Implementing Genomic Medicine Programs—Financial Impact

Joanne Armstrong, MD
May 3-4, 2012
## Aetna at a Glance

### Employees & Customers
- We serve ~33.8M unique people and 69% of Fortune 100 companies
- Customers include individuals, employer groups, health plans, hospitals/physicians and government-sponsored plans
- ~66% members are from large, self-insured employers

### Membership
- 17.9 million medical members
- 8.6 million pharmacy members
- 13.6 million dental members

### USA Networks
- More than 1 million health care professionals (>575K primary care doctors and specialists) and more than 5K hospitals
- A network of specialist physicians, recognized with Aexcel® designation, based on clinical performance and cost efficiency

### International Presence
- Health benefits for expatriate employees and dependents
- Access to >61K health care providers in 195 countries
- UK operations, with presence in Europe, Asia & Middle East

### Medical Management
- Products/services that help improve member care and lower costs, including:
  - Wellness programs
  - Disease management and case/utilization management

### Health Information Technology
- Evidence-based clinical rules engine (CareEngine®) identifies gaps in care
- Targeted search based on clinical condition(s) identified in PHR
- Medicity provides the largest installed base of enterprise HIE systems for hospitals, physicians and other health care providers
The Big Picture

Health care spending in the US is increasing rapidly

In 2011, 18% of GDP was spent on health care
By 2015, 20% GDP projected to be for health care

Poor quality and misallocation of resources are well documented

IOM reports that 44,000 to 98,000 Americans die each year from medical errors

Americans spend an estimated $70 billion per year on incorrectly prescribed drugs

Rand studies demonstrate compliance with reasonable evidence-based guidelines is about 53%

Reference: “To Err is Human - Building a Safer Health System”, IOM Committee on Quality of Health Care in America, National Academy Press, Washington DC, copyright 1999
The Emergence of Genetic Laboratory Tests

Rapid increase in the availability of genetic tests

Reported increase in utilization of genetic tests is steep

- 20% increase in utilization of genetic diagnostic tests per year vs. 1%-3% for non-genetic diagnostic tests.

Data on utilization of genetic tests and clinical interventions based on these tests is limited

2. SunTrust Robinson Humphrey, March 2002
The Emergence of Genetic Laboratory Tests

Genetic/molecular diagnostics represent $3B of $50B laboratory testing market and are estimated to grow at 20%-50% annual trend

Source: Generation Health, 2009
Piper Jaffray IVD Report, 2008
Genetic and Molecular Testing Cost Impact

Aetna financial cost of genetic testing and molecular diagnostic tests is modest relative to total medical spending, but the trends are steep

- Genetic tests costs 0.74pmpm (<0.5% of total medical spending) – 2011
  - 1/3 cancer, 1/3 reproductive genetics, 1/3 other
    (infectious disease, GI, cardiac)
- Genetic tests cost trend 11% - 2008 – 2011

Blockbuster diagnostic tests are here

- BRCA - $2,400
- Oncotype Dx - $3,400
- Familion Index - $5,400
Emergence of new biologic therapies

Rapid increase in availability of new biologic/PG medications
Biologics represent 25% of new drugs approved by FDA since 20001

The cost and trend of biologic therapy is higher than traditional therapy
Nationally reported drug trend projections for specialty drugs is 12%-16% with non-specialty drug trend projected at 3-5% 1

Oncology drug sales grow at 12-15% per year and currently $80B per year worldwide

Per drug costs of some biologics can be very high 2
Herceptin - $55,000 per treated member per year
Kalydeco - $350,000 per treated member per year
## Companion diagnostics to optimize drug therapies

<table>
<thead>
<tr>
<th>Class</th>
<th>Drug</th>
<th>Companion Dx</th>
<th>Tx Cost per year</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oncology</td>
<td>Campath (alemtuzumab)</td>
<td>CD52</td>
<td>$76,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Oncology</td>
<td>Erbitux (cetuximab)</td>
<td>KRAS</td>
<td>$100,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Oncology</td>
<td>Gleevec (imatinib)</td>
<td>cKIT (CD117), BCR-ABL</td>
<td>$83,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Oncology</td>
<td>Herceptin (trastuzumab)</td>
<td>Her-2</td>
<td>$55,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>Kalydeco (ivacaftor)</td>
<td>G551D</td>
<td>$350,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Oncology</td>
<td>Ontak (denileukin)</td>
<td>CD25</td>
<td>$223,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Infectious Disease</td>
<td>Peginterferon</td>
<td>Hep C genotyping IL28B Polymorphism</td>
<td>$30,000</td>
<td>Yes/No</td>
</tr>
<tr>
<td>Cardiac</td>
<td>Plavix (clopidogrel)</td>
<td>CYP2C19</td>
<td>$2,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Oncology</td>
<td>Rituxin (rituximab)</td>
<td>CD20</td>
<td>$60,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Oncology</td>
<td>Sprycel (dasatinib)</td>
<td>BRC-ABL T315</td>
<td>$92,000</td>
<td>Yes</td>
</tr>
</tbody>
</table>
## Companion diagnostics to optimize drug therapies

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<th>Tx Cost</th>
<th>Coverage</th>
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</thead>
<tbody>
<tr>
<td>Neurolog</td>
<td>Tegretol (carbamazepine)</td>
<td>HLA-B*1502</td>
<td>$700</td>
<td>Yes-Asian pop. only</td>
</tr>
<tr>
<td>Oncology</td>
<td>Tarceva (erlotinib)</td>
<td>EGFR&lt; KRAS</td>
<td>$57,000</td>
<td>Yes</td>
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<tr>
<td>Oncology</td>
<td>Tasigna (nilotinib)</td>
<td>BCR-ABL T3151</td>
<td>$86,000</td>
<td>Yes</td>
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<tr>
<td>Oncology</td>
<td>Tykerb (lapatinib)</td>
<td>Her-2</td>
<td>$45,000</td>
<td>Yes</td>
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<tr>
<td>Oncology</td>
<td>Vectibix (panitumumab)</td>
<td>KRAS</td>
<td>$124,000</td>
<td>Yes</td>
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<tr>
<td>Oncology</td>
<td>Xalkori (crizotinib)</td>
<td>ALK fusion</td>
<td>$117,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Neurology</td>
<td>Xenazine (tetrabenazine)</td>
<td>CYP2D6</td>
<td>$73,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Oncology</td>
<td>Zelboraf ( vemurafenib)</td>
<td>BRAF V600E</td>
<td>$120,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Infectious</td>
<td>Ziagen (abacavir)</td>
<td>HLA-B*5701</td>
<td>$7,000</td>
<td>Yes</td>
</tr>
<tr>
<td>Neurology</td>
<td>Aricept (donepezil)</td>
<td>CYP2D6</td>
<td>$500</td>
<td>No</td>
</tr>
<tr>
<td>Oncology</td>
<td>Camptosar (irinotecan)</td>
<td>UGT1A1</td>
<td>$1,300</td>
<td>No</td>
</tr>
<tr>
<td>Psych</td>
<td>SSRI</td>
<td>CYP450 poly.</td>
<td>$400</td>
<td>No</td>
</tr>
<tr>
<td>Oncology</td>
<td>Tamoxifen</td>
<td>CYP450 poly.</td>
<td>$200</td>
<td>No</td>
</tr>
<tr>
<td>Cardiology</td>
<td>Warfarin</td>
<td>VK0RC1/CYP450</td>
<td>$100</td>
<td>No</td>
</tr>
</tbody>
</table>
The Value Proposition

Will genetic/personalized medicine improve the quality, safety, and/or cost effectiveness of delivered health care?

or....

Will genetic/personalized medicine drive additional medical costs with marginal health care gains?
Challenges to the (Greater) Adoption of Genetic Medicine

Concerns about effectiveness and cost effectiveness

Science limitations:
  - Clinical validity, clinical utility, actionability

Clinician and patient/consumer preparedness
  - Need for effective decision support tools
  - Direct to consumer marketing concerns

CPT coding challenges

Privacy considerations

Disparities in use of genetic technologies
Aetna Coverage Policy Principles

- Services are related to prevention, diagnosis, or treatment of an illness.
- Information will affect the course of treatment of the member.
- Care and/or treatment is likely to improve outcome.
- Improvement must be attainable outside investigational settings.
- Services are consistent with plan design.

...Same coverage policy principles for genetic technologies as for all other technologies.
Evidence Standards for Coverage

Covered services must have:

- Published, peer reviewed, scientific evidence that permits conclusions concerning test performance and the effect of the technology on health outcomes.
  
  Analytic validity
  
  Clinical validity
  
  Clinical utility

- Final approval from the appropriate governmental regulatory bodies, when required

- Demonstrate improved net health outcome and be as beneficial as any established alternatives

...Same evidence standards for genetic technologies as for all other technologies.
What is the Role of Cost and Cost-Effectiveness in Coverage Decisions?

- Aetna reviews the comparative effectiveness of new medical technologies
- Cost-effectiveness is not a determinant of the coverage decisions
- Cost and cost effectiveness does influence process by which technologies are managed within plan
  - Precertification
  - Predetermination
  - Disease management
  - Pharmacy management
Precertification to Promote Evidence-Based use of Genomic Services

**Oncotype Dx** – predicts recurrence of breast cancer to guide adj chemotherapy
  Results: 9% requests are not consistent with guidelines

**KRAS/Erbilux** – predicts non-response to cetuximab (Erbilux)
  • Results: 5% requests are not consistent with guidelines

**Hepatitis C** – Use of viral genotyping to guide interferon/ribavirin therapy
  • Results: 10% reduction in avoidable drug therapy

**PGD** – Preimplantation genetic diagnosis
  • Results: 40% requests are not medically appropriate

**BRCA** – Inherited susceptibility to breast and ovarian cancer
  • Results: 23% requests are not consistent with guidelines
Direct to consumer marketing and physician detailing have driven demand for BRCA testing

- 244% increase in demand for BRCA following DTC campaign \(^1\)
- 10% increase in Aetna test request year over year 2004-present

Marketing results in both medically appropriate and non evidence based requests for testing

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2. Aetna, 2011
Aetna Clinical Policies

- Policies developed by a dedicated team of clinicians
- Policies reviewed annually, or more frequently
  
  - FDA decision, new policy from professional organization, practice pattern change, request from providers or medical specialty societies
- All policies available on-line
  
  www.Aetna.com
- CPB includes:
  
  - Background, detailed rationale for policy
  - Coding,
  - References
  
  - Comprehensive revision history

NHGRI
Clinical and Consumer Preparedness

Shortage of trained genetic specialists and significant knowledge gaps in clinician workforce

Fewer than 900 Board certified medical geneticists and 2,000 genetic counselors in US

72% non-genetics MDs rate their knowledge of genetics as fair to poor (2000)

65%-75% PCP uncomfortable interpreting genetic tests (2012)

Genetic decision making requires significant genetics literacy... and consumers are not up to the task

Fewer than 7% of Americans are scientifically literate

82% of consumers cannot correctly answer most genetic medicine knowledge questions in national surveys

3. UnitedHealthcare, 2012
4. Genetics and Public Policy Center Survey 2002
Strategies to Promote Evidence-Based use of Genomic Services

Member Alerts/Care Considerations Delivered to PHR

Member Health Profile

CareEngine®

Disease Management
Wellness counseling

Delivery to Providers
MD Portals and Links
Strategies to Promote Evidence-Based use of Genomic Services

Genetic focused Care Considerations

- Family History of Abdominal Aortic Aneurysm (AAA) - Consider Screening for AAA
- COPD with Family History of COPD - Consider Screening for Alpha-1 Antitrypsin Deficiency
- Familial Adenomatous Polyposis - Consider Sigmoidoscopy or Colonoscopy
- Hereditary Nonpolyposis Colorectal Cancer - Consider Colonoscopy
- Pediatric Type 1 Diabetes and FHx of CAD Risk Factors - Consider Lipid Panel Monitoring
- Male Breast Cancer - Consider Genetic Counseling
- Breast Cancer with Risk Factors - Consider Genetic Counseling
- Breast Cancer (Age less than 40) - Consider Genetic Counseling
- Ovarian cancer and genetic counseling (pending)
### BCR/ABL-t(9;22) by RT PCR (Quantitative)

<table>
<thead>
<tr>
<th>2011 CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>83891 (2)</td>
<td>Extraction of highly purified nucleic acid</td>
</tr>
<tr>
<td>83892 (2)</td>
<td>Enzymatic digestion</td>
</tr>
<tr>
<td>83896 (4)</td>
<td>Nucleic acid probe(s)</td>
</tr>
<tr>
<td>83902 (2)</td>
<td>Mutation scanning by physical properties</td>
</tr>
<tr>
<td>83912</td>
<td>Interpretation and report</td>
</tr>
</tbody>
</table>

**Indication for use:** Gleevec monitoring for CML (leukemia)

#### 2012 CPT

**CPT 81206**

BRC/ABL MAJOR/MINOR/OTHER BREAKPOINTS

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### UGT1A1 Testing for Colorectal Cancer

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<td>Extraction of highly purified nucleic acid</td>
</tr>
<tr>
<td>83892 (2)</td>
<td>Enzymatic digestion</td>
</tr>
<tr>
<td>83896 (12)</td>
<td>Nucleic acid probe(s)</td>
</tr>
<tr>
<td>83902 (4)</td>
<td>Mutation scanning by physical properties</td>
</tr>
<tr>
<td>83908 (4)</td>
<td>Signal amplification of patient nucleic acid</td>
</tr>
<tr>
<td>83912</td>
<td>Interpretation and report</td>
</tr>
</tbody>
</table>

**Indication for use:** Irinotecan monitoring for colorectal cancer

#### 2012 CPT

**CPT 81350**


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The conversion of stack CPT codes to specific codes will improve ability to track utilization, enable decision support tools, and enforce coverage policy
Strategies to Promote Evidence-Based use of Genomic Services

On-line resources

- **Physician CME**
  - Genetics in Health Care: An Overview
  - Genetic Counseling: Helping your patients
  - Genetics in Clinical Practice: A Team Approach
  - Inherited Breast and Ovarian Cancer: Identifying and Managing
  - Cross Cultural Issues in Genetic Counseling
  - Genetic Resource Tools

- **Member guides on InteliHealth**

- **Opportunities for deeper “engagement” with mobile applications**
Strategies to Promote Evidence-Based use of Genomic Services

Network Strategies

- **Telephonic genetic counseling for wide range of conditions.**
  - Passive availability
  - Active steerage under selected circumstances—e.g. BRCA, HNPCC

- **Oncology Network Strategies**
  - Efforts underway to create oncology medical homes
  - Reimbursement model is based on adherence to care pathways and measured outcomes
  - Significant software available and in development to provide decision support to support all aspects of care, including pathways
Examples of Potential P4V or PCMH Measures in Oncology Networks

% of chemotherapy treatments that have adhered to NCCN guidelines or pathways. / % Adherence to Level I pathways by line of therapy and by Cancer Type

% of cancer pts with documented clinical or pathologic staging prior to initiation of 1st course of treatment. (QOPI 2011#2) / Cancer staging *tumor histology and biomarker included if applicable

# of hospital admissions per chemotherapy patient per year / Chemotherapy-sensitive Inpatient Admissions/1,000
Research Collaborations

• Determinants of primary care physician use of genetic cancer counseling services - Fox Chase Cancer Center-Determinants (2009)

• Clinical utility of selected genetic tests (Her 2 and Oncotype Dx) in chemotherapy decision making management – UCSF/Harvard Partners (2010)

• Coding specificity and utility of health plan claims data in clinical research – UCSF/Harvard Partners (2010)

• American BRCA Outcomes and Utilization of Testing (ABOUT) Study – University of South Florida, ACA –ongoing

• Evaluation of disparities in receipt of genetic services – UCLA/Harvard Partners – (3Q 2012)
## Genomics Personalized Medicine
### Privacy Concerns

What uses of genetic tests do you support?

<table>
<thead>
<tr>
<th>Uses</th>
<th>Access to Results</th>
<th>Trusted with Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctors to provide care</td>
<td>93%</td>
<td>86%</td>
</tr>
<tr>
<td>Researchers</td>
<td>93%</td>
<td>66%</td>
</tr>
<tr>
<td>Health insurance companies for eligibility and pricing</td>
<td>15%</td>
<td>24%</td>
</tr>
<tr>
<td>Employers for hiring and promotion</td>
<td>19%</td>
<td>16%</td>
</tr>
</tbody>
</table>

Activities to support member needs in genomic medicine space must be sensitive to privacy concerns.
Thank you