

Coverage and Reimbursement of Genetic Tests and Services

**Final Report of the
Secretary's Advisory Committee on
Genetics, Health, and Society**

February 2006

SACGHS Mandate

- To explore, analyze and deliberate on the broad range of human health and societal issues raised by the development and use, as well as potential misuse, of genetic technologies
- To make recommendations to the Secretary of HHS and other Departments upon request

SACGHS Scope

- Integration of genetic technologies into health care and public health
- Clinical, ethical, legal, and societal implications of new medical applications
- Research and data collection
- Misuse of genetics in bioterrorism
- Patent policy and licensing practices
- Broader social applications of genetics (forensics, education, etc.)
- Emerging applications and issues

Current Priorities

(as of Feb 2006)

- Genetic discrimination
- Coverage & reimbursement
- Pharmacogenomics
- Large population studies
- DTC marketing
- Patents and licensing
- Oversight
- Genetics education and training
- Access
- Public awareness
- Genetic exceptionalism
- Vision statement

SACGHS Work Products

(as of Feb 2006)

- Reports
 - *A Roadmap for the Integration of Genetics and Genomics in Society: Report on the Study Priorities of SACGHS*
 - Coverage and Reimbursement for Genetic Tests and Services
- Resolution on genetics education and training of health professionals

SACGHS Work Products to Date

- Letters
 - Three letters on genetic discrimination and
 - Compilation of public comments
 - DVD highlights of public testimony
 - Legal analysis of existing federal laws
 - Two letters on DTC marketing of genetic tests
 - Letter on national health information infrastructure
 - Letter on family history

Coverage and Reimbursement Report

- **Problem statement**
 - Problems with coverage and reimbursement of genetic tests and services are limiting their accessibility and integration into the health care system
- **Purpose**
 - To describe the state of coverage and reimbursement of genetic tests and services
 - To describe problems with current coverage and reimbursement mechanisms that are affecting access to genetic tests and services
 - To offer recommendations on how current coverage and reimbursement mechanisms might be improved
- **Objective**
 - To improve appropriate access to and utilization of health-related genetic tests and services by ensuring appropriate coverage and reimbursement throughout the health care system

Nine Recommendations

- Evidence-based coverage decisions
- Influence of Medicare on private plans
- National vs. local Medicare coverage policies
- Medicare screening exclusion
- Medicaid and SCHIP coverage
- Medicare Clinical Laboratory Fee Schedule
- Billing and reimbursement of genetic counseling services
- Public awareness
- Provider education and training in genetics

Evidence-based Coverage Decisions

- Need for greater emphasis on evidence-based coverage decision making
- Evidence needed to make informed coverage decisions is lacking for many genetic tests and services
- Challenges:
 - Difficult to establish causal link between genetic tests and services and improved health outcomes
 - Many genetic tests lack therapeutic and preventive options
 - Difficult to amass sufficient evidence for rare disease genetic tests
 - Costs many not be recouped in a short enough timeframe

Evidence-based Coverage Decisions

Recommendation 1:

The Secretary should appoint a group to:

- Develop a set of principles to guide coverage decision making for genetic tests and services
- Determine whether the evidence for genetic tests and services is adequate to establish their analytical validity, clinical validity and clinical utility
- Identify gaps in evidence

Evidence-based Coverage Decisions

Recommendation 1 cont:

Principles should address:

- Role of cost-effectiveness in decision making
- Rare disease tests for which evidence may be minimal
- Genetic tests for conditions that lack therapeutic and preventive options

Influence of Medicare on Private Plans

- Medicare's decisions are important to and monitored closely by private health insurance plans
- Medicare may not be an appropriate model for coverage of genetic tests and services
 - Medicare's coverage of preventive services is limited
 - Many genetic tests inform reproductive decision making and life planning
 - Most hereditary diseases manifest before age 65

Influence of Medicare on Private Plans

Recommendation 2:

Private payers should be encouraged and provided with information to make their own coverage determinations relative to the populations they serve.

Medicare Coverage Process

- Medicare coverage decisions are made at both the national and local levels
 - National decisions apply to all beneficiaries
 - Local decisions apply only to those beneficiaries living in that region
- Variation in local decisions can lead to inconsistencies in coverage from one region to another
- Dual national-local processes can impede quick, widespread coverage of genetic tests and services

Medicare Coverage Process

Recommendation 3:

CMS should:

- Develop a plan for evaluating local coverage decisions to determine which should be adopted nationally and to what extent greater consistency in Medicare coverage policy can be achieved
- Consider a mechanism that would automatically initiate a national coverage review process for any test or service that is approved for coverage by a certain number of local Medicare contractors

Medicare Screening Exclusion

- Federal statute prevents Medicare from covering preventive services unless explicitly authorized by Congress
 - Predictive and predispositional genetic tests are considered screening tests, and thus are not covered by Medicare
- CMS policy: Tests performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered unless explicitly authorized by statute
 - Family history of disease does not meet the personal history criterion
- Medicare coverage for genetic counseling also is limited by the program's screening exclusion

Medicare Screening Exclusion

Recommendation 4:

The Secretary should:

- Urge Congress to add a benefit category for preventive services
- Direct CMS to clarify that, in certain cases as scientific evidence warrants, "personal history" can include having a family history

Medicaid Coverage

- With the exception of newborn screening, genetic tests and services are an optional Medicaid benefit
- Coverage for genetic tests and services can be affected by state budget cuts
- Changes in states' Medicaid funding can create instability in access to genetic tests and services year to year
- Variation in Medicaid coverage across states can result in disparate access to genetic tests and services

Medicaid Coverage

Recommendation 5:

- The Secretary should share with states existing evidence on genetic tests and services to inform Medicaid coverage decisions.
- HHS should continue to provide states with grants that encourage coverage, adoption and provision of genetic services that have a sound evidence base.

Medicare Clinical Laboratory Fee Schedule

- Many providers contend that Medicare's payment rates for genetic tests do not reflect their true cost
- Congressionally-mandated freeze on payment rates for clinical laboratory tests prohibits fee updates until 2009
- HHS has "inherent reasonableness" authority to correct payment amounts for items or services that are so grossly excessive or deficient that they threaten to reduce beneficiary access to care or that represent inappropriate use of taxpayer dollars

Medicare Clinical Laboratory Fee Schedule

Recommendation 6:

CMS should address variations in payment rates for genetic test laboratory codes through its inherent reasonableness authority

Billing and Reimbursement of Genetic Counseling Services

- The highest-level E&M CPT code available for billing for genetic counseling services may be insufficient for longer counseling sessions
- NPs, PAs, CNSs, certified nurse midwives, clinical psychologists, and clinical social workers are statutorily eligible to directly bill Medicare; all others must bill “incident to” a physician and are limited to using certain CPT codes
- Only three states have authorized licensing of genetic counselors

Billing and Reimbursement of Genetic Counseling Services

Recommendation 7a:

The Secretary should identify a mechanism for determining:

- Which health professions are qualified to provide genetic counseling services
- Among those qualified, which health professions should be able to practice without physician supervision and, thus, directly bill for their services

If this review process results in a determination that a health profession should be allowed to practice independently, then the Secretary should urge Congress to add this health profession to the list of non-physician practitioners eligible to directly bill Medicare.

Billing and Reimbursement of Genetic Counseling Services

Recommendation 7b:

HHS should assess the adequacy of existing CPT E&M codes and their RVUs with respect to genetic counseling services and address any inadequacies.

Recommendation 7c:

The Secretary should direct CMS to allow “incident to” health providers to use the full range of CPT E&M codes when billing for their services.

Billing and Reimbursement of Genetic Counseling Services

Recommendation 7d:

The Secretary should ensure that government programs are reimbursing CPT prolonged service codes when reasonable and necessary.

Recommendation 7e:

CMS should deem all non-physician health providers who are permitted to directly bill any health plan – public or private – eligible for a National Provider Identifier.

Provider Education

- Providers who are not adequately trained in genetics may provide inappropriate services to their patients and expect to get reimbursed for them
- Providers need adequate genetics education and training to know when genetic tests are appropriate and to help their patients make the right decision about testing
- Genetics education also is important for health payers so that they may make informed coverage decisions

Provider Education

Recommendation 8:

The Secretary should:

- Develop a plan for HHS agencies to work collaboratively with federal, state and private organizations to develop, catalogue and disseminate case studies and practice models that demonstrate the relevance of genetics and genomics to clinical practice
- Provide financial support to assess the impact of genetics education and training on health outcomes

Public Awareness

- Public awareness of new health care tests and treatments can create consumer demand
- The complexity of genetics can result in inappropriate demand for genetic tests and services

Public Awareness

Recommendation 9:

The Secretary should ensure that educational resources are widely available through federal government websites and other appropriate mechanisms to inform decisions about genetic tests and services.

For more information about SACGHS,
please visit:

<http://www4.od.nih.gov/oba/SACGHS.HTM>

For a copy of the
Coverage and Reimbursement Report or
other SACGHS Work Products,
please visit:

<http://www4.od.nih.gov/oba/sacghs/reports/reports.html>