



# Medicare Coverage of Genomic Testing

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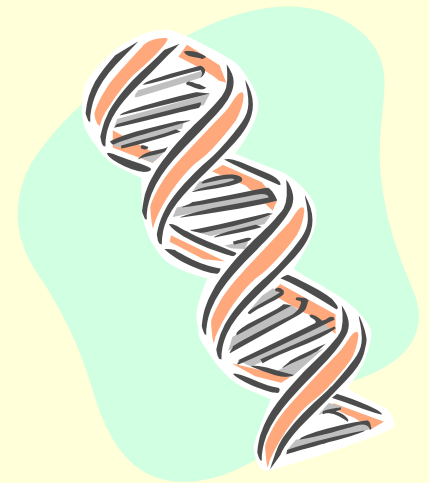
# Social Security Act 1862(a)(1)(A)

“Notwithstanding any other provision of this title, no payment may be made...for items or services - which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

This has been interpreted historically to prohibit payment for screening and prevention, unless Congress creates specific exceptions, which it has done periodically, e.g. for colorectal cancer screening. Thus, Medicare's ability to consider payment for genomic services is currently limited to such uses that are neither screening nor preventive in nature.

# Clinical Uses of GT

- **Diagnosis of disease**
  - Detection / differentiation / confirmation
  - Predict or monitor response to therapy
  - Detect recurrence
- **Prediction**
  - Likelihood of future disease
  - Susceptibility for a condition
  - Response to therapy (e.g., drug)
- **Identify/rule out carriers**



The indications highlighted in blue are thus challenging for Medicare.

# How We Apply R&N Today

- Sufficient level of confidence that evidence is adequate to conclude that the item or service improves clinically meaningful health outcomes in Medicare beneficiaries
- Evidence assessed using standard principles of evidence-based medicine (EBM)

# Most Coverage Policy is Local

National  
10%



Local

National

Local  
90%

# Coverage Determinations as of June 2008

If you search Medicare's online coverage policy database with the search terms [genetic] OR [genomic] in the title, you will find only one NCD, and only one local contractor, Noridian Administrative Services, has developed LCDs.

Medicare does not have a broad national coverage policy on genomic testing. Therefore local Medicare contractors may make policies that apply only within their own jurisdictions. However, since many genomic tests are provided in a single location, i.e. all specimens are sent to a single laboratory, the decision of the local contractor having oversight of that laboratory has national implications.

# NCD 190.3 (1998)

- Cytogenetic Studies
  - Genetic disorders in a fetus;
  - Failure of sexual development;
  - Chronic myelogenous leukemia;
  - Acute leukemias lymphoid (FAB L1-L3), myeloid (FAB M0-M7), and unclassified; or
  - Myelodysplasia

# LCD (NAS, 2007)

- Hereditary Breast and Ovarian Cancer
  - Hereditary Colorectal and Endometrial Cancer Syndromes
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.
  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.
  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.
  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 (e.g. surgery, the extent of surgery, a change in surveillance, hormonal manipulation, or a change from standard therapeutic or adjuvant chemotherapy).



# LCD (continued)

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 agree to post-test counseling is required. This consent form must be available on request by Medicare.

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;
- Successful participation in the American College of Medical Genetics (ACMG)/College of American Pathologists (CAP) inspection and survey program;
- appropriate state licensing; and
- credentialing of laboratory directors and staff by the American Board of Medical Genetics (ABMG).

# Challenges in the Evidence

- The topic is very broad
- The evidence base is small and unevenly distributed
- The science is evolving
- The ultimate health outcomes that will be attributable to genomic testing are not clear at this time

# More Challenges

- Some claimed benefits of genomic testing may be diminished in the core Medicare population.
  - Most persons make childbearing decisions well before reaching age 65.
  - Lifestyle changes (e.g. smoking cessation) are better begun earlier in life.
  - Minimizing adverse drug effects is important at all ages, so better to have that info in childhood.
  - Prevention of premature disease begins well before age 65.

If genomic testing does provide value, that value is logically maximized by testing early in life rather than waiting until most people become Medicare eligible.

# The Preferred Road to Diagnostic Coverage

- ✓ Provide adequate evidence that
- ✓ The incremental information obtained by new diagnostic technology compared to alternatives
- ✓ Changes physician recommendations
- ✓ Resulting in changes in therapy
- ✓ That improve clinically meaningful health outcomes
- ✓ In Medicare beneficiaries

# Health Outcomes

## *More Impressive*

- Longer life and improved function/participation
- Longer life with arrested decline
- Significant symptom improvement allowing better function/participation
- Reduced need for further burdensome tests and treatments

## *Less Impressive*

- Earlier detection without improved survival
- Test result is a better number
- Image/scan looks better
- Doctor feels more confident

Bottom line: what real life difference does this test make compared to management without this test? To date, the evidence on genomic testing remains largely preliminary, e.g. test accuracy. It is unclear in many cases that the test actually makes a difference.

# Assessing the “promise”

- From the National Health Policy Forum:
  - “ ... Although headlines have proclaimed a coming ‘genetic revolution’ in healthcare, most of the anticipated advances in pharmacogenomics are **still in the early research stage** ... environmental, behavioral, and dietary factors interact with gene variation to affect drug response. So far, only a handful of drugs ‘tailored’ to specific genotypes have been developed and approved.”

*Source: NPHF Background Paper: “Pharmacogenomics Primer for Policymakers” (January 2008) ([www.nphf.org](http://www.nphf.org))*