February 21, 2014

Elaine Jeter, MD  
Palmetto GBA  
PO Box 100190  
Columbia, SC 29202

Sent Via Email: J11B.policy@PalmettoGBA.com

RE: PROPOSED/ DRAFT Local Coverage Determination (LCD): CYP2C19, CYP2D6, CYP2C9 and VKORC1 Genetic Testing (DL 34499)

Dear Dr. Jeter:

AdvaMedDx appreciates the opportunity to comment on the above-referenced Local Coverage Determination (LCD) related to pharmacogenetic testing. We are writing to request that Palmetto clarify the rationales for its proposed coverage decisions, by providing additional information regarding the clinical evidence it assessed, and describing how it determined that the evidence in some cases is insufficient to support coverage. We further request that Palmetto extend the comment period on this LCD to allow stakeholders adequate opportunity to respond to the complex issues it raised.

AdvaMedDx, which operates as a division of the Advanced Medical Technology Association (or AdvaMed), represents the world’s leading diagnostics manufacturers by advocating for the power of medical diagnostic tests to promote wellness, improve patient outcomes, and advance public health in the United States and abroad. AdvaMedDx member companies produce innovative, safe and effective diagnostic tests that facilitate evidence-based medicine, improve quality of care, promote wellness, enable early detection of disease and often reduce health care costs.

In the proposed LCD, Palmetto proposes to limit coverage or to non-cover multiple personalized medicine tests that analyze the way an individual patient will metabolize a variety of medications for different indications, including tests that are approved by the Food and Drug Administration (FDA) that are produced by AdvaMedDx member companies.

Genetic testing can allow physicians to identify the right drug for the right patient, to guide treatment and to determine appropriate dosage. As noted in the proposed LCD, differences in metabolism can have a dramatic effect on the safety and efficacy of some drugs. The FDA labeling for many commonly-prescribed drugs today includes warnings, precautions and adverse reactions for “poor metabolizers” of the drug, requiring dosing adjustments or even treatment using alternative therapies.¹ In many cases, the FDA label will cite the availability of approved laboratory

¹See http://www.fda.gov/drugs/scienceresearch/researchareas/pharmacogenetics/ucm083378.htm
tests to identify “poor metabolizers” of the drug. Such tests can aid physicians in the selection of certain drugs and determining or adjusting dosage, avoiding complications and adverse reactions and improving health care quality.

AdvaMedDx supports an evidence-based approach to developing coverage policy regarding items and services, including diagnostic tests, used by Medicare beneficiaries. In this draft LCD, Palmetto assesses genetic testing of multiple genes and proposes limited coverage in some cases where Palmetto has determined the test to be medically necessary to guide medical treatment and/or dosing for certain drugs and indications. Palmetto proposes non-coverage of such tests in other cases, citing “insufficient evidence” to warrant genotyping or to support genotyping to determine medical management, but providing little detail regarding its analysis of the evidence beyond its finding that the evidence is lacking.

It is critical for stakeholders to understand the types and levels of evidence that would be sufficient to support a positive coverage decision. AdvaMedDx therefore urges Palmetto to provide additional details, including a fuller discussion of the applicable evidence that was used to support the decisions that were reached, so that interested parties can readily understand the reasoning behind the decision and can meaningfully respond.

In addition to the limited rationale behind its proposed coverage decisions, Palmetto provided only a very short, 48-day comment period for stakeholders, including manufacturers, to respond in a meaningful way.

We are concerned that non-coverage of this type of testing will impact physicians’ ability to provide the best care for their patients, and could adversely affect patient safety. However, we are also concerned that parties seeking coverage for these tests will continue to face obstacles, because payers’ expectations regarding the evidence are not clearly understood.

Because of the scope and complexity of the proposed coverage policies contained in the draft LCD and the limited time period for responding in a meaningful way, AdvaMedDx requests that Palmetto extend the comment period by three months, to May 24, 2014. We believe this would provide adequate time for AdvaMedDx member companies to respond to the multiple proposals in the LCD with necessary clinical and scientific support.

Once again, we appreciate the opportunity to provide comments on the proposed LCD. Please feel free to contact Chandra Branham, JD, Vice President, Payment & Health Care Delivery Policy, at cbranham@advamed.org or (202) 434-7219 if you have any questions concerning our comments.

Sincerely,

Andrew C. Fish
Executive Director