



DEFENSE
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**PUBLICATIONS SYSTEM CHANGE TRANSMITTAL
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The TRICARE Management Activity has authorized the following addition(s)/revision(s).

CHANGE TITLE: EVALUATION OF NON-UNITED STATES FOOD AND DRUG ADMINISTRATION
LABORATORY DEVELOPED TESTS DEMO

CONREQ: 17007

PAGE CHANGE(S): See page 2.

SUMMARY OF CHANGE(S): This demonstration is intended to evaluate whether it is feasible for the Agency to review Non-Federal Drug Administration approved Lab Developed Tests (LDTs) to determine if they meet TRICARE requirements for safety and effectiveness according to the hierarchy of reliable evidence. This demonstration also extends coverage for prenatal and preconception cystic fibrosis carrier screening, when provided in accordance with the most current American Congress of Obstetricians and Gynecologists guidelines. For consistency, updates to the current LDT demonstration have been made regarding the BRCA1/2 (breast cancer 1 and 2) Coverage Guidelines.

EFFECTIVE DATE: July 18, 2014.

IMPLEMENTATION DATE: September 4, 2014.

This change is made in conjunction with Feb 2008 TSM, Change No. 64.

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