

Revised Draft Report on Coverage and Reimbursement of Genetic Tests and Services

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Chair, Coverage and Reimbursement Task Force

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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 current state of, and problems associated with, coverage and reimbursement of genetic tests and services
 - To offer recommendations on how current mechanisms for coverage and reimbursement of genetic tests and services might be improved
- Goal
 - 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

Report Sections

- Preface
 - Reviews topic selection and report development process
- Introduction
 - Statement of report purpose and goal
- Genetic Tests and Services: Challenges to the U.S. Health Care System
 - Describes challenges genetic tests and services pose to health care system
- Coverage
- Billing and Reimbursement
- Broader Issues
- Appendices
 - Overview of the U.S. Health Care System
 - List of public commenters (TBD)

Proposed Recommendations

- 12 proposed recommendations addressing:
 - Evidence-based coverage decisions
 - Medicare coverage of preventive services
 - Consistency in Medicare coverage
 - CPT codes for genetic tests & genetic counseling services
 - Medicare Clinical Laboratory Fee Schedule
 - Adequacy of payment for genetic tests & genetic counseling services
 - Qualifications of genetic counseling providers
 - Genetics education of the public and health providers

C&R Task Force Activity

October 2004 - February 2005

- Draft report revised based on October meeting discussion
- C&R TF reviewed revised draft
- TF conference call held to discuss revised draft
- Draft report revised further based on TF input

Coverage and Reimbursement Task Force Members

- Cynthia Berry (chair)
- Debra Leonard
- Reed Tuckson
- Emily Winn-Deen
- Francis Chesley (AHRQ)
- Muin Khoury (CDC)
- Steve Phurrough (CMS)
- **Marc Williams (ad hoc)**

Goal of Session

- To address each barrier and reach consensus on recommendations
- To be in a position to move forward after meeting with formal Request for Public Comment through Federal Register announcement

Discussion Materials

- Focus of discussion will be on the following chapters:
 - Coverage (pp.19-34)
 - Billing and Reimbursement (pp. 35-52)
 - Broader Issues (pp. 53-55)
- See *Proposed Recommendations* handout in table folders

Genetic Counseling Services Work Group

- At October meeting, SACGHS requested information on the value and effectiveness of genetic counseling services provided by a range of health providers
- Genetic Counseling Services Work Group formed to respond to this request

Work Group Members

- Kelly Ormond (NSGC)
- Andrew Faucett (ABGC)
- Anne Greb (ABGC)
- Dale Lea (ISONG)
- Daniel Riconda (NSGC Licensure & Reimbursement Subcommittee)
- Judith Cooksey (HRSA Workforce Study)
- Cynthia Berry (SACGHS liaison)

Work Group Task

- List of legitimate credentialing programs for genetic counseling services
- List of providers who are qualified to offer and be reimbursed for these services and explanation of their qualifications
- A literature review and analysis of evidence that demonstrates:
 - The value and effectiveness of genetic counseling services
 - The importance of reimbursing these services
 - Licensure of genetic counselors is reasonable and needed and the potential harm that could result from non-licensure
 - Non-physician genetic counseling providers are qualified to provide counseling services without the supervision of a physician
 - Harms are resulting because non-physician genetic counseling providers are not able to bill directly for their services

Report of the Genetic Counseling Work Group

Kelly Ormond (NSGC)
Andrew Faucett (ABGC)
Judith Lewis (ISONG)
Judith Cooksey (HRSA Workforce Study)

Billing and Reimbursement of Genetic Counseling (pp. 48-51)

- Existing CPT E&M codes may not adequately account for time spent counseling patients, resulting in incommensurate reimbursement
- Health providers billing incident to a physician are limited in which E&M codes they can use for billing Medicare
- Other barriers to billing for genetic counseling services (e.g., licensure, eligibility for provider identifiers) that vary by provider type
- Recommendations 8-10 in handout and p. 49 and p. 51 of report

Evidence-based Coverage Decisions (pp. 19-26)

- No clearly defined, uniform guidance on what constitutes sufficient evidence to warrant coverage of genetic tests and services
- No clearly defined, uniform process for evaluating genetic tests
- Genetic tests and services that are personally useful but lack therapeutic options may have difficulty demonstrating medical effectiveness. Also raises questions about whether informational utility alone warrants coverage.
- Recommendation 1 in handout and p. 26 of report

Influence of Medicare on Private Plans (p. 27)

- Medicare policies are closely followed and frequently adopted by other public and private health plans
- May not be appropriate for genetic tests and services
 - Preventive genetic tests not considered for coverage due to Medicare's screening exclusion
 - Primary users of genetic tests are under age 65
- Recommendation 2 in handout and p. 27 in report

National vs. Local Medicare Coverage Policies (pp. 28-30)

- Bifurcated system allows flexibility but can create inequities in coverage
- Recommendation 3 in handout and p. 30 in report

Screening Exclusion (pp. 31-32)

- Longstanding CMS policy that “tests that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered unless explicitly authorized by statute”
- Predictive and pre-symptomatic genetic tests and services are not covered under this policy
- Recommendation 4 in handout and p. 32 in report

Medicaid and SCHIP Coverage (pp. 33-34)

- State-to-state heterogeneity in coverage could be creating inequities in access to genetic services
- States' balanced budget requirements may create instability in coverage for genetic services
- Recommendation 5 in handout and p. 34 in report

CPT Code Modifiers (pp. 36-37)

- CPT laboratory code modifiers help clarify whether a test is covered under a patient's policy and are anticipated to decrease payment denial and improve utilization and quality tracking
- There has been mixed reaction by health plans on whether and how best to implement and use the modifier codes
- Recommendation 6 in handout and p. 37 of report

Medicare Clinical Laboratory Fee Schedule (p. 43-45)

- In many instances, actual costs of genetic tests exceed Medicare payment rates
- With lab fees frozen until 2009, no changes to payment rates expected in near future
- A complete overhaul of the lab fee schedule will likely affect other fees for tests that are presently over-reimbursed
- Recommendation 7 in handout and p. 45 of report

Reimbursement of Genetic Tests

(pp. 45-48)

- Payment rates for genetic tests often do not cover the full actual cost of performing the test and any licensing fees
- Inadequate reimbursement can lead to decreased access if:
 - Laboratories perform tests at a financial loss, thereby threatening the viability of the laboratory and their willingness to continue offering the test
 - Costs are transferred to the patient
- No recommendation currently drafted

Provider Education & Training (p. 54)

- Genetics education and training will enable health providers, patients, and others involved in coverage and reimbursement decision-making to assess a test's clinical utility and the ELSI issues associated with a test
- Recommendation 11 in handout and p. 54 in report

Public Awareness (pp. 72-73)

- Consumer demand can influence coverage decisions
- Genetics education of the public can ensure that consumer demand for genetic tests and services is based on valid and complete information
- Recommendation 12 in handout and pp. 54-55 in report

Concluding Questions & Next Steps

- Any additional recommendations not discussed
- Plans for seeking public comment