2018 EXECUTIVE WAR COLLEGE

SIFTING THROUGH A FRAGMENTED PAYER MARKET – EVALUATING NGS IN ONCOLOGY

MAY 2019
Navigant Consulting Inc. is a consulting firm serving industry sectors that require highly specialized solutions.

**WHO WE ARE:**
- **200+ Consulting Professionals**
- **2,700 Business Process Management Professionals**

**A TEAM OF:**
- Clinicians
- Data Analysts
- Strategists
- Scientists
- Former Industry Execs
- Former Govt Leaders

With PhDs, Masters, and Bachelors degrees

**WHAT WE DO:**
- Strategy
- Operational Improvement
- Business Process Management

**DELIVERED TO:**
- Life Sciences
- Payers
- Providers
- Governments

**22 OF THE 25 TOP GLOBAL PHARMACEUTICAL COMPANIES**

**#5 ON MODERN HEALTHCARE’S LARGEST HEALTHCARE MANAGEMENT CONSULTING FIRMS**

**BEST IN KLAS**

Recognized for Revenue Cycle Consulting, Outsourcing and CDI Services

**FORBES – AMERICA’S BEST MANAGEMENT CONSULTING FIRMS: HEALTHCARE 4 STARS**
# Agenda

1. **Today’s Objectives**
2. **A Brief Look at NGS**
3. **Clinical Considerations**
4. **Evaluating the Business Case**
5. **Key Takeaways From Your Lab**
6. **Q&A**
## Agenda

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Objectives for today’s discussion

1. Discuss context of Next Generation Sequencing (NGS) for today’s presentation
2. Provide a brief history of NGS reimbursement in oncology
3. Recap key milestones in 2018
4. Outline potential 2019 trends and impact on your lab’s decision making
Today will focus on 3 key considerations for your lab

What is the clinical value proposition? How are ‘panels’ perceived regarding medical necessity?

What operational challenges should be considered?

What is the business case and key considerations for bringing in-house?
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Next generation sequencing (NGS) became available in the clinical laboratory in late 2013 after the U.S. Food and Drug Administration (FDA) approved the first NGS system from Illumina.

NGS is a high throughput technique for rapidly sequencing of DNA or RNA samples; FDA-approved in vitro diagnostic or lab-developed NGS tests can complement standard quantitative PCR and microarrays.

NGS is scalable, from a subset of genes of interest to a full genome; the ability to evaluate multiple genes on one assay makes NGS cost-effective and reduces time to actionable results.

NGS genome sequencing enables increased diagnostic accuracy, sensitivity, and speed to support targeted clinical decision-making for oncology patients.

NGS Workflow

1. **Sample preparation**
2. **Library preparation and enrichment**
3. **Alignment and variant calling**
4. **Data analysis and variation confirmation**
5. **Data reporting**
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Precision medicine, and NGS, allows for better patient stratification to ensure optimized and personalized treatment regimens.

Implemented optimally, NGS is positioned to positively impact clinician treatment decision-making as well as subsequent patient health outcomes and improved adverse event profiles.
Targeted treatment and multi marker testing leads to many benefits across payers, providers, and patients

- Directing targeted therapy and reducing trial-and-error prescribing;
- Reducing adverse drug reactions;
- Revealing additional targeted uses for medicines and drug candidates;
- Reducing high-risk invasive test procedures;
- Improve turn around time
- Conserve patient tissue
- Helping to control the overall cost of healthcare

Dark Daily How Next-Generation Sequencing Helps Molecular Laboratories Deliver Personalized Medicine Services to Their Client Physicians
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6. **Q&A**
The business case for your lab offering NGS should consider revenue implications and workflow / operational requirements

**Lab Archetypes**

- Large academic hospitals – *precision medicine is a part of the 5 year mission*

- Middle Tier – $1M - $3B hospitals *actively evaluating the future of in-house lab programs*

- Small community hospitals – *resource constrained*

**Key Questions**

**What’s the market demand?**

**Who pays for it and under what circumstances (reimbursement)?**
- Will payers pay and under what circumstance?
- When paid, what will be the rate?

**What’s the operational impact?**
- What is the capital outlay and fixed/variable cost?
- Do I have the space?
- Do I have / can I hire staff to perform this?
While progress has been made, many obstacles still remain and labs need to determine how much risk is warranted.

Rogers Innovation Adoption Curve

<table>
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<tr>
<th>INFRASTRUCTURE</th>
<th>TECHNOLOGY</th>
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<tr>
<td>1. Condition Management</td>
<td>1. Operational Disruption</td>
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<td>2. Triggers for the technology</td>
<td>2. Set-up Scalability</td>
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<tr>
<td>3. Body of Evidence</td>
<td>3. Ease of Use / Usability</td>
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<tr>
<td>5. Reimbursement &amp; Coverage</td>
<td>5. Performance Reliability</td>
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<tr>
<td>7. Provider Capacity</td>
<td>7. Industry Engagement</td>
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Barriers to Adoption

- Condition Management
- Triggers for the technology
- Body of Evidence
- Guidelines / Standards
- Reimbursement & Coverage
- Stakeholder Economics
- Provider Capacity
- Operational Disruption
- Set-up Scalability
- Ease of Use / Usability
- Technology or Pt. Maintenance
- Performance Reliability
- Patient Burden
- Industry Engagement
With the advent of “NGS Panel” codes, payers have greater visibility into testing modality… and greater control over claims adjudication

- Historically, labs could ‘code stack’ for each gene on a panel, registering a la carte payment
- New coding became effective in January 1\textsuperscript{st}, 2016, TELLING payers this is NGS and this is a panel
- Volume has increased while denial rates have decreased

![Medicare Part B NGS Claims](chart.png)

Medicare Part B NGS Claims

- 81445, Solid, 5-50 Genes
- 81450, Heme, 5-50
- 81455, Solid or Heme, 51+
- All NGS

NGS Denial Rate

Medicare Physician Supplier Procedure Summary File, 2015 – 2017
While the overall volume of hospital based claims remains low, the 3-year CAGR is over 100% growth, compared to ~50% for other sites of service.

- Demand is increasing but remains primarily in a ‘partnership’ test send out arrangement.

**Medicare Part B NGS Claims by Place of Service**

<table>
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<tr>
<th>Year</th>
<th>Office /Other</th>
<th>Hospital</th>
<th>Independent Lab</th>
</tr>
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<tbody>
<tr>
<td>2015</td>
<td>326</td>
<td>5102</td>
<td>52</td>
</tr>
<tr>
<td>2016</td>
<td>539</td>
<td>10,535</td>
<td>173</td>
</tr>
<tr>
<td>2017</td>
<td>1,430</td>
<td>11,426</td>
<td>417</td>
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Medicare Physician Supplier Procedure Summary File, 2015 – 2017
Rate of denied claims has diminished partly due to Medicare’s NCD, finalized in 2018 creating more ‘scalable’ access for a patient subset

- Foundation Medicine’s FoundationOne CDx™ (F1CDx) companion diagnostic was accepted into Parallel Review in 2016

- In November of 2017, Medicare’s CAG issued a proposed NCD providing positive coverage for NGS, which was finalized in spring 2018

**Over-Simplified Version of NCD**

- Recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer

**-AND-**

- FDA approval / clearance as a CDx; and
- FDA indication for use in that patient’s cancer
However, a National Coverage Decision does not make access turn key and can limit scalability of revenue -- who is YOUR patient pool?

- Medicare
  - 57M Lives
  - (~33% MA)

- Commercial
  - 180M+ Lives

- Medicaid
  - 73M Lives
  - (74% Managed Medicaid)

AIS Dataset, Kaiser Family Foundation 2017, Medicaid.gov
However, many commercial plans remain “wait and see” and view NGS as experimental / investigational, limiting predictable payment / collections.

*Includes payers using Lab Benefit Managers (LBMs); Navigant Analysis September 2018.
In addition to PAYER fragmentation, we also see INDICATION fragmentation, creating even more uncertainty over coverage and payment.

Only ~1/2 of plans cover other indications.

NSCLC has been the “turn key” indication for NGS acceptance.

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**Commercial Payer Coverage by Indication**

<table>
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<tr>
<th>Indication</th>
<th>Silent / No Policy</th>
<th>Negative</th>
<th>Positive</th>
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<tr>
<td>&quot;Other&quot; Indications</td>
<td>9%</td>
<td>69%</td>
<td>22%</td>
</tr>
<tr>
<td>NGS</td>
<td>9%</td>
<td>37%</td>
<td>54%</td>
</tr>
<tr>
<td>NSCLC</td>
<td>9%</td>
<td>37%</td>
<td>54%</td>
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1Based on top 25 commercial payers by covered lives
Supplemental content (non-therapy directing) makes the whole panel experimental

Clinical and health economic evidence is lacking or inconclusive

No explicit society guideline recommendations for “NGS” creates ambiguity for payers

Society Positions

Testing should be conducted as part of broad molecular profiling

Payer Concerns

The difficulty with expanded molecular panels is that most of the genetic markers tested haven’t been shown to affect either cancer growth or cancer therapies. Because more study is needed, expanded molecular panels are considered investigational.  
- Premera Medical Policy

There is insufficient published evidence to support the wide use of molecular profiling to guide treatment decisions for malignant tumors. The available published literature consists of one randomized controlled trial, a small number of uncontrolled studies, and non-randomized trials that use imperfect comparators.  
- Anthem Medical Policy
Patient cost share ... what’s your patient collection strategy?

- The use of in-house testing requires labs to ensure patient collection and revenue cycle management systems are properly in place.

- The emergence of ‘high deductible’ plans means patient collections can be thousand of dollars up front.

- In addition to deductible, non-covered NGS services places a greater burden on patient collection for non-covered services.
  - These out of pocket costs can be quite surprising to patients.

Will health insurance cover the costs of genetic testing?
• UnitedHealthcare began implementing in Nov 2017 (via Beacon)

• Continue to scale utilization of these tools in 2019

• Other payers, including Anthem and regional Blue Cross plans, also implementing

**Thou shalt ask… Prior Auth continues to create workflow challenges**

**UnitedHealthcare Genetic and Molecular Lab Testing Notification/Prior Authorization Requirement**

Beginning March 1, 2019, UnitedHealthcare will require prior authorization/notification for genetic and molecular testing performed in an outpatient setting for UnitedHealthcare Community Plan members (excluding Medicare Advantage) in Florida. This requirement will take effect April 1, 2019 for UnitedHealthcare Community Plan members (excluding Medicare Advantage) in New Jersey, Pennsylvania and Rhode Island.

For more information on genetic and molecular testing notification/prior authorization, visit UHCprovider.com/en/prior-auth-advance-notification/genet2c-molecular-lab.html

**Anthem’s Genetic Testing Program FAQs**

**Q: What services are included in the Anthem Genetic Testing Program?**

**A:** AIM Specialty Health® (AIM) will perform the medical necessity review of all genetic testing services as pre-authorization requests against health plan clinical criteria in phases as follows:

- All fully insured except Virginia effective July 1, 2017.
- Medicare and Medicaid phased beginning 11/1/17
- National Accounts, Local ASO, Unicare and Healthlink for JAA effective January 1, 2018 for any groups that buy the program.
- Virginia fully insured (except HMO) and local ASO PPO effective November 1, 2018

  - Important Note: VA HMO requests will continue to be managed by Anthem local VA Medical Management. VA HMO no authorization needed if done by LabCorp
Outside of coverage, payment rates remain a key question on profitability of in-house testing due to PAMA

- Enacted April 1, 2014 under Sec. 216
- Applies to independent labs, physician office labs and hospital outreach labs that meet certain threshold requirements
- Requires collection and reporting of private payor payment and test volume data to CMS
- Establishes a new market-based “weighted median” payment methodology to pay for most clinical laboratory tests on the CLFS
- Data collection: 2016
  Data reporting: 2017
  Rates in effect: 2018

PAMA: Protecting Access to Medicare Act
The payment file released in 2018 included 1,359 codes
- 204 codes were ‘new’ or did have historical 2017 data
- 1,014 codes saw a decrease in payment, averaging a ~30% cut, though PAMA caps reductions to 10% year over year
- 141 codes saw an increase in payment, averaging a 74% uptick

*Note that PAMA caps YoY decreases at 10%
The business case recap...

- Payer coverage is spotty across payer segments and indications
- Payers likely remain ‘pragmatic’ by using indication by indication coverage
- Payment rates remain steady and predictable
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It is not a zero sum game for hospital vs. reference labs… collaboration and partnerships remain critical in the patient journey

Is there strong regional market demand? Is your lab prioritizing ‘precision medicine’ as a key clinical initiative for 2020 and beyond?

Do you have the footprint, space, and staffing to implement investments in NGS?

Does your patient and payer mix support predictable and profitable revenue streams?

Evaluate the business case before you jump in feet first… there is a way to create the pro forma

Continue test send-out partnerships and reevaluate as market steadies
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