

August 15, 2005

TO: Trailblazer Health Enterprises, LLC.

RE: Cytogenetics Studies – L-96AB

The undersigned clinical laboratory associations and medical professional societies, who represent the collective expertise of the cytogenetics testing community, are writing to express a major concern with Trailblazer Health Enterprise's proposed Local Coverage Determination (LCD) for Cytogenetics and ask that Trailblazer significantly expand the number of disease entities for which cytogenetics tests and FISH technology should be medically covered for reimbursement. Trailblazer's LCD for Cytogenetics is considerably outdated and thus inadequate for today's medical cytogenetics testing modalities.

Specifically, many important ICD-9 codes have been omitted from the proposed LCD. These include diagnostic categories where cytogenetics studies have become the standard of care in the diagnosis and/or treatment of patients and materially improve their clinical outcome and management. Without changes to the coverage policy, Medicare patients will be denied access to tests that have become the standard of care for an ever-increasing number of acquired and constitutional disorders.

Cytogenetics studies are used in the care of patients with hematopoietic and solid tumor disorders. Cytogenetics laboratories routinely identify acquired chromosome abnormalities that diagnose a hematopoietic disorder as present or incipient. This may confirm what other laboratory work and patient examinations have suggested, or may predict what is about to develop. Cytogenetic analysis is used to monitor the effects of therapy, check for minimal residual disease after therapy, or demonstrate that disease progression is imminent or actually occurring. Frequently the absence of any cytogenetically abnormal cells can be of clinical significance. For example, essential thrombocythemia is a diagnosis of exclusion, often confirmed by the absence of the t(9;22) that, when present, signifies Chronic Myelogenous Leukemia (CML).

Equally important is the use of cytogenetics for patients who present with some of the symptoms and signs of a disorder, such as Acute Myeloid Leukemia (AML), CML, Myelodysplastic Syndromes (MDS), Myeloproliferative Disorders (MPD), lymphomas or other lymphoproliferative disorders, but are not clinically at the point where the referring physician can be certain, a priori, of the diagnosis. In such cases, chromosome analysis may be used to rule out such a diagnosis, rather than to confirm it.

For these reasons, chromosome analysis has become part of the standard of care for laboratory testing of virtually every diagnosis code related to a hematopoietic disorder. Yet only a few conditions [CML (205.10-.11, Acute Leukemias (204.00-.01, 205.00-.01, 208.00-.01) and MDS (238.7)] are specified in this draft LCD. This does not take lymphoma (200 – 202), most lymphoproliferative (e.g. 203, 273.3), and myeloproliferative (e.g. 238.4, 289.0, 287.3 - 287.5, 289.9) disorders, multiple myelomas and anemias (284 – 285, etc.) into consideration. Virtually every one of these conditions has been associated with one or more chromosome abnormalities, and these have diagnostic, prognostic, and disease/therapeutic monitoring implications.

It should also be noted, however, that not all patients with such disorders will present with cytogenetic changes. Therefore, it is not feasible for the laboratory to add a "chromosome abnormality" code after the analysis has been completed, since many such patients present with normal karyotypes, even after a diagnosis has been confirmed with other test modalities. An analogous situation exists for solid tumors. Suffice it to say that the list of ICD-9 codes that could be attached to a solid tumor sample submitted for chromosome analysis is too long to be included here. Yet the entire concept of non-hematopoietic cancer cytogenetics is also ignored by this proposed LCD.

A similar situation also exists for constitutional chromosome abnormalities. There are numerous diagnosis codes that can be legitimate indications for chromosome analysis in a fetus, newborn, child or adolescent, infertile patient, mentally retarded patient, or products of conception specimen, yet only some of these are listed in this LCD. For example, some of the most common indications laboratories receive for chromosome analysis are 783.41-.43, which involve developmental delay in a child. Chromosome analysis is absolutely standard of care in such cases, yet these codes are not listed. Although these indications may not as frequently apply to the Medicare beneficiary population, they should be included as medically necessary.

There is also a long and expanding list of applications of FISH technology which extends far beyond the traditional cytogenetics study that must also be considered (e.g. HER-2/neu for breast cancer, FISH for bladder cancer, FISH panels for lymphoproliferative disorders, the recent discovery of clinically significant FISH-detectable deletions on the derivative chromosome 9 in CML patients with the "Philadelphia" rearrangement, etc.). Monitoring residual disease by FISH is standard of care for many malignancies and crucial for therapy evaluation. As a methodology rather than a specific test, the applications of FISH will continue to expand, and cannot be limited to a select few diagnosis codes.

In summary, based on the collective experience of the cytogeneticists and molecular pathologists who serve clinicians and their patients on a daily basis, the proposed LCD barely scratches the surface of the long list of diagnostic codes routinely used every day in clinical practice for submission of samples for chromosome and/or FISH analysis. We urge Trailblazer to substantially broaden the list of approved diagnoses to reflect the current standards of clinical care.

The group of undersigned organizations is currently developing a list of the additional ICD-9 codes that should be included as approved diagnoses for cytogenetics testing, derived from the current medical literature. We ask for the opportunity to discuss this critically important issue with you as the supporting documentation is prepared. Please respond to David Mongillo at the American Clinical Laboratory Association, 202 637-9705 or dmongillo@clinical-labs.org to schedule a time for a conference call or meeting. Thank you in advance for your full consideration.

Sincerely,

American Association for Clinical Chemistry
American Clinical Laboratory Association
American College of Medical Genetics
Association for Molecular Pathology
American Society for Clinical Pathology
American Society for Microbiology
College of American Pathologists