, cost-effectiveness (including cost diversion), comparators, clinical utility, potential for unnecessary care, impact on clinical management and patient outcomes. Payers acknowledge that value has an expansive definition. Current assessment models do not fully capture the value of CGP, such as patient-reported outcomes.
- **Alternative evidence models to demonstrate the value of CGP are needed.** Building real-world data and value-based models of evidence merit exploration. This work can strengthen collaborations between payers, health systems, industry, biopharma, patient advocates, and other stakeholders throughout the health care system.

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Introduction

According to the U.S. Centers for Disease Control and Prevention (CDC), "Cancer is the second leading cause of death in the United States, exceeded only by heart disease. One of every four deaths in the United States is due to cancer."[1] Next-generation sequencing (NGS) has shown that cancer is a disease of the genome.[2] Comprehensive genomic profiling (CGP), also known as somatic tumor profiling, biomarker testing and other names, yields opportunities for cancer patients to be offered targeted treatments, immunotherapy, genomic information to inform diagnosis and prognosis, as well as clinical trials.[3] Clinical practice guidelines and regulatory agencies increasingly recommend tumor profiling and biomarker tests, which may be companion diagnostics to approved treatments.[4]

Relatedly, U.S. health care payers navigate tumor profiling claims and coverage policies with aims to evaluate clinical utility, value (including economic considerations), and enable medically necessary care while leading to improved outcomes for their members and beneficiaries. This is challenging when the clinical utility of tumor profiling is found within an expanding and dynamic evidence base, one not ideally suited to the "gold standard" of randomized-controlled trials, with data trapped within disconnected, heterogeneous systems. These challenges leave gaps in coverage and utility.

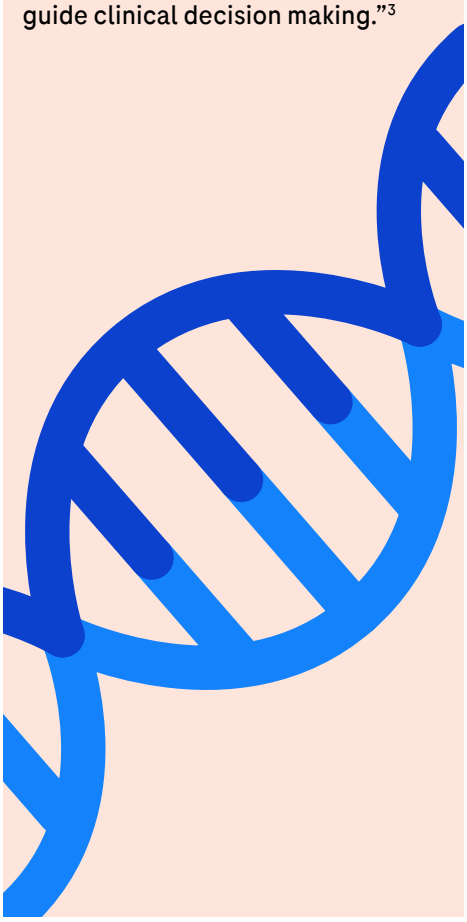
In May 2022, Roche Diagnostics Corporation and Foundation Medicine held an inaugural CGP Advisory Board meeting. This small advisory group, consisting of payers from health plans as well as individuals from Roche and Foundation Medicine, with a focus on assessing the clinical utility of tumor profiling in oncology, coverage among health plans, and new ideas for ways to improve access and health equity in this space.[5]

The Advisory Board was moderated by a consultant with research expertise in the application of new precision medicine technologies to improve health care. All advisors were employed by payer organizations or lab benefits management organizations. Advisors had expertise in health maintenance organization (HMO) strategy and affordability, evaluation of precision medicine services, and research analysis for medical policy and technology evaluation. Following presentations by internal and external teams, the moderator guided focused discussions.

These conversations yielded themes reflecting an evolution and advancement of complex issues that payers navigate related to CGP. Beginning with historical context, this document, informed by the Advisory Board discussions, offers evolving themes, new ideas, and suggests future collaborations between payer, industry, patient advocacy, and other health care system stakeholders to improve medical care and outcomes for cancer patients.

What is CGP?

As defined by the U.S. Centers for Medicare & Medicaid Services (CMS), "CGP refers to NGS-based molecular assays that provide additional insight beyond individual gene hotspots; these assays seek to describe the genomic makeup of a tumor and can help identify underlying mechanisms of disease to guide clinical decision making."[3]



Growth of Comprehensive Genomic Profiling

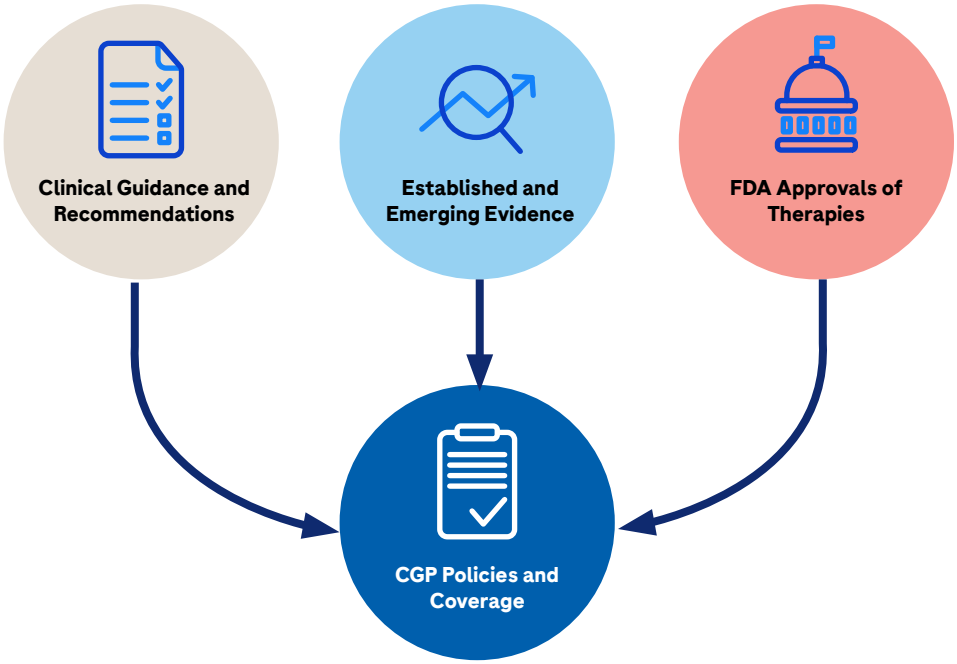
NGS technologies have driven many testing approaches from gene-based (genetic testing) to genome-based (genomic testing).[6] Genomic testing is now utilized in various clinical contexts, from patients with rare disease to those with advanced cancer. In oncology, CGP results document that specific genetic alterations and biomarkers cause and drive cancer growth.[7] Distinct patterns of genomic markers and biomarkers can inform decisions that cancer care clinicians navigate with their patients, going beyond what is possible using traditional approaches. These include targeted therapy or immunotherapy, therapy avoidance, clinical trial eligibility, or more precise diagnosis and prognosis. In this way, CGP provides distinct value and utility to clinicians determining treatment or other aspects of care for advanced cancer patients.

CGP assays are increasingly available in the worldwide market.[8] Using solid tumor tissue or blood-based liquid biopsy samples, these assays analyze relevant genomic alterations and biomarkers; they are informed by a growing, dynamic evidence base. Patient treatment plans and other aspects of care are developed based on real-time knowledge of these genomic alterations and biomarkers. Key factors influence U.S. payers considering CGP policies and coverage, summarized in **Figure 1** and all described in detail on pages 5-6.

Distinct patterns of genomic markers and biomarkers can inform decisions that cancer care clinicians navigate with their patients, going beyond what is possible using traditional approaches.

Figure 1.

Key factors that influence U.S. Payer Coverage of CGP



FDA Approvals of Therapies

Personalized medicines, such as targeted cancer therapies, have accounted for 25% of U.S. Food & Drug Administration (FDA) approvals since 2015.[9] Certain CGP tests are companion diagnostics associated with some of these approvals.[10]

Examples:

- CGP (solid tissue) as a companion diagnostic for *BRAF* inhibitor therapeutics in melanoma[11]
- CGP (liquid biopsy) as a companion diagnostic for *EGFR* exon 20-targeted treatment, for non-small cell lung cancer (NSCLC)[12,13]

Clinical Guidance and Recommendations

The National Comprehensive Cancer Network® (NCCN®), recommends "broad molecular profiling" in specific clinical practice guidelines. Example NCCN® guidelines for patients with advanced or metastatic NSCLC:

- Molecular biomarker testing recommended to establish histologic subtype[14]
- Molecular biomarker testing recommended for first-line treatment selection[11]

The American Society of Clinical Oncology (ASCO) states, "Patients with metastatic or advanced cancer should undergo genomic sequencing in a certified laboratory if the presence of one or more specific genomic alterations has regulatory approval as biomarkers to guide the use of or exclusion from certain treatments for their disease."[15] These recommendations are inclusive of CGP, a single assay that includes relevant biomarkers and identifies emerging biomarkers.

Clinicians and payers are challenged to evaluate a rising number of tumor and treatment profiles for clinical or coverage purposes

- Stakeholders face practical and knowledge gaps to implementing precision medicine in oncology, including biomarker testing[5,16]
- Clinical utility of CGP is a central element of evaluation. It is also inconsistently understood, defined differently, and/or difficult to evaluate[12]

All of the above factors impact and challenge payers considering claims, policies, and coverage for CGP. Overall, coverage is increasing but inconsistent.[17] Additionally, policies are not always aligned with clinical guidelines.[18] Individual policies and coverage are variable, often interpreted individually or by tumor type.[14]

- U.S. commercial payer coverage patterns for CGP and other genomic testing are inconsistent across U.S. states [19]
- U.S. commercial payer coverage for CGP may not be harmonized with published clinical guidelines (e.g. NCCN®), and in many cases may be more restrictive than what guidelines recommend.[17]

Set in historical context over time, it is apparent that payers are considering a rising number of variables in their CGP coverage decisions. This complicates decisions that are already complex, and Advisory Board conversations explored this further.

Evolving Themes

- Evaluating the clinical utility of CGP remains an element of achieving medically necessary care. However, this is difficult to assess as the number and complexity of CGP assays increase. This leads to knowledge and coverage gaps.
- Payers apply inconsistent definitions and understandings of clinical utility, making it challenging to incorporate into coverage decisions.
- There is an appetite for building shared definitions and approaches to determining clinical utility, reflecting an opportunity for future discussions with stakeholders.

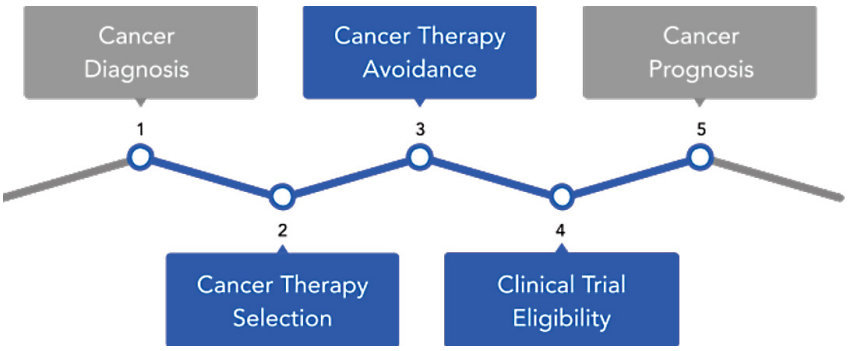
Evaluating Clinical Utility

Payers, clinicians, health systems, test developers, and other health care system stakeholders need to evaluate the clinical utility of CGP assays in order to deliver optimal care to advanced cancer patients. Advisory Board conversations uncovered differences and inconsistencies in how stakeholders define clinical utility and a lack of shared language erodes mutual understanding. There is also a variable "amount" of clinical utility that is "good enough" for stakeholders to make their decisions. However, advisors agreed that clinical utility includes medically necessary care, and that is a requirement for coverage. As such, establishing clinical utility of CGP remains a high priority because it is embedded within an immutable piece of coverage decisions.

Advisors shared feedback about a novel framework for considering the clinical utility of CGP, which categorizes five key elements across the advanced cancer patient care journey. These elements may be found within a CGP test report, clinical practice guidelines and other guidance documents, scientific literature, public and proprietary databases, or other sources.

Figure 2.

Clinical Utility of CGP: 5 Elements Across the Patient Care Journey



Note: Blue color denotes areas that are well-established based upon scientific evidence; gray color denotes emerging areas.

While the clinical utility of CGP is found in these elements, discerning them in practice can be difficult. For example, clinical practice guidelines may be written in a non-specific way to prevent excluding certain patients from a treatment or service. However, payers using guidelines to evaluate clinical utility while setting policy, a common practice, find the non-specific nature of some guidelines to be unhelpful. Payers try to balance these elements and the "value" of CGP against a rising test cost and number of genes included in an assay.

Evolving Themes

- Payers and others in the market have an inconsistent understanding of the elements underpinning clinical utility for CGP and do not prioritize them in the same way.
- Genetic testing claims (inclusive of CGP, as categorized by payers) are a subset of many claims that payers need to address. It is difficult to stay current on "medically actionable" genetic alterations or therapeutic options when evaluating clinical utility.
- Considering clinical utility on a gene-by-gene basis is not sustainable. Many have moved towards considering a CGP assay as a whole.
- Common inputs to coverage decisions include practice guideline recommendations, the number of included genes, and cost. A smaller number of "medically actionable" genes is less concerning, but there is inconsistency when it comes to genes that are not "well-established."
- The concept of "value" came up several times with advisors and reflects an evolution over time, beyond economic considerations. This presents an opportunity to further flesh out what value means across stakeholders to build shared understanding.

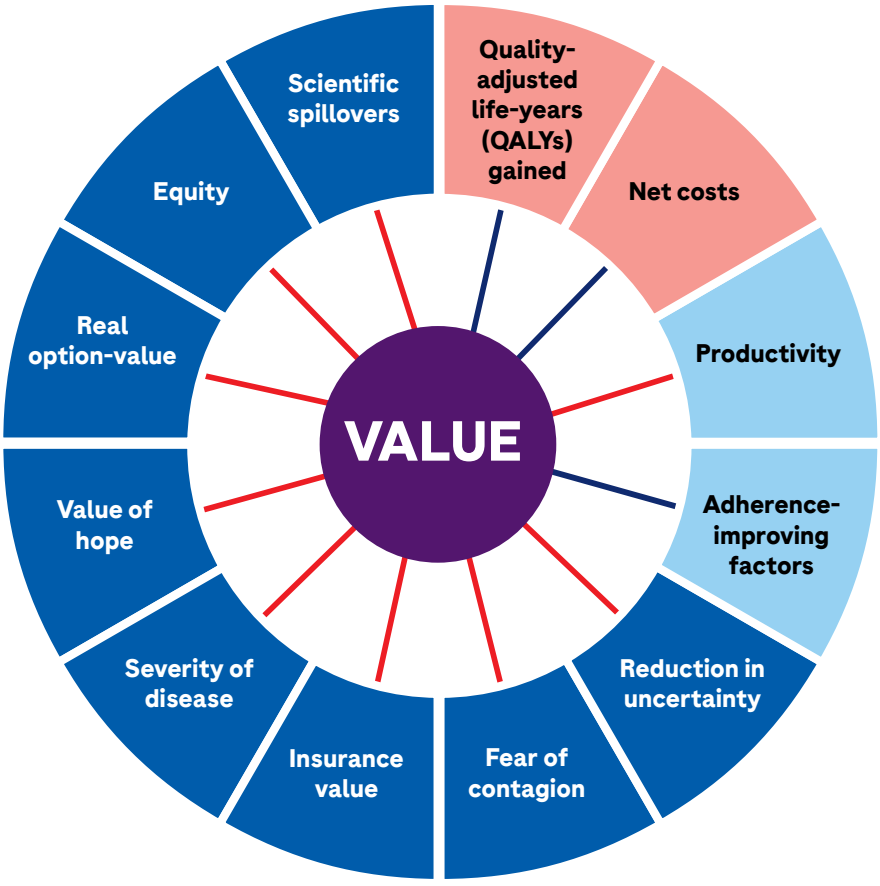
Determining and Achieving Value

Value in health care is a concept that feels like it should be simple to identify, yet is complex and changing. This is particularly so with CGP assays, which are not always suited to current value assessment models.[20] Health technology assessments (HTAs), for example, are limited for evaluating the value of CGP because they do not capture all relevant elements.[14] These include broader societal impacts, refining the use of resources, and avoiding testing overuse. As Lakdawalla ***et al.*** discussed (**see Figure 3**), value contains an increasing number of interrelated components, yet is often boiled down to quality-adjusted life-years gained and net costs.[21] Similar to clinical utility, health care system stakeholders define and consider value differently.

Health technology assessments (HTAs), for example, are limited for evaluating the value of CGP because they do not capture all relevant elements.[14]

Figure 3.

Elements of Value in Health Care (from Lakdawalla DN, *et al.*, 2018).[15]



Note: Pink circles: core elements of value; light blue circles: common but inconsistently used elements of value; dark blue circles: potential novel elements of value; blue line: value element included in traditional payer or health plan perspective; and red line: value element also included in societal perspective.

Challenge: Map each element into an underlying economic framework for value assessment.

The concept of value frequently arose during Advisory Board discussions. Similar to clinical utility, advisors shared that determining a test's value is an essential part of coverage decisions. While the evaluation of value varied, there were common elements. For example, the cost and quality of the test must be weighed against the possibility for medically unnecessary care and harm (e.g. improper treatment delays, improper changes to standard of care, incorrect treatment selection) that the test could provoke. Additionally, payers acknowledged that achieving value in individual coverage decisions can help further value-based care throughout the health care system. This calls for an opportunity to explore value-based evidence models.

Evolving Themes

- Several aspects are important to determining the value of CGP, which may be prioritized differently: quality (sometimes discerned in part from a test report), cost and cost-effectiveness compared to alternatives, cost diversion via clinical trials, potential for unnecessary care, clinical utility, impact on clinical management, impact on outcome.
- Cost-effectiveness of CGP is yet to be determined and of high interest.[22] As the number of included genes has risen, so have assay costs.[23] Payers struggle with determining the value of CGP in this dynamic landscape.
- Costs of ancillary testing to CGP results are also a concern. These include additional tests, imaging, consultations, or repeating CGP testing.
- CGP assays can yield clinical trial opportunities for patients, which guidelines support. Guidelines increasingly indicate that the best management for any patient with cancer is in a clinical trial.[24] The potential for cost diversion via clinical trials with CGP may be attractive to payers.
- Value-based frameworks of evidence that integrate real-world data are necessary to explore. Patient outcomes, patient-reported data, and impact on health equity offer value, but current evidence models are not designed to capture these elements. Advisors expressed openness to alternative models. This represents an opportunity to revisit existing evidence standards, such as randomized-controlled trials, which do not always suit CGP study.

Reframing the Evidence "Gold Standard"

Current models for constructing and evaluating evidence related to CGP are limited. Randomized-control trials (RCTs) are long held as the highest standard by which to evaluate scientific evidence. This rigorous model of study holds many virtues, but is not an ideal fit for CGP or other oncology contexts.[25] Selective RCT inclusion criteria may yield findings for a very small population that are difficult to extrapolate and apply broadly.[19] Medicare and Medicare Advantage beneficiaries living with advanced cancer receive CGP coverage for solid tumors under a national coverage determination.[26] As such, an RCT for CGP could randomize participants away from a covered benefit. Comparators in CGP RCTs are not always possible because approved treatment alternatives may not exist. Given this, including controls in CGP RCTs are problematic because participants often have prior lines of unsuccessful cancer treatment and the study intervention (e.g. CGP to inform treatment selection or avoidance) represents the only opportunity for them. RCTs for CGP are available, but there are reasons to reframe this gold standard and consider alternatives.

Real-world data, such as that found within health systems, are important inputs and not always considered or available for evidence analysis. These include data from electronic health records (EHRs), provider utilization, health insurance claims, and patient registries.[27]

Challenges to incorporating real-world data in coverage decisions include a fragmentation of these datasets across health systems and care centers. In the U.S., these datasets are siloed, leaving the full power of them unavailable to stakeholders. Efforts and studies are underway to understand these datasets to build broader, more inclusive and representative value models.[28,29,30] This represents an evolution in thinking and opportunities for collaborations between stakeholders. While not a focus of the Advisory Board, including the perspectives of patients via advocacy groups and registries is essential to building representative data sets to better understand how to address barriers, foster health equity, and improve patient outcomes.

While payers may have been skeptical about how to use real-world evidence or the value of it previously, this has shifted. Advisors suggested an openness and focus to real-world datasets that are important to their coverage decisions, including:

- Patients receiving unnecessary alternative care due to a lack of CGP
- Missed opportunities for care due to a lack of CGP
- Connections between CGP and necessary vs. unnecessary treatment (e.g. alignment of test results with therapies received or avoided)
- Patient-reported outcomes following genomically-informed treatment, including the absence of harm outcomes balanced with technology innovation

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Evolving Themes

- Gaps and limitations in traditional evidence models used to evaluate CGP, such as RCTs, are increasingly apparent.
- The importance of leveraging real-world evidence to build broad datasets is increasing.
- Real-world evidence is present, yet practically unavailable due to disconnected, fragmented systems. New frameworks are needed to incorporate these unused pieces of evidence.
- Payers repeatedly seek answers to key questions and concerns in coverage decisions; some of these answers are suited to real-world evidence.
- Now is the time for future collaboration and work towards building alternative and more representative evidence sources, such as real-world evidence and value-based datasets.

Limitations

While this document offers advancements in thinking based on conversations with the Advisory Board, the number of participants was small. Thus, opinions shared are not necessarily generalizable across U.S. payers at large. Advisory Board participants were highly informed and knowledgeable about precision medicine, specifically with CGP. Advisors indicated that many payers lack internal precision medicine or genomic testing experts, often relying on third-party vendors or other outsourced expertise. Lastly, this paper focused on U.S. payers and the U.S. market. This is a topic of global interest, but individual health systems and circumstances vary.

Conclusion

Clinicians regularly consider and use CGP for their patients living with advanced cancer. This is informed by evidence reflected in well-powered studies, clinical guidelines, regulatory approvals, payer coverage policies, and other rationale suggesting CGP as standard of care for specific cancer patients. As more CGP claims and coverage decisions come before U.S. payers, conversations are evolving around how to determine the value of CGP in the service of achieving medically necessary care with informed treatment decisions, improved patient outcomes, minimized harm and waste, and contained costs. This yields new opportunities.

Advisory Board participant conversations signaled shifts and advancements in thinking. Enabling medically necessary care to achieve optimal patient care remains a steadfast goal for payers making coverage decisions, but the pathways to make meaning of this are diversifying. The value of CGP is increasingly complex, embedded within disconnected datasets across health systems and care centers. The status quo to assess this value needs reconsidering. Some of the current data streams align with traditional evidence models like RCTs, but others suit real-world datasets and value-based models. Building out alternative models can also create more inclusive, equitable, and representative datasets that promote health equity and better outcomes for patients, particularly those who are underserved.

This document is a moment-in-time reflection of Advisory Board conversations and plants seeds for future thought and potential. There is energy and enthusiasm to keep conversations progressing and include others along the way. The hope is to keep these topics alive and advancing by convening further discussions and collaborations. Future partnerships between partners in industry, biopharma, along with payers, scientists, clinicians, and patient advocates can help to uncover new ways of leveraging critical real-world datasets and broader value-based models that may be hiding in plain sight.

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