



Coverage of Genetic Tests and Services by Private Health Plans

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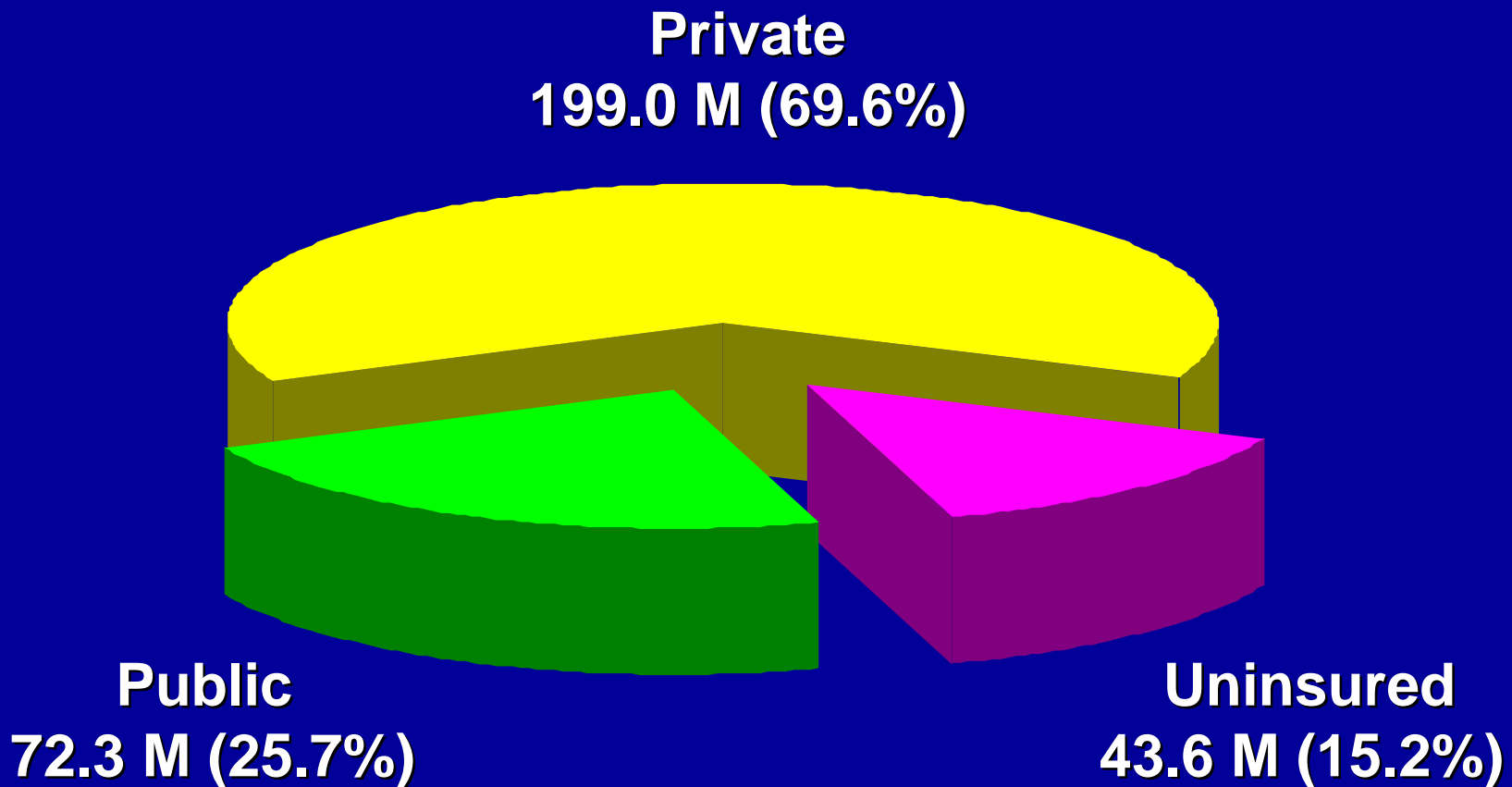
Secretary's Advisory Committee on
Genetics, Health and Society

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Overview

- ▶ **Health Insurance Coverage in U.S.**
- ▶ **Coverage Process**
- ▶ **Payment Process**
- ▶ **Examples**

Health Insurance Coverage in the U.S.



SOURCE: Health Insurance Coverage in the United States:
2002. U.S. Census Bureau (<http://www.census.gov/prod/2003pubs/p60-223.pdf>)

Private Insurance Products

- ▶ **Indemnity (e.g. BCBS)**

- ▶ Financing only
- ▶ Fee for service (usually retrospective)
- ▶ Historically excluded preventive services

- ▶ **Managed care**

- ▶ Financing and delivery of services
- ▶ Prior authorization and case management
- ▶ Generally include some preventive services

Managed Care Products

▶ HMO

- ▶ Integrated financing and delivery of the services
- ▶ Prepaid comprehensive services
- ▶ Limited to plan physicians

▶ PPO

- ▶ Payer contracts with physician groups for primary care or specialty services
- ▶ Discounted fees in exchange for volume

▶ POS

- ▶ HMO/PPO hybrid



Coverage Process

Coverage Decisions

- ▶ **Case-by-case determinations**
 - ▶ Contract dependent
 - ▶ Broadly defined benefit category (e.g., lab services)
 - ▶ Specific decisions at time of processing claims
- ▶ **Coverage policy**
 - ▶ More precise description of scope of benefits for all policy holders meeting pre-specified criteria
 - ▶ Developed to respond to: new technology, changes in existing technology, new information, or federal or state mandates
 - ▶ May include limits on provider type, facility type or frequency of service
 - ▶ Still subject to terms of individual insurance contract

Who Decides Coverage?

- ▶ **Medical Director**
- ▶ **Medical Policy Advisory Committee**
 - ▶ Local medical experts
 - ▶ Consumers
 - ▶ Legal counsel
- ▶ **Employers**
 - ▶ CEOs, Human resource personnel
- ▶ **Other large groups**
 - ▶ Unions, churches, academic centers, etc.
- ▶ **State and federal mandates**

Coverage Criteria

- 1. Technology must have final approval from appropriate governmental regulatory bodies.**
 - ▶ TEC can evaluate unapproved indications
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.**
 - ▶ Evidence is evaluated on quality and consistency of results.
 - ▶ Technology can measure changes related to disease.
 - ▶ Evidence must demonstrate that the measurements affect outcomes.

SOURCE: Blue Cross Blue Shield Association Technology Evaluation Center (TEC): <http://bcbs.com/tec/teccriteria.html>

Coverage Criteria (continued)

3. The technology must improve the net health outcome.
4. The technology must be as beneficial as any established alternatives.
5. The improvement must be attainable outside the investigational settings.

Others:

- ▶ Cost-effectiveness

Sources of Scientific Evidence

- ▶ **Peer reviewed literature**
- ▶ **Professional organizations**
 - ▶ ACMG, ASHG, ACOG, ASCO, AMA, ACS, etc.
- ▶ **Government Agencies**
 - ▶ FDA, CDC, AHRQ, NIH consensus statements
- ▶ **Technology Assessment Groups**
 - ▶ BCBS TEC, Hayes, Inc.
- ▶ **Coverage Policies of Other Payers**
 - ▶ CMS, individual BCBS plans, Aetna, Humana
- ▶ **Websites**
 - ▶ GeneTests, disease associations, academic medical centers, health sites, manufacturers, lay press

Coverage for Genetic Tests

- ▶ **Medically necessary when:**
 - ▶ Personal or family history indicates high risk for inherited condition
 - ▶ Sensitivity of the test is known
 - ▶ Results directly impact treatment or management of patient
 - ▶ Diagnosis remains uncertain following examination and completion of conventional diagnostic studies
 - ▶ Pre- and post-test counseling provided

Typical Exclusions

- ▶ **Population screening in absence of personal or family history (regardless of ethnicity)**
- ▶ **Testing for information only**
- ▶ **Testing of minors for adult diseases (cancer)**
- ▶ **Coverage for family members of policy holders. Exception:**
 - ▶ **Information from family member is necessary to make medical decision for policy holder and can provide proof of denial of coverage from family member's insurance.**

Examples of Covered Tests

- ▶ **Chromosomal abnormality**
 - ▶ Prenatal or Pre-Implantation Diagnosis
 - ▶ AMA, suspected fetal anomaly, multiple miscarriage
- ▶ **Specific Tests**
 - ▶ Hereditary cancer testing: BRCA1 and 2, colon cancer (FAP, HNPCC), medullary carcinoma of thyroid
 - ▶ Cystic Fibrosis, Tay-Sachs
 - ▶ Hereditary Hemochromatosis
- ▶ **Pharmacogenetic/genomic applications**
 - ▶ Herceptin (HER-2/neu)
 - ▶ 6-Mercaptopurine/Azathioprine (TPMT)
 - ▶ Gleevec (Philadelphia Chromosome, c-kit)

Alzheimer's Disease

▶ **Markers**

- ▶ ApoE4 for susceptibility
- ▶ Presenilin-1 and -2
- ▶ Amyloid Precursor Protein (APP)

▶ **Universally not covered (12/12 plans)**

- ▶ Investigational: safety and effectiveness not established
- ▶ Insufficient information to demonstrate that genotypes are associated with phenotype with a high positive predictive value

Colon Cancer

▶ **HNPCC**

- ▶ Criteria: Family History (Amsterdam or Bethesda criteria)

▶ **FAP: > 20 polyps or 1st degree relative w/ FAP**

▶ **16 insurers developed policies**

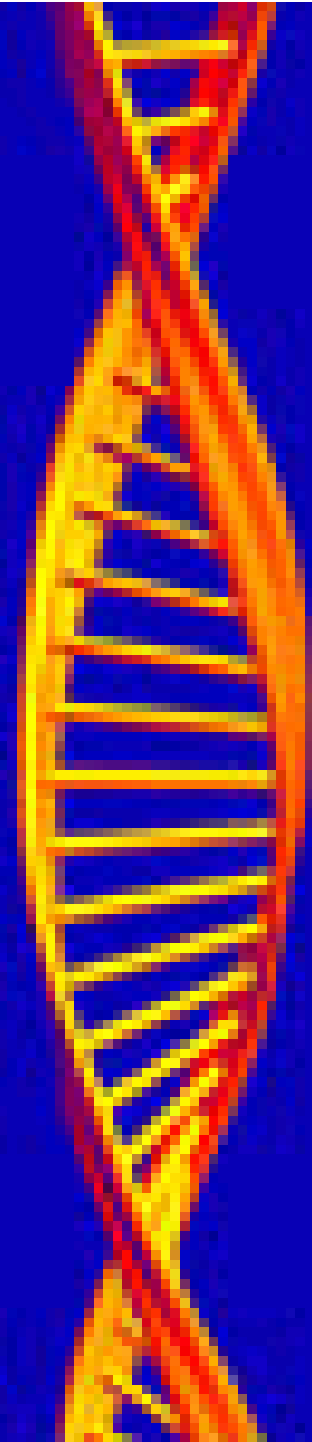
- ▶ 4 cover “genetic testing”
- ▶ 5 cover APC, MLH1, MSH2 mutation analysis
- ▶ 4 cover APC, MLH1, MSH2 and MSI analysis
- ▶ 1 covers APC only
- ▶ 2 do not cover genetic test

▶ **Common exclusions**

- ▶ MSI analysis in stool specimens (5/16)
- ▶ I1307 mutation (5/16)

TPMT

- ▶ **TPMT catalyzes Azathioprine (6-MP) into active metabolites.**
- ▶ **Activity is genotype dependent:**
 - ▶ wt/wt = high activity (90%)
 - ▶ Wt/mut = intermediate activity (10%): **Lower dose**
 - ▶ Mut/mut = low activity (0/3%): **TOXICITY**
- ▶ **6 plans had policies:**
 - ▶ 3 covered both genotyping & metabolite markers
 - ▶ 2 covered only the metabolite markers
 - ▶ 1 did not cover either



Payment Process

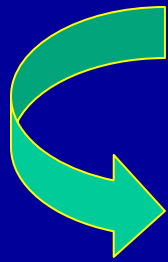
Payment

- ▶ **Rates based on many factors**
 - ▶ Geographic location
 - ▶ Prevailing, usual or customary charges
 - ▶ Specific provider
 - ▶ Provider specialty groups
 - ▶ % billed charges (0-100%)
 - ▶ Negotiated fees
 - ▶ Fee schedules
 - ▶ Clinical Laboratory Fee Schedule, Physician Fee Schedule
- ▶ **Poor payment rates have same impact as a non-coverage decision**

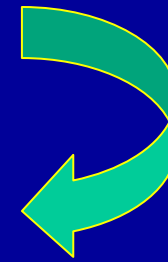
Reimbursement of Services

ICD-9

CPT



\$\$ Payment \$\$



- ▶ **Provide correct information**
 - ▶ Provider/patient identifiers
 - ▶ Date(s) of service
- ▶ **Documentation**

CPT codes: Laboratory

- ▶ **83890-83912 Molecular diagnostics**
- ▶ **88230-88299 Cytogenetic studies**
- ▶ **Issues**
 - ▶ Need multiple codes to describe a test
 - ▶ Specialty specific
 - ▶ Unlisted codes for new tests usually perceived as “investigational”
 - ▶ Need timely development of new codes
- ▶ **HCPCS Level II**
 - ▶ S3818-S3851

Summary

- ▶ **Most 'traditional' genetic conditions are covered, including counseling**
- ▶ **Insurers perceived to be slow to adopt new technologies**
 - ▶ **Lack of data to support medical benefit**
 - ▶ **Studies rarely evaluate whether the information from a test impacts patient management**
- ▶ **Need for cost data**
- ▶ **Need communication**