# PBGH – Putting New Technologies to Work


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Sequenom, a LabCorp Company


Integrated ONCOLOGY
LabCorp Specialty Testing Group

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- Process of a CDx Launch
- Considerations For Broad Access
- Market Access & Reimbursement
- Summary

# Integrated Oncology footprint

More than **490,000 tests** performed on **225,000+ patients** annually

**Test menu** of more than **450** genetic, pathology, IHC, and FISH tests, including 15 oncology-specific pharmacogenetic assays

Staff of more than **75 pathologists, PhDs, and genetic counselors** dedicated to oncology and familial cancer testing

**1,600 contractual relationships** with plans, payors, and other health care organizations

Integrated with more than **700 electronic medical records (EMR)** and practice management systems

More than **65** oncology- and pathology-specific **publications** and presentations since 2013

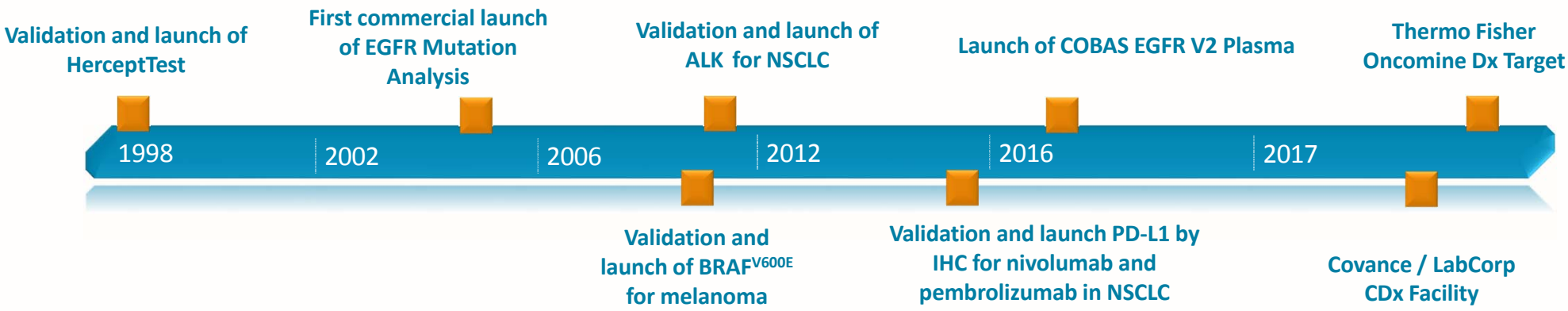
Research Triangle Park, NC
- +60,000 sqf
- 5 MD pathologists
- 12 PhDs
- CAP, CLIA, ISO 15189, NYS, COG accreditation

Phoenix, AZ
- +60,000 sqf
- 10 MD pathologists
- 4 PhDs
- CAP, CLIA, ISO 15189, NYS, COG accreditation

Brentwood, TN
- +55,000 sqf
- 10 MD pathologists
- 3 PhDs
- CAP, CLIA, ISO 15189, NYS accreditation

New York, NY
- +80,000 sqf
- 12 MD pathologists
- 3 PhDs
- CAP, CLIA, NYS, COG accreditation

# Sample of Integrated Oncology's experience in CDx commercialization



# Launching of CDx tests in laboratories requires cross a functional approach

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## Laboratory Operations

- Assay Validation
- Laboratory Workflow
- Test Requirements / Specification

## Technical & Clinical

- Pathologist / Phd Training
- Report / Test Result Interpretation

## Logistics

- Test Request Process
- Specimen Transport & Intake
- Result / Report Delivary

## Communications

- Communication Plan
- Test Education Materials

## Sales

- Client / Prospect Targeting Prioritization
- In-service & Educate on Test & Process
- Assess / Address Test Patterns

## Market Access

- Evaluate / Determine CPT Coding
- Set Price Structure
- Assess / Address Policy & Contracting

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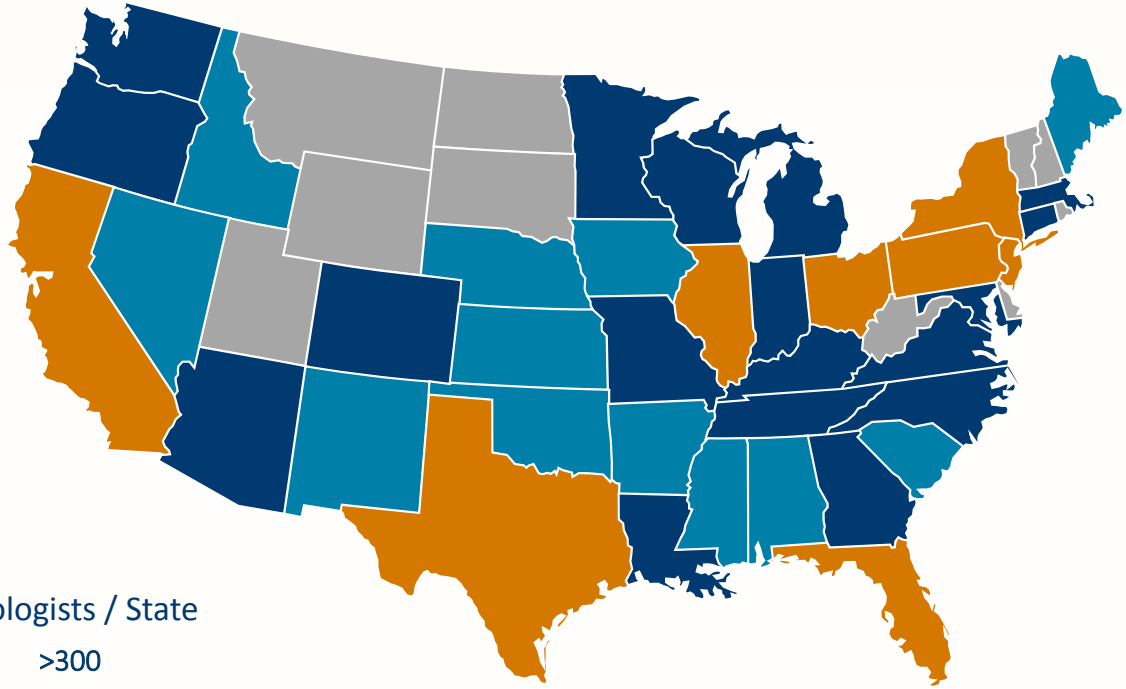
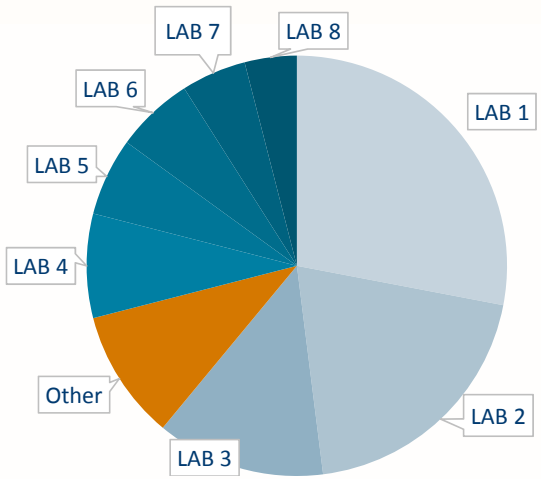
# Physician & testing distribution



Oncologists / State

- >300
- 100-300
- 50-100
- <50

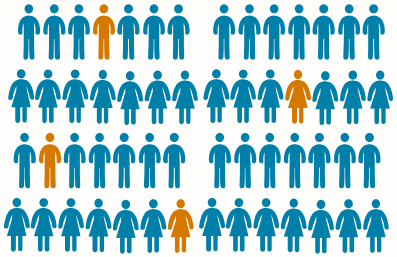
Market Share for Cancer Testing - Pathology



# What is the distribution of target population

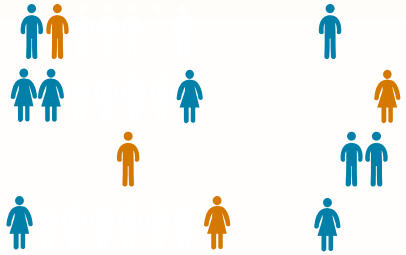
Significant portion of a large patient population

- E.g. PD-L1 in NSCLC
- Prevalence of disease + target pop + impact of CDx can drive uptake
- Requires a scalable platform



Relatively small portion of a large patient population

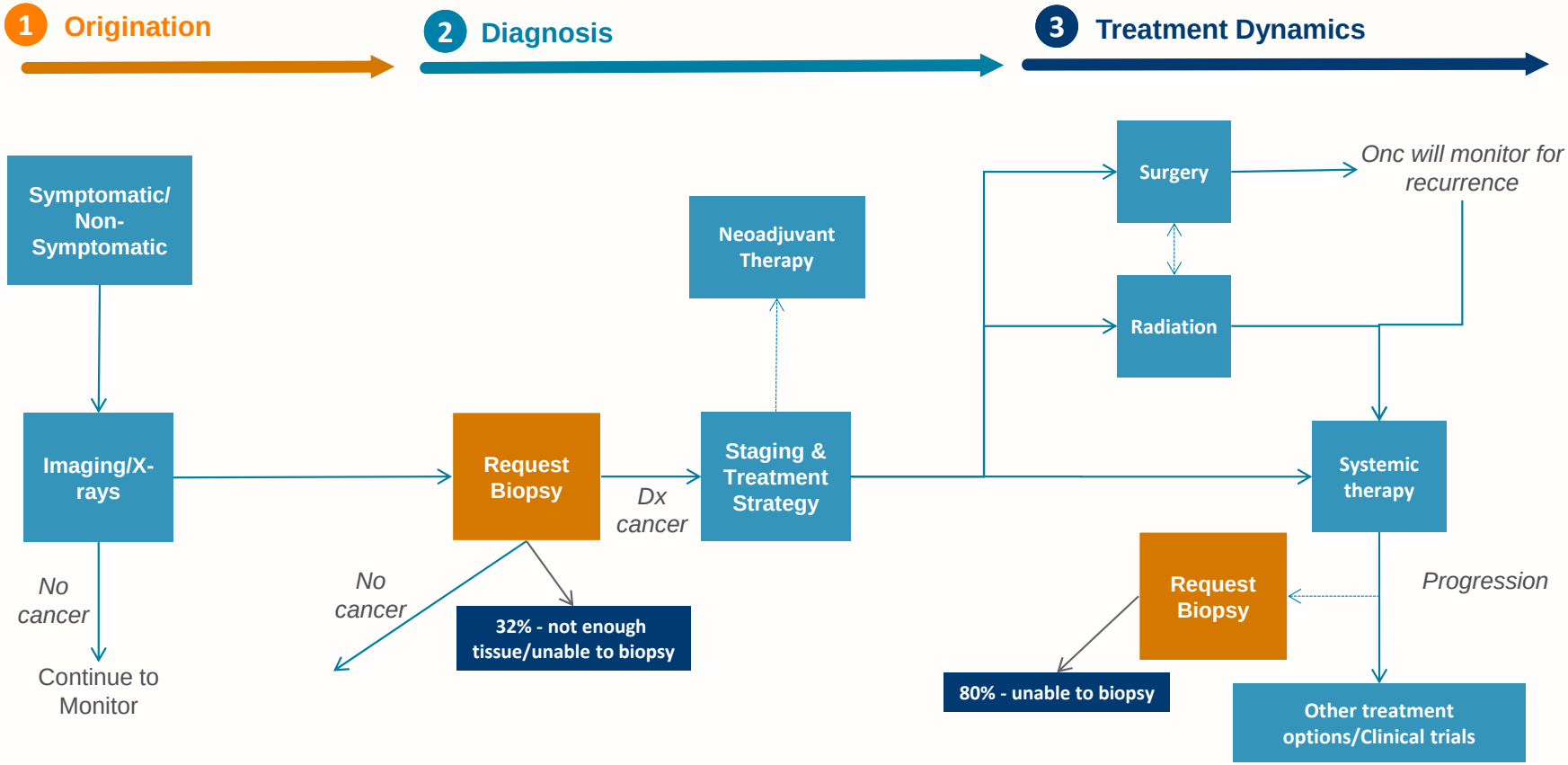
- E.g. BRAF in NSCLC
- Size of target pop can limit awareness
- Sample size & prioritization of testing may limit uptake



Significant portion of a small patient population

- E.g. FLT3 in AML / 17p in CLL
- Setting of care (general oncology vs specialists) can impact uptake
- Low frequency of patients may limit awareness
- CDx platform needs to be efficient for small batches

# Does testing fit into the standard of care patient flow



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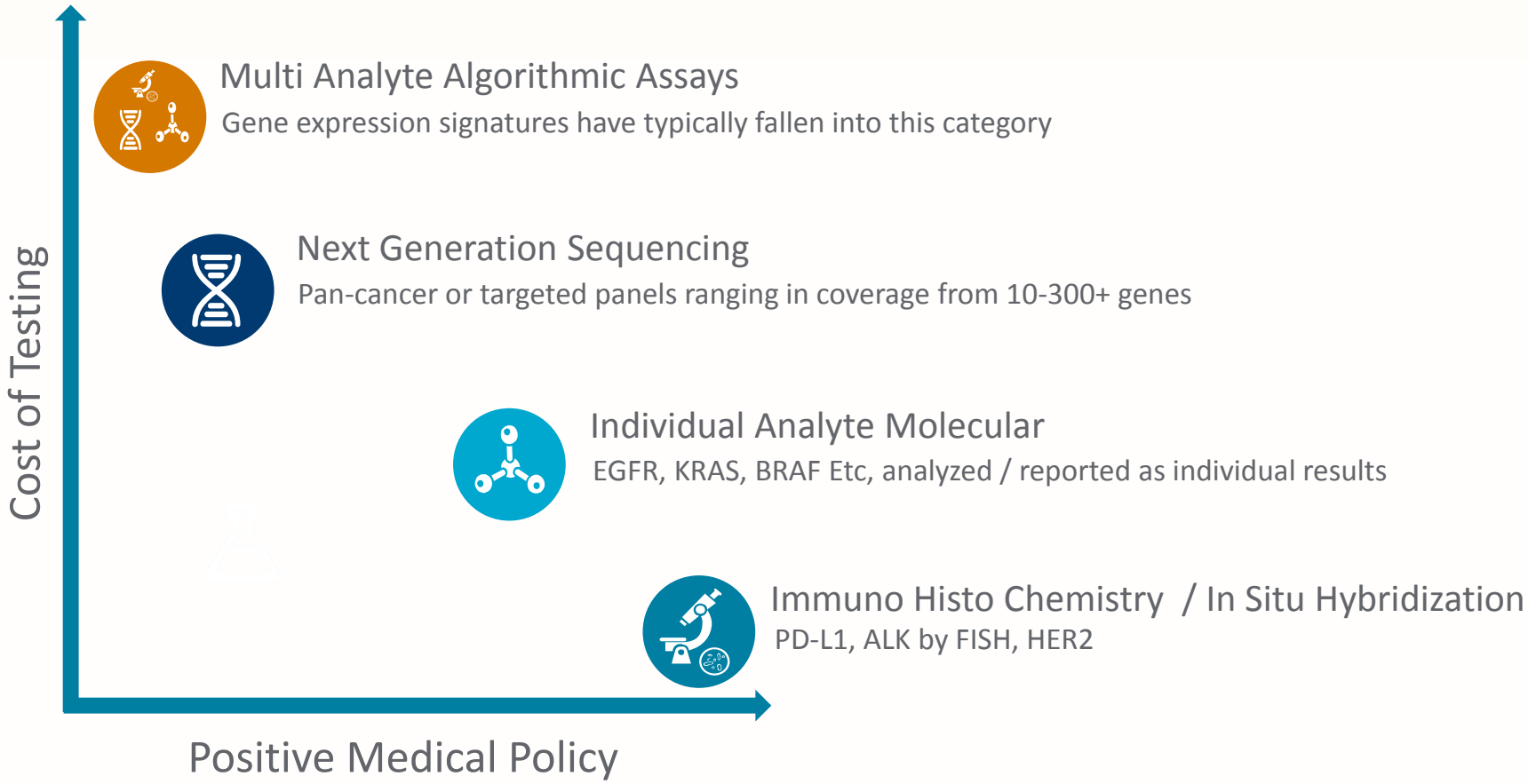
# Cost and policy adoption vary across diagnostic technologies



# Payers are implementing mechanism to manger laboratory utilization

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## Test utilization

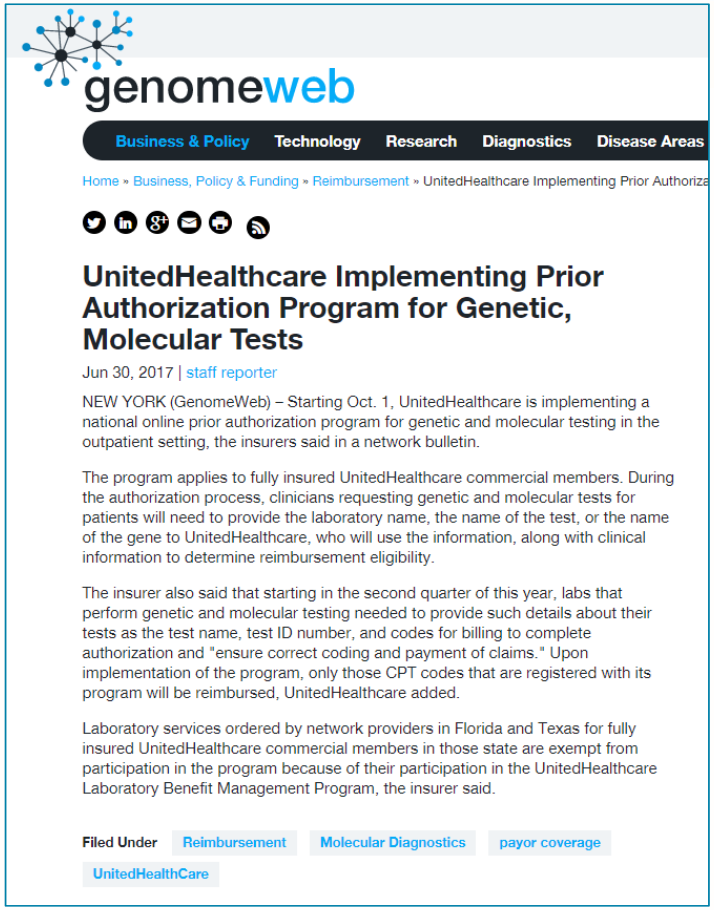
- Rapid growth of molecular and genetic testing
- Small portion of health care spend, but high cost per encounter compared to historical trends

## Broad categorization

- Programs being placed on well established / guideline supported tests and new tests alike
- UnitedHealthcare's program will include all molecular CPT codes

## Varied implementation

- Not all members fall under the program but it is hard for providers to discern which do or do not
- Most programs will only allow notification / authorization to be submitted by ordering physician, with some allowing recourse for labs



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**UnitedHealthcare Implementing Prior Authorization Program for Genetic, Molecular Tests**

Jun 30, 2017 | staff reporter

NEW YORK (GenomeWeb) – Starting Oct. 1, UnitedHealthcare is implementing a national online prior authorization program for genetic and molecular testing in the outpatient setting, the insurers said in a network bulletin.

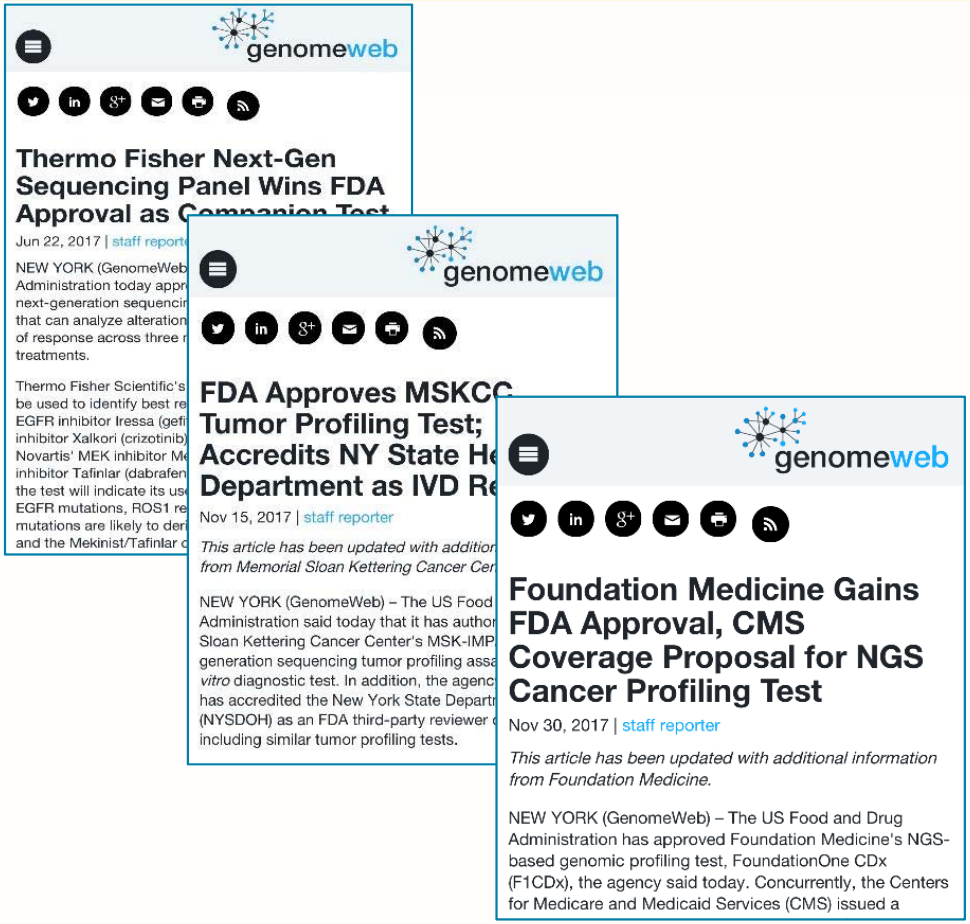
The program applies to fully insured UnitedHealthcare commercial members. During the authorization process, clinicians requesting genetic and molecular tests for patients will need to provide the laboratory name, the name of the test, or the name of the gene to UnitedHealthcare, who will use the information, along with clinical information to determine reimbursement eligibility.

The insurer also said that starting in the second quarter of this year, labs that perform genetic and molecular testing needed to provide such details about their tests as the test name, test ID number, and codes for billing to complete authorization and "ensure correct coding and payment of claims." Upon implementation of the program, only those CPT codes that are registered with its program will be reimbursed, UnitedHealthcare added.

Laboratory services ordered by network providers in Florida and Texas for fully insured UnitedHealthcare commercial members in those state are exempt from participation in the program because of their participation in the UnitedHealthcare Laboratory Benefit Management Program, the insurer said.

Filed Under Reimbursement | Molecular Diagnostics | payor coverage | UnitedHealthCare

# Evolving regulatory landscape for Next Generation Sequencing (NGS) based CDx



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**Thermo Fisher Next-Gen Sequencing Panel Wins FDA Approval as Companion Test**

Jun 22, 2017 | staff reporte

NEW YORK (GenomeWeb
Administration today appr
next-generation sequencin
that can analyze alteration
of response across three
treatments.

Thermo Fisher Scientific's
be used to identify best re
EGFR inhibitor Iressa (gefi
inhibitor Xalkori (crizotinib)
Novartis' MEK inhibitor M
inhibitor Tafinlar (dabrafen
the test will indicate its us
EGFR mutations, ROS1 re
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and the Mekinist/Tafinlar c

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**FDA Approves MSKCC Tumor Profiling Test; Accredits NY State He Department as IVD Re**

Nov 15, 2017 | staff reporter

*This article has been updated with additior from Memorial Sloan Kettering Cancer Cer*

NEW YORK (GenomeWeb) – The US Food
Administration said today that it has author
Sloan Kettering Cancer Center's MSK-IMP
generation sequencing tumor profiling assa
*vitro* diagnostic test. In addition, the agenc
has accredited the New York State Departr
(NYSDOH) as an FDA third-party reviewer
including similar tumor profiling tests.

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**Foundation Medicine Gains FDA Approval, CMS Coverage Proposal for NGS Cancer Profiling Test**

Nov 30, 2017 | staff reporter

*This article has been updated with additional information from Foundation Medicine.*

NEW YORK (GenomeWeb) – The US Food and Drug Administration has approved Foundation Medicine's NGS-based genomic profiling test, FoundationOne CDx (F1CDx), the agency said today. Concurrently, the Centers for Medicare and Medicaid Services (CMS) issued a

## Multiple Approvals

- Both kitted and laboratory developed tests (LDT)
- Allow for testing multiple biomarkers on single platform

## Tiered reporting

- Top tier for clinically validated biomarkers
- Tiers 2 & 3 allows for analytically validated biomarkers that have 3rd party data supporting therapeutic impact to be included

## NY State DOH 3rd party review

- Provides a pathway for LDT NGS assays to gain FDA approval
- Will not be the pathway for CDx indications

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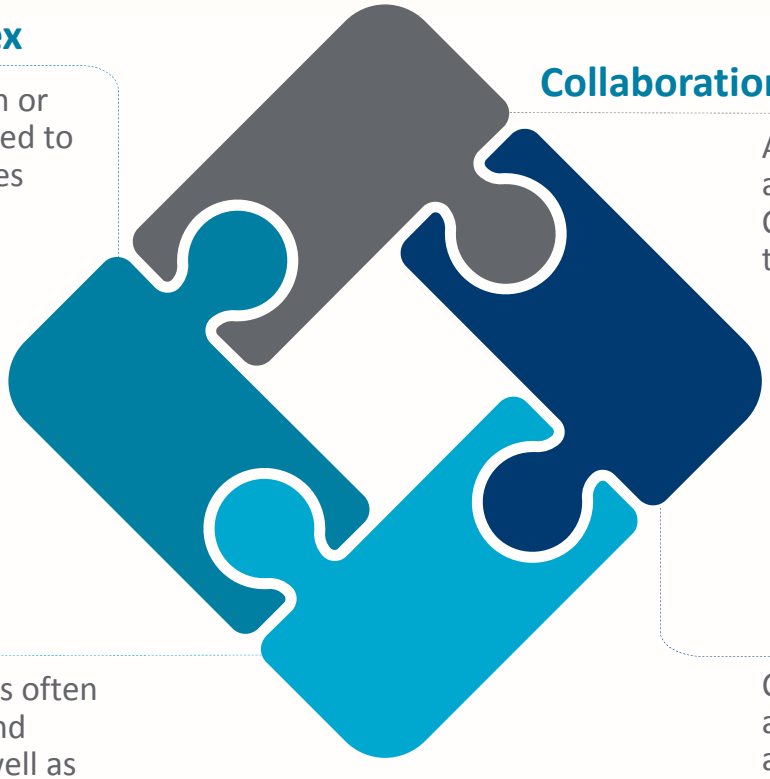
# Key considerations for CDx launch

## CDx Launches are Complex

The need to have testing available on or close to FDA approval creates the need to shorten conventional launch timelines



## Collaboration Among Stakeholders is a Must

A cooperative approach among manufacturer and laboratories will ensure more successful CDx launches that support access to impactful therapeutic innovations

## Adoption is Multifaceted

Labeling of the therapy and the CDx is often not enough to drive adoption. Size and spread of the target populations as well as the fit to patient flows need to be addressed

## Access Conditions are Evolving

Coding, pricing and access were once a given, as technology and the market evolves the access approach for CDx tests will have to become more sophisticated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