

TRICARE EVALUATION OF CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) APPROVED LABORATORY DEVELOPED TESTS (LDTs) DEMONSTRATION PROJECT

1.0. PURPOSE

The purpose of the demonstration project is to improve the quality of health services for TRICARE beneficiaries. The demonstration is intended to determine whether it is feasible for the Department of Defense (DoD) to review CMS approved LDTs, which have not received U.S. Food and Drug Administration (FDA) medical device 510(k) clearance or premarket approval (therefore considered non-FDA approved), to determine if they meet TRICARE requirements for safety and effectiveness according to the hierarchy of reliable evidence (32 CFR 199.2(b)) and allow those that do to be covered as a benefit under the TRICARE Program. The demonstration project will operate throughout the Continental United States (CONUS), and in the TRICARE overseas regions.

2.0. BACKGROUND

2.1. *On December 27, 2011 a notice was published in the Federal Register (76 FR 80905-80907) announcing the start of a demonstration project in which the DoD will determine whether it is feasible for the DoD to evaluate the potential improvement of the quality of health care services for TRICARE beneficiaries who could access CMS approved LDTs not yet examined by the FDA. An evaluation will be conducted during the third year of the demonstration period to determine how many TRICARE approved LDTs were provided to beneficiaries across all TRICARE regions. The evaluation will also include a review of the LDT review and recommendation process. These results of the evaluation will provide an evaluation of the potential improvement of the quality of healthcare services for beneficiaries who would not otherwise have access to these safe and effective tests. Based on the utilization results, a decision will be made to modify 32 CFR 199.4(g)(15)(i)(A) to remove the restriction for non-FDA approved devices and allow TRICARE cost-sharing of CMS approved LDTs determined to meet the TRICARE criteria for safety and effectiveness.*

2.2. *According to 32 CFR 199.4(g)(15)(i)(A) the TRICARE Management Activity (TMA) may not cost-share medical devices including LDTs if the tests are non-FDA approved, that is, they have not received FDA marketing 510(k) clearance or premarket approval. Non-FDA approved LDTs are not covered, except under the LDT demonstration project.*

2.3. *An LDT is a test developed by a single clinical laboratory that provides testing to the public but does not sell the lab kit to other labs. In the past, these were relatively simple tests used to diagnose or monitor diseases and other conditions within a single laboratory usually at a local large hospital or academic medical center. Today, these tests are highly complex.*

2.4. *Laboratories are assessed and accredited under quality standards set by CMS under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. CMS regulates laboratories that use*

LDTs as well as FDA approved tests. Laboratories performing moderate or high complexity tests are subject to specific regulatory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections. CLIA certification and periodic inspections ensure the analytical validity of laboratory tests, including LDTs. Analytical validity refers to how well a test performs in the laboratory; that is, how well the test measures the properties or characteristics it is intended to measure.

2.5. *CMS regulations do not have a specific requirement that devices be FDA approved. As a result CMS policy provides a mechanism for the review and payment of non-FDA approved LDTs (Section 522 of the Benefits Improvement and Protection Act). Non-FDA approved LDTs which meet CMS's standards are approved through its National Coverage Determination (NCD) or Local Coverage Determination (LCD) process. Once a LDT receives a LCD, it is effectively considered a nationwide Medicare covered benefit.*

3.0. POLICY

3.1. *A demonstration project was initiated by the TMA to test whether CMS approved LDTs which have not received FDA medical device 510(k) clearance or premarket approval (therefore considered non-FDA approved) are safe and effective for cost-sharing for TRICARE beneficiaries. The demonstration project will establish a process for TRICARE to evaluate the subset of non-FDA approved LDTs currently covered by a CMS NCD or LCD for TRICARE-eligible patients prescribed LDTs for the diagnosis and treatment of cancer. Any LDT approved for cost-sharing under the demonstration project will be covered as of the date of approval by the Director/TMA as defined in Figure 20-12-1.*

3.2. *LDTs approved by the Director, TMA shall be limited to only those that significantly inform clinical decision making for cancer surveillance, surgery for cancer, chemotherapy, or radiation therapy for cancer. The demonstration project shall provide an evaluation of the potential improvement of the quality of health care services for TRICARE beneficiaries with diagnoses of specific oncological diseases, procedures, and treatments, who would not otherwise have access to these tests.*

3.3. *LDTs approved by the Director, TMA for cost-sharing shall follow existing TMA processes for inclusion as a TRICARE benefit during the demonstration period. Those LDTs included in the demonstration project will have met the TRICARE requirements for safety and efficacy.*

3.4. *Notification to the contractors of LDT eligibility for cost-sharing shall be published, periodically, to this chapter of the TOM, as detailed in Figure 20-12-1. The codes listed in Figure 20-12-1 which are payable under this demonstration project may also remain on the No Government Pay List (NGPL) since the tests are not covered under the TRICARE Basic Program. LDTs listed in Figure 20-12-1 are covered only as part of the demonstration project as denoted with the special processing code which shall be associated with each claim.*

3.5. *TMA shall cost-share all medical care and treatment associated with the LDT in the same manner it would any other care or treatment associated with the provision of medically needed care. TMA will reimburse, as directed in policy, and as covered under the TRICARE Basic Program and TRICARE policy, the costs associated with the purchase and administration of all approved*

chemotherapy agents, all inpatient and outpatient care, including diagnostic and laboratory services for eligible TRICARE beneficiaries if the following conditions are met:

3.5.1. *The specific LDT has been approved by the Director, TMA for cost-sharing to eligible TRICARE beneficiaries; and*

3.5.2. *The contractor has preauthorized the LDT, and verified that the TRICARE authorized provider has determined the eligible patient's medical need for the LDT in accordance with all indications detailed in [Figure 20-12-1](#); and*

3.5.3. *The contractor has verified that the patient's clinical diagnoses support the medical need and are fully documented according to and consistent with all indications detailed in [Figure 20-12-1](#); and*

3.5.4. *The contractor has, as noted in TRICARE Policy Manual (TPM), [Chapter 1, Section 7.1, paragraph II.](#), for dual eligible beneficiaries, applied all requirements when TRICARE is primary payer. As secondary payer, TRICARE will rely on and not replicate Medicare's determination of medical necessity and appropriateness in all circumstances where Medicare is primary payer. In the event that TRICARE is primary payer for these services and preauthorization was not obtained, the contractor shall obtain the necessary information and perform a retrospective review.*

3.6. *Cost-shares and deductibles applicable to TRICARE also apply under this demonstration. For TRICARE Prime enrollees, including those enrolled in Uniformed Services Family Health Plan (USFHP), applicable copays apply.*

3.7. *The demonstration will expire on January 26, 2015. Requirements of this chapter as related to the laboratory tests demonstration cease at midnight on January 26, 2015. Only TRICARE beneficiaries with current eligibility, as defined in [paragraph 7.0.](#) may participate in the LDT demonstration project. Claims shall not be processed for individuals not eligible for TRICARE benefits. All medical care, treatments, or testing, with the exception of the LDT which has approval during the demonstration period only, must be TRICARE eligible care provided to TRICARE eligible beneficiaries. This applies to all care rendered during or after the end date of the LDT demonstration project.*

3.8. *The records management requirements described in [Chapter 2](#) apply to the LDT demonstration project.*

4.0. APPLICABILITY

4.1. *The demonstration applies to all TRICARE-eligible beneficiaries. Active duty members continue to be eligible for Direct Care (DC) system services. All eligible TRICARE beneficiaries will be included in the demonstration project.*

4.2. *The benefit for non-FDA approved LDTs covered by the LDT demonstration project differs from the Basic TRICARE benefit. Coverage inquiries shall be submitted to, and resolved by the appropriate contractor (referencing the TRICARE Evaluation of CMS Approved LDTs Demonstration Project). Regarding a beneficiary with other insurance that provides primary coverage, any medically*

necessary reviews the contractor believes are necessary, to act as a secondary payer, shall be performed on a retrospective basis. As noted in TPM, Chapter 1, Section 7.1, paragraph II., for dual eligible beneficiaries, these requirements apply when TRICARE is primary payer. As secondary payer, TRICARE will rely on and not replicate Medicare's determination of medical necessity and appropriateness in all circumstances where Medicare is primary payer. In the event that TRICARE is primary payer for these services and preauthorization was not obtained, the contractor shall perform a retrospective claims review, and apply the special processing code after obtaining all necessary supporting information identified in this chapter and specified in Figure 20-12-1.

4.3. *Since the DoD has no authority to cost-share non-FDA approved medical devices such as LDTs special appeals rights do not apply. Therefore, denials are not appealable.*

5.0. GENERAL DESCRIPTION OF ADMINISTRATIVE PROCESS

5.1. *The TRICARE authorized provider shall determine the eligible patient's needs and consult with the contractor to request preauthorization of the LDT.*

5.2. *The contractor shall preauthorize LDTs to verify that the TRICARE authorized provider has determined the eligible patient's medical need based on the patient's clinical diagnoses which support the medical need and, the contractor shall document these facts according to and consistent with the American Medical Association (AMA) Current Procedural Terminology (CPT), International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes, and according to all indications detailed in Figure 20-12-1. Following the contractor's identification of an appropriate request for an approved LDT, as identified within the terms of the demonstration, the TRICARE authorized provider requesting/ordering the LDT shall be notified that they are authorized to utilize the LDT for the purpose of informed clinical decision making for cancer related surveillance, surgical interventions, chemotherapy, and radiation therapy. The contractor shall issue the notification of decision to authorize use of the LDT in writing to both the applicant provider and the beneficiary receiving the LDT. In the event that TRICARE is primary payer for approved LDTs, and preauthorization was not obtained, the contractor shall obtain the necessary information and perform a retrospective review to assure that all Figure 20-12-1 criteria for coverage have been met. If met, the LDT is eligible for TRICARE cost-sharing. The contractor shall identify each claim with the special processing code.*

5.3. *LDTs with current FDA 510(k) clearance or premarket approval shall not be considered for this demonstration project; but shall continue to be considered for coverage under the current routine coverage determination process of the TRICARE program.*

5.4. *All claims for approved care under the demonstration shall be submitted to the contractor for adjudication. In the event of contractor transition to another contractor, the outgoing contractor shall provide a list of all patients under approved LDT care.*

6.0. TMA RESPONSIBILITIES

6.1. *The LDT Demonstration Project will be paid by TMA as non-financially underwritten transactions in accordance with each respective contractor's agreement and shall follow vouchering rules in Chapter 3 or Section G of the contract.*

6.2. *LDTs approved by the Director, TMA for cost-sharing under the demonstration will include the assignment of the special processing code to identify each TRICARE Encounter Data (TED) record to allow LDT identification.*

6.3. *The special processing code shall be assigned to identify all claims paid under the demonstration. The intent of this policy is to process claims for the TMA identified LDTs with the special processing code and the associated technical and professional components associated with the LDT-related CPTs. All other medical care, treatments, and associated testing based on medical necessity as a result of the LDTs results are to be processed under the basic TRICARE benefit.*

6.4. *Perform periodic review and evaluation of the demonstration claims adjudication process.*

6.5. *Provide specific written guidance to the Managed Care Support Contractor (MCSC) or other contractor with jurisdiction for the claim regarding laboratory services and claims adjudication services to be provided by the claims processor under the terms of the demonstration.*

6.6. *The Assistant Secretary of Defense (Health Affairs) (ASD(HA)) is the designated executive agent for the demonstration project. They shall designate a project officer in the Office of the Chief Medical Officer (OCMO) for the demonstration. The project officer shall provide clinical oversight and ongoing program management of the demonstration.*

7.0. CONTRACTOR RESPONSIBILITIES

The contractor shall:

7.1. *Verify the patient's eligibility on the Defense Enrollment Eligibility Reporting System (DEERS).*

7.2. *The patient shall be referred to the pass/ID card section of the military installation nearest their home for an eligibility determination. The patient shall be notified that participation in the LDT Demonstration is dependent on current eligibility.*

7.3. *If a patient is listed on DEERS as being eligible as of the date the LDT is performed, all services provided shall be covered. This also applies to patients whose treatment is in progress when the demonstration expires.*

7.4. *Issue an authorization or denial letter to the applicant provider and patient once a determination is made. It is the contractors' responsibility to correctly voucher the TED records for payment.*

7.5. *The contractor shall preauthorize LDTs and verify medical need based according to all indications detailed in [Figure 20-12-1](#). The contractor shall issue the notification of decision to authorize use of the LDT in writing to both the applicant provider and the beneficiary receiving the LDT. In the event that TRICARE is primary payer for approved LDTs, and preauthorization was not obtained, the contractor shall obtain the necessary information and perform a retrospective review to assure that all [Figure 20-12-1](#) criteria for coverage have been met. In addition, for all retrospective claims, the contractor shall include the special processing code.*

7.6. *The contractor shall manage and resolve all inquiries related to the demonstration project, including claims inquiries related to LDTs approved for cost-sharing during the LDT demonstration project.*

8.0. CLAIMS PROCESSING REQUIREMENTS

8.1. *Verify TRICARE-eligibility on the DEERS prior to payment. It is the contractors' responsibility to correctly voucher the TED records for payment.*

8.2. *Both laboratory and professional charges shall be reimbursed based on existing TRICARE reimbursement rules. The contractor shall develop a prevailing charge following the procedures in TRICARE Reimbursement Manual (TRM), Chapter 5, Section 1.*

8.2.1. *For purposes of the LDT demonstration project, Molecular Pathology Procedure test codes, when applicable, will be assigned to the list of approved LDTs in Figure 20-12-1. Beginning January 1, 2012, 101 additional Molecular Pathology Procedure test codes were released by the AMA's CPT Editorial Panel and published in the CMS publication, MLN Matters at website: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7654.pdf>. These new molecular pathology procedure test codes are in the following CPT Code range: 81200 through 81299, 81300 through 81383 and 81400 through 81408. Each of these new molecular pathology procedure test codes represents a test that is currently being used. TMA understands that, for LDT identification and billing purposes, existing, valid, genetic laboratory CPT test codes are "stacked" or "bundled" to represent a given test. For example, Laboratory A has a genetic test that is generally billed in the following manner - 83891 (one time) + 83898 (multiple times) + 83904 (multiple times) + 83909 (multiple times) - in order to represent the performance of the entire test. All TED records for this demonstration shall be coded with the special processing code and should follow all TED requirements stated in the TRICARE Systems Manual (TSM), Chapter 2.*

8.2.2. *The contractor shall assure that the LDT manufacturers/laboratories submit all charges on the basis of fully itemized bills. Each service and supply shall be individually identified and submitted on the appropriate claim form. If a claim associated with the demonstration project has missing information, Chapter 8, Section 6 guidelines shall be followed to either return or develop the claim requesting the missing information.*

8.2.3. *All claims for the approved LDT shall meet the requirements outlined in Figure 20-12-1. All other covered care associated with treatment will be provided in accordance with the respective provisions of the TPM or TRM. Care associated with the LDT must be medically needed and appropriate medical care and not otherwise excluded as a TRICARE benefit.*

8.3. *Cost-shares and deductibles applicable to TRICARE shall also apply under the demonstration. For TRICARE Prime enrollees, including those enrolled in USFHP, applicable copays shall apply.*

8.3.1. *Normal Double coverage provisions apply to LDTs approved under the demonstration. Acceptable evidence of processing by the double coverage plan is outlined in TRM, Chapter 4. In double coverage situations, the demonstration shall pay the balance after the Other Health Insurance (OHI) has paid.*

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8.3.2. *Claims for this demonstration shall be paid from the applicable non-underwritten bank account (see [Chapter 3](#)), and submitted through normal TRICARE Encounter Data (TED) processing as required in the TSM and in accordance with each respective contractor's agreement if claims data is not submitted through the TED system.*

8.3.3. *Claims for this demonstration shall be submitted either by Electronic Media Claim (EMC), through the dedicated demonstration mailing address, or through the appropriate regional claims processing address(es).*

9.0. EFFECTIVE DATE

This demonstration is effective for claims for services provided on or after the date the LDT was approved by the Director, TMA as defined in [Figure 20-12-1](#).

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CHAPTER 20, SECTION 12

TRICARE EVALUATION OF CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

APPROVED LABORATORY DEVELOPED TESTS (LDTs) DEMONSTRATION PROJECT

FIGURE 20-12-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs)

LDT #1 Name:	Oncotype DX[®] Breast Cancer Assay (Oncotype DX[®])
LDT #1 Effective Date of Coverage:	22 May 2012
LDT #1 Manufacturer & Address:	Genomic Health, Inc. 301 Penobscot Road Redwood City, CA 94063 CLIA ID Number-05D1018272
LDT #1 Coverage Guidelines:	Oncotype DX [®] is covered for the following: <ul style="list-style-type: none"> • Estrogen Receptor (ER) positive (+), lymph node (N) negative (-) breast cancer who are considering whether to use adjuvant chemotherapy in addition to hormonal therapy. • ER+ (or progesterone receptor +), N-, human epidermal growth factor receptor 2 negative (HER2-) women with stage I or II breast cancer who are considering whether to have adjuvant chemotherapy.

LDT #2 Name:	BRACAnalysis[®]
LDT #2 Effective Date of Coverage:	22 May 2012
LDT #2 Manufacturer & Address:	Myriad Genetic Laboratories, Inc. 320 Wakara Way Salt Lake City, UT 84108 CLIA ID Number-46D0880690

¹. Given the complexity of risk assessment and test interpretation, as well as the importance of adequate medical management, **genetic counseling is very important** for all individuals with or at risk of carrying a deleterious BRAC1 or BRCA2 gene variant. Genetic counseling may only be provided by TRICARE-authorized providers, in accordance with TRICARE Policy Manual 6010.54-M, [Chapter 6, Section 3.1](#).

². Close blood relatives include first-, second-, and third-degree relatives as described in the NCCN Guidelines Version 1.2012 Breast and/or Ovarian Cancer Genetic Assessment Pedigree: First-, Second-, and Third-degree relatives of Proband.

FIGURE 20-12-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) (CONTINUED)

<p><i>LDT #2</i> <i>Coverage Guidelines:</i></p>	<p><i>BRACAnalysis[®] testing assesses a person's risk of developing hereditary breast and ovarian cancer based on detection of mutations in the breast cancer 1 (BRCA1) and breast cancer 2 (BRCA2) genes. For the purposes of this demonstration, BRACAnalysis[®] testing is covered for individuals with a personal and/or family history consistent with hereditary breast or ovarian cancer in accordance with current National Comprehensive Cancer Network (NCCN) Guidelines[™]. These include individuals with early-onset breast cancer, epithelial ovarian cancer, multiple primary tumors (i.e., bilateral breast cancer or breast or ovarian cancer in the same individual), male breast cancer, or an ethnic background associated with a high prevalence of BRCA1 or BRCA2 variants, as well as affected or unaffected individuals with a strong family history of BRCA1/2-related malignancies. BRACAnalysis[®] gene testing is covered for individuals at increased risk for hereditary breast and ovarian cancer. For purposes of this demonstration project, increased risk is defined according the NCCN Guidelines[™] Version 1.2011 Breast Cancer Screening and Diagnosis (or current edition). The NCCN increased risk category consists of six groups: (1) women who have previously received therapeutic thoracic irradiation or mantle irradiation; (2) women 35 years or older with a five-year risk of invasive breast carcinoma $\geq 1.7\%$; (3) women with a lifetime risk of breast cancer $> 20\%$ based on models largely dependent on family history; (4) women with a strong family history or genetic predisposition; (5) women with lobular carcinoma in situ or atypical hyperplasia; and (6) women with a prior history of breast cancer.</i></p> <p><i>BRACAnalysis[®] is covered for the following¹:</i></p> <ul style="list-style-type: none"> <i>• Individuals from families transmitting a known BRCA1/2 variant</i> <i>• Individuals with a history breast cancer and at least one of the following:</i> <ul style="list-style-type: none"> <i>• Breast cancer diagnosed ≤ 45 years of age</i> <i>• Breast cancer diagnosed ≤ 50 years of age and a close family member with breast cancer ≤ 45 years of age or ovarian cancer at any age</i> <i>• Two breast primaries with one diagnosed at or before age 50</i> <i>• A diagnosis of triple negative breast cancer at or before age 60</i>
<p><i>¹. Given the complexity of risk assessment and test interpretation, as well as the importance of adequate medical management, genetic counseling is very important for all individuals with or at risk of carrying a deleterious BRCA1 or BRCA2 gene variant. Genetic counseling may only be provided by TRICARE-authorized providers, in accordance with TRICARE Policy Manual 6010.54-M, Chapter 6, Section 3.1.</i></p> <p><i>². Close blood relatives include first-, second-, and third-degree relatives as described in the NCCN Guidelines Version 1.2012 Breast and/or Ovarian Cancer Genetic Assessment Pedigree: First-, Second-, and Third-degree relatives of Proband.</i></p>	

FIGURE 20-12-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) (CONTINUED)

	<ul style="list-style-type: none"> • <i>Breast cancer diagnosed at any age and at least two close relatives with breast and/or ovarian cancer</i> • <i>Breast cancer diagnosed at any age and at least two close relatives diagnosed with pancreatic cancer</i> • <i>A close male relative² with breast cancer</i> • <i>An ethnic background associated with a higher frequency of BRCA1/2 variants (i.e., Ashkenazi Jewish)</i> • <i>Individuals with a personal history of epithelial ovarian cancer</i> • <i>Individuals with male breast cancer</i> • <i>Individuals with a personal history of pancreatic cancer and at least two close relatives with breast, ovarian, and/or pancreatic cancer</i> • <i>Unaffected individuals (with no personal history of cancer) who have one of the following:</i> <ul style="list-style-type: none"> • <i>A first- or second-degree relative satisfying the above criteria</i> • <i>A third-degree relative with breast and/or ovarian cancer and at least two more relatives with breast cancer (at least one diagnosed before age 50) and/or ovarian cancer</i>
<p>^{1.} <i>Given the complexity of risk assessment and test interpretation, as well as the importance of adequate medical management, genetic counseling is very important for all individuals with or at risk of carrying a deleterious BRCA1 or BRCA2 gene variant. Genetic counseling may only be provided by TRICARE-authorized providers, in accordance with TRICARE Policy Manual 6010.54-M, Chapter 6, Section 3.1.</i></p> <p>^{2.} <i>Close blood relatives include first-, second-, and third-degree relatives as described in the NCCN Guidelines Version 1.2012 Breast and/or Ovarian Cancer Genetic Assessment Pedigree: First-, Second-, and Third-degree relatives of Proband.</i></p>	