Analysis of Reimbursement for Next Generation Sequencing (NGS) on Patients’ Tumors in the Context of a Personalized Medicine Program

Brown TD\textsuperscript{1}, Tameishi M\textsuperscript{1}, Liu X\textsuperscript{1}, Scanlan JM\textsuperscript{2}, Beatty JD\textsuperscript{1}, Drescher CW\textsuperscript{1}, Pagel JM\textsuperscript{1}, Gold PJ\textsuperscript{1}, Alexander S\textsuperscript{1}, Summers LK\textsuperscript{1}, Brindle M\textsuperscript{1}, Varghis N\textsuperscript{1}, Yates J\textsuperscript{1}, Fondren KN\textsuperscript{3}, Birchfield GR\textsuperscript{1}, Dong DE\textsuperscript{1}, Benkers TL\textsuperscript{1,4}, Wahl TA\textsuperscript{1}, Ramsey SD\textsuperscript{5}, Berry AB\textsuperscript{1,3}.

\textsuperscript{1}Swedish Cancer Institute, Seattle, WA; \textsuperscript{2}Swedish Medical Center, Seattle, WA; \textsuperscript{3}CellNetix Pathology & Laboratories, Seattle, WA; \textsuperscript{4}Swedish Neuroscience Institute, Seattle, WA; \textsuperscript{5}Fred Hutchinson Cancer Research Center, Seattle, WA
Background

• Increasingly, genomic changes in patients’ tumors are used to inform individualized management.

• Reimbursement policies for NGS testing vary widely among private and public insurers.

• While drug costs are the greatest challenge in personalized or precision medicine, cost and reimbursement are substantial barriers to genomic profiling with NGS.

• We examined variation in coverage and reimbursement for a cohort of cancer patients treated at a tertiary oncology center.
Background: Swedish Cancer Institute (SCI)
Personalized Medicine Research Program (PMRP)

• 2015 Jan: SCI Molecular Tumor Board.
• 2015 Nov: Cloud-based PMRP IT Platform.
SCI PMRP: Methods

- A custom designed NGS 68 gene alteration (GA) panel, covering clinically relevant genes and regions, was offered early in the course of management.
- GA were categorized as actionable (on label indication), or applicable [off label and/or clinical trial (CT) indication].
- The NGS results were used to:
  - Prioritize standard therapies;
  - Match patients (pts) with clinical trials (CT);
  - Serve as a data mining resource.
SCI PMRP: Methods (Cont’d)

• An IRB approved prospective registration protocol was activated in 2014, to establish a centralized longitudinal, molecular phenotypic, and research data repository.
  • NGS panel ordered based on medical necessity.
  • A cloud-based informatics platform was developed to:
    – Manage PMRP;
    – Facilitate CT matching;
    – Perform quality assurance/quality improvement;
    – Pursue research initiatives.
SCI PMRP: Methods (Cont’d)

- **Cost to Participate in PMRP:** None.
- **Languages:** Consent form in English, Vietnamese, Korean, Japanese, Mandarin & Cantonese, Russian and Spanish.
- **Evaluation of Reimbursement for NGS:** performed from Jan, 2015 through May, 2017, with use of CPT code 81455.
- **Reimbursement Analyzed Based on:** payer type; pt age and gender; diagnosis; localized vs. metastatic disease; and actionability of data.
SCI PMRP: Results

Demographics and Stage

• As of 05/5/2017, 951 pts gave informed consent, with 930 pts enrolled.
• 602 pts evaluable on PMRP with NGS reimbursement and demographic data.
  • Median age 62.
  • 262 (44%) male; 340 (56%) female.
  • Of pts with documented race: Caucasian-501 pts (89%); Asian-39 pts (7%); African American/African-15 (3%); Native American or Alaska Native-7 (1%); Native Hawaiian or Other Pacific Islander-2 (<1%)
  • Of solid tumor pts with documentable stage: 183 pts (52%) had Stages I, II, or III; 170 pts had Stage IV (48%).
SCI PMRP: Results
Primary Cancer Site

Most Common Documented Primary Sites

<table>
<thead>
<tr>
<th>Primary Site</th>
<th># of Pts</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central Nervous System</td>
<td>102</td>
<td>(18%)</td>
</tr>
<tr>
<td>Breast</td>
<td>67</td>
<td>(12%)</td>
</tr>
<tr>
<td>Colon and Rectum</td>
<td>65</td>
<td>(12%)</td>
</tr>
<tr>
<td>Lung</td>
<td>55</td>
<td>(10%)</td>
</tr>
<tr>
<td>Ovary</td>
<td>39</td>
<td>(7%)</td>
</tr>
<tr>
<td>Hematologic</td>
<td>35</td>
<td>(6%)</td>
</tr>
<tr>
<td>Pancreas</td>
<td>30</td>
<td>(5%)</td>
</tr>
<tr>
<td>Uterus</td>
<td>24</td>
<td>(4%)</td>
</tr>
<tr>
<td>Skin</td>
<td>15</td>
<td>(3%)</td>
</tr>
<tr>
<td>Esophagus</td>
<td>13</td>
<td>(2%)</td>
</tr>
<tr>
<td>Intrahepatic Bile Ducts</td>
<td>11</td>
<td>(2%)</td>
</tr>
</tbody>
</table>

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Abstract #6506
SCI PMRP: NGS Results

Evaluable 602 Pts with NGS Cases

- No Gene Alteration: 20 Pts (3%)
- No NGS Results: 14 Pts (2%)
- Unknown Significance: 137 Pts (24%)
- Gene Alterations: 568 Pts (95%)
- Actionable/Applicable: 431 Pts (76%)

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Abstract #6506
SCI PMRP: Top Actionable Gene Alterations (GAs)

- **KRAS**: 82 (62%)
- **PIK3CA**: 13 (10%)
- **EGFR**: 11 (8%)
- **BRAF**: 9 (7%)
- **NRAS**: 7 (5%)
- **PTEN**: 2 (2%)
- **TET2**: 2 (2%)
- **AKT1**: 2 (2%)
- **VHL**: 1 (1%)
- **GNA11**: 1 (1%)
- **ERBB2**: 1 (1%)
- **HRAS**: 1 (1%)
SCI PMRP: Top Applicable Gene Alterations (GAs)

- TP53: 177 (27%)
- TPMT: 65 (10%)
- APC: 56 (9%)
- TVMS: 55 (8%)
- PTEN: 51 (8%)
- PIK3CA: 50 (8%)
- IDH1: 34 (5%)
- CDKN2A: 20 (3%)
- TET2: 18 (3%)
- BRAF: 14 (2%)
- CTNNB1: 12 (2%)
- FBXW7: 11 (2%)
- KRAS: 10 (2%)

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Abstract #6506
Reimbursement Frequency and Payment by Payer

- Medicare HMO has higher frequency of reimbursement than Private HMO ($p<.04$).
- Payments by both Private and Medicare HMOs were higher than other payers ($p<.001$).

<table>
<thead>
<tr>
<th>Payer</th>
<th>Frequency of Reimbursement (%</th>
<th>Mean ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid</td>
<td>57%</td>
<td>30 pts $1,341</td>
</tr>
<tr>
<td>Private Non-HMO</td>
<td>21%</td>
<td>55 pts $1,596</td>
</tr>
<tr>
<td>Private HMO</td>
<td>51%</td>
<td>37 pts $2,075</td>
</tr>
<tr>
<td>Medicare Non-HMO</td>
<td>0%</td>
<td>153 pts $0</td>
</tr>
<tr>
<td>Medicare HMO</td>
<td>66%</td>
<td>33 pts $1,526</td>
</tr>
</tbody>
</table>

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Abstract #6506
Association of Actionability with Reimbursement

- Frequency of reimbursement and payment for pts with \( \geq 2 \) actionable mutations were significantly lower than for pts with 0 or 1 actionable mutations (\( p < .01 \)).

<table>
<thead>
<tr>
<th>Mean R ($)</th>
<th>Frequency of Reimbursement (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$600</td>
<td>35%</td>
</tr>
<tr>
<td>$400</td>
<td>30%</td>
</tr>
<tr>
<td>$200</td>
<td>25%</td>
</tr>
<tr>
<td>$0</td>
<td>20%</td>
</tr>
</tbody>
</table>

| 171 Pts  | (33%) |
| 206 Pts  | (29%) |
| 225 Pts  | (18%) |

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Abstract #6506
Association of Age with Reimbursement

- Younger age was associated with more frequent and higher reimbursement (31% in pts < 65 years, 17% in pts ≥ 65 yo) (p < .001).
- Among pts ≥ 65 yo, frequency (p < .001) and payments (p < .005) by Medicare HMO (69%; $1,003) were higher than Private payers (19%; $361).
NGS Reimbursement Denial Based on Denial Codes

- Denials based on “not covered,” and “investigational therapy” were the most common reasons for lack of reimbursement.

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Conclusions

• One third of patients received some reimbursement for NGS testing.
• Reimbursement was more frequent and higher in managed care programs, both Private and Medicare. No reimbursement was received from non-HMO Medicare.
• Reimbursement was more likely for younger age patients.
• Actionable NGS results were associated with less frequent and lower reimbursement.
Conclusions (Cont’d)

• Neither cancer diagnosis nor stage were significantly associated with reimbursement.

• “Not covered” and “Investigational” were the most common reasons for denial.

• These data demonstrate the need for rational, transparent, and consistent reimbursement policies, along with a value-based reimbursement model for NGS across all payer groups.
SCI PMRP TEAM

Principal Investigator
- Thomas D Brown, MD, MBA

Co-Principal Investigator
- Philip J Gold, MD
- Anna Berry, MD

Co-Principal Investigator
- Charles W Drescher, MD

Co-Principal Investigator
- John Pagel, MD, PhD

Technical Expert
- Danbin Xu, MD, PhD

Investigator
- Shlece Alexander
- David Beatty
- Madeleine Brindle
- Andy Case
- Janell Duey
- Patra Grevstad
- Desiree Iriarte
- Ryan Johnson
- Justin Jones
- John Kaneko
- Soohee Lee
- Xiaoyu Liu
- Donielle O’Connor
- Scott Ramsey (HICOR/Fred Hutch)
- James Scanlan
- Lauren Summers
- Mariko Tameishi
- Paul Tittel
- Nina Varghis
- Jim Yates