

Implementing Genomic Medicine Programs- Financial Impact

Joanne Armstrong, MD

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Aetna at a Glance



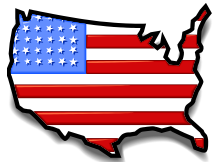
Employees & Customers

- 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

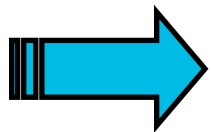
The Big Picture

Health care spending in the US is increasing rapidly

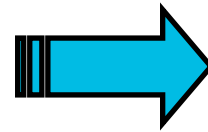
In 2011, 18% of GDP was spent on health care

By 2015, 20% GDP projected to be for health care

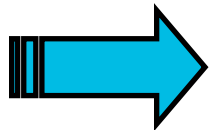
Poor quality and misallocation of resources are well documented



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%.

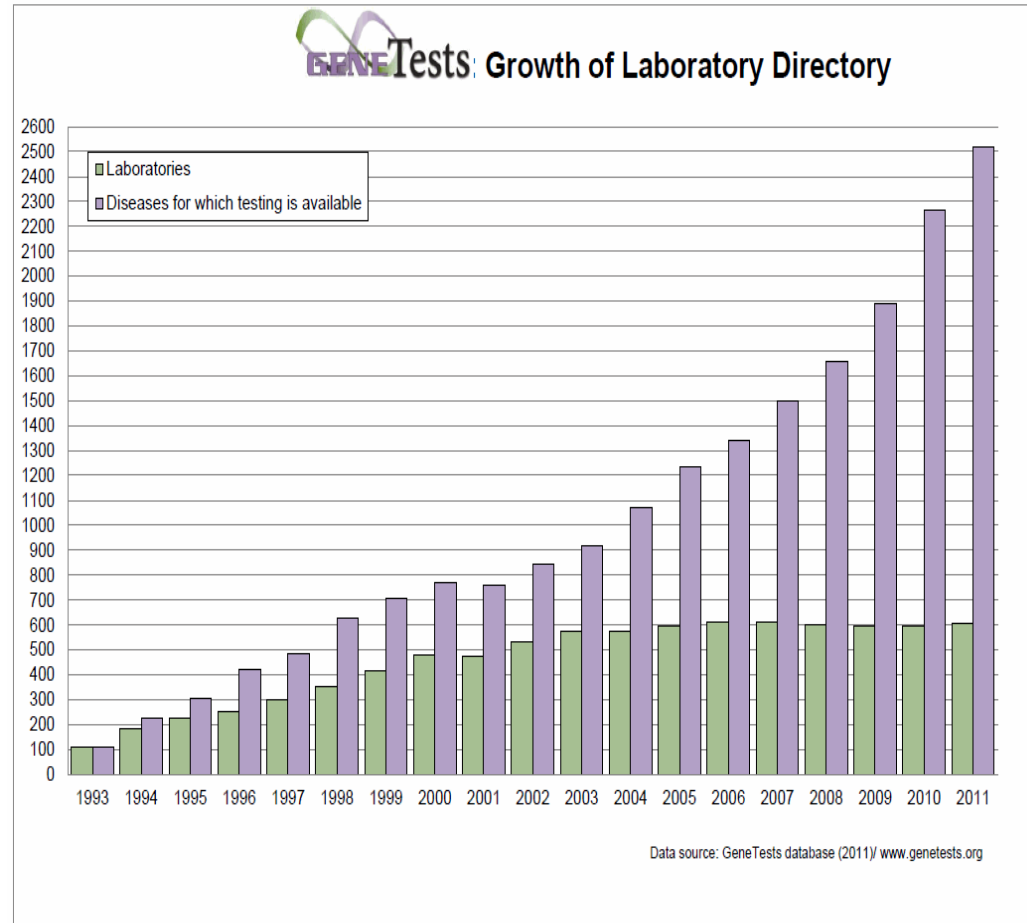
The Emergence of Genetic Laboratory Tests

Rapid increase in the availability of genetic tests ¹

Reported increase in utilization of genetic tests is steep

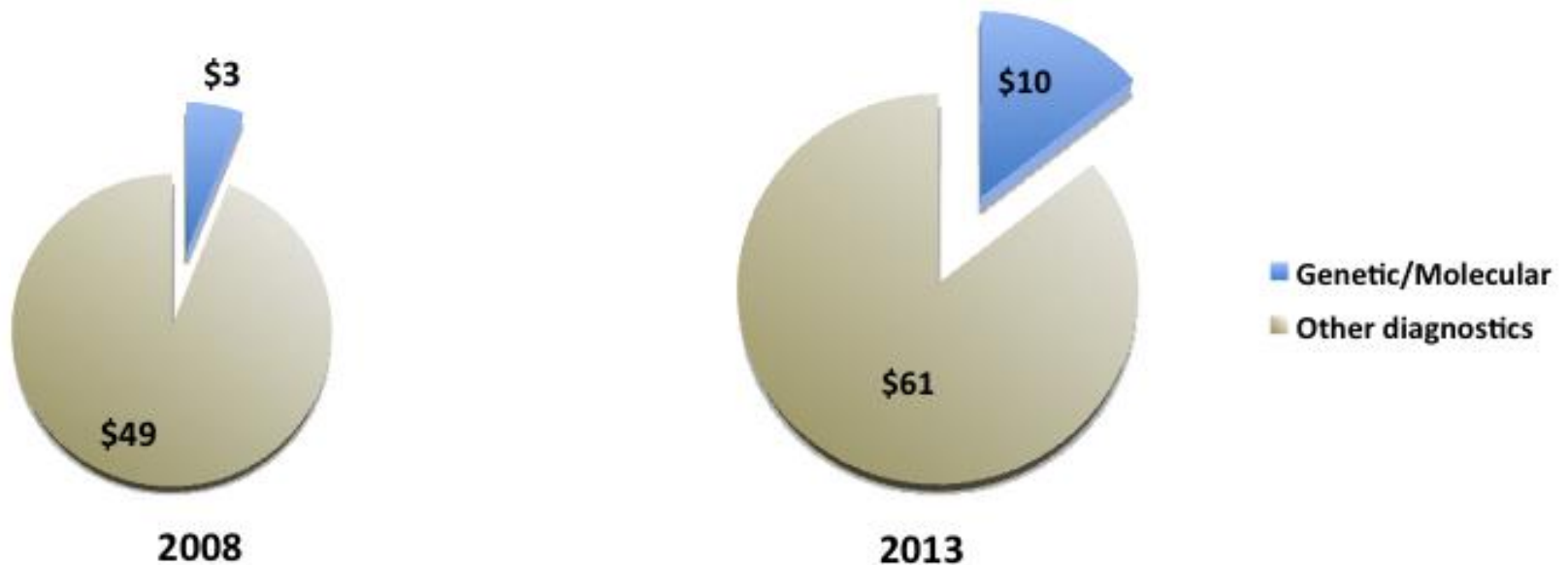
- 20% increase in utilization of genetic diagnostic tests per year vs. 1%-3% for non-genetic diagnostic tests. ²

Data on utilization of genetic tests and clinical interventions based on these tests is limited³



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



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
 - o 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 high²

Herceptin - \$55,000 per treated member per year

Kalydeco - \$350,000 per treated member per year

Companion diagnostics to optimize drug therapies

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

Companion diagnostics to optimize drug therapies

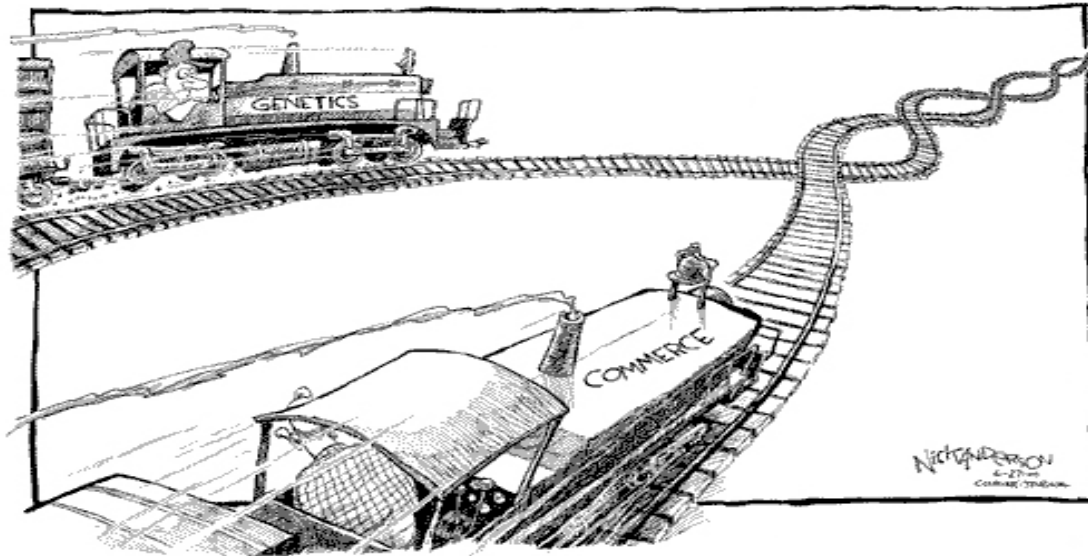
Class	Drug	Companion Dx	Tx Cost	Coverage
Neurolog	Tegretol (carbamezepine)	HLA-B*1502	\$700	Yes-Asian pop. only
Oncology	Tarceva (erlotinib)	EGFR< KRAS	\$57,000	Yes
Oncology	Tasigna (nilotinib)	BCR-ABL T3151	\$86,000	Yes
Oncology	Tykerb (lapatinib)	Her-2	\$45,000	Yes
Oncology	Vectibix (panitumumab)	KRAS	\$124,000	Yes
Oncology	Xalkori (crizotinib)	ALK fusion	\$117,000	Yes
Neurology	Xenazine (tetrabenazine)	CYP2D6	\$73,000	Yes
Oncology	Zelboraf (vemurafenib)	BRAF V600E	\$120,000	Yes
Infectious Disease	Ziagen (abacavir)	HLA-B*5701	\$7,000	Yes
Neurology	Aricept (donepezil)	CYP2D6	\$500	No
Oncology	Camptosar (irinotecan)	UGT1A1	\$1,300	No
Psych	SSRI	CYP450 poly.	\$400	No
Oncology	Tamoxifen	CYP450 poly.	\$200	No
Cardiology	Warfarin	VKORC1/CYP450	\$100	No

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/Erbitux –predicts non-response to cetuximab (Erbitux)

- 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

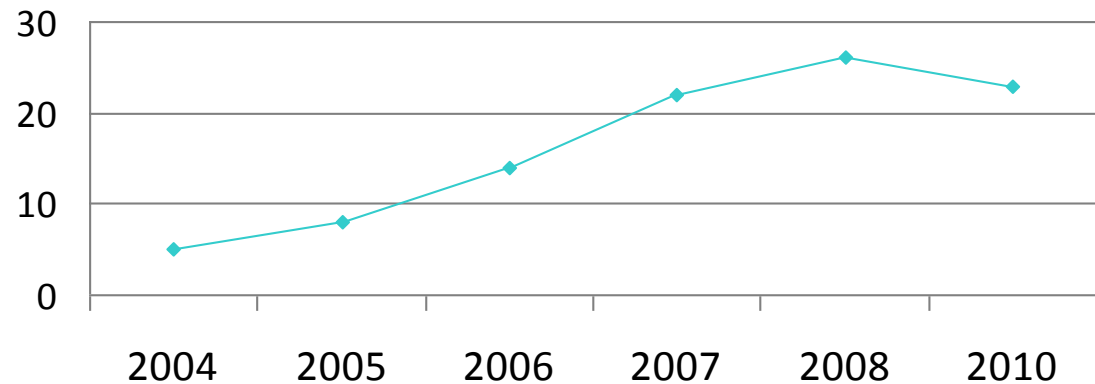
Impact of Marketing of Genetic Tests

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

Aetna BRCA Non-evidence Based Requests (% of total)



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

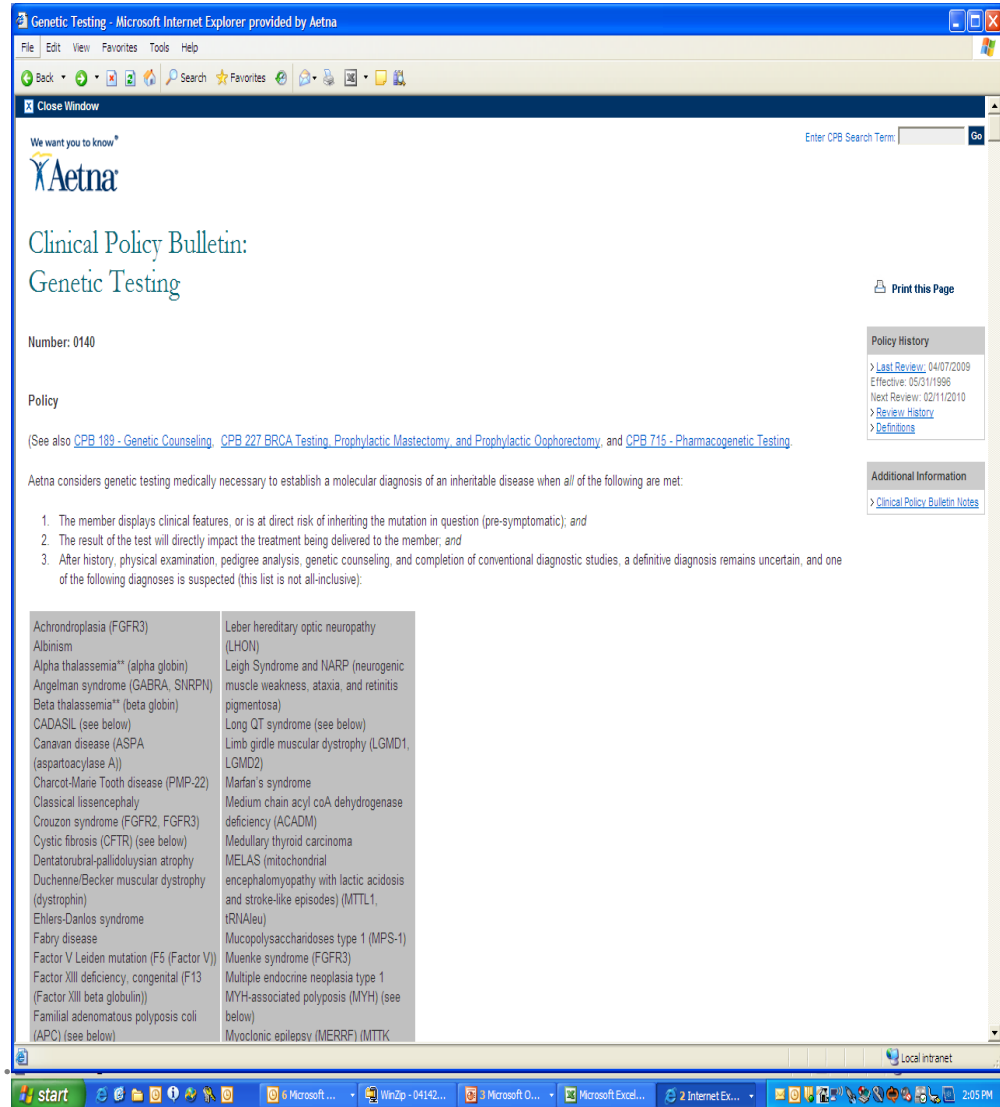
- CPB includes:

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 ¹

72% non-genetics MDs rate their knowledge of genetics as fair to poor (2000)²

65%-75% PCP uncomfortable interpreting genetic tests (2012)³

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

Fewer than 7% of Americans are scientifically literate ⁴

82% of consumers cannot correctly answer most genetic medicine knowledge questions in national surveys ⁵

1. Judith Cooksey, MD, SACGHS Testimony, Oct 22, 2003

2. Menasha. The Mt. Sinai J of Med 67(2):144-51,2000

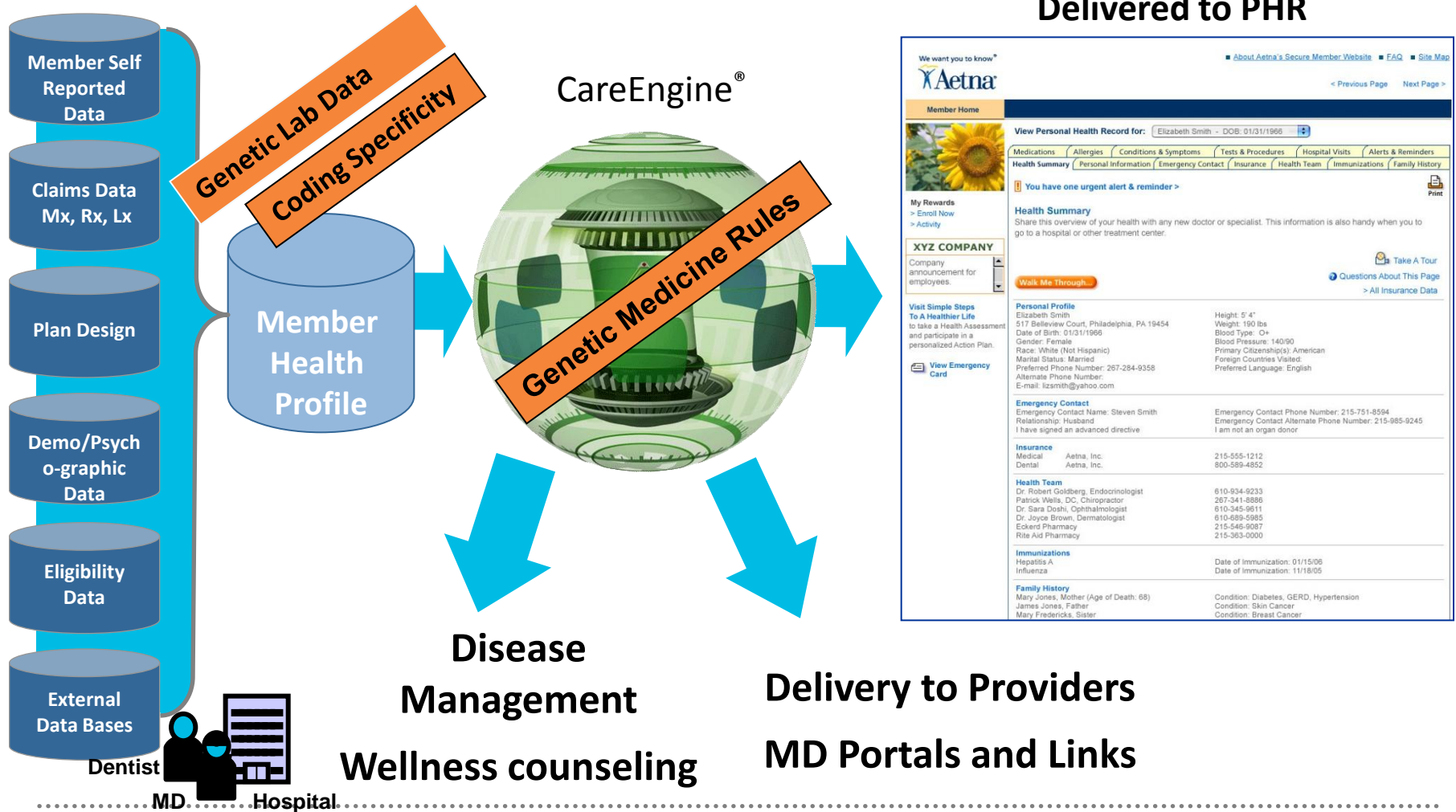
3. UnitedHealthcare, 2012

4. Genetics and Public Policy Center Survey 2002

5. Miller, Jon. 1998. *Public Understanding of Science* 7:203-223

Strategies to Promote Evidence-Based use of Genomic Services

Member Alerts/Care Considerations Delivered to PHR



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)

Coding and IT Challenges/Opportunities

BCR/ABL-t(9;22) by RT PCR (Quantitative)

Indication for use: Gleevec monitoring for CML (leukemia)

2011 CPT Code	Description
83891 (2)	Extraction of highly purified nucleic acid
83892 (2)	Enzymatic digestion
83896 (4)	Nucleic acid probe(s)
83902 (2)	Mutation scanning by physical properties
83912	Interpretation and report

2012 CPT
CPT 81206

BRC/ABL MAJOR/MINOR/OTHER
BREAKPOINTS

UGT1A1 Testing for Colorectal Cancer

Indication for use: Irinotecan monitoring for colorectal cancer

2011 CPT Code	Description
83891	Extraction of highly purified nucleic acid
83892 (2)	Enzymatic digestion
83896 (12)	Nucleic acid probe(s)
83903 (4)	Mutation scanning by physical properties
83908 (4)	Signal amplification of patient nucleic acid
83912	Interpretation and report

2012 CPT
CPT 81350

UGT1A1 (UDP
GLUCURONOSYLTRANSFERASE 1 FAMILY,
POLYPEPTIDE A1) GENE ANALYSIS,
COMMON VARIANTS (EG, *28, *36, *37)

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 IntelithHealth**
- **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 steering 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?
How much trust do you have with your test results?¹

	<u>Access to Results</u>	<u>Trusted with Results</u>
Doctors to provide care	93%	86%
Researchers	93%	66%
Health insurance companies for eligibility and pricing	15%	24%
Employers for hiring and promotion	19%	16%

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

Thank you

aetnaSM