Statement of:

The American Clinical Laboratory Association

for:

United States House of Representatives
Armed Services Committee
Military Personnel Subcommittee

Hearing on:

Defense Health Agency

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2:00pm

ACLA
1100 New York Avenue, NW, Suite 725W
Washington, DC 20005

The American Clinical Laboratory Association (ACLA) thanks the Members of the House Military Personnel Subcommittee for consideration of our comments for the hearing, "Defense Health Agency." ACLA is a not-for-profit association representing the nation's leading national and regional clinical laboratories on key issues of common concern, including federal and state government reimbursement and regulatory policies.

Clinical laboratories provide critical testing services to TRICARE beneficiaries. Clinical laboratory tests guide more than 70% of medical decisions made by healthcare professionals. The information provided by clinical labs helps diagnose, treat and monitor patients as accurately and quickly as possible. Our member laboratories proudly provide clinical laboratory services to our men and women in the armed services and their families.

ACLA submits this statement for the record as to express its strong opposition to TRICARE's current policy of non-coverage for molecular diagnostic tests provided to TRICARE beneficiaries seeking care through the community provider network. There is no sound clinical or regulatory rationale for this decision. The decision should be reversed and coverage restored so that TRICARE beneficiaries and their families have access to the same standard of care available to TRICARE beneficiaries at Military Treatment Facilities and to patients covered by hundreds of public and private insurance plans.

The Defense Health Agency (DHA) ceased providing coverage for over 100 molecular diagnostic tests in January 2013. These tests were placed on the No Government Pay Procedure Code List (NGPPCL) without notice or explanation, and denied reimbursement. These tests include critical tests for Cystic Fibrosis, Fragile X syndrome, spinal muscular atrophy, and many common cancers.

It is important to note that these molecular diagnostic tests were not new tests in 2013; they were simply assigned new CPT codes (the procedure codes used to identify various medical procedures). Prior to 2013, laboratories billed for these services using a series of methodology and procedure codes representing the steps the laboratory performed to complete the test. Under the old coding, virtually all private and public payers, including TRICARE, reimbursed laboratories for these services.

In January 2013, all payers switched to new codes identifying the individual test. Most payers promptly covered the tests utilizing the new codes; however, TRICARE has become an outlier with its persistent policy of non-coverage. What is more perplexing, is that TRICARE's policy of non-coverage is inconsistent as these tests are covered if provided through a Military Treatment Facility, but not if provided through TRICARE's community provider network.

Molecular diagnostic tests represent the ever-advancing forefront of diagnostic medicine, and ensure that patients receive appropriate treatment. Without such testing, TRICARE beneficiaries will receive care that is inferior to that available to the general public. Molecular diagnostics ensure that disease is defined with enough precision that the right intervention can be available

from the start of treatment, not after trial and error with multiple drug regimens and not after the disease has gotten worse.

Many of the molecular tests currently being denied reimbursement represent the standard of care as expressed in professional guidelines. Cystic Fibrosis testing is the Standard of Care under the VA/DoD Clinical Practice Guideline for Management of Pregnancy and the American Congress of Obstetricians and Gynecologists' (ACOG) Guidelines. Furthermore, accurate EGFR mutation testing has been shown to both lower treatment costs and improve patient outcomes in non-small cell lung cancer (NSCLC), and is recommended for all NSCLC patients prior to initiating chemotherapy in the National Comprehensive Cancer Network (NCCN) guidelines. However, these tests, along with most other molecular diagnostic tests, are currently uncovered procedures, thereby depriving TRICARE beneficiaries of these valuable diagnostic tools.

TRICARE's rationale for failing to cover these tests is that they are Laboratory Developed Tests (LDTs); that is, they are tests that are created in-house by the laboratories furnishing them in accordance with the requirements of the federal Clinical Laboratory Improvement Amendments (CLIA). Laboratories do not sell the LDTs themselves, but use them to perform tests whose results are then furnished to physicians. Many, if not most, molecular diagnostics today are performed as LDTs. Despite TRICARE's history of covering these laboratory developed tests, and TRICARE's ongoing coverage of many other LDTs, the Defense Health Agency has stated that this subset of LDTs can no longer be covered because, it argues, the tests are medical devices and have not been approved by the Food & Drug Administration (FDA).

This position is a plain misinterpretation of TRICARE's own regulations. Those regulations look to whether or not a medical device can be lawfully marketed without approval or clearance from the FDA when determining TRICARE coverage. If it cannot, then TRICARE will not cover it. However, no such restriction applies to LDTs. LDTs can, and are, legally marketed without FDA approval; and therefore, TRICARE has no basis to exclude LDTs from coverage. In fact, FDA has repeatedly stated that it is exercising enforcement discretion and not requiring pre-market approval of LDTs.

TRICARE is also wrong in other key areas. ACLA disagrees with the determination that LDTs are medical devices; rather they are services performed and validated by certified medical physicians and professionals. Further, TRICARE's position is in conflict with the definition of "device" in the Food, Drug and Cosmetic Act as well as the definition of "taxable medical device" in the Internal Revenue Service final regulations implementing the medical device excise tax under the Affordable Care Act.

Finally, TRICARE continues to cover many LDTs not approved or cleared by the FDA outside of molecular diagnostic tests. Currently, all TRICARE beneficiaries have access to most laboratory developed tests. These tests include complete blood counts, pap tests, screening for cholesterol and diabetes, and many other LDTs. These tests continue to be covered by TRICARE, despite the fact that they are LDTs and they do not have FDA approval.

In the case of the molecular diagnostic tests, such as Cystic Fibrosis and EGFR testing, these tests are available for some – but not all – TRICARE beneficiaries. DHA has confirmed that these tests remain available to beneficiaries accessing services at a Military Treatment Facility (MTF), but they are not available for beneficiaries obtaining care from a civilian provider. DHA has also stated that Cystic Fibrosis screening, which is recommended by DoD/VA Clinical Guidelines for the Management of Pregnancy, is available for newborns, but not for pregnant women who do not receive services at an MTF.

Recognizing the vital role of these tests in health care delivery, many clinical laboratories continued to provide these services to TRICARE beneficiaries, despite the lack of reimbursement. This cannot continue, and TRICARE beneficiaries may have to pay the out-of-pocket costs of these tests, or may choose to forego care.

The decision by DHA to deny reimbursement for molecular diagnostic testing is not supported by regulations, or by best medical practices. We strongly believe TRICARE must resume paying for these tests immediately.

Thank you for the opportunity to share our views. We look forward to continuing to work with you and the Defense Health Agency on policies that maintain TRICARE beneficiary access to laboratory diagnostic testing and services.