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

Cynthia Berry, J.D.
Chair, Coverage and Reimbursement Task Force

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Report Purpose and Goal

- Purpose
  - To describe the current state of coverage and reimbursement for genetic tests and services
  - To offer recommendations on how current mechanisms for coverage and reimbursement for 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

June-October 2004 Activity

- June 14-15 SACGHS meeting
  - Deliberated on first draft report - discussion of recommendations focused on Medicare's preventive screening exclusion and assessment of sufficiency of clinical validity and utility evidence
  - Formed Coverage and Reimbursement Task Force (C&R TF)
- Revised draft report based on written comments from SACGHS and the public received in June
- September 8 C&R TF meeting
- Further revisions based on TF meeting deliberations

Coverage and Reimbursement Task Force Members

- Cynthia Berry (chair)
- Debra Leonard
- Reed Tuckson
- Emily Winn-Deen
- Kaytura Felix-Aaron (AHRQ)
- Muin Khoury (CDC)
- Steve Phurrough (CMS)

September C&R TF Meeting Participants

- Cynthia Berry
- Reed Tuckson
- Emily Winn-Deen
- Paul Billings (LabCorp)
- Tammy Karnes (LabCorp)
- Linda Bradley (CDC)
- Terrence Kay (CMS)
- Joe Kelly (CMS)
- Steve Phurrough (CMS)
- Don Thompson (CMS)

September C&R TF Meeting Goals

- To review, provide further input into, and, as necessary, make specific changes to a second draft of C&R report
- To develop recommendations for the full Committee to consider at October meeting
- To plan the October coverage and reimbursement session

Presentation on EGAPP Project

- At the June meeting, the Committee requested a presentation on CDC's EGAPP project to determine whether it is a model that could be endorsed in the Coverage and Reimbursement report as a possible mechanism for assessing when the evidence base is sufficient for establishing clinical utility and making coverage decisions

Report Sections

- Preface
- Introduction
- Genetic Tests and Services
- Background
  - Health Care Financing in the United States
  - Coverage Decisions
  - Payment Decisions
  - Billing Process
- Barriers and Potential Recommendations

Preface

- Reviews topic selection and report development process
  - Priority-setting process in which C&R was identified as high-priority issue warranting in-depth analysis and deliberation
  - March 2004 coverage and reimbursement session
  - Formation of C&R Task Force
  - Request for public comments (planned)

Introduction

- Describes value of genetic tests and services
- Describes constraints of the health care system in which genetic tests and services are provided
- Statement of report purpose and goal
- Limitations of report

Genetic Tests & Services

- Describes genetic tests and services in the broad context of laboratory services (e.g., detect biological products, use similar sample collection and processing procedures)
- Describes ways in which they are different (e.g., provide more precise, accurate information about disease susceptibility, clarify family history)
- Describes challenges genetic tests and services pose to health care system (e.g., immutability of genetic risk factors, implications for blood relatives)

U.S. Health Care Financing System

- Overview of:
  - Medicare
  - Medicaid and SCHIP
  - Other public programs (e.g., Tricare, VA system)
  - Indemnity plans
  - Managed care
  - Consumer-driven health plans
  - Uninsured and underinsured

Coverage Decisions

- Medicare coverage decision-making process
  - National Coverage Decisions (NCDs)
  - Local Coverage Decisions (LCDs)
- Coverage decisions in the private sector
  - How decisions are made (e.g., formal technology assessments)
  - Coverage considerations (e.g., FDA approval)
- Current coverage of genetic tests and services
- Role of economic evaluations in coverage decisions

Payment Decisions

- Medicare Clinical Laboratory Fee Schedule
- Current payment rates for genetic tests and services

Billing Process

- Coding systems
  - Current Procedural Terminology (CPT)
  - Healthcare Common Procedural Coding System (HCPCS)
  - International Classification of Diseases (ICD)
- Billing practices
  - Health professions allowed to directly bill Medicare
  - Factors influencing direct billing eligibility of non-physicians (e.g., eligibility for a Unique Physician Identifier Number, credentialing and licensure)
  - Alternate billing methods for health professions not allowed to directly bill (e.g., “incident to” billing)

Barriers and Potential Recommendations

- Barriers
  - Medicare-specific barriers
  - Medicaid- and SCHIP-specific barriers
  - Barriers applicable to public and private insurers
  - Broader issues bearing on coverage and reimbursement of genetic tests and services
- Potential recommendations (blue boxes)
  - Possible ways to address identified barriers
  - Limitations and consequences of proposed recommendations

Organization of Discussions Today and Tomorrow

- Focus on Barriers and Potential Recommendations chapter (pp. 49-73)
- Proceed through chapter section by section
- Briefly review each barrier and potential recommendations at beginning of discussion
- Discuss whether recommendation is needed and appropriate and, if so, what specifically to recommend

Goal of Session

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

Medicare-specific Barriers

Screening Exclusion (pp. 51-54)

- 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
- Any preventive services covered by Medicare have been legislatively mandated (e.g., mammography, diabetes screening)

Screening Exclusion: Potential Recommendations (pp. 53-54)

1. Congress to amend the Social Security Act by adding a benefit category for preventive services (e.g., Medicare Preventive Services Coverage bill)

2. CMS to issue a national coverage decision (NCD) stating that family history constitutes a medical justification for a test being "reasonable and necessary" for the treatment and diagnosis of an illness

3. CMS to redefine predisposition and predictive genetic tests as diagnostic laboratory tests through a rulemaking process or an NCD stating that genetic tests, in the presence of a strong family history of disease, are considered to be diagnostic tests

4. CMS to change its longstanding interpretation of Section 1862(7) of Title XVIII of the Social Security Act allowing the agency to consider coverage for screening services without legislative action

National vs. Local Coverage Policies (pp. 54-55)

- Local Coverage Decisions (LCDs)
  - Allow Medicare to be responsive to local health care needs
  - More rapid process
  - Facilitate the amassing of additional data for an NCD
  - Regional variation may result in inequitable access to services
- National Coverage Decisions (NCDs)
  - National applicability
  - Pre-empts local policies

NCDs vs. LCDs: Potential Recommendations (p. 55)

1. Although a mixed local-national coverage decision-making process is a reasonable approach to making Medicare coverage decisions, CMS should be encouraged to move forward with plans to evaluate new LCDs to determine which should undergo national review and to what extent greater consistency in Medicare coverage policy can be achieved

Genetic Counseling (pp. 55-56)

- Statute does not permit genetic counselors to directly bill Medicare
- Licensing programs would help but changes in Medicare statute would also be necessary
- Reimbursement for genetic counseling would remain limited by Medicare's restrictions on screening tests

Genetic Counseling: Potential Recommendations (p. 56)

1. Increased state licensure of certified genetic counselors
2. Congress to add genetic counselors to list of non-physician providers eligible to bill Medicare directly
3. Congress to authorize CMS to conduct demonstration project that evaluates the distinctiveness of genetic counseling and the value and effectiveness of genetic counselors
4. Institute of Medicine to conduct study to assess the effectiveness of genetic counselors
5. Consensus needed on which health disciplines should be allowed to provide counseling, the appropriate level of supervision for each, and under what conditions they should be reimbursed

Clinical Laboratory Fee Schedule (p. 57)

- 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

Clinical Laboratory Fee Schedule: Potential Recommendation (p. 57)

1. CMS to assess the "inherent reasonableness" of genetic test laboratory fees to determine whether fee should be changed to rectify extreme discrepancies between current fee and actual cost

Medicaid- and SCHIP-specific Barriers (pp. 58-59)

- State-to-state heterogeneity in coverage presumably may be creating inequities in access to genetic services
- States' balanced budget requirements may create instability in coverage for genetic services

Medicaid- and SCHIP-specific Barriers: Potential Recommendations (p. 59)

1. HHS to disseminate to states information about the existing evidence base for genetic tests and services to inform Medicaid/SCHIP coverage decisions
2. HHS to provide states with incentives to cover genetic services having a sound evidence base

Barriers Applicable to Public and Private Insurers

Medicare as a National Leader in Health Care Financing (p. 59)

- 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

Medicare as a National Leader in Health Care Financing: Potential Recommendation (p. 59)

1. Private insurers should not wait for Medicare to make coverage determinations on genetic tests and services with a prevention component. Such services should be considered specifically with respect to what they can offer the different populations they serve.

UPIN System (p. 60)

- Genetic counselors not eligible for a unique provider identification number (UPIN)
- Many private plans voluntarily use Medicare's UPIN system
- Genetic counselors' ineligibility for a UPIN may be adversely affecting their ability to directly bill private insurers
- National provider identifier (NPI) system replacing UPIN system; genetic counselors expected to be eligible for NPI

UPIN System: Potential Recommendation (p. 60)

1. Until the NPI system is implemented, private health plans could create their own provider numbers for genetic counselors to use for billing purposes

Informational Utility and Medical Effectiveness (pp. 60-61)

- Health plans use medical effectiveness to ensure that covered health services meet evidence standards
- Genetic tests and services that are personally useful but lack therapeutic options may have difficulty demonstrating medical effectiveness
- Raises questions about whether informational utility alone warrants coverage and what role, if any, consumer demand should have in coverage decisions

Preventive Nature of Genetic Services (pp. 61-62)

- Preventive services such as genetic tests can have long-term health benefits and be cost-effective
- Because people often change health plans every few years, coverage for preventive genetic services may be difficult to rationalize from an individual health plan's perspective
- Insurers may be reluctant to bear the cost of genetic tests and services in order to spare another insurer the cost of treating future illness

Factoring Cost into Coverage Decisions (p. 62)

- Uncertainty about whether and how best to incorporate cost-effectiveness data in coverage decision making
- Minimal data on cost-effectiveness of genetic tests and services due to paucity of effectiveness data

Informational Utility and Medical Effectiveness

Preventive Nature of Genetic Services

Factoring Cost into Coverage Decisions: Potential Recommendation (p. 61)

1. HHS to establish group to develop set of principles for employers and public programs to use when making decisions about genetic tests and services benefits
   - Principles would identify criteria to determine which genetic tests should always be covered, which genetic tests should never be covered, and which genetic tests fall into an uncertain gray zone
   - Principles should address the issues of cost-effectiveness, preventive nature or experimental status of genetic test, and the test's clinical versus informational benefit

Experimental Exclusions and Rare Disease Testing (pp. 62-64)

- CLIA certification is a requirement for reimbursement
- The cost of and data requirements for obtaining CLIA certification can be particularly burdensome for laboratories conducting rare disease tests, thereby deterring labs from offering rare disease testing

Experimental Exclusions and Rare Disease Testing: Potential Recommendations (p. 64)

1. HHS to develop guidance to clarify when scientific evidence is sufficient to allow a rare disease genetic test to be considered ready for clinical use and to be covered and reimbursed by health insurers
2. CMS to increase educational outreach efforts to facilitate CLIA certification of research laboratories
3. HHS to make funds available to research laboratories to support the administrative costs and additional costs required for obtaining and maintaining CLIA certification

NOTE: Rare Disease conference is in process of drafting similar recommendations

CPT Code Modifiers (pp. 64-65)

- Current CPT codes available for billing genetic tests and services are not specific enough to allow insurers to make informed claim determinations, which can result in claims being denied
- Repeated denial of payment may lead to underutilization and decreased accessibility
- AMA considering development of CPT code modifiers to address this problem

CPT Code Modifiers: Potential Recommendation (p. 65)

1. HHS to encourage AMA to approve CPT code modifiers to supplement existing laboratory CPT codes

Generation of New CPT Codes (p. 65)

- No CPT codes specific to genetic counseling
- Generic E&M codes may not adequately account for time spent counseling patients

Generation of New CPT Codes: Potential Recommendation (p. 65)

1. HHS to promote the development and application of adequate CPT codes that:
   - Distinguish between genetic counseling and doctor visits
   - Accurately reflect the amount of time and resources involved in providing genetic services
   - Represent all steps involved in genetic testing

Evidence-Based Coverage Decisions (pp. 66-69)

- No clearly defined, uniform process for evaluating genetic tests
- No clearly defined, uniform guidance on what constitutes sufficient evidence to warrant coverage of genetic tests and services
- Coverage decisions lacking an adequate evidence base could be harmful to patients, increase overall health care costs, and restrict access to other beneficial services
- Lack of coverage for well-supported genetic tests and services limits patient access to beneficial care

Evidence-Based Coverage Decisions: Potential Recommendations (p. 69)

1. HHS to task a group to assess the evidence for specific tests to determine whether evidence is sufficient in type, quality, and quantity to establish clinical utility
2. For genetic tests found to be lacking sufficient evidence of clinical utility, HHS to establish a mechanism (e.g., RFAs) that would promote and fund studies that aim to address identified gaps in evidence

Need for Uniformity in Coverage Decision-Making (pp. 69-70)

- Different public and private health insurers use different processes and levels of evidence to make coverage decisions
- Multiplicity in processes and evidence base can increase inequities in access
- On the other hand, early coverage by a few health plans can facilitate accrual of evidence to support future coverage decisions by other insurers

Need for Uniformity in Coverage Decision-Making: Potential Recommendation (p. 70)

1. HHS to develop a standard process that public and private payers can use when making coverage decisions for genetic tests
   - This process could include the use of a checklist of the factors that need to be considered when assessing the evidence

Reimbursement Determinations (p. 70)

- Low reimbursement rates provide incentive for the development of more cost-efficient technologies and keep down health care costs
- If actual costs exceed the payment rate, access may become limited due to decreased willingness of laboratories and providers to offer genetic services
- Cyclical problem: Utilization data to support coverage and reimbursement decisions may be difficult to obtain without reimbursement
- Low reimbursement not unique to genetic tests and services

Reimbursement Determinations: Potential Recommendation (p. 70)

1. Public and private sector insurers to establish a process for obtaining data from clinical laboratories and medical device manufacturers on the actual costs of performing genetic tests

Broader Issues

Health Disparities (p. 71)

- Numerous documented examples of disparities in health status and utilization of health services by age, gender, race/ethnicity, education, income, disability, and geography
- Underutilization among certain populations may result in incomplete data and coverage decisions that further limit access and exacerbate existing disparities

Health Disparities: Potential Recommendation (p. 71)

1. HHS to facilitate the performance of a large multi-dimensional, population-based research study on interactions between genetics, the environment, and disease

Provider Education and Training (p. 72)

- Genetics education and training will enable health providers, patients, and others involved in coverage and reimbursement decision-making to assess when genetic tests and services are appropriate and when they are not

Provider Education and Training: Potential Recommendations (p. 72)

1. Recommendations to reference SACGHS Education Resolution
   - HHS agencies to work collaboratively with state, federal, and private organizations to support the development, cataloguing and dissemination of case studies and practice models that demonstrate the current relevance of genetics and genomics to clinical and public health practice
   - HHS to strive to incorporate genetics and genomics into relevant HHS initiatives

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

Public Awareness: Potential Recommendation (p. 73)

1. HHS to facilitate the development and wide dissemination of reliable and trustworthy information about genetics and genetic technologies that allow patients and consumers to evaluate health plan benefits and health providers
   - This could be accomplished through the development of performance and efficiency measures for evaluating the quality and safety of genetic tests and services

Next Steps

Oct 29	Due date for additional edits
Nov 2004	Staff to prepare next draft and FR Request for Public Comments
Dec 04-Jan 05	Public comment period
SACGHS mtg Feb 28-Mar 1, 2005	SACGHS to review public comments and finalize recommendations