

Update: CMS and Genetic Applications in Health Care

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SACGHS Meeting

March 12, 2009

What we'll cover today

- History of Coverage for Genetic Testing in the Medicare program
- What CMS is or will be doing re: genetics
 - Genomics Work Group
 - MedCAC, February 25: Diagnostic uses
 - MedCAC, May 6: Screening uses
 - CLIA-related activities
 - Pending Decision: PGx and Warfarin Response
 - Research and future NCD priorities for CMS

Coverage for Genetic Testing Under Medicare: History

Genetic Testing: Coverage History

- Medicare beneficiaries are covered for genetic testing services for the diagnosis of specific diseases:
 - Cytogenetic Testing, under a National Coverage Determination (NCD)
 - Genetic variants associated with certain forms of heritable cancers, under Local Coverage Determinations (LCD)

Medicare and Cytogenetics

- Defined as “the microscopic examination of the physical appearance of human chromosomes”
- Reasonable and necessary for:
 - Genetic disorders in a fetus (e.g., Trisomy 21);
 - Failure of sexual development;
 - Chronic myelogenous leukemia;
 - Acute leukemias; or
 - Myelodysplasia.

Local Coverage Determinations (LCDs)

- Medicare Administrative Contractors (MACs) may determine, absent national coverage policy, which Medicare benefits, including diagnostic tests, are covered within their regions.
- Advantages of LCDs:
 - More flexible;
 - More responsive to local needs and situations; and
 - Permit local input about coverage
- Disadvantages
 - Lack of consistency across MACs
 - Less broad, national input
 - Local resource constraints may impede decision-making

LCD Database

- In CMS' publicly available database of local and national coverage decisions, available through <http://www.cms.hhs.gov>, LCDs about genetic testing include:
 - Hereditary Breast and Ovarian Cancer (*BRCA1 / BRCA2*)
 - Hereditary Colorectal and Endometrial Cancer Syndromes (*bMLH1, bMSH2, bMSH6 / APC / MYH*)

LCDs and Genetic Testing

- LCDs about genetic testing specify that:
 1. Genetic tests for cancer are only a covered benefit for a beneficiary with a personal history of an illness, injury, or signs/symptoms thereof (i.e. clinically affected). A person with a personal history of a relevant cancer is a clinically affected person, even if the cancer is considered cured.
 - Genetic testing is considered a non-covered screening test for patients unaffected by a relevant illness, injury, or signs/symptoms thereof.

LCDs and Genetic Testing

- LCDs about genetic testing specify that:
 2. Predictive or pre-symptomatic genetic tests and services, in the absence of past or present illness in the beneficiary, are not covered under national Medicare rules.
 - For example, Medicare does not cover genetic tests based on family history alone.

LCDs and Genetic Testing

- LCDs about genetic testing specify that:
 3. A covered genetic test must be used to manage a patient.
 - Medicare does not cover a genetic test for a clinically affected individual for purposes of family planning, disease risk assessment of other family members, when the treatment and surveillance of the beneficiary will not be affected, or in any other circumstance that does not directly affect the diagnosis or treatment of the beneficiary.

LCDs and Genetic Testing

- LCDs about genetic testing specify that:
 4. The results of the genetic test must potentially affect at least one of the management options considered by the referring physician in accordance with accepted standards of medical care.
 - Management options might include surgery, the extent of surgery, a change in surveillance, hormonal manipulation, or a change in drug dosage, or from standard therapeutic or adjuvant chemotherapy.

LCDs and Genetic Testing

- LCDs about genetic testing specify:
 5. Pre-test genetic counseling must be provided by a qualified and appropriately trained practitioner.
 6. An informed consent form signed by the patient prior to testing which includes a statement that he/she agrees to post-test counseling is required.
 - This consent form must be available on request from Medicare.

LCDs and Genetic Testing

- LCDs about genetic testing specify that:
 7. Genetic analysis must be provided through a laboratory which meets the American Society of Clinical Oncology (ASCO) recommended requirements:
 - The lab must meet appropriate Clinical Laboratory Improvement Amendment (CLIA) 1988 regulations;
 - The lab must successfully participate in the American College of Medical Genetics (ACMG)/College of American Pathologists (CAP) proficiency testing program;
 - The lab must have appropriate state licensing; and
 - The lab's laboratory directors and staff must be credentialed by the American Board of Medical Genetics (ABMG).

CMS and New Diagnostic Technologies

Council on Technology and Innovation (CTI)

- Established pursuant to the Medicare Modernization Act of 2003
- Involves different components of CMS responsible for coverage & payment policy development
- Facilitates exchange of information about new technology
- Enhances coordinated response to coverage, coding or payment issues

Council on Technology and Innovation (CTI)

- “Innovators’ Guide to Navigating CMS” *(2008)*
 - Assist stakeholders in understanding the processes used to determine coverage, coding, and payment for new technologies under the Medicare fee-for-service program.
 - Provide summarized and simplified versions of existing statutes, regulations, and other policy materials for guidance.
 - Facilitate timely introduction of innovative technology for care of beneficiaries.

Genomics Working Group

- Multi-component work group that will support CTI specifically on genomics and personalized medicine
- Primary leadership from CMS CMO, Director and Staff of Coverage and Analysis Group
- Issues
 - Coverage, payment coding
 - CLIA
 - Medicare FFS, MA and Medicaid/CHIP
 - Personalized healthcare coordination within CMS
 - Collaboration across other HHS agencies

Evidence and Coverage of Testing Under Medicare

Technical Advice to CMS

- The Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) assists CMS in determining the characteristics of evidence to support coverage decisions about medical services, items and devices, etc., for Medicare beneficiaries.
 - MEDCAC meets several times each year, and complies with FACA requirements
- CMS also uses outside Technical Advice vehicles
 - AHRQ
 - Academic and other contractors

MEDCAC on Genetic Testing

- A recent MEDCAC meeting (2/25/2009) reviewed current recommendations about evaluating sources of evidence for the patient-focused health outcome benefits from diagnostic uses of genetic testing.
- These diagnostic uses could include:
 - Diagnostic applications
 - Prognostic applications
 - Pharmacogenomic applications
- Second MEDCAC on genomics: May 6, 2009

MEDCAC (2/25/09) Highlights

- Some highlights of this MEDCAC meeting:
 - Recommendation to use a standard framework and methods to evaluate evidence about diagnostic uses of genetic testing
 - Recommendation to encourage evidence from clinical studies with high internal validity about patient-focused health outcomes due to use of genetic results in care management
 - Encouragement of collaboration among federal agencies involved in research and health care policy

Preventive Services Benefits

- Medicare originally did not provide for preventive services benefits
- Congress added these services individually by statute
- Current Medicare beneficiaries may be eligible for specific preventive services benefits for diseases, including but not limited to:
 - Breast cancer (mammography) and cervical cancer;
 - Colorectal cancer;
 - Prostate cancer; and
 - Cardiovascular diseases (and others)
- Such preventive services aim at early detection and prevention of specific diseases.

MEDCAC on Screening GT

- MIPPA 2008 (Section 101) gives authority to DHHS Secretary to consider additional preventive services benefits (e.g., those with an “A” or “B” rating from US Preventive Services Task Force) through Medicare NCD process
 - Allows cost-effectiveness to be used in this specific NCD decision process
- In May 2009, MEDCAC will meet again to consider screening uses of genetic testing, as a preventive services benefit for Medicare beneficiaries.
 - At this meeting, MEDCAC will be asked to recommend what kinds of evidence to use for evaluating screening uses of genetic testing for early detection and prevention.

CMS and Oversight of Genetic Testing: CLIA Update

CLIA and Genetic Testing

- Under the current Clinical Laboratory Improvement Act (CLIA) regulations, CMS continues to:
 - Certify laboratories where CLIA is applicable
 - Update the CLIA database of laboratories' certification status; includes a demographic search tool which provides facility address, CLIA number, certificate type, and certificate expiration date
 - Provide standards for all moderate and high complexity laboratory testing, which includes genetic testing

CLIA and Genetic Testing

- To promote a highly expert level of laboratory performance, CMS/CLIA staff meet and consult with
 - Partner Federal agencies (FDA/CDC/NIH)
 - National professional societies, advisory & standard-setting groups (e.g., CLIAC/CLSI)
 - Other partners and stakeholders

CLIA and Genetic Testing

- To adapt current regulations to the changing needs of the laboratory testing industry:
 - CMS provides specific guidance and updates with its CLIA surveyor training; and has hired new staff with expertise in genetic testing;
 - CMS has initiated development of a proposed rule to update the proficiency testing (PT) regulations for PT programs and laboratories; specifically, to add genetic tests and better alternate assessment mechanisms
 - CMS is working with laboratories offering direct-to-consumer genetic testing to ensure compliance where CLIA is applicable.

CLIA and Genetic Testing

- Additional CLIA projects in progress (1/2):
 - Establish a work group of partners and stakeholders, e.g., CDC, FDA, NIH, FTC and AOs, on genetic testing issues, including:
 - Coordinated augmented monitoring and
 - Data collection and analysis;
 - Participate in professional meetings to:
 - Disseminate educational information, like CLIA brochures;
 - Facilitate CLIA compliance and assist surveyors; and
 - Maintain expertise and provide current CLIA information.

CLIA and Genetic Testing

- Additional CLIA projects in progress (2/2):
 - Educational:
 - Publish (through CDC/MMWR) best practices for genetic laboratories;
 - Facilitate CLIA compliance and maintain up-to-date references for CLIA requirements; and
 - Enhance CMS/CLIA website to include Direct-to-Consumer laboratories and other pertinent resources.
 - Standards:
 - Publish proposed notice for final PT regulations;
 - Incorporate more relevant professional standards into Interpretative Guidelines; and
 - Continue collaboration with standards development organizations.

CMS and Future NCD Topics

Pending NCD: Genetic Testing For Warfarin Responsiveness

- In August 2008, CMS opened an NCD to consider coverage for genetic testing to determine warfarin responsiveness.
- Technology assessment, conducted in partnership with AHRQ, evaluated current evidence from published articles.
- Proposed decision memo expected by no later than early May 2009.
 - Public comments will be encouraged during the 30 days following the posting of the proposed decision memo.

Possible Future NCDs

- CMS invites public participation in determining and prioritizing topics for consideration for NCDs.
- Genetic tests mentioned recently included:
 - Pharmacogenomics
 - Screening for heritable forms of cancer
- CMS is open to public questions about the NCD process, and to proposals about new NCDs.

Possible Topics for Future NCDs

- In December 2008, CMS published 20 potential NCD topics for public comment, including:
 - Gene expression profiles in oncology
 - “ ... to inform cancer therapy decisions.”
 - CMS comment: “It is unclear if the widespread addition of such testing to the evaluation of patients with would result in a meaningful change in disease management and improved health outcomes.”
 - Pharmacogenomic testing
 - “ ... detects DNA variants ... associated with altered response to therapeutic drugs ... to optimize drug selection or modify drug dosage to improve effectiveness and/or to avoid adverse drug events. ... Testing for certain variants in *VKORC1* and *CYP2C9* genes (and possibly others) may permit more accurate calibration of warfarin dosage for individuals to prevent thrombosis or thromboembolism; ... “

Possible Future NCDs

Circumstances favoring CMS topic review:

- 1) Inquiries from the public, providers, or patients;
- 2) New evidence or re-examination of available evidence;
- 3) Inconsistent or conflicting local coverage policies;
- 4) Program integrity concerns;
- 5) Substantial clinical advances;
- 6) Technologies for which rapid diffusion could have a significant programmatic impact; or
- 7) Significant uncertainty about the health benefit, patient selection, or appropriate facility and staffing requirements for a new technology.

Selected References

- CMS website www.cms.hhs.gov
 - Medicare NCD Manual 100-03, Ch. 1, Part 3, #190.3 (Cytogenetics)
 - To obtain a copy of the “Innovators’ Guide to Navigating CMS” (2008), link to http://www.cms.hhs.gov/CouncilonTechInnov/Downloads/InnovatorsGuide8_25_08.pdf
 - See CMS or Medicare website for guides to Preventive Services Benefits under the Medicare program, for patients and for providers.
 - http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=19 for possible NCD topics, December 2008

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