Green Park Collaborative

A partnership for innovation and effectiveness

CREATING POLICY MODEL GUIDELINES FOR COVERAGE OF NEXT GENERATION SEQUENCING IN CLINICAL ONCOLOGY: PHASE 2

BACKGROUND

"Next generation" sequencing (NGS) methods are important new tools to enable clinical genomics and the realization of personalized medicine. Yet a number of challenges have hindered the uptake of NGS-based DNA sequencing for clinical purposes, including significant gaps in demonstrating the clinical utility of this approach, and substantial uncertainty and variability in health plan coverage policies for these tests. These challenges include:

1. NGS differs from previous generations of multiplex arrays and Sanger-based sequencing panels in both the sheer volume of information produced, and in the ability of this technology to detect genetic variants not anticipated to exist and not specifically looked for by treating physicians. This poses challenges for coverage and reimbursement decisions, as most current test coverage policies are predicated on the traditional model of a "medically necessary test."
2. NGS platforms represent a significant challenge for coverage decision-making due to the complexity and variability of procedures across the entire test cycle. Between-laboratory differences in technology, quality metrics, and procedures can also result in substantive differences in the information patients receive for decision-making.
3. Coverage of variants that may be clinically important has been hindered by a lack of supporting clinical evidence. Current policies require demonstration of health benefit to the patient from use of the test (clinical utility), generally calling for randomized studies comparing outcomes of patients managed with use of the test (a single test result) compared to standard practice without the test results.

In response to the challenges described above, the Center for Medical Technology Policy (CMTP), through its Green Park Collaborative (GPC) convened a series of multi-stakeholder discussions to develop evidence standards and policy to support the coverage and reimbursement of NGS testing. These exchanges led to the development of model policy guidelines, released in August 2015, designed to balance the policy objectives of health plans with the need for more rapid adoption of clinically useful DNA sequencing methods. Key features of the guidelines include:

1. A consensus recommendation for payers to cover NGS panels comprising between 5 and 50 genes when those panels include a subset of constituent genes that are considered to be standard-of-care and medically necessary for the patient.
2. A recommendation for payers to rely on the College of American Pathologists (CAP) accreditation program and proficiency testing to assure the analytic validity of NGS.
3. A proposal for payers to cover larger, comprehensive NGS cancer panels with preauthorization under circumstances of extenuating medical need.

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4. Initial exploration of a suggestion to offer coverage of NGS-directed off-label use of drugs if the patient experiences benefit after 3 months of use.
5. Proposals for the use of coverage and reimbursement policy levers to incentivize laboratory and clinician sharing of data, to promote patient participation in clinical trials and registries, and to support robustly designed, well-curated data repositories and of clinical research initiatives such as the Medical Evidence Consortium (MED-C), the American Society for Clinical Oncology's (ASCO) TAPUR and others.

PHASE 2 PROJECT OBJECTIVES

Phase 2 builds on this successful first phase of work and **aims to map out and implement the specific arrangements, relationships, and standards needed for a system that works well for all key stakeholders**. Phase 2 activities include:

- Obtain broader public consultation (e.g. a wider assortment of patient groups, academic laboratories, community cancer centers) to gain the perspectives and support of key stakeholder groups that have not yet been engaged in the first phase of this effort. We also seek to engage a larger universe of public and private payers (beyond the GPC community that has been engaged to date) to review and consider adoption of the guidelines and participate in the refinement process.
- Meetings with CAP, the Centers for Medicare and Medicaid Services (CMS), Palmetto GBA, major payers, and other stakeholders to discuss ways to make the CAP NGS accreditation program results useful to payers, and to further discuss programs such as those under development by the US Food and Drug Administration (FDA) and the Tapestry Network SPOT/Dx Working Group.
- Meetings with major payers, CMS, and pharmaceutical companies to discuss potential policy options for covering off-label drugs when targeted agents are identified as potentially beneficial through genomic testing.
- Discussion of specific policy mechanisms that will incentivize data-sharing, enhanced clinical trial participation of patients, and real-world systematic data collection to capitalize on supplemental variant information found when analyzing NGS cancer panels.
- Discussion of future conditions under which comprehensive NGS cancer panels (larger than 50 genes) may be covered, and the type of evidence needed to support the clinical utility of large scale genomic sequencing approaches, such as whole exome and whole genome sequencing, in oncology.

PROJECT TIMELINE

4th Quarter 2015	1st Quarter 2016	2nd Quarter 2016	3rd Quarter 2016
Seek broader public comment and input on the model policy guidelines	Convene working meeting on CAP NGS accreditation and payer policies to support research	Convene working meeting on off-label use of NGS-directed drugs, comprehensive cancer panels, and clinical utility of large scale sequencing	Finalize recommendations on coverage of genomic testing in oncology and policy tools for evaluation of genomic testing

PROJECT PARTICIPANTS

Some participant organizations engaged in Phase 1 of this work are listed below; many are expected to join us in Phase 2:

***SPONSORS**:* Aetna Foundation, Covidien, Novartis Pharmaceuticals, Millennium, National Pharmaceutical Council, Merck & Co. Inc., Eli Lilly & Company, Illumina, Inc., MolecularHealth, Inc., Genoptix, Inc., Laboratory Corporation of America, Pfizer Inc., MDxHealth, Clovis Oncology, Genentech, Inc., ThermoFisher Scientific Inc., Medtronic, Foundation Medicine, AstraZeneca, Sanofi U.S., NantHealth, Quest Diagnostics, Clovis Oncology, and Caris Life Sciences.

***ADVOCACY ORGANIZATIONS**:* Friends of Cancer Research; Patient Advocates in Research; National Coalition for Cancer Survivorship; The Angiogenesis Foundation; Breast International Group; Research Advocacy Network.

***PAYERS**:* Blue Cross Blue Shield Association (BCBSA); Centers for Medicare & Medicaid Services (CMS); Kaiser Permanente; Aetna; Humana; Anthem Inc., Maryland Physicians Care, Palmetto GBA, Novitas Solutions, Inc.; Oklahoma Health Care Authority (Medicaid).

***PROFESSIONAL ASSOCIATIONS AND GUIDELINE DEVELOPERS**:* American Society of Clinical Oncology (ASCO); Association for Molecular Pathology (AMP); MAWD Pathology Group; National Comprehensive Cancer Network (NCCN); National Cancer Institute (NCI); Molecular Evidence Development Consortium; College of American Pathologists (CAP).

***ACADEMIC and MEDICAL INSTITUTIONS**:* University of Carver College of Medicine; University of Texas MD Anderson Cancer Center; Hospital of the University of Pennsylvania; Cleveland Clinic, Washington University in St. Louis School of Medicine; Broad Institute of MIT and Harvard; Indiana University; Fred Hutchinson Cancer Research Center.

OTHER: IntegriGuard; Federal Healthcare Knowledge Centre (Belgium); Food and Drug Administration.