



Genetics: Promoting Quality, Safety, and Evidence-Based Care

**Secretary's Advisory Committee on Genetics,
Health, and Society (SACGHS)**

***Roundtable on Genetics and the Future of the
Health Care System***

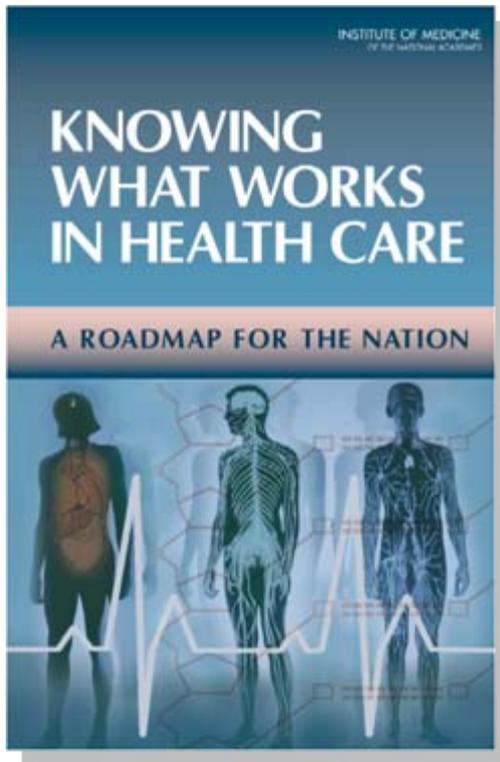
March 13, 2009

Sam Nussbaum, M.D.
Executive Vice President and Chief Medical Officer

A New Model For Determining What Works In Health Care



INSTITUTE OF MEDICINE *OF THE NATIONAL ACADEMIES*



- Establish National Clinical Effectiveness Assessment program
- Identify and evaluate clinical services with highest potential effectiveness
- Recommend process to evaluate research and evidence
- Recommend organizational framework for evidence-based clinical policy development

Increasing Specialty Drug Development and Associated Costs

Clinical Conditions

- Oncology
- HIV/AIDS
- Multiple Sclerosis
- Rheumatoid Arthritis
- Hemophilia
- Hepatitis C
- Respiratory Syncytial Virus
- Infertility
- Gaucher's Disease
- Crohn's Disease
- Immune Disorders
- Growth Hormone Deficiency
- Pulmonary Hypertension

- Highly sophisticated protein structures derived from recombinant DNA technologies, most often given by injection or infusion.
- Specialty pharmaceuticals now represent 24% of all drug costs, projected to 37% by 2020
- Expenditures exceed \$73 billion annually, rising at twice the rate of conventional drugs
- Average cost per prescription is nearly \$2,000, with annual treatment costs ranging from \$5,000 to \$350,000
- Over 600 specialty drugs in development for 100 different diseases, including
 - 250 for cancer,
 - 160 for infectious diseases,
 - 60 for autoimmune diseases,
 - 35 for HIV/AIDS

The Need for Evidence-Based Care: Diagnosis and Treatment of Breast Cancer

History: Bone Marrow Transplant

- Bone marrow transplantation (BMT) for breast cancer entered medical market in the 1980s before meaningful effectiveness studies were done
- Between 1988-1998, 30,000 procedures and \$5 Billion in medical costs
- Congress and States enacted mandatory coverage legislation in 1994
- 1999 research showed no difference in survival and lower quality of life
- Delayed research and introduction of promising therapies

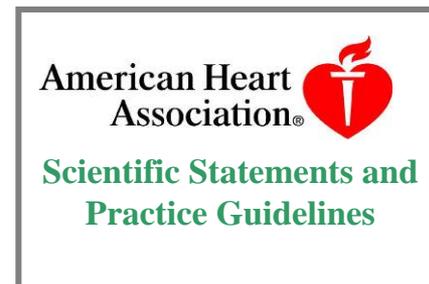
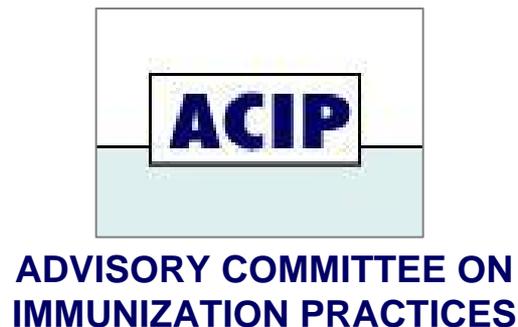
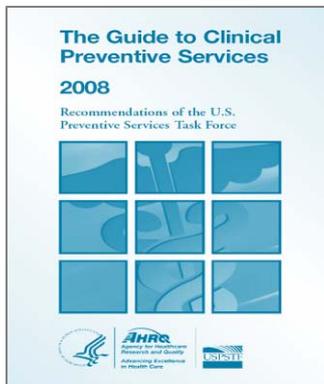
Today: HER2 Genetic Testing

- 215,000 new breast cancer cases annually; 25-30% of women with breast cancer express the HER2 protein
- Trastuzumab (Herceptin®) is a recombinant DNA monoclonal antibody that targets tumor cells that over express the HER2 protein
- In 2005, two new major clinical trials expanded indications for this biotechnology
- Within two weeks, WLP Hematology-Oncology Medical Policy & Technology Assessment Subcommittee evaluated results and adopted new medical policy consistent with reported clinical studies

Establishing the Evidence Base: Medical Policy and Technology Assessment

Medical Policy and Technology Assessment determines coverage decisions that promote evidence-based care and proven science

- Corporate medical policies are the foundation for clinical decision making
- Assess effectiveness, promote evidence-based care, inform national health policy
- Engagement of medical specialty societies (33) and academic medical centers; consideration of community practice patterns and standards
- “Technology Compendium” promotes consistency across the BCBSA



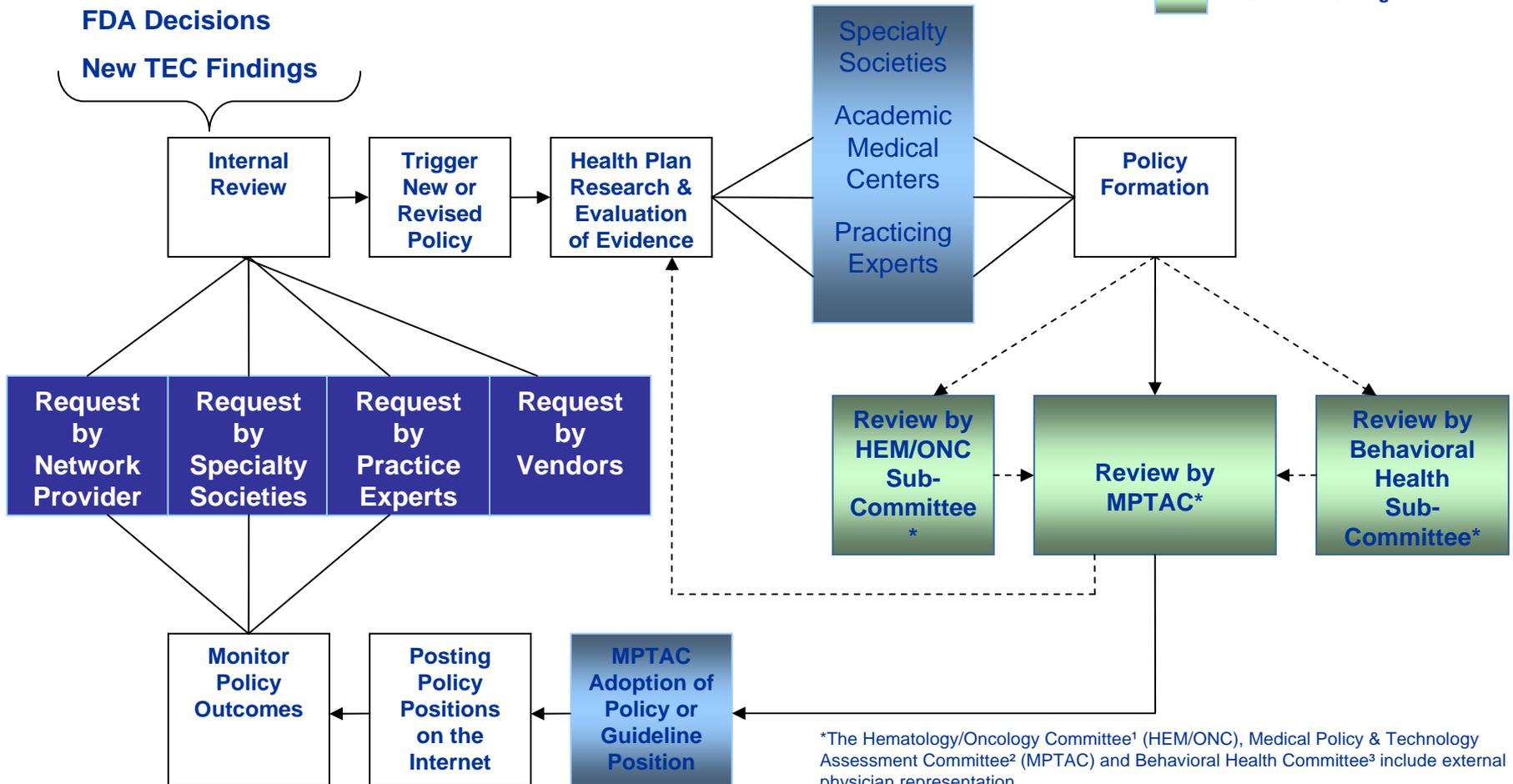
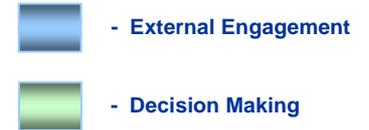
Evidence-Based Medicine: WellPoint Medical Policy and Process

Annual Policy Review

Changing Practice Patterns

FDA Decisions

New TEC Findings



*The Hematology/Oncology Committee¹ (HEM/ONC), Medical Policy & Technology Assessment Committee² (MPTAC) and Behavioral Health Committee³ include external physician representation

- All policies available via Plan websites
- Accessible by network physicians
- Includes background, coding, and definitions
- Detailed rationale
- References to:
 - Peer-reviewed journals
 - Other authoritative publications
- Comprehensive revision history

Subject: Genetic Testing and Biochemical Markers for the Diagnosis of Alzheimer's Disease
Policy #: GENE.00003 **Current Effective Date:** 07/09/2008
Status: Revised **Last Review Date:** 05/15/2008

Description/Scope

This document addresses the use of testing for genetic mutations, polymorphisms, or biochemical markers for either the diagnosis or screening of Alzheimer's disease.

Policy Statement

Investigational and Not Medically Necessary:

Genetic testing (including both genetic polymorphisms and genetic mutations) or measurements of biochemical markers (including but not limited to tau protein, AB-42, neural thread protein) is considered **investigational and not medically necessary** as a diagnostic technique for individuals with symptoms suggestive of Alzheimer's disease.

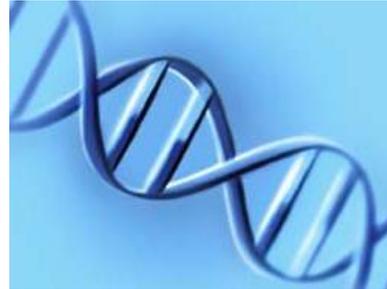
References

Peer Reviewed Publications:

1. Andreasen N, Blennow K. CSF biomarkers for mild cognitive impairment and early Alzheimer's disease. *Clinical Neurol Neurosurg.* 2005; 107:165-173.
2. Colciaghi F, Marcello E, Borroni B, et al. Platelet APP, ADAM 10 and BACE alterations in the early stages of Alzheimer disease. *Neurology.* 2004; 62(3):498-501.
3. Du Y, Dodel R, Hampel H, et al. Reduced levels of amyloid beta-peptide antibody in Alzheimer disease. *Neurol.* 2001; 57(5):801-805.
4. Farlow MR. Alzheimer's disease: clinical implications of the apolipoprotein E genotype. *Neurology.* 1997; 48

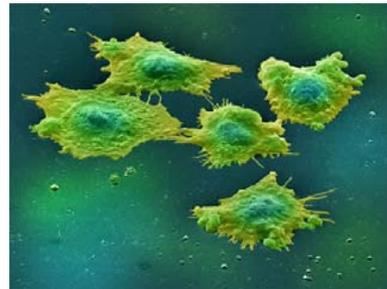
Key Medical Policy Considerations for Genetic Tests

Analytic and Diagnostic Validity



Does the test accurately determine presence or absence of specific genetic variation?

Clinical Validity



Does the test reliably link the specific genetic variation with a relevant clinical attribute?

Clinical Utility



Is there incremental health benefit compared to current care / not performing test?

Examples of Medically Necessary Genetic Tests

Genetic tests are covered, when specified criteria are met, based on evidence of clinical utility and/or general acceptance by specialists

- **GENE.00001: Genetic Testing for Cancer Susceptibility**

- Covers BRCA1 and BRCA2; Hereditary Non-Polyposis Colorectal Cancer (HNPCC); Familial Adenomatous Polyposis (FAP); Medullary Thyroid Cancer; Multiple Endocrine Neoplasia Type 2, (MEN2); MYH-associated Polyposis (MAP)

- **GENE.00002: Pre-implantation Genetic Diagnosis Testing**

- Pre-implantation genetic testing for individuals undergoing assisted reproduction technology procedures at risk for genetic mutations or aneuploidy

- **GENE.00011: Gene Expression Profiling for Managing Breast Cancer Treatment**

- Covered: OncoType DX to predict response to or need for additional chemotherapy
- Not Covered: MammaPrint, 76-Gene “Rotterdam signature” assay, or 41-gene signature assay

- **GENE.00014 Analysis of KRAS Status in Metastatic Colorectal Cancer**

- Patients with wild-type (vs. mutant) KRAS gene respond significantly better to anti-EGFR drugs

Examples of Investigational or Not Medically Necessary Genetic Tests

Tests are not covered due to lack of current evidence of clinical utility and/or likelihood of better health outcomes

- **GENE.00003: Testing / Biochemical Markers for Diagnosis of Alzheimer's Disease**
 - Not yet proven to reliably confirm diagnosis
 - Not yet proven to reliably screen asymptomatic patients with or without family history
- **GENE.00006: Epithelial Growth Factor Receptor in Patients with Small Cell Lung Cancer**
 - Not yet proven to reliably test for EGFR to predict treatment response to tyrosine kinase inhibitor therapy
- **GENE.00007: Cardiac Ion Channel Genetic Testing**
 - Not yet proven to reliably diagnose, predict, or treat long QT syndrome and subsequent possibility of lethal cardiac arrhythmia
- **GENE.00010 Genotype for Genetic Polymorphisms to Determine "Metabolizer" Status**
 - Accurately identifies genetic make-up of patients
 - Insufficient evidence to predicts how well patient will metabolize and respond to (e.g.) warfarin; tamoxifen; 5-FU; cytochrome P450; thymidylate synthetase; and others

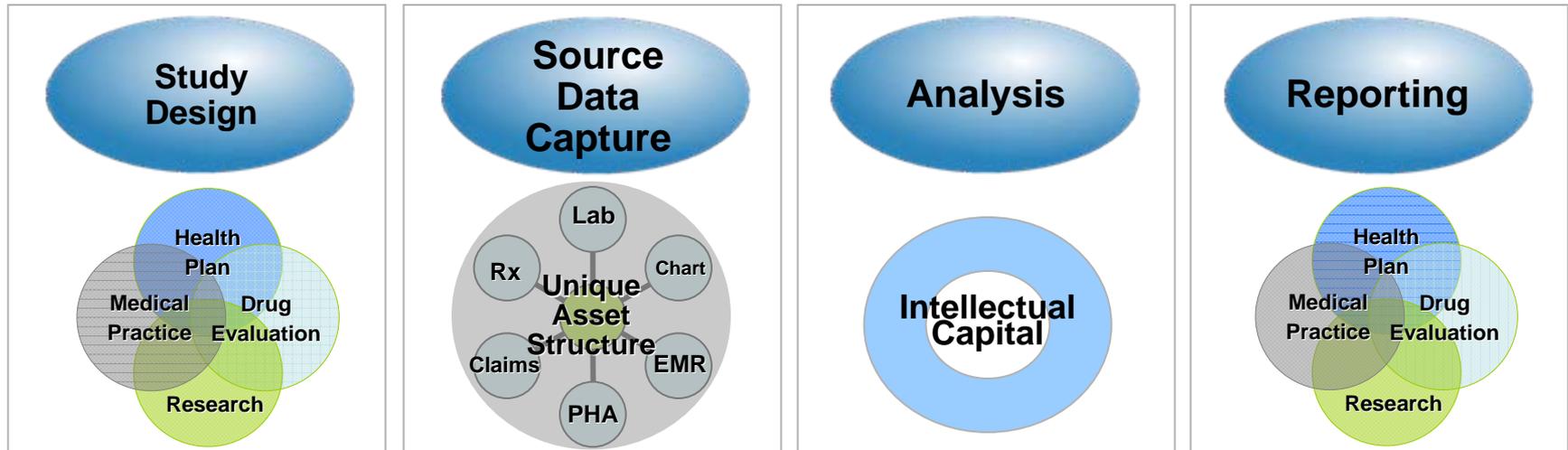
Potential Rewards

- Diagnose disease in patients
- Diagnose risk and predisposition to disease
- Diagnose prenatal disease
- Determine potential response to / benefit of pharmaceuticals
- Diagnose properties of cancer cells to better guide care

Potential Risks

- False negatives may result in failure to seek necessary care
- False positives lead to unnecessary services and avoidable anguish
- Accurate (but misleading): some patients may never develop condition
- Unsustainable costs

HealthCore: Outcomes Research and Advancing Medical Knowledge



“Real World” Research Drives Quality, Cost Effective Care

- Partnerships with health plans provide access to networks and data
- Integrates data sources for outcomes research and analysis
- Strong collaborative research relationships (Harvard, Kettering, Duke, USC)
- More than 110 research projects underway (breast cancer, asthma, rheumatoid arthritis, low back pain, acute coronary syndrome)

The Integrated Research Network: Disseminating “What Works” in Health Care

Collaborative research community to generate evidence-based clinical information and influence real-world care delivery

- Integrated medical and pharmacy claims data supplemented with physician-level clinical information
- Two-way information exchange among physicians, hospitals, government agencies, insurers, and academic centers
- Rapid dissemination of research findings and implementation at care delivery to improve quality, cost-effective care delivery

*Partnership with Clinical and Translational
Research Institute (CTSI) at Indiana University
and Purdue University*



Messaging the Patient: Closing the Gaps in Evidence-Based Care

Report of: Adam
Birth Date: February 28, 1946

Member ID : 00123456-01
Group Number: GRX 123678

Your Medical & Prescription Claims

Your recent medical and prescription claims as of

May 23, 2008

Suggestions for You

Suggestions are based on your available claims as of

May 23, 2008

Date	Service/Prescription	Qty	Days	Doctor/Prescriber(*)	Paid(**)
Visits					
05/23/08	Office Visit	--	--	Lynn, Samuel F.	\$85.00
05/17/08	Office Visit	--	--	Wilson, Michelle L.	\$85.00
05/15/08	Office Visit	--	--	Lynn, Samuel F.	\$85.00
04/12/08	Office Visit	--	--	Jones, Terry M.	\$85.00
02/02/08	Office Visit	--	--	Wilson, Michelle L.	\$195.00
Prescriptions					
05/01/08	Metformin - 500 mg	30	30	Jones, Terry M.	\$15.50
03/23/08	Metformin - 500 mg	30	30	Wilson, Michelle L.	\$46.50
02/10/08	Lipitor - 20 mg	30	30	Lynn, Samuel F.	\$85.95
01/18/08	Lipitor - 20 mg	30	30	Lynn, Samuel F.	\$85.95
03/28/08	Accupril - 20 mg	60	30	Lynn, Samuel F.	\$66.99
02/18/08	Accupril - 20 mg	60	30	Lynn, Samuel F.	\$66.99
01/12/08	Accupril - 20 mg	60	30	Lynn, Samuel F.	\$66.99
02/12/08	Nexium - 20 mg	30	30	Lynn, Samuel F.	\$115.60
01/10/08	Nexium - 20 mg	30	30	Lynn, Samuel F.	\$115.60
Other Medical Services					
05/23/08	Cholesterol Panel	--	--	LabCorp Laboratories	\$110.40
04/26/08	Medical Equipment	--	--	Lynnwood Medical Mart	\$198.00
03/28/08	Ambulatory ER Visit	--	--	St. Lucy's Hospital ER	\$766.50
03/28/08	Metabolic Panel	--	--	LabCorp Laboratories	\$110.40
02/04/08	CT X-Ray, Sinuses	--	--	Radiology Assoc. - SFSL	\$854.35
01/15/08	CT X-Ray, Sinuses	--	--	Mercy Hospital - Rad	\$854.35



Ask your doctor about blood thinner medication [10235] *

Your medical claims show you have a heart condition called atrial fibrillation, and your prescription claims show you are not taking a blood thinner medication. Atrial fibrillation is an uneven heartbeat that can cause blood clots and strokes. Blood thinners can prevent blood clots and lower your risk of a stroke. Ask your doctor soon if you should take a blood thinner.



Keep taking Metformin as directed [119] *

Your prescription claims show you take metformin. Although you recently refilled your prescription, your claims show you are not refilling it as often as you should. This drug can help lower your risk of heart disease, stroke and blindness. If you think your medication is not helping you, or if you are worried about cost or side effects, talk to your doctor soon. Keep taking metformin as directed until you talk to your doctor.



Save \$396 - Ask your doctor about switching from Accupril [3582] *

Your prescription claims show you take Accupril. You can save money if you take quinapril, a generic drug that is as safe and effective as Accupril. Ask your doctor if quinapril is right for you.

Drug Name	Your Cost	Your Annual Cost	You Save
Accupril - 20 mg	\$40	\$480	---
Quinapril - 20 mg	\$ 7	\$ 84	\$396

* Doctor/Prescriber listed may be another name from that medical office/practice.

** This amount is the total paid by you and your health plan.

Promoting National Pharmaceutical Safety: The HealthCore Safety Sentinel System

National drug and vaccine safety surveillance system in partnership with FDA, NIH and premier academic institutions

Safety Sentinel System

- Analyzes medical, lab and pharmacy data from over 35 million members
- Monitors safety of pharmaceuticals and other therapies after FDA approval
- Identifies safety risks associated with drugs and other health care decisions
- Allows health care professionals to make more informed decisions for their patients



Advancing Health Care Quality and Safety Through Evidence-Based Care

To recognize true value of genetic technologies they must be proven and improve health outcomes

Continuously evaluate new technologies to establish evidence-based medical policy

Determine “what works” through comparative effectiveness and outcomes research

Disseminate clinical information to translate clinical research into clinical action

Close gaps in care and provide clinical information at the point of care

