Draft Report on
Coverage and Reimbursement of
Genetic Technologies and Services

June 14, 2004

Background

- SACGHS’ priority-setting process identified coverage and reimbursement of genetic technologies and services as one of the highest priority issues for analysis and deliberation
- March 2004 meeting: Session on current practices and limitations of coverage and reimbursement for genetic technologies and services
- June 2003: Presentation by John Rowe, Chair and CEO of Aetna Healthcare
- Previous work of SACGT: Draft reports of Access Work Group

Report Purpose and Goals

- Purpose
  - To provide background on the current state of coverage and reimbursement for genetic technologies and services
  - To offer recommendations on how the current health care system might be improved in relation to genetic technologies and services
- Goal
  - To improve access to health-related genetic technologies and services by ensuring coverage and appropriate reimbursement in all health care settings

Report Sections

- Introduction
- Genetic Technologies and Services
- General Principles
- Background
  - Health Care Financing in the United States
  - Coverage Decisions
  - Payment Decisions
  - Billing Process
- Barriers and Policy Options
- Recommendations

Introduction

- Genetic technologies can enhance clinical care through the elucidation of genetic determinants of disease and drug effects
- Limitations in coverage and reimbursement can impede access to genetic technologies and services

Genetic Technologies & Services

- Genetic technologies and services pose unique challenges to the U.S. health care system
  - Predictive nature
  - Complex social and personal issues
  - Personal benefit but no therapeutic options available
  - Team approach to providing genetic services
- Integration of technologies and services depends on the system’s flexibility and responsiveness to these characteristics

General Principles

- Offers general principles that are fundamental to ensuring appropriate access to genetic technologies and services:
  - Data collection should be a priority to facilitate evidence-based decision-making
  - Oversight systems should be in place to ensure that genetic technologies are valid and adhere to quality standards
  - Patients should be well-informed of the clinical, ethical, legal, and social implications of genetic technologies
  - Improved access to all areas of health care should be a priority
  - Federal genetic non-discrimination is needed
  - Others?

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 Medical Review Policies (LMRPs)
- 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 technologies and services
- Role of economic evaluations in coverage decisions

Payment Decisions

- Medicare Clinical Laboratory Fee Schedule
  - Payment rates frozen at current levels until 2009
- Current payment rates for genetic technologies and services

Billing Process

- Coding systems
  - Current Procedural Terminology (CPT)
  - Healthcare Common Procedural Coding System (HCPCS)
  - International Classification of Diseases (ICD)
- Not all health providers permitted to directly bill for their services
  - Licensure and credentialing
  - Availability of Unique Physician Identifier Number (UPIN)
  - Federal Medicare statute

Barriers

- Medicare-specific barriers
- Medicaid- and SCHIP-specific barriers
- Barriers applicable to all insurers
- Broader issues bearing on coverage and reimbursement of genetic technologies and services

Medicare-specific Barriers

Screening Exclusion

- Longstanding CMS policy that “tests for screening purposes 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
- CMS policy based on interpretation of Medicare statute

Local vs. National Coverage Policies

- LMRPs
  - Allow Medicare to be responsive to local health care needs
  - Evidence requirements usually less compared to NCDs
  - Regional variation may result in inequitable access to services
- NCDs
  - National applicability
  - Pre-empts local policies

Genetic Counselors

- Statute does not permit genetic counselors to directly bill Medicare
  - Thus, not able to obtain UPIN
- Licensing programs would help but changes in Medicare statute would also be necessary
- Reimbursement for genetic counseling would still be limited by Medicare’s restrictions on screening tests

Medicare as a National Leader in Health Care

- Medicare policies are closely followed and adopted by other public and private health plans
- May not be appropriate for genetic technologies and services
  - Preventive nature of genetic technologies and Medicare’s screening exclusion
  - Primary users of genetic technologies are under age 65
  - Cost of services not considered by Medicare

Medicaid- and SCHIP-specific Barriers

- State variation creates inequity in access to genetic services
- State balanced budget requirements create instability in coverage

Barriers Applicable to All Insurers

Informational Benefit vs. Medical Necessity

- Medical necessity criterion serves to ensure appropriate access to health care that meets evidence standards
- Genetic technologies and services may not meet medical necessity criteria if there are no therapeutic options available
- Does the informational value alone warrant coverage?
- What role, if any, should consumer demand have in coverage decisions?

Future Benefit

- On average, a person changes health plans every 2-3 years
- With pre-symptomatic genetic tests, current health insurers pay and other insurers benefit
- Insurers are reluctant to bear the cost of genetic technologies and services in order to spare another insurer the cost of treating future illness

Role of Cost in Coverage Decisions

- Cost not explicitly considered in coverage decision-making process
- In some cases, the value of genetic technologies and services is predicated on their long-term ability to offset future health care costs

Experimental Exclusions

- Most insurers will not cover experimental procedures
- Many genetic technologies will never leave the research phase (e.g., tests for rare diseases)

CPT Code Modifiers

- Inadequate descriptions of a service and reasons for provision may result in claims being denied
  - Repeated denial of payment may lead to underutilization and decreased accessibility
- Coding systems must keep pace with current technology
  - AMA considering development of CPT code modifiers for laboratory codes

Genetic Counseling CPT Codes

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

Evidence-Based Coverage Decisions

- No clearly defined, uniform process for evaluating genetic technologies
- No clearly defined, uniform guidance on what constitutes sufficient evidence to warrant coverage of genetic technologies 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 technologies and services prevents patients from benefiting from medical advances

Payment Rates

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

Broader Issues

Health Disparities

- Numerous documented examples of differences 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

Education and Training

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

Topics for Discussion

- Report content and tone
- Guiding principles
- Recommendations

Possible Topics for Recommendations

- **Medicare**
  - Screening exclusion
  - Coverage decisions
  - Genetic counselors as a billable entity
  - UPINs/NPIs
  - Medicare's role as a national leader in health care
- **Medicaid/SCHIP**
  - Medicaid state variation
  - State Medicaid budgets
- **All Insurers**
  - Informational benefit and medical necessity
  - Preventive nature of genetic services
- **All Insurers (cont)**
  - Experimental exclusions
  - CPT code modifers
  - CPT codes for genetic counseling
  - Evidence-based coverage decisions
  - Lack of uniformity in coverage decision-making
  - Reimbursement determinations
- **Broader Issues**
  - Health disparities
  - Provider education and training