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HEALTH AGENCY

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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.

JACOBS.KENNET
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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 [Chapter 4](#). In double coverage situations, the demonstration shall pay the balance after the Other Health Insurance (OHI) has paid.

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, 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 18.13-1](#).

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Laboratory Developed Tests (LDTs) Demonstration Project

FIGURE 18.13-1 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. 	
CPT Coding when clinically indicated by Coverage Guidelines:	CPT ⁴ Code	84999 (unlisted chemistry procedure)
	HCPCS "S" Code required for LDT Demonstration	S3854 (Gene expression profiling panel for use in the management of breast cancer treatment)

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 *BRCA1* or *BRCA2* gene variant. Genetic counseling may only be provided by TRICARE-authorized providers, in accordance with TRICARE Policy Manual (TPM) 6010.54-M, [Chapter 6, Section 3.1](#).

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

³ Lynch syndrome-associated cancers include endometrial, ovarian, gastric, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma), and small intestine cancers, as well as sebaceous gland adenomas/carcinomas and keratoacanthomas.

⁴ CPT only © 2006 American Medical Association (or such other date of publication of CPT). All Rights Reserved.

⁵ When current NCCN Guidelines™ for Colorectal Cancer Screening state "genetic testing" or "consider genetic testing."

FIGURE 18.13-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) (CONTINUED)

<p>LDT #2 Coverage Guidelines:</p>	<p>BRACAnalysis® testing assesses a person’s risk of developing hereditary breast and ovarian cancer based on detection of mutations in the breast cancer 1 (<i>BRCA1</i>) and breast cancer 2 (<i>BRCA2</i>) 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 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 <i>BRCA1</i> or <i>BRCA2</i> variants, as well as affected or unaffected individuals with a strong family history of <i>BRCA1/2</i>-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.</p> <p>Detection of large genomic rearrangements (e.g., BRACAnalysis® Large Rearrangement Test (BART)) is considered medically necessary for individuals who meet the testing criteria for <i>BRCA1/BRCA2</i>, have no known familial <i>BRCA1/BRCA2</i> mutations, and the original BRACAnalysis® test was negative. BART is not covered as a stand-alone test.</p> <p>BRACAnalysis® is covered for the following¹:</p> <ul style="list-style-type: none"> • Individuals from families transmitting a known <i>BRCA1/2</i> variant • Individuals with a history breast cancer and at least one of the following: <ul style="list-style-type: none"> • Breast cancer diagnosed ≤ 45 years of age • Breast cancer diagnosed ≤ 50 years of age and a close family member with breast cancer • Two breast primaries with one diagnosed at or before age 50 • A diagnosis of triple negative breast cancer at or before age 60 • Breast cancer diagnosed at any age and at least one close relative with breast cancer before age 50 and/or epithelial ovarian cancer at any age • Breast cancer diagnosed at any age and at least two close relatives diagnosed with breast, pancreatic, and/or prostate (Gleason ≥ 7) cancer at any age • A close male relative² with breast cancer
<p>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 <i>BRCA1</i> or <i>BRCA2</i> gene variant. Genetic counseling may only be provided by TRICARE-authorized providers, in accordance with TRICARE Policy Manual (TPM) 6010.54-M, Chapter 6, Section 3.1.</p> <p>² Close blood relatives include first-, second-, and third-degree relatives as described in the National Comprehensive Cancer Network (NCCN) Guidelines Version 1.2012 Breast and/or Ovarian Cancer Genetic Assessment Pedigree: First-, Second-, and Third-degree relatives of Proband.</p> <p>³ Lynch syndrome-associated cancers include endometrial, ovarian, gastric, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma), and small intestine cancers, as well as sebaceous gland adenomas/carcinomas and keratoacanthomas.</p> <p>⁴ CPT only © 2006 American Medical Association (or such other date of publication of CPT). All Rights Reserved.</p> <p>⁵ When current NCCN Guidelines™ for Colorectal Cancer Screening state “genetic testing” or “consider genetic testing.”</p>	

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FIGURE 18.13-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) (CONTINUED)

<p>LDT #2 Coverage Guidelines (Continued):</p>	<ul style="list-style-type: none"> • An ethnic background associated with a higher frequency of <i>BRCA1/2</i> variants (i.e., Ashkenazi Jewish) • Individuals with a personal history of epithelial ovarian cancer • Individuals with male breast cancer • Individuals with a personal history of pancreatic or prostate (Gleason ≥ 7) cancer and at least two close relatives with breast, ovarian, prostate (Gleason ≥ 7), and/or pancreatic cancer • Unaffected individuals (with no personal history of cancer) who have one of the following: <ul style="list-style-type: none"> • A first- or second-degree relative satisfying the above criteria • 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 		
<p>CPT Coding when clinically indicated by Coverage Guidelines:</p>	<p>1. Comprehensive BRCAAnalysis: Full sequence analysis and common deletion/duplication panel of <i>BRCA1</i> and <i>BRCA2</i>. <i>BRCA1</i> and <i>BRCA2</i> gene sequence analysis and a panel of five common large rearrangement for susceptibility to breast and ovarian cancer.</p>		
	<table border="1"> <tr> <td data-bbox="505 869 683 905">CPT⁴ Code</td> <td data-bbox="688 869 1409 905">81211</td> </tr> </table>	CPT ⁴ Code	81211
CPT ⁴ Code	81211		
	<p>2. Multisite 3 BRCAAnalysis: Analysis of the three most common <i>BRCA1</i> or <i>BRCA2</i> mutations in individuals of Ashkenazi Jewish ancestry.</p>		
	<table border="1"> <tr> <td data-bbox="505 974 683 1010">CPT⁴ Code</td> <td data-bbox="688 974 1409 1010">81212</td> </tr> </table>	CPT ⁴ Code	81212
CPT ⁴ Code	81212		
	<p>3. Reflex BRCAAnalysis: Full sequence analysis and common deletion/duplication panel for individuals whose results from the Multisite 3 BRCAAnalysis are negative.</p>		
	<table border="1"> <tr> <td data-bbox="505 1079 683 1115">CPT⁴ Code</td> <td data-bbox="688 1079 1409 1115">81211 with modifier 59</td> </tr> </table>	CPT ⁴ Code	81211 with modifier 59
CPT ⁴ Code	81211 with modifier 59		
	<p>4. BRCAAnalysis Rearrangement Test (BART): Comprehensive analysis for deletions/duplications in <i>BRCA1</i> and <i>BRCA2</i>.</p>		
	<table border="1"> <tr> <td data-bbox="505 1184 683 1220">CPT⁴ Code</td> <td data-bbox="688 1184 1409 1220">81213</td> </tr> </table>	CPT ⁴ Code	81213
CPT ⁴ Code	81213		
	<p>5. BRCA1 Analysis: Full sequence and common deletion/duplication analysis of <i>BRCA1</i>.</p>		
	<table border="1"> <tr> <td data-bbox="505 1268 683 1304">CPT⁴ Code</td> <td data-bbox="688 1268 1409 1304">81214</td> </tr> </table>	CPT ⁴ Code	81214
CPT ⁴ Code	81214		
	<p>6. Single Site BRCA1: Known familial variant analysis of <i>BRCA1</i>.</p>		
	<table border="1"> <tr> <td data-bbox="505 1352 683 1388">CPT⁴ Code</td> <td data-bbox="688 1352 1409 1388">81215</td> </tr> </table>	CPT ⁴ Code	81215
CPT ⁴ Code	81215		
	<p>7. BRCA2 Analysis: Full sequence and common deletion/duplication analysis of <i>BRCA2</i>.</p>		
	<table border="1"> <tr> <td data-bbox="505 1436 683 1472">CPT⁴ Code</td> <td data-bbox="688 1436 1409 1472">81216</td> </tr> </table>	CPT ⁴ Code	81216
CPT ⁴ Code	81216		
<p>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 <i>BRCA1</i> or <i>BRCA2</i> gene variant. Genetic counseling may only be provided by TRICARE-authorized providers, in accordance with TRICARE Policy Manual (TPM) 6010.54-M, Chapter 6, Section 3.1.</p> <p>² Close blood relatives include first-, second-, and third-degree relatives as described in the National Comprehensive Cancer Network (NCCN) Guidelines Version 1.2012 Breast and/or Ovarian Cancer Genetic Assessment Pedigree: First-, Second-, and Third-degree relatives of Proband.</p> <p>³ Lynch syndrome-associated cancers include endometrial, ovarian, gastric, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma), and small intestine cancers, as well as sebaceous gland adenomas/carcinomas and keratoacanthomas.</p> <p>⁴ CPT only © 2006 American Medical Association (or such other date of publication of CPT). All Rights Reserved.</p> <p>⁵ When current NCCN Guidelines™ for Colorectal Cancer Screening state “genetic testing” or “consider genetic testing.”</p>			

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FIGURE 18.13-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) (CONTINUED)

CPT Coding when clinically indicated by Coverage Guidelines (Continued)	8. Single Site BRCA2: Known familial variant analysis of BRCA2.	
	CPT ⁴ Code	81217

LDT #3 Name:	Colaris® for Lynch Syndrome (Colaris®) for Affected and Non-Affected Beneficiaries
LDT #3 Effective Date of Coverage:	11 Mar 2013
LDT #3 Manufacturer & Address:	Myriad Genetic Laboratories, Inc. 320 Wakara Way, Salt Lake City, UT 84108 CLIA ID Number-46D0880690
LDT #3 Coverage Guidelines:	<p>Colaris® for Lynch Syndrome (Hereditary Non-Polyposis Colorectal Cancer (HNPCC))</p> <p>Colaris® testing assesses a person's risk of developing hereditary colorectal cancer and a woman's risk of developing hereditary gynecologic cancers. Colaris® detects disease-causing mutations in the <i>MLH1</i>, <i>MSH2</i>, <i>MSH6</i>, <i>PMS2</i>, and <i>EPCAM</i> genes which are responsible for Lynch syndrome.</p> <p>The provider is able to request testing based on their patient's clinical situation, e.g., comprehensive testing of all the genes responsible for Lynch syndrome, testing of a specific gene (or genes) based on the results of tumor analysis, or testing for a known mutation previously identified in a family member.</p> <p>Colaris® testing is covered for a beneficiary who has or has had colorectal or endometrial cancer and meets one of the following criteria:</p> <p>1. <u>Amsterdam II Criteria for Lynch syndrome genetic testing.</u></p> <p>At least two close blood relatives of the affected beneficiary must have or have had a cancer associated with Lynch syndrome; and all of the following criteria must be present:</p> <ul style="list-style-type: none"> • One must be a first-degree blood relative of the other two; • At least two successive generations must be affected; • At least one of the blood relatives or the beneficiary with cancer associated with HNPCC should be diagnosed before the age 50 years; • Familial Adenomatous Polyposis (FAP) should be excluded in the colorectal cancer case(s) (if any); and • Histologic diagnosis of tumors should be verified whenever possible.

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 (TPM) 6010.54-M, [Chapter 6, Section 3.1](#).

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

³ Lynch syndrome-associated cancers include endometrial, ovarian, gastric, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma), and small intestine cancers, as well as sebaceous gland adenomas/carcinomas and keratoacanthomas.

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⁵ When current NCCN Guidelines™ for Colorectal Cancer Screening state "genetic testing" or "consider genetic testing."

FIGURE 18.13-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) (CONTINUED)

<p>LDT #3 Coverage Guidelines (Continued):</p>	<p>2. <u>Revised Bethesda guidelines:</u></p> <ul style="list-style-type: none"> • Colorectal cancer diagnosed in a beneficiary at less than 50 years of age. • Presence of synchronous or metachronous Lynch syndrome-associated cancers³, regardless of age. • Colorectal cancer with the MSI-H histology diagnosed in a beneficiary who is less than 60 years of age. • Colorectal cancer with one or more first-degree blood relatives with a Lynch syndrome-associated cancer³, with one of the cancers being diagnosed under age 50 years. • Colorectal cancer with two or more first- or second-degree blood relatives with Lynch syndrome-associated cancers³, regardless of age. <p>3. Has a blood relative with a known Lynch syndrome related gene mutation.</p> <p>4. Endometrial cancer diagnosed in a beneficiary at less than 50 years of age.</p> <p>5. If any of the revised Bethesda guidelines are met, Microsatellite Instability (MSI) and/or Immunohistochemistry (IHC) testing on the colon cancer tissue may be clinically appropriate. If the tumor is MSI positive or mutation of one of the Mismatch Repair (MMR) genes is indicated by failure of IHC staining, then genetic testing should be undertaken. Further unnecessary testing can often be avoided by performance of IHC prior to any MSI testing.</p> <ul style="list-style-type: none"> • Colaris® testing is covered for symptomatic or asymptomatic patients > 18 years of age who are at risk of having a known familial sequence variant in a MMR gene.
<p>CPT Coding when clinically indicated by Coverage Guidelines:</p>	<p>Integrated COLARIS®-Full sequence and deletion/duplication analysis of <i>MLH1</i>, <i>MSH2</i>, <i>MSH6</i>, and <i>PMS2</i>. Allowable CPT⁴ codes include 81292, 81294, 81295, 81297, 81298, 81300, 81317, and 81319.</p> <p><i>MLH1</i> Analysis-Full sequence analysis of <i>MLH1</i>, Deletion/duplication analysis of <i>MLH1</i>. Allowable CPT⁴ codes include 81292 with modifier 59, 81294.</p> <p>Single Site <i>MLH1</i>-Known familial variant analysis of <i>MLH1</i>. Allowable CPT⁴ codes include 81293.</p> <p><i>MSH2</i> Analysis-Full sequence analysis of <i>MSH2</i>, Deletion/duplication analysis of <i>MSH2</i>. Allowable CPT⁴ codes include 81295 with modifier 59, 81297.</p> <p>Single Site <i>MSH2</i>-Known familial variant analysis of <i>MSH2</i>. Allowable CPT⁴ codes include 81296.</p> <p><i>MSH6</i> Analysis-Full sequence analysis of <i>MSH6</i>, Deletion/duplication analysis of <i>MSH6</i>. Allowable CPT⁴ codes include 81298 with modifier 59, 81300.</p>
<p>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 <i>BRCA1</i> or <i>BRCA2</i> gene variant. Genetic counseling may only be provided by TRICARE-authorized providers, in accordance with TRICARE Policy Manual (TPM) 6010.54-M, Chapter 6, Section 3.1.</p> <p>² Close blood relatives include first-, second-, and third-degree relatives as described in the National Comprehensive Cancer Network (NCCN) Guidelines Version 1.2012 Breast and/or Ovarian Cancer Genetic Assessment Pedigree: First-, Second-, and Third-degree relatives of Proband.</p> <p>³ Lynch syndrome-associated cancers include endometrial, ovarian, gastric, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma), and small intestine cancers, as well as sebaceous gland adenomas/carcinomas and keratoacanthomas.</p> <p>⁴ CPT only © 2006 American Medical Association (or such other date of publication of CPT). All Rights Reserved.</p> <p>⁵ When current NCCN Guidelines™ for Colorectal Cancer Screening state “genetic testing” or “consider genetic testing.”</p>	

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FIGURE 18.13-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) (CONTINUED)

CPT Coding when clinically indicated by Coverage Guidelines (Continued):	<p>Single site <i>MSH6</i>-Known familial variant analysis of <i>MSH6</i>. Allowable CPT⁴ codes include 81299.</p> <p><i>PMS2</i> Analysis-Full sequence analysis of <i>PMS2</i>, Deletion/duplication analysis of <i>PMS2</i>. Allowable CPT⁴ codes include 81317 with modifier 59, 81319.</p> <p>Single site <i>PMS2</i>-Known familial variant analysis of <i>PMS2</i>. Allowable CPT⁴ codes include 81318.</p>
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LDT #4 Name:	Colaris AP® for detection of germline mutations in the Adenomatous Polyposis Coli (APC) and mutY homolog (MYH) genes
LDT #4 Effective Date of Coverage:	March 11, 2013
LDT #4 Manufacturer & Address:	<p>Myriad Genetic Laboratories, Inc. 320 Wakara Way, Salt Lake City, UT 84108 CLIA ID Number-46D0880690</p>
LDT #4 Coverage Guidelines:	<p>Colaris AP® coverage indications:</p> <p><i>APC</i> gene testing may be considered for individuals with clinical symptoms consistent with FAP, Attenuated Familial Adenomatous Polyposis (AFAP), Gardner's syndrome, or Turcot's syndrome. It may also be considered for risk assessment in relatives of patients with known deleterious <i>APC</i> gene variants.</p> <p><u>For purposes of the demonstration project, Colaris AP testing is not covered for prenatal diagnosis or Preimplantation Genetic Diagnosis (PGD) in couples affected with, or at-risk for, FAP.</u></p> <p>Other than prenatal diagnosis or PGD, testing is covered:</p> <ul style="list-style-type: none"> • For genetic testing for <i>APC</i> variants in individuals with clinical symptoms consistent with FAP. • For genetic testing for <i>APC</i> variants in individuals with clinical symptoms consistent with AFAP. • For genetic testing for <i>APC</i> variants in individuals with clinical symptoms consistent with Turcot's or Gardner's syndromes. • For testing individuals with an <i>APC</i>-associated polyposis syndrome for the purpose of identifying a variant that may be used to screen at-risk relatives. • For the presymptomatic testing of at-risk relatives for a known familial variant. • NOT COVERED for prenatal testing or PGD in couples at risk for FAP.

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 (TPM) 6010.54-M, [Chapter 6, Section 3.1](#).

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

³ Lynch syndrome-associated cancers include endometrial, ovarian, gastric, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma), and small intestine cancers, as well as sebaceous gland adenomas/carcinomas and keratoacanthomas.

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⁵ When current NCCN Guidelines™ for Colorectal Cancer Screening state "genetic testing" or "consider genetic testing."

FIGURE 18.13-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) (CONTINUED)

<p>LDT #4 Coverage Guidelines (Continued):</p>	<p><i>MYH</i> gene testing may be performed in patients with colorectal polyposis of unknown etiology, and in the siblings and offspring of known <i>MYH</i>-Associated Polyposis (MAP) patients:</p> <ul style="list-style-type: none"> • For the diagnosis of MAP in <i>APC</i>-negative polyposis patients, or in polyposis patients who have a family history consistent with autosomal recessive inheritance. • For the diagnosis of MAP in asymptomatic siblings of patients with known <i>MYH</i> variants. • For the testing of offspring or asymptomatic siblings of known MAP patients in order to provide an accurate recurrence risk to offspring⁵.
<p>CPT Coding when clinically indicated by Coverage Guidelines:</p>	<p>Comprehensive COLARIS AP®-Full Sequence and large rearrangement analysis of <i>APC</i> and mutation panel of <i>MYH</i>: Allowable CPT⁴ codes include 81201 and 81203 with modifier 59.</p> <p>Single Site COLARIS AP®-Mutation-specific analysis for individuals with a known <i>APC</i> mutation(s) in the family: Allowable CPT⁴ codes include 81202.</p> <p><i>MYH</i> Sequence Analysis-Full sequence and large arrangement analysis of <i>MYH</i>: Allowable CPT⁴ codes include 81406.</p> <p>Single Site <i>MYH</i>-Mutation-specific analysis for individuals with a known <i>MYH</i> mutation in the family: Allowable CPT⁴ codes include 81403.</p> <p><i>MYH</i> Mutation Panel-Analysis of the two most common <i>MYH</i> mutations in individuals of European ancestry: Allowable CPT⁴ codes include 81401.</p>
<p>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 <i>BRCA1</i> or <i>BRCA2</i> gene variant. Genetic counseling may only be provided by TRICARE-authorized providers, in accordance with TRICARE Policy Manual (TPM) 6010.54-M, Chapter 6, Section 3.1.</p> <p>² Close blood relatives include first-, second-, and third-degree relatives as described in the National Comprehensive Cancer Network (NCCN) Guidelines Version 1.2012 Breast and/or Ovarian Cancer Genetic Assessment Pedigree: First-, Second-, and Third-degree relatives of Proband.</p> <p>³ Lynch syndrome-associated cancers include endometrial, ovarian, gastric, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma), and small intestine cancers, as well as sebaceous gland adenomas/carcinomas and keratoacanthomas.</p> <p>⁴ CPT only © 2006 American Medical Association (or such other date of publication of CPT). All Rights Reserved.</p> <p>⁵ When current NCCN Guidelines™ for Colorectal Cancer Screening state “genetic testing” or “consider genetic testing.”</p>	

- END -

TRICARE Management Activity (TMA) Evaluation Of Non-United States Food and Drug Administration (FDA) Approved Laboratory Developed Tests (LDTs) Demonstration Project

1.0 PURPOSE

The purpose of this demonstration project is to improve the quality of health care services for TRICARE beneficiaries. This demonstration is intended to evaluate whether it is feasible for the Department of Defense (DoD) to review Laboratory Developed Tests (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 199.4(g)(15)(i)(C)) and 32 CFR 199.2(b)), or TRICARE's rare disease policy (32 CFR 199.4(g)(15)(ii)) in the case of LDTs used in the diagnosis or medical management of a rare disease, and otherwise meet TRICARE criteria for coverage. Those that do will be covered as a benefit under this demonstration. The demonstration project will evaluate feasible alternatives to FDA approval to support modifications to 32 CFR 199.4(g)(15)(i)(A) to allow coverage for non-FDA approved LDTs that otherwise meet the TRICARE requirements for safety and effectiveness. The DoD currently has an ongoing demonstration project to test this same provision for LDTs with a Centers for Medicare and Medicaid Services (CMS) national or local coverage determination that were submitted by laboratories for consideration for coverage under TRICARE. However, this new demonstration is being conducted in order to evaluate the feasibility of establishing a cost-effective and efficient way to review an expanded pool of non-FDA approved LDTs prioritized based on their potential high utilization and clinical utility within the TRICARE population. This new demonstration project will also extend coverage for preconception and prenatal Cystic Fibrosis (CF) carrier screening, when provided in accordance with the most current American College of Obstetricians and Gynecologists (ACOG) guidelines in order to allow the DoD to establish whether there is a benefit to offering such testing to TRICARE beneficiaries. The demonstration project will operate throughout the continental United States, and in the TRICARE overseas regions.

2.0 BACKGROUND

2.1 On June 18, 2014, a notice was published in the **Federal Register** (79 FR 34726) announcing the start of a demonstration project in which the TRICARE Management Activity (TMA) will review LDTs which have not received FDA clearance or approval to determine if they meet TRICARE requirements for safety and effectiveness according to the hierarchy of reliable evidence or TRICARE's rare disease policy as stated above and approve those that do for cost-sharing under this demonstration. An annual evaluation of the new demonstration will be conducted to determine how many of these non-FDA approved LDTs were provided to beneficiaries across all TRICARE regions. The evaluation will also include a review of the LDT examination and recommendation

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process to assess feasibility, resource requirements, and cost-effectiveness of the TMA establishing an internal safety and efficacy review process for these LDTs for TRICARE cost-sharing purposes. These results will provide an evaluation of the potential improvement of the quality of health care services for beneficiaries who would not otherwise have access to these safe and effective tests. Based on the results, a recommendation will be made on whether to modify [32 CFR 199.4\(g\)\(15\)\(i\)\(A\)](#) to remove the restriction for non-FDA approved LDTs and permit TRICARE cost-sharing of LDTs that are found to otherwise meet TRICARE requirements for safety and effectiveness.

2.2 This new demonstration project also extends coverage for preconception and prenatal CF carrier screening, when provided in accordance with the most current ACOG guidelines. This demonstration project will allow the DoD to establish whether there is a benefit to offering such testing for purposes of determining whether to permanently establish coverage as part of the family planning genetic testing benefit at [32 CFR 199.4\(e\)\(3\)\(ii\)](#), the maternity benefit at [32 CFR 199.4\(e\)\(16\)](#), or otherwise as a special benefit. By extending coverage for CF carrier screening in accordance with the most current ACOG guidelines under this demonstration project, the DoD will be able to gather the necessary data to evaluate whether there is a benefit to offering such screening, including evaluating the impact on follow-on care that a patient is given based on testing results and any other identified benefits of the testing. The Director, TMA, or designee, shall issue guidelines for collection of data involving individual cases of CF carrier screening covered under this demonstration as necessary for evaluation of the benefits resulting from such screening.

2.3 According to [32 CFR 199.4\(g\)\(15\)\(i\)\(A\)](#), the 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. LDTs with FDA approval are available for cost-sharing under the TRICARE Basic Program as long as they otherwise meet TRICARE criteria for coverage.

2.4 An LDT is an In Vitro Diagnostic (IVD) that is designed, manufactured, and used within a single laboratory. In the past, these were relatively simple tests used within a single laboratory, usually at a local large hospital or academic medical center, to diagnose rare diseases or for other uses to meet the needs of a local patient population. Today, these tests may be highly complex. LDTs range from identifying one specific gene to identifying just a variant of the gene, while others can assess a person's risk of developing specific cancers or diseases. For purposes of this demonstration, LDTs approved for coverage under the TRICARE Program will be identified by the specific gene they test for as detailed in [Figure 18.17-1](#).

2.5 Laboratories are assessed and accredited under minimum quality standards set by CMS under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. CMS regulates laboratories that use non-FDA approved 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 evaluate whether the laboratory has determined the analytical validity of the tests they offer, 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. CLIA certification does not, however, assure a device is safe and effective for its intended use, or impose any type of post-market surveillance or adverse event reporting requirements.

2.6 On December 27, 2011, the DoD published a notice in the **Federal Register** (76 FR 80905-80907), announcing the TRICARE Evaluation of Centers for Medicare and Medicaid Services (CMS) Approved Laboratory Developed Tests (LDTs) Demonstration Project. LDTs for this demonstration were limited to only those that had a CMS national or local coverage determination and significantly informed clinical decision making for surveillance, surgical interventions, chemotherapy, or radiation therapy for cancer. The demonstration project was based on interested laboratories submitting their LDTs for consideration. Limited participation from industry in the demonstration served as a constraining factor and did not provide sufficient data for the DoD to make an affirmative decision regarding the feasibility of developing a cost-effective and efficient method of reviewing non-FDA approved LDTs for safety and efficacy. This three year demonstration will continue until it expires or is terminated via separate notice and LDTs covered under the current demonstration will continue to be covered (see [Chapter 18, Section 13](#)).

3.0 POLICY

3.1 A new and expanded demonstration project was initiated by the TMA to review non-FDA approved LDTs to determine if they meet TRICARE requirements for safety and effectiveness according to the hierarchy of reliable evidence ([32 CFR 199.4\(g\)\(15\)\(i\)\(C\)](#) and [32 CFR 199.2\(b\)](#)), or TRICARE's rare disease policy ([32 CFR 199.4\(g\)\(15\)\(ii\)](#)) in the case of LDTs used in the diagnosis or medical management of a rare disease, and otherwise meet TRICARE criteria for coverage and approve those that do for cost-sharing under this demonstration. The demonstration will evaluate an expanded pool of non-FDA approved LDTs. For example, LDTs evaluated under the new demonstration are not limited to those associated with cancer and do not require a CMS national or local coverage determination. Further, consideration of specific gene testing as part of the ongoing demonstration, discussed above, does not also prevent consideration under the new demonstration.

3.2 Non-FDA approved LDTs will be prioritized and reviewed for analytical validity, clinical validity, and clinical utility. LDT reviews will be based on the TRICARE hierarchy of reliable evidence to determine whether the specific test is proven safe and effective.

3.3 Reliable evidence is defined in [32 CFR 199.2\(b\)](#) and includes:

3.3.1 Well-controlled studies of clinically meaningful endpoints, published in refereed medical literature;

3.3.2 Published formal technology assessments;

3.3.3 The published reports of national professional medical associations;

3.3.4 Published national medical policy organization positions; and,

3.3.5 The published reports of national expert opinion organizations.

3.3.6 The hierarchy of reliable evidence of proven medical effectiveness, established by [paragraphs 3.3.1](#) through [3.3.5](#), is the order of the relative weight to be given to any particular source. With respect to clinical studies, only those reports and articles containing scientifically valid

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data and published in the refereed medical and scientific literature shall be considered as meeting the requirements of reliable evidence. Specifically not included in the meaning of reliable evidence are reports, articles, or statements by providers or groups of providers containing only abstracts, anecdotal evidence, or personal professional opinions. Also not included in the meaning of reliable evidence is the fact that a provider or a number of providers have elected to adopt a drug, device, or medical treatment or procedure as their personal treatment or procedure of choice or standard of practice.

3.4 There may also be non-FDA approved LDTs reviewed under the new demonstration project for use in the diagnosis or medical management of a rare disease. TRICARE defines a rare disease as any disease or condition that has a prevalence of less than 200,000 persons in the U.S. Due to the rare nature of the condition and lack of clinical research, the hierarchy of reliable evidence may not be met. In accordance with [32 CFR 199.4\(g\)\(15\)\(ii\)](#), benefits for rare diseases are reviewed on a case-by-case basis. In reviewing proposed benefits for rare diseases under the new demonstration, consistent with TRICARE's rare disease policy, any or all of the following sources may be consulted to determine if the proposed non-FDA approved LDT for a rare disease is considered safe and effective:

- 3.4.1** Trials published in refereed medical literature;
- 3.4.2** Formal technology assessments;
- 3.4.3** National medical policy organization positions;
- 3.4.4** National professional associations; and,
- 3.4.5** National expert opinion organizations.

3.5 Cystic Fibrosis (CF) Carrier Screening

3.5.1 This new demonstration project will also extend coverage for preconception and prenatal CF carrier screening, as well as the follow-on prenatal CF diagnostic genetic testing, such as amniocentesis, chorionic villus sampling, or chordocentesis, when provided in accordance with the most current ACOG guidelines, in order to allow the DoD to establish whether there is a benefit to offering such testing to TRICARE beneficiaries. CF carrier screening will be covered from January 1, 2013, through the end of the demonstration in order to obtain sufficient data to be able to conduct a cost benefit analysis of providing this screening for our beneficiary population. Additionally, the CF screening test is exempt from the preauthorization requirements of this demonstration. Due to the volume of CF screening tests performed in the TRICARE population, it is not practicable or cost-effective for these tests to be preauthorized. Instead, the contractors shall ensure the test is provided in accordance with the most current ACOG guidelines, e.g. if a patient has been screened previously, CF screening results should be documented but the test should not be repeated.

3.5.2 Preconception and prenatal CF carrier screening is excluded from the TRICARE Basic Program regardless of whether an FDA approved kit or non-FDA approved test is utilized.

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3.6 Non-FDA approved LDTs approved by the Director, TMA, or designee, during the demonstration period, as outlined in [Figure 18.17-1](#), will become available for cost-sharing for qualified TRICARE beneficiaries during the demonstration period when performed by CLIA certified labs.

3.7 Non-FDA approved LDTs that lack sufficient reliable evidence for safety and efficacy based on the TRICARE hierarchy of reliable evidence will remain excluded from TRICARE coverage.

3.8 Notification to the contractors of non-FDA approved LDT eligibility for cost-sharing shall be published, periodically, to this Chapter of the TRICARE Operations Manual (TOM), as detailed in [Figure 18.17-1](#). The codes listed in [Figure 18.17-1](#) which are on the No Government Pay Procedure Code List (NGPL) but payable under this demonstration project will remain on the NGPL, since these non-FDA approved LDTs are not covered under the TRICARE Basic Program. Non-FDA approved LDTs listed in [Figure 18.17-1](#) may be covered only as part of the demonstration project as denoted with the Special Processing Code (SPC) which shall be associated with each claim (see the TRICARE Systems Manual (TSM), [Chapter 2](#)). The TRICARE Encounter Data (TED) SPC for the new LDT demonstration is "L2 Non-FDA Approved Laboratory Developed Tests (LDTs) Demonstration." The LD SPC shall continue to apply to those LDTs covered under the demonstration found in [Chapter 13](#).

3.9 The TMA shall cost-share all medical care and treatment associated with the LDT approved under the demonstration in the same manner it would any other care or treatment associated with the provision of medically necessary and appropriate care if the following conditions are met:

3.9.1 The specific non-FDA approved LDT has been approved by the Director, TMA, or designee, for cost-sharing to eligible TRICARE beneficiaries; and

3.9.2 The contractor has preauthorized the LDT approved under the demonstration, when required, 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 18.17-1](#); and

3.9.3 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 18.17-1](#); and

3.9.4 The contractor has, as noted in TRICARE Policy Manual (TPM), [Chapter 1, Section 7.1, paragraph 2.0](#), for dual eligible beneficiaries, applied all requirements when TRICARE is primary payer. As secondary payer under the TRICARE Dual Eligible Fiscal Intermediary Contract (TDEFIC), 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, when required, was not obtained, the contractor shall obtain the necessary information and perform a retrospective review.

3.10 The demonstration will expire on July 18, 2017. Requirements of this Chapter as related to this demonstration cease at midnight on July 18, 2017. Only TRICARE beneficiaries with current eligibility, as defined in [paragraph 7.0](#), may participate in this demonstration project. Claims shall not be processed for individuals not eligible for TRICARE benefits. All medical care, treatments, or

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testing, with the exception of the LDT which has approval during the demonstration period only, must be a TRICARE covered benefit provided to TRICARE eligible beneficiaries. This applies to all care rendered during or after the end date of this demonstration project.

3.11 The records management requirements described in [Chapter 2](#) apply to this demonstration project.

4.0 APPLICABILITY

4.1 This demonstration applies to all TRICARE-eligible beneficiaries. Additionally, for purposes of [Chapter 17, Section 3](#), LDTs are covered for service members as specified in the demonstration and no Supplemental Health Care Program (SHCP) waiver is required. The SPC **L2** shall accompany ADSM claims.

4.2 The benefit for LDTs approved under this demonstration project differs from the TRICARE Basic Program benefit. Coverage inquiries shall be submitted to, and resolved by the appropriate contractor (referencing the TMA Evaluation of Non-FDA Approved LDTs Demonstration Project). Regarding a beneficiary with other insurance that provides primary coverage, any medical necessity reviews the contractor believes are necessary, to act as a secondary payer, shall be performed on a retrospective basis.

4.3 The DoD has no authority to cost-share non-FDA approved medical devices such as LDTs, under the TRICARE Basic Program. While these non-FDA approved LDTs may be covered under the demonstration, appeal rights do not apply. Denials under the new demonstration are not appealable. Further, the inclusion or exclusion of LDTs under the new demonstration is not appealable.

5.0 GENERAL DESCRIPTION OF THE ADMINISTRATIVE PROCESS

5.1 With the exception of the CF carrier screening test which must be provided in accordance with the most current ACOG guidelines, the contractor shall preauthorize all other demonstration approved LDTs, to verify that the TRICARE authorized provider has determined the eligible beneficiary's medical need based on the beneficiary's clinical diagnoses which support the medical need and, the contractor shall document these facts according to and consistent with the 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 18.17-1](#). 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 beneficiary. The contractor shall issue the notification of decision to authorize use of the demonstration approved LDT in writing to both the applicant provider and the beneficiary receiving the LDT. The contractor shall identify each claim with the SPC **L2**.

5.2 For LDTs which must be performed on an emergency basis, contractors shall perform a retrospective authorization review and approval prior to payment (e.g., PML/RaRalpha testing performed in an emergency room or inpatient hospital setting for acute promyelocytic leukemia

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patients where results are urgently needed and will immediately impact medical management/treatment decisions).

5.3 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 beneficiaries under demonstration approved LDT care.

5.4 Because some provisions of this demonstration are retroactive to January 1, 2013, exceptions may be granted to the time limitations on filing claims as outlined in [Chapter 8, Section 3](#).

6.0 TMA RESPONSIBILITIES

6.1 The TMA Evaluation of Non-FDA Approved LDTs Demonstration Project will be paid by the 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 Perform periodic review and evaluation of the demonstration claims adjudication process.

6.3 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.

7.0 CONTRACTOR RESPONSIBILITIES

The contractor shall:

7.1 Verify the beneficiary's eligibility on the Defense Enrollment Eligibility Reporting System (DEERS). It is the contractor's responsibility to correctly voucher the TED records for payment.

7.2 Issue an authorization or denial letter to the applicant provider and beneficiary once a determination is made.

7.3 The contractor shall preauthorize the demonstration approved LDTs as required and verify medical necessity according to all indications detailed in [Figure 18.17-1](#). Only the indications listed in the Coverage Guidelines may be considered for cost-sharing. 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.

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

8.0 CLAIMS PROCESSING REQUIREMENTS

8.1 Both laboratory and professional charges shall be reimbursed based on existing TRICARE reimbursement rules. In the absence of a CHAMPUS Maximum Allowable Charge (CMAC) for the specific test, the contractor shall develop a prevailing charge following the procedures in the TRICARE Reimbursement Manual (TRM), [Chapter 5, Section 1](#).

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8.2 The contractor shall assure that the 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 has missing information, [Chapter 8, Section 6](#) guidelines shall be followed to either return or develop the claim and request the missing information.

8.3 All claims for the demonstration approved LDT shall meet the requirements outlined in [Figure 18.17-1](#). 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 necessary and appropriate medical care and not otherwise excluded as a TRICARE benefit.

8.4 Cost-shares and deductibles applicable to TRICARE shall also apply under the demonstration.

8.5 Normal double coverage provisions apply to LDTs approved under the demonstration. Acceptable evidence of processing by the double coverage plan is outlined in [Chapter 4](#).

8.6 Claims for this demonstration shall be paid from the applicable non-underwritten bank account (see [Chapter 3](#)), and submitted through normal 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.

8.7 SPC **L2** shall be assigned to identify all claims paid under the new demonstration. The intent of this policy is to process claims for the demonstration approved LDTs with the SPC and the associated technical and professional components associated with the LDT-related CPTs. Medical care, treatments, and associated testing based on medical necessity as a consequence of the demonstration approved LDT's results are to be processed under the TRICARE Basic Program benefit.

8.8 Claims for this demonstration shall be submitted either by Electronic Media Claim (EMC) or by paper claim using the dedicated demonstration mailing address or using the appropriate regional claims processing address(es).

9.0 EFFECTIVE DATE

The effective date for coverage of LDTs approved under this demonstration project will be the later of:

9.1 January 1, 2013; or

9.2 The date on which there is sufficient reliable evidence to determine that the non-FDA approved LDT is proven safe and effective for TRICARE cost-sharing purposes. Effective dates of coverage for specific testing are included in [Figure 18.17-1](#).

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FIGURE 18.17-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) FOR THE FOLLOWING GENES

GENE:		APC	
Effective Date:	January 1, 2013		
Coverage Guidelines:	APC gene testing is covered for the following indications: <ul style="list-style-type: none"> • Testing for APC variants in individuals with clinical symptoms consistent with Familial Adenomatous Polyposis (FAP). • Testing for APC variants in individuals with clinical symptoms consistent with Attenuated Familial Adenomatous Polyposis (AFAP). • Testing for APC variants in individuals with clinical symptoms consistent with Turcot's or Gardner's syndromes. • Testing individuals with an APC-associated polyposis syndrome for the purpose of identifying a variant that may be used to screen at-risk relatives. • For the presymptomatic testing of at-risk relatives for a known familial variant. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81201	APC (Adenomatous Polyposis Coli) (e.g., Familial Adenomatosis Polyposis [FAP], attenuated FAP) gene analysis; full gene sequence
		81202	known familial variants
		81203	duplication/deletion variants

GENE:		BCR/ABL1	
Effective Date:	January 1, 2013		
Coverage Guidelines:	BCR/ABL1 gene testing is covered for the following indications: <ul style="list-style-type: none"> • Diagnostic assessment of individuals with suspected Chronic Myelogenous Leukemia (CML) by quantitative RT-PCR (RQ-PCR). • Diagnostic assessment of individuals with suspected CML by qualitative RT-PCR. • Monitoring response to Tyrosine Kinase Inhibitor (TKI) therapy, such as imatinib, in individuals with CML by RQ-PCR. • Testing for the presence of the BCR/ABL1 p.Thr315Ile variant in CML patients to guide treatment selection following resistance to first-line imatinib therapy. • Testing for the presence of BCR/ABL1 variants other than p.Thr315Ile in CML patients to guide treatment selection following resistance to first-line imatinib therapy. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81206	BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative
		81207	BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis; minor breakpoint, qualitative or quantitative
		81208	BCR/ABL1 (t(9;22)) (e.g., chronic myelogenous leukemia) translocation analysis; other breakpoint, qualitative or quantitative

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FIGURE 18.17-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) FOR THE FOLLOWING GENES (CONTINUED)

GENE:	BMPR1A	
Effective Date:	January 1, 2013	
Coverage Guidelines:	BMPR1A gene testing is covered for the following indications: <ul style="list-style-type: none"> • To clarify the diagnosis of individuals with Juvenile Polyposis Syndrome (JPS). • If a known SMAD4 mutation is in the family, genetic testing should be performed in the first six months of life due to hereditary hemorrhagic telangiectasia risk. 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81479 Unlisted molecular pathology procedure

GENE:	BRAF	
Effective Date:	January 1, 2013	
Coverage Guidelines:	BRAF gene testing is covered for the following indications: <ul style="list-style-type: none"> • To predict response to vemurafenib therapy in patients with a positive cobas 4800 BRAF mutation test result. • For individuals with indeterminate thyroid Fine-Needle Aspiration (FNA) biopsy cytology for diagnosis of papillary thyroid carcinoma. 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81210 BRAF (v-raf murine sarcoma viral oncogene homolog B1) (e.g., colon cancer), gene analysis, V600E variant 81406 BRAF (v-raf murine sarcoma viral oncogene homolog B1) (e.g., Noonan syndrome), full gene sequence

GENE:	BRCA1/BRCA2	
Effective Date:	January 1, 2013	
Coverage Guidelines:	BRCA1/BRCA2 gene testing is covered for the following indications: <ul style="list-style-type: none"> • For individuals from families transmitting a known BRCA1/2 variant. • For individuals with a history of breast cancer and at least one of the following: <ul style="list-style-type: none"> • Breast cancer diagnosed ≤ 45 years of age. • Breast cancer diagnosed ≤ 50 years of age and a close family member with breast cancer. • Two breast primaries with one diagnosed at or before age 50. • A diagnosis of triple negative breast cancer at or before age 60. • Breast cancer diagnosed at any age and at least one close relative with breast cancer before age 50 and/or epithelial ovarian cancer at any age. • Breast cancer diagnosed at any age and at least two close relatives diagnosed with breast, pancreatic, and/or prostate (Gleason ≥ 7) cancer at any age. • A close male relative, which includes first-, second-, and third-degree relatives, with breast cancer. • An ethnic background associated with a higher frequency of BRCA1/2 variants (i.e., Ashkenazi Jewish). 	

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FIGURE 18.17-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) FOR THE FOLLOWING GENES (CONTINUED)

Coverage Guidelines (Continued):	<ul style="list-style-type: none"> • For individuals with a personal history of epithelial ovarian cancer. • For individuals with male breast cancer. • For individuals with a personal history of pancreatic cancer or prostate (Gleason \geq 7) and at least two close relatives with breast, ovarian, prostate (Gleason \geq 7), and/or pancreatic cancer. • For unaffected individuals (with no personal history of cancer) who have one of the following: <ul style="list-style-type: none"> • A first- or second-degree relative satisfying the above criteria. • 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. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81211	BRCA1, BRCA2 (breast cancer 1 and 2) (e.g. hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants in BRCA1 (i.e., exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)
		81212	185delAG, 5385insC, 617delT variants
		81213	uncommon duplication/deletion variants
		81214	BRCA1 (breast cancer 1) (e.g. hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants (i.e., exon 13 del 3.835kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)
		81215	known familial variant
		81216	BRCA2 (breast cancer 2) (e.g. hereditary breast and ovarian cancer) gene analysis; full sequence analysis
		81217	known familial variant

GENE:	CEBPA		
Effective Date:	January 1, 2013		
Coverage Guidelines:	CEBPA gene testing is covered for the following indications: <ul style="list-style-type: none"> • To guide the treatment decisions for individuals with Acute Myeloid Leukemia (AML). 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81403	CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (e.g., acute myeloid leukemia) full gene sequence
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GENE:	CFTR	
Effective Date:	January 1, 2013	
Coverage Guidelines:	<p>CFTR gene testing is covered for the following indications:</p> <ul style="list-style-type: none"> • Confirmation of diagnosis in individuals showing clinical symptoms of Cystic Fibrosis (CF) or having a high sweat chloride level. • Identification of newborns who are affected with CF. • Identification of individuals with the p.Gly551Asp variant who will respond to treatment with ivacaftor. • Male infertility testing and treatment. • Preconception and prenatal carrier screening in accordance with the most current ACOG guidelines. 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	<p>81220 CFTR (cystic fibrosis transmembrane conductance regulator) (e.g. cystic fibrosis) gene analysis, common variants</p> <p>81221 known familial variants</p> <p>81222 duplication/deletion variants</p> <p>81223 full gene sequence</p> <p>81224 intron 8 poly-T analysis (e.g. male infertility)</p>
GENE:	Cytogenomic Constitutional Microarray Analysis	
Effective Date:	January 1, 2013	
Coverage Guidelines:	<p>Cytogenomic Constitutional Microarray Analysis gene testing is covered for the following indications:</p> <ul style="list-style-type: none"> • Diagnostic evaluation of patients suspected of having a genetic syndrome (i.e., have congenital anomalies, dysmorphic features, Developmental Delay (DD), and/or intellectual disability). • Diagnostic evaluation of individuals with Autism Spectrum Disorder (ASD), including autism, Asperger syndrome, and pervasive developmental disorder. 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	<p>81228 Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g., Bacterial Artificial Chromosome [BAC] or oligo-based Comparative Genomic Hybridization [CGH] microarray analysis)</p> <p>81229 interrogation of genomic regions for copy number and Single Nucleotide Polymorphism (SNP) variants for chromosomal abnormalities</p> <p>81406 Cytogenomic microarray analysis, neoplasia (e.g., interrogation of copy number, and loss-of-heterozygosity via Single Nucleotide Polymorphism [SNP]-based Comparative Genomic Hybridization [CGH] microarray analysis)</p>
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GENE:	EGFR	
Effective Date:	January 1, 2013	
Coverage Guidelines:	EGFR gene testing is covered for the following indications: <ul style="list-style-type: none"> To help guide administration of Epidermal Growth Factor Receptor (EGFR) TKIs in the first-line treatment of non-small cell lung cancer. 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81235 EGFR (epidermal growth factor receptor) (e.g. non-small cell lung cancer) gene analysis, common variants (e.g. exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q)

GENE:	F2	
Effective Date:	January 1, 2013	
Coverage Guidelines:	Prothrombin (Factor II) related thrombophilia gene testing is covered for the following indications: <ul style="list-style-type: none"> Diagnostic evaluation of individuals with a prior Venous Thromboembolism (VTE) during pregnancy or puerperium. For patients with VTE with a personal or family history of recurrent VTE (more than two in the same person). For patients with their first VTE before age 50 with no precipitating factors. For venous thrombosis at unusual sites such as the cerebral, mesenteric, portal, or hepatic veins. For VTE associated with the use of estrogen-containing oral contraceptives, Selective Estrogen Receptor Modulators (SERMs), or Hormone Replacement Therapy (HRT). To diagnose an inherited thrombophilia in female family members of individuals with an inherited thrombophilia if the female family member is pregnant or considering pregnancy or oral contraceptive use. 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81240 F2 (prothrombin, coagulation factor II) (e.g., hereditary hypercoagulability) gene analysis, 20210G>A variant 81400 F2 (coagulation factor 2) (e.g., hereditary hypercoagulability), 1199G>A variant

GENE:	F5	
Effective Date:	January 1, 2013	
Coverage Guidelines:	Factor V Leiden thrombophilia gene testing is covered for the following indications: <ul style="list-style-type: none"> Diagnostic evaluation of individuals with a prior VTE during pregnancy or puerperium. For patients with VTE with a personal or family history of recurrent VTE (more than two in the same person). For patients with their first VTE before age 50 with no precipitating factors. For venous thrombosis at unusual sites such as the cerebral, mesenteric, portal, or hepatic veins. 	

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Coverage Guidelines (Continued):	<ul style="list-style-type: none"> For VTE associated with the use of estrogen-containing oral contraceptives, Selective Estrogen Receptor Modulators (SERMs), or Hormone Replacement Therapy (HRT). To diagnose an inherited thrombophilia in female family members of individuals with an inherited thrombophilia if the female family member is pregnant or considering pregnancy or oral contraceptive use. 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	<p>81241 F5 (coagulation factor V) (e.g., hereditary hypercoagulability) gene analysis, Leiden variant</p> <p>81400 F5 (coagulation factor V) (e.g., hereditary hypercoagulability), HR2 variant</p>

GENE:	FMR1	
Effective Date:	January 1, 2013	
Coverage Guidelines:	<p>FMR1 gene testing is covered for the following indications:</p> <ul style="list-style-type: none"> Testing for CGG repeat length for diagnosis of patients of either sex with mental retardation, intellectual disability, developmental delay, or autism. <p>FMR1 gene testing for Fragile X-Associated Tremor/Ataxia Syndrome is covered for the following individuals:</p> <ul style="list-style-type: none"> Males and females older than age 50 years who have progressive cerebellar ataxia and intention tremor with or without a positive family history of FMR1-related disorders in whom other common causes of ataxia have been excluded. Women with unexplained Premature Ovarian Insufficiency (POI). 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	<p>81243 FMR1 (fragile X mental retardation 1) (e.g., fragile X mental retardation) gene analysis; evaluation to detect abnormal (e.g., expanded) alleles</p> <p>81244 characterization of alleles (e.g., expanded size and methylation status)</p>

GENE:	HBA1/HBA2	
Effective Date:	January 1, 2013	
Coverage Guidelines:	<p>HBA1/HBA2 gene testing is covered for the following indications:</p> <ul style="list-style-type: none"> To confirm the diagnosis of alpha-thalassemia in a symptomatic individual. To confirm the diagnosis in a pregnant woman with low hemoglobin when alpha-thalassemia is suspected. 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	<p>81257 HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis, for common deletions or variant (e.g., Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, and Constant Spring)</p> <p>81404 HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia), duplication/deletion analysis</p> <p>81405 HBA1/HBA2 (alpha globin 1 and alpha globin 2) (e.g., alpha thalassemia), full gene sequence</p>
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GENE:		HEXA	
Effective Date:	January 1, 2013		
Coverage Guidelines:	HEXA gene testing is covered for the following indications: <ul style="list-style-type: none"> As an adjunct to biochemical testing in patients with low hexosaminidase A levels in blood. When individuals are identified with apparent deficiency of hexosaminidase A enzymatic activity, targeted mutation analysis can then be used to distinguish pseudodeficiency alleles from disease-causing alleles. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81255	HEXA (hexosaminidase A [alpha polypeptide]) (e.g., Tay-Sachs disease) gene analysis, common variants (e.g., 1278insTATC, 1421+1G>C, G269S)
		81406	HEXA (hexosaminidase A, alpha polypeptide) (e.g., Tay-Sachs disease), full gene sequence

GENE:		HFE	
Effective Date:	January 1, 2013		
Coverage Guidelines:	HFE-associated hereditary hemochromatosis gene testing is covered for the following indications: <ul style="list-style-type: none"> Diagnosis of patients with or without symptoms of iron overload with a serum transferrin saturation >45% and/or elevated serum ferritin. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81256	HFE (hemochromatosis) (e.g., hereditary hemochromatosis) gene analysis, common variants (e.g., C282Y, H63D)

GENE:		HLA	
Effective Date:	January 1, 2013		
Coverage Guidelines:	HLA gene testing is covered for the following indications: <ul style="list-style-type: none"> To determine histocompatibility of tissue between organ and bone marrow donors and recipients prior to transplant. For platelet transfusion for patients refractory to treatment due to alloimmunization. Diagnosis of celiac disease in symptomatic patients with equivocal results on small bowel biopsy and serology, or in previously symptomatic patients who are asymptomatic while on a gluten-free diet. Testing for the HLA-B*1502 allele prior to initiating treatment with carbamazepine in patients from high-risk ethnic groups. Testing for the HLA-B*5701 allele for hypersensitivity reactions in patients prior to initiation or reinitiation with treatments containing abacavir. Testing for the HLA-B*58:01 allele in patients prior to initiating treatment with allopurinol. 		

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CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81370	HLA Class I and II typing, low resolution (e.g. antigen equivalents); HLA-A, -B, -C, -DRB1/3/4/5, and -DQB1
		81371	HLA-A, -B, and -DRB1 (e.g., verification typing)
		81372	HLA Class I typing, low resolution (e.g. antigen equivalents); complete (i.e., HLA-A, -B, and -C)
		81373	one locus (e.g., HLA-A, -B, or -C) each
		81374	one antigen equivalent (e.g. B*27), each
		81375	HLA Class II typing, low resolution (e.g. antigen equivalents); HLA-DRB1/3/4/5 and -DQB1
		81376	one locus (e.g., HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each
		81377	one antigen equivalent, each
		81378	HLA Class I and II typing, high resolution (i.e., alleles or allele groups), HLA-A, -B, -C, and -DRB1
		81379	HLA Class I typing, high resolution (i.e., alleles or allele groups); complete (i.e., HLA-A, -B, and -C)
		81380	one locus (e.g., HLA-A, -B, or -C), each
		81381	one allele or allele group (e.g., B*57:01P), each
		81382	HLA Class II typing, high resolution (i.e., alleles or allele groups); one locus (e.g., HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each
		81383	one allele or allele group (e.g., HLA- DQB1*06:02P), each

GENE:	JAK2		
Effective Date:	January 1, 2013		
Coverage Guidelines:	<p>JAK2 gene testing is covered for the following indications:</p> <ul style="list-style-type: none"> • Diagnostic evaluation of individuals presenting with clinical, laboratory, or pathological findings suggesting classic forms of myeloproliferative neoplasms (MPN), that is, Polycythemia Vera (PV), Essential Thrombocythemia (ET), or Primary Myelofibrosis (PMF). • Diagnostic evaluation of PV through JAK2 Exon 12 variant detection in JAK2 p.Val617Phe negative individuals. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81270	JAK2 (Janus kinase 2) (e.g., myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant
		81403	JAK2 (Janus kinase 2) (e.g., myeloproliferative disorder), exon 12 sequence and exon 13 sequence, if performed

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GENE:	KRAS	
Effective Date:	January 1, 2013	
Coverage Guidelines:	KRAS gene testing is covered for the following indications: <ul style="list-style-type: none"> To help guide administration of anti-EGFR monoclonal antibodies. 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81275 KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene) (e.g., carcinoma) gene analysis, variants in codons 12 and 13

GENE:	MECP2	
Effective Date:	January 1, 2013	
Coverage Guidelines:	MECP2 gene testing is covered for the following indications: <ul style="list-style-type: none"> Testing for MECP2 sequence variants in patients who meet established clinical diagnostic criteria for classic or variant Rett Syndrome (RS). Testing for MECP2 sequence variants in patients who have symptoms of RS, but do not meet established clinical diagnostic criteria. 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81302 MECP2 (methyl CpG binding protein 2) (e.g., Rett syndrome) gene analysis; full sequence analysis 81303 known familial variant 81304 duplication/deletion variants

GENE:	MLH1, MSH2, MSH6, MSI, PMS2, and EPCAM	
Effective Date:	January 1, 2013	
Coverage Guidelines:	Genetic testing for Lynch syndrome is covered for a beneficiary who has or has had colorectal or endometrial cancer and meets one of the following criteria: <ol style="list-style-type: none"> <u>Amsterdam II criteria for Lynch syndrome genetic testing.</u> At least two close blood relatives of the affected beneficiary must have or have had a cancer associated with Lynch syndrome; and all of the following criteria must be present: <ul style="list-style-type: none"> One must be a first-degree blood relative of the other two; At least two successive generations must be affected; At least one of the blood relatives or the beneficiary with cancer associated with HNPCC should be diagnosed before age 50 years; FAP should be excluded in the colorectal cancer case(s) (if any); and Histologic diagnosis of tumors should be verified whenever possible. <u>Revised Bethesda guidelines:</u> <ul style="list-style-type: none"> Colorectal cancer diagnosed in a beneficiary at less than 50 years of age. 	

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FIGURE 18.17-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) FOR THE FOLLOWING GENES (CONTINUED)

<p>Coverage Guidelines (Continued)</p>	<ul style="list-style-type: none"> • Presence of synchronous or metachronous Lynch syndrome-associated cancers, regardless of age. Lynch syndrome-associated cancers include endometrial, ovarian, gastric, pancreas, ureter and renal pelvis, biliary tract, brain (usually glioblastoma), and small intestine cancers, as well as sebaceous gland adenomas/carcinomas and keratoacanthomas. • Colorectal cancer with the MSI-H histology diagnosed in a beneficiary who is less than 60 years of age. • Colorectal cancer with one or more first-degree blood relatives with a Lynch syndrome-associated cancer³, with one of the cancers being diagnosed under age 50 years. • Colorectal cancer with two or more first- or second-degree blood relatives with Lynch syndrome-associated cancers³, regardless of age. <p>3. Has a blood relative with a known Lynch syndrome related gene mutation.</p> <p>4. Endometrial cancer diagnosed in a beneficiary at less than 50 years of age.</p> <p>5. If any of the revised Bethesda guidelines are met, Microsatellite Instability (MSI) and/or Immunohistochemistry (IHC) testing on the colon cancer tissue may be clinically appropriate. If the tumor is MSI positive or mutation of one of the mismatch repair genes is indicated by failure of IHC staining, then genetic testing should be undertaken. Further unnecessary testing can often be avoided by performance of IHC prior to any MSI testing.</p> <ul style="list-style-type: none"> • Genetic testing is covered for symptomatic or asymptomatic patients > 18 years of age who are at risk of having a known familial sequence variant in a Mismatch Repair (MMR) gene. 	
<p>CPT Coding When Clinically Indicated By Coverage Guidelines:</p>	<p>CPT¹ Code</p>	<p>81292 MLH1 (mutL homolog 1, colon cancer, non-polyposis type 2) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis</p> <p>81293 known familial variants</p> <p>81294 duplication/deletion variants</p> <p>81295 MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis</p> <p>81296 known familial variants</p> <p>81297 duplication/deletion variants</p> <p>81298 MSH6 (mutS homolog 6 [E. coli]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis</p> <p>81299 known familial variants</p> <p>81300 duplication/deletion variants</p> <p>81301 Microsatellite instability analysis (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (e.g., BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed</p>

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CPT Coding When Clinically Indicated By Coverage Guidelines (Continued):	CPT ¹ Code	81317	PMS2 (postmeiotic segregation increased 2 [<i>S. cerevisiae</i>]) (e.g. hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
		81318	known familial variants
		81319	duplication/deletion variants
		81403	EPCAM (epithelial cell adhesion molecule) (e.g., Lynch syndrome), duplication/deletion analysis

GENE:	MPL		
Effective Date:	January 1, 2013		
Coverage Guidelines:	MPL gene testing is covered for the following indications: <ul style="list-style-type: none"> Diagnostic evaluation of Myeloproliferative Leukemia (MPL) variants to include Trp515Leu and Trp515Lys in JAK2 p.Val617Phe-negative individuals showing symptoms. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81402	MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (e.g., myeloproliferative disorder), common variants (e.g., W515A, W515K, W515L, W515R)
		81403	MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (e.g., myeloproliferative disorder), exon 10 sequence

GENE:	MUTYH		
Effective Date:	January 1, 2013		
Coverage Guidelines:	MUTYH or MYH gene testing is covered for the following indications: <ul style="list-style-type: none"> Diagnosis of MYH-Associated Polyposis (MAP) in APC-negative colorectal polyposis patients, or in polyposis patients who have a family history consistent with autosomal recessive inheritance. Diagnosis of MAP in asymptomatic siblings of patients with known MYH variants. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81401	MUTYH (mutY homolog [<i>E. coli</i>]) (e.g., MYH-associated polyposis), common variants (e.g., Y165C, G382D)
		81406	MUTYH (mutY homolog [<i>E. coli</i>]) (e.g., MYH-associated polyposis), full gene sequence

GENE:	NPM1		
Effective Date:	January 1, 2013		
Coverage Guidelines:	NPM1 gene testing is covered for the following indications: <ul style="list-style-type: none"> To guide treatment decisions for individuals with AML. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81310	NPM1 (nucleophosmin) (e.g., acute myeloid leukemia) gene analysis, exon 12 variants

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GENE:	PAX8	
Effective Date:	January 1, 2013	
Coverage Guidelines:	PAX8 gene testing is covered for the following indications: <ul style="list-style-type: none"> • For individuals with indeterminate thyroid FNA biopsy cytology for diagnosis of papillary thyroid carcinoma. 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81401 PAX8/PPARG (t(2;3) (q13;p25)) (e.g., follicular thyroid carcinoma), translocation analysis

GENE:	PML/RARalpha	
Effective Date:	January 1, 2013	
Coverage Guidelines:	PML/RARalpha gene testing is covered for the following indications: <ul style="list-style-type: none"> • Diagnostic assessment of individuals with suspected acute promyelocytic leukemia (APL) by quantitative RT-PCR (RQ-PCR). • Diagnostic assessment of individuals with suspected APL by qualitative RT-PCR. • Monitoring response to treatment and disease progression in individuals with APL by RQ-PCR. 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81315 PML/RARalpha, (t(15;17)), promyelocytic leukemia/retinoic acid receptor alpha (e.g., promyelocytic leukemia) translocation analysis; common breakpoints (e.g. intron 3 and intron 6), qualitative or quantitative 81316 single breakpoint (e.g., intron 3, intron 6 or exon 6), qualitative or quantitative

GENE:	PMP22	
Effective Date:	January 1, 2013	
Coverage Guidelines:	PMP22 gene testing is covered for the following indications: <ul style="list-style-type: none"> • For the accurate diagnosis and classification of hereditary polyneuropathies. 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81324 PMP22 (peripheral myelin protein 22) (e.g. Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; duplication/deletion analysis 81325 full sequence analysis 81326 known familial variant

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FIGURE 18.17-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) FOR THE FOLLOWING GENES (CONTINUED)

GENE:		PTEN	
Effective Date:	January 1, 2013		
Coverage Guidelines:	PTEN gene testing is covered for the following indications: <ul style="list-style-type: none"> • For patients with Autism Spectrum Disorders (ASDs) and macrocephaly (Head circumference greater than 2 standard above the mean for age). • PTEN variant testing in individuals suspected of being affected with Cowden Syndrome (CS) or Bannayan-Riley-Ruvalcaba Syndrome (BRRS). 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81321	PTEN (phosphatase and tensin homolog) (e.g. Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis
		81322	known familial variant
		81323	duplication/deletion variant

GENE:		RET	
Effective Date:	January 1, 2013		
Coverage Guidelines:	RET gene testing is covered for the following indications: <ul style="list-style-type: none"> • Multiple endocrine neoplasia type 2 (MEN2) gene testing in patients with the clinical manifestations of MEN2A, MEN2B, or familial medullary thyroid carcinoma (FMTC), including those with apparently sporadic Medullary Thyroid Carcinoma (MTC) or pheochromocytoma. • MEN2 gene testing to confirm a diagnosis in the at-risk relatives of genetically confirmed MEN2 patients. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81404	RET (ret proto-oncogene) (e.g., multiple endocrine neoplasia, type 2B and familial medullary thyroid carcinoma), common variants (e.g., M918T, 2647_2648delinsTT, A883F)
		81405	RET (ret proto-oncogene) (e.g., multiple endocrine neoplasia, type 2A and familial medullary thyroid carcinoma), targeted sequence analysis (e.g., exons 10, 11, 13-16)

GENE:		SMAD4	
Effective Date:	January 1, 2013		
Coverage Guidelines:	SMAD4 gene testing is covered for the following indications: <ul style="list-style-type: none"> • To clarify the diagnosis of individuals with JPS. • If a known SMAD4 mutation is in the family, genetic testing should be performed in the first six months of life due to hereditary hemorrhagic telangiectasia risk. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81405	SMAD4 (SMAD family member 4) (e.g., hemorrhagic telangiectasia syndrome, juvenile polyposis), duplication/deletion analysis
		81406	SMAD4 (SMAD family member 4) (e.g., hemorrhagic telangiectasia syndrome, juvenile polyposis), full gene sequence

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FIGURE 18.17-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) FOR THE FOLLOWING GENES (CONTINUED)

GENE:	SMN1/SMN2	
Effective Date:	January 1, 2013	
Coverage Guidelines:	<p>SMN1/SMN2 gene testing is covered for the following indications:</p> <ul style="list-style-type: none"> • Diagnosis of patients with hypotonia and muscle weakness who are suspected of having Spinal Muscular Atrophy (SMA). 	
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	<p>81400 SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy), exon 7 deletion</p> <p>81401 SMN1/SMN2 (survival of motor neuron 1, telomeric/survival of motor neuron 2, centromeric) (e.g., spinal muscular atrophy), dosage analysis (e.g. carrier testing)</p> <p>81403 SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy), known familial sequence variant(s)</p> <p>81405 SMN1 (survival of motor neuron 1, telomeric) (e.g., spinal muscular atrophy), full gene sequence</p>

GENE:	SNRPN/UBE3A	
Effective Date:	January 1, 2013	
Coverage Guidelines:	<p>SNRPN/UBE3A gene testing is covered for the following indications:</p> <ul style="list-style-type: none"> • When a clinical diagnosis of Prader-Willi Syndrome (PWS) is suspected, the following findings justify genetic testing: <ul style="list-style-type: none"> • From birth to age two: Hypotonia with poor suck (neonatal period). • From age two to age six: Hypotonia with history of poor suck, global developmental delay. • From age six to age 12: Hypotonia with history of poor suck, global developmental delay, excessive eating with central obesity if uncontrolled. • From age 13 years to adulthood: Cognitive impairment, usually mild intellectual disability; excessive eating with central obesity if uncontrolled, hypothalamic hypogonadism and/or typical behavior problems. • When a clinical diagnosis of Angelman Syndrome is suspected, the following findings justify genetic testing: <ul style="list-style-type: none"> • As part of the evaluation of patients with developmental delay, regardless of age. • As part of the evaluation of patients with a balance or movement disorder such as ataxia of gait. May not appear as frank ataxia but can be forward lurching, unsteadiness, clumsiness, or quick, jerky motions. • As part of the evaluation of patients with uniqueness of behavior: any combination of frequent laughter/smiling; apparent happy demeanor; easily excitable personality, often with uplifted hand-flapping or waving movements; hypermotoric behavior. • Speech impairment, none or minimal use of words; receptive and non-verbal communication skills higher than verbal ones. 	

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FIGURE 18.17-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) FOR THE FOLLOWING GENES (CONTINUED)

CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81331	SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and ubiquitin protein ligase E3A) (e.g., Prader-Willi syndrome and/or Angelman syndrome), methylation analysis
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GENE:	STK11		
Effective Date:	January 1, 2013		
Coverage Guidelines:	STK11 gene testing is covered for the following indications: <ul style="list-style-type: none"> To confirm a diagnosis of Peutz-Jeghers Syndrome (PJS) in proband patients with a presumptive or probable diagnosis of PJS. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81404	STK11 (serine/threonine kinase 11) (e.g., Peutz-Jeghers syndrome), duplication/deletion analysis
		81405	STK11 (serine/threonine kinase 11) (e.g., Peutz-Jeghers syndrome), full gene sequence

GENE:	TP53		
Effective Date:	January 1, 2013		
Coverage Guidelines:	TP53 gene testing is covered for the following indications: <ul style="list-style-type: none"> Diagnosis of patients satisfying the criteria for classic Li-Fraumeni Syndrome (LFS) or Li-Fraumeni-Like Syndrome (LFLS), or the Chompret criteria for TP53 gene testing. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81404	TP53 (tumor protein 53) (e.g., tumor samples), targeted sequence analysis of 2-5 exons
		81405	TP53 (tumor protein 53) (e.g., Li-Fraumeni syndrome, tumor samples), full gene sequence or targeted sequence analysis of >5 exons

GENE:	TRG		
Effective Date:	January 1, 2013		
Coverage Guidelines:	TRG gene testing is covered for the following indications: <ul style="list-style-type: none"> Diagnosis and treatment of T-cell neoplasms. 		
CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	81342	TRG@ (T cell antigen receptor, gamma) (e.g., leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal populations

GENE:	VHL		
Effective Date:	January 1, 2013		
Coverage Guidelines:	VHL gene testing is covered for the following indications: <ul style="list-style-type: none"> Diagnosis of Von Hippel-Lindau (VHL) syndrome in patients presenting with pheochromocytoma, paraganglioma, or central nervous system hemangioblastoma. Confirmation of diagnosis in individuals with symptoms consistent with VHL syndrome. 		

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FIGURE 18.17-1 APPROVED LABORATORY DEVELOPED TESTS (LDTs) FOR THE FOLLOWING GENES (CONTINUED)

CPT Coding When Clinically Indicated By Coverage Guidelines:	CPT ¹ Code	
	81403	VHL (von Hippel-Lindau tumor suppression) (e.g., von Hippel-Lindau familial cancer syndrome), deletion/duplication analysis
	81404	VHL (Von Hippel-Lindau tumor suppression) (e.g., von Hippel-Lindau familial cancer syndrome), full gene sequence

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- END -

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Acronyms And Abbreviations

CAP/DME	Capital and Direct Medical Education
CAPD	Continuous Ambulatory Peritoneal Dialysis
CAPP	Controlled Access Protection Profile
CAQH	Council for Affordable Quality Health
CARC	Claim Adjustment Reason Code
CAS	Carotid Artery Stenosis
CAT	Computerized Axial Tomography
CB	Consolidated Billing
CBC	Cypher Block Chaining
CBE	Clinical Breast Examination
CBHCO	Community-Based Health Care Organizations
CBL	Commercial Bill of Lading
CBP	Competitive Bidding Program
CBSA	Core Based Statistical Area
CC	Common Criteria Convenience Clinic Criminal Control (Act)
CC&D	Catastrophic Cap and Deductible
CCCT	Clomiphene Citrate Challenge Test
CCD	Corporate Credit or Debit
CCDD	Catastrophic Cap and Deductible Data
CCEP	Comprehensive Clinical Evaluation Program
CCMHC	Certified Clinical Mental Health Counselor
CCN	Case Control Number
CCPD	Continuous Cycling Peritoneal Dialysis
CCR	Cost-To-Charge Ratio
CCTP	Custodial Care Transitional Policy
CD	Compact Disc
CDC	Centers for Disease Control and Prevention
CDCF	Central Deductible and Catastrophic Cap File
CDD	Childhood Disintegrative Disorder
CDH	Congenital Diaphragmatic Hernia
CD-I	Compact Disc - Interactive
CDR	Clinical Data Repository
CDRL	Contract Data Requirements List
CD-ROM	Compact Disc - Read Only Memory
CDT	Current Dental Terminology
CEA	Carotid Endarterectomy
CEIS	Corporate Executive Information System
CEO	Chief Executive Officer
CEOB	CHAMPUS Explanation of Benefits
CES	Cranial Electrotherapy Stimulation

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CF	Conversion Factor Cystic Fibrosis
CFO	Chief Financial Officer
CFR	Code of Federal Regulations
CFRD	Cystic Fibrosis-Related Diabetes
CFS	Chronic Fatigue Syndrome
CGMS	Continuous Glucose Monitoring System
CHAMPUS	Civilian Health and Medical Program of the Uniformed Services
CHAMPVA	Civilian Health and Medical Program of the Department of Veteran Affairs
CHBC	Criminal History Background Check
CHBR	Criminal History Background Review
CHC	Civilian Health Care
CHCBP	Continued Health Care Benefits Program
CHCS	Composite Health Care System
CHEA	Council on Higher Education Accreditation
CHKT	Combined Heart-Kidney Transplant
CHOP	Children's Hospital of Philadelphia
CI	Counterintelligence
CIA	Central Intelligence Agency
CID	Central Institute for the Deaf
CIF	Central Issuing Facility Common Intermediate Format
CIO	Chief Information Officer
CIPA	Classified Information Procedures Act
CJCSM	Chairman of the Joint Chiefs of Staff Manual
CL	Confidentiality Level (Classified, Public, Sensitive)
CLIA	Clinical Laboratory Improvement Amendment
CLIN	Contract Line Item Number
CLKT	Combined Liver-Kidney Transplant
CLL	Chronic Lymphocytic Leukemia
CMAC	CHAMPUS Maximum Allowable Charge
CMHC	Community Mental Health Center
CML	Chronic Myelogenous Leukemia
CMN	Certificate(s) of Medical Necessity
CMO	Chief Medical Officer
CMP	Civil Money Penalty
CMR	Cardiovascular Magnetic Resonance
CMS	Centers for Medicare and Medicaid Services
CMVP	Cryptographic Module Validation Program
CNM	Certified Nurse Midwife
CNS	Central Nervous System Clinical Nurse Specialist
CO	Contracting Officer

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FDB	First Data Bank
FDL	Fixed Dollar Loss
Fed	Federal Reserve Bank
FEHBP	Federal Employee Health Benefit Program
FEL	Familial Erythrophagocytic Lymphohistiocytosis
FEV ₁	Forced Expiratory Volume
FFM	Foreign Force Member
FHL	Familial Hemophagocytic Lymphohistiocytosis
FI	Fiscal Intermediary
FIPS	Federal Information Processing Standards (or System)
FIPS PUB	FIPS Publication
FISH	Fluorescence In Situ Hybridization
FISMA	Federal Information Security Management Act
FL	Form Locator
FMCRA	Federal Medical Care Recovery Act
FMRI	Functional Magnetic Resonance Imaging
FOBT	Fecal Occult Blood Testing
FOC	Full Operational Capability
FOIA	Freedom of Information Act
FOUO	For Official Use Only
FPO	Fleet Post Office
FQHC	Federally Qualified Health Center
FR	Federal Register Frozen Records
FRC	Federal Records Center
FSH	Follicle Stimulating Hormone
FSO	Facility Security Officer
FTE	Full Time Equivalent
FTP	File Transfer Protocol
FX	Foreign Exchange (lines)
FY	Fiscal Year
GAAP	Generally Accepted Accounting Principles
GAO	General Accounting Office
GAF	Geographic Adjustment Factor
GDC	Guglielmi Detachable Coil
GFE	Government Furnished Equipment
GHP	Group Health Plan
GHz	Gigahertz
GIFT	Gamete Intrafallopian Transfer
GIQD	Government Inquiry of DEERS
GP	General Practitioner
GPCI	Geographic Practice Cost Index

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GTMCPA	General Temporary Military Contingency Payment Adjustment
H/E	Health and Environment
HAC	Health Administration Center Hospital Acquired Condition
HAVEN	Home Assessment Validation and Entry
HBA	Health Benefits Advisor
HBO	Hyperbaric Oxygen Therapy
HCC	Health Care Coverage
HCDP	Health Care Delivery Program
HCF	Health Care Finder
HCFA	Health Care Financing Administration
HCG	Human Chorionic Gonadotropin
HCIL	Health Care Information Line
HCM	Hypertrophic Cardiomyopathy
HCO	Healthcare Operations Division
HCP	Health Care Provider
HCPC	Healthcare Common Procedure Code (formerly HCFA Common Procedure Code)
HCPCS	Healthcare Common Procedure Coding System (formerly Healthcare Common Procedure Coding System)
HCPR	Health Care Provider Record
HCSR	Health Care Service Record
HDC	High Dose Chemotherapy
HDC/SCR	High Dose Chemotherapy with Stem Cell Rescue
HDE	Humanitarian Device Exemption
HDGC	Hereditary Diffuse Gastric Cancer
HDL	Hardware Description Language
HDR	High Dose Radiation
HEAR	Health Enrollment Assessment Review
HEDIS	Health Plan Employer Data and Information Set
HepB-Hib	Hepatitis B and Hemophilus influenza B
HH	Home Health
HHA	Home Health Agency
HHA PPS	Home Health Agency Prospective Payment System
HHC	Home Health Care
HHC/CM	Home Health Care/Case Management
HHRG	Home Health Resource Group
HHS	Health and Human Services
HI	Health Insurance
HIAA	Health Insurance Association of America
HIC	Health Insurance Carrier
HICN	Health Insurance Claim Number
HINN	Hospital-Issued Notice Of Noncoverage

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HINT	Hearing in Noise Test
HIPAA	Health Insurance Portability and Accountability Act (of 1996)
HIPEC	Hyperthermic Intraperitoneal Chemotherapy
HIPPS	Health Insurance Prospective Payment System
HIQH	Health Insurance Query for Health Agency
HIV	Human Immunodeficiency Virus
HL7	Health Level 7
HLA	Human Leukocyte Antigen
HMAC	Hash-Based Message Authentication Code
HMO	Health Maintenance Organization
HNPCC	Hereditary Non-Polyposis Colorectal Cancer
HOPD	Hospital Outpatient Department
HPA&E	Health Program Analysis & Evaluation
HPSA	Health Professional Shortage Area
HPV	Human Papilloma Virus
HRA	Health Reimbursement Arrangement
HRG	Health Resource Group
HRS	Heart Rhythm Society
HRT	Heidelberg Retina Tomograph Hormone Replacement Therapy
HSCRC	Health Services Cost Review Commission
HSWL	Health, Safety and Work-Life
HTML	HyperText Markup Language
HTTP	HyperText Transfer (Transport) Protocol
HTTPS	Hypertext Transfer (Transport) Protocol Secure
HUAM	Home Uterine Activity Monitoring
HUD	Humanitarian Use Device
HUS	Hemolytic Uremic Syndrome
HVPT	Hyperventilation Provocation Test
IA	Information Assurance
IATO	Interim Approval to Operate
IAVA	Information Assurance Vulnerability Alert
IAVB	Information Assurance Vulnerability Bulletin
IAVM	Information Assurance Vulnerability Management
IAW	In accordance with
IBD	Inflammatory Bowel Disease
IC	Individual Consideration Integrated Circuit
ICASS	International Cooperative Administrative Support Services
ICD	Implantable Cardioverter Defibrillator
ICD-9-CM	International Classification of Diseases, 9th Revision, Clinical Modification
ICD-10-CM	International Classification of Diseases, 10th Revision, Clinical Modification

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ICD-10-PCS	International Classification of Diseases, 10th Revision, Procedure Coding System
ICF	Intermediate Care Facility
ICMP	Individual Case Management Program
ICMP-PEC	Individual Case Management Program For Persons With Extraordinary Conditions
ICN	Internal Control Number
ICSP	Individual Corporate Services Provider
ID	Identification Identifier
IDB	Intradiscal Biacuplasty
IDD	Internal or Intervertebral Disc Decompression
IDE	Investigational Device Exemption Investigational Device
IDEA	Individuals with Disabilities Education Act
IDES	Integrated Disability Evaluation System
IDET	Intradiscal Electrothermal Therapy
IDME	Indirect Medical Education
IdP	Identity Protection
IDTA	Intradiscal Thermal Annuloplasty
IE	Interface Engine Internet Explorer
IEA	Intradiscal Electrothermal Annuloplasty
IEP	Individualized Educational Program
IFC	Interim Final Rule with comment
IFR	Interim Final Rule
IFSP	Individualized Family Service Plan
IG	Implementation Guidance
IgA	Immunoglobulin A
IGCE	Independent Government Cost Estimate
IHC	Immunohistochemistry
IHI	Institute for Healthcare Improvement
IHS	Indian Health Service
IIHI	Individually Identifiable Health Information
IIP	Implantable Infusion Pump
IM	Information Management Instant Message/Messaging Intramuscular
IMRT	Intensity Modulated Radiation Therapy
IND	Investigational New Drugs
INR	International Normalized Ratio Intramuscular International Normalized Ratio
INS	Immigration and Naturalization Service
IOC	Initial Operational Capability
IOD	Interface Operational Description

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IOLs	Intraocular Lenses
IOM	Internet Only Manual
IOP	Intraocular Pressure
IORT	Intra-Operative Radiation Therapy
IP	Inpatient
IPC	Information Processing Center (outdated term, see SMC)
IPHC	Intraperitoneal Hyperthermic Chemotherapy
IPN	Intraperitoneal Nutrition
IPP	In-Person Proofing
IPPS	Inpatient Prospective Payment System
IPS	Individual Pricing Summary
IPSEC	Secure Internet Protocol
IQ	Intelligence Quotient
IQM	Internal Quality Management
IRB	Institutional Review Board
IRF	Inpatient Rehabilitation Facility
IRR	Individual Ready Reserve
IRS	Internal Revenue Service
IRTS	Integration and Runtime Specification
IS	Information System
ISN	Investigation Schedule Notice
ISO	International Standard Organization
ISP	Internet Service Provider
IT	Information Technology
ITSEC	Information Technology Security Evaluation Criteria
IV	Initialization Vector Intravenous
IVD	In Vitro Diagnostic Ischemic Vascular Disease
IVF	In Vitro Fertilization
JC	Joint Commission (formerly Joint Commission on Accreditation of Healthcare Organizations (JCAHO))
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
JCIH	Joint Committee on Infant Hearing
JCOS	Joint Chiefs of Staff
JFTR	Joint Federal Travel Regulations
JNI	Japanese National Insurance
JTF-GNO	Joint Task Force for Global Network Operations
JUSDAC	Joint Uniformed Services Dental Advisory Committee ⁷
JUSMAC	Joint Uniformed Services Medical Advisory Committee
JUSPAC	Joint Uniformed Services Personnel Advisory Committee
KB	Knowledge Base
KO	Contracting Officer

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LAA	Limited Access Authorization
LAC	Local Agency Check
LAK	Lymphokine-Activated Killer
LAN	Local Area Network
LASER	Light Amplification by Stimulated Emission of Radiation
LCD	Local Coverage Determination
LCF	Long-term Care Facility
LCIS	Lobular Carcinoma In Situ
LDL	Low Density Lipoprotein
LDLT	Living Donor Liver Transplantation
LDR	Low Dose Rate
LDT	Laboratory Developed Test
LGS	Lennox-Gastaut Syndrome
LH	Luteinizing Hormone
LLLT	Low Level Laser Therapy
LNT	Lexical Neighborhood Test
LOC	Letter of Consent
LOD	Letter of Denial/Revocation Line of Duty
LOI	Letter of Intent
LOS	Length-of-Stay
LOT	Life Orientation Test
LPN	Licensed Practical Nurse
LSIL	Low-grade Squamous Intraepithelial Lesion
LSN	Location Storage Number
LTC	Long-Term Care
LUPA	Low Utilization Payment Adjustment
LV	Left Ventricle [Ventricular]
LVEF	Left Ventricular Ejection Fraction
LVN	Licensed Vocational Nurse
LVRS	Lung Volume Reduction Surgery
LVSD	Left Ventricular Systolic Dysfunction
MAC	Maximum Allowable Charge Maximum Allowable Cost
MAC III	Mission Assurance Category III
MAID	Maximum Allowable Inpatient Day
MAP	MYH-Associated Polyposis
MB&RB	Medical Benefits and Reimbursement Branch
MBI	Molecular Breast Imaging
MCIO	Military Criminal Investigation Organization
MCS	Managed Care Support
MCSC	Managed Care Support Contractor

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MCSS	Managed Care Support Services
MCTDP	Myelomeningocele Clinical Trial Demonstration Protocol
MD	Doctor of Medicine
MDI	Mental Developmental Index Multiple Daily Injection
MDR	MHS Data Repository
MDS	Minimum Data Set
MEB	Medical Evaluation Board
MEC	Marketing and Education Committee
MEI	Medicare Economic Index
MEPS	Military Entrance Processing Station
MEPRS	Medical Expense Performance Reporting System
MESA	Microsurgical Epididymal Sperm Aspiration
MET	Microcurrent Electrical Therapy
MFCC	Marriage and Family Counseling Center
MGCRB	Medicare Geographic Classification Review Board
MGIB	Montgomery GI Bill
MH	Mental Health
MHCC	Maryland Health Care Commission
MHO	Medical Holdover
MHS	Military Health System
MHSO	Managing Health Services Organization
MHSS	Military Health Services System
MI	Myocardial Infarction
MI&L	Manpower, Installations, and Logistics
MIA	Missing In Action
MIAP	Multi-Host Internet Access Portal
MIDCAB	Minimally Invasive Direct Coronary Artery Bypass
mild®	Minimally Invasive Lumbar Decompression
MIRE	Monochromatic Infrared Energy
MLNT	Multisyllabic Lexical Neighborhood Test
MMA	Medicare Modernization Act
MMEA	Medicare and Medicaid Extenders Act (of 2010)
MMP	Medical Management Program
MMPCMHP	Maryland Multi-Payer Patient-Centered Medical Home Program
MMPP	Maryland Multi-Payer Patient
MMR	Mismatch Repair
MMSO	Military Medical Support Office
MMWR	Morbidity and Mortality Weekly Report
MNR	Medical Necessity Report
MOA	Memorandum of Agreement
MOH	Medal Of Honor

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MOMS	Management of Myelomeningocele Study
MOP	Mail Order Pharmacy
MOU	Memorandum of Understanding
MPI	Master Patient Index
MR	Magnetic Resonance Medical Review Mentally Retarded
MRA	Magnetic Resonance Angiography
MRHFP	Medicare Rural Hospital Flexibility Program
MRI	Magnetic Resonance Imaging
MRPU	Medical Retention Processing Unit
MRS	Magnetic Resonance Spectroscopy
MS	Microsoft® Multiple Sclerosis
MSA	Metropolitan Statistical Area
MSC	Military Sealift Command
MSI	Microsatellite Instability
MSIE	Microsoft® Internet Explorer
MSP	Medicare Secondary Payer
MSS	Medical Social Services
MST	Mountain Standard Time
MSUD	Maple Syrup Urine Disease
MSW	Masters of Social Work Medical Social Worker
MT	Mountain Time
MTF	Military Treatment Facility
MUE	Medically Unlikely Edits
MV	Multivisceral (transplant)
MVS	Multiple Virtual Storage
MWR	Morale, Welfare, and Recreation
MYH	mutY homolog
N/A	Not Applicable
N/D	No Default
NAC	National Agency Check
NACHA	National Automated Clearing House Association
NACI	National Agency Check Plus Written Inquiries
NACLCL	National Agency Check with Law Enforcement and Credit
NADFM	Non-Active Duty Family Member
NARA	National Archives and Records Administration
NAS	Naval Air Station Non-Availability Statement
NATO	North Atlantic Treaty Organization
NAVMED	Naval Medical (Form)

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NBCC	National Board of Certified Counselors
NCCI	National Correct Coding Initiatives
NCCN	National Comprehensive Cancer Network
NCD	National Coverage Determination
NCE	National Counselor Examination
NCF	National Conversion Factor
NCI	National Cancer Institute
NCMHCE	National Clinical Mental Health Counselor Examination
NCPAP	Nasal Continuous Positive Airway Pressure
NCPDP	National Council of Prescription Drug Program
NCQA	National Committee for Quality Assurance
NCVHS	National Committee on Vital and Health Statistics
NDAA	National Defense Authorization Act
NDC	National Drug Code
NDMS	National Disaster Medical System
NED	National Enrollment Database
NETT	National Emphysema Treatment Trial
NF	Nursing Facility
NG	National Guard
NGPL	No Government Pay List
NHLBI	National Heart, Lung and Blood Institute
NHSC	National Health Service Corps
NICHHD	National Institute of Child Health and Human Development
NIH	National Institutes of Health
NII	Networks and Information Integration
NIPRNET	Nonsecure Internet Protocol Router Network
NIS	Naval Investigative Service
NISPOM	National Industrial Security Program Operating Manual
NIST	National Institute of Standards and Technology
NLDA	Nursery and Labor/Delivery Adjustment
NLT	No Later Than
NMA	Non-Medical Attendant
NMES	Neuromuscular Electrical Stimulation
NMOP	National Mail Order Pharmacy
NMR	Nuclear Magnetic Resonance
NMT	Nurse Massage Therapist
NOAA	National Oceanic and Atmospheric Administration
NoPP	Notice of Private Practices
NOSCASTC	National Operating Standard Cost as a Share of Total Costs
NP	Nurse Practitioner
NPDB	National Practitioner Data Bank
NPI	National Provider Identifier

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NPPES	National Plan and Provider Enumeration System
NPR	Notice of Program Reimbursement
NPS	Naval Postgraduate School
NPWT	Negative Pressure Wound Therapy
NQF	National Quality Forum
NRC	Nuclear Regulatory Commission
NRS	Non-Routine [Medical] Supply
NSDSMEP	National Standards for Diabetes Self-Management Education Programs
NSF	Non-Sufficient Funds
NTIS	National Technical Information Service
NUBC	National Uniform Billing Committee
NUCC	National Uniform Claims Committee
O/ATIC	Operations/Advanced Technology Integration Center
OA	Office of Administration
OAE	Otoacoustic Emissions
OASD(HA)	Office of the Assistant Secretary of Defense (Health Affairs)
OASD (H&E)	Office of the Assistant Secretary of Defense (Health and Environment)
OASD (MI&L)	Office of the Assistant Secretary of Defense (Manpower, Installations, and Logistics)
OASIS	Outcome and Assessment Information Set
OB/GYN	Obstetrician/Gynecologist
OBRA	Omnibus Budget Reconciliation Act
OCE	Outpatient Code Editor
OCHAMPUS	Office of Civilian Health and Medical Program of the Uniformed Services
OCMO	Office of the Chief Medical Officer
OCONUS	Outside of the Continental United States
OCR	Office of Civil Rights Optical Character Recognition
OCSP	Organizational Corporate Services Provider
OCT	Optical Coherence Tomograph
OD	Optical Disk
OF	Optional Form
OGC	Office of General Counsel
OGC-AC	Office of General Counsel-Appeals, Hearings & Claims Collection Division
OGP	Other Government Program
OHI	Other Health Insurance
OHS	Office of Homeland Security
OIG	Office of Inspector General
OMB	Office of Management and Budget
OP/NSP	Operation/Non-Surgical Procedure
OPD	Outpatient Department
OPM	Office of Personnel Management

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OPPS	Outpatient Prospective Payment System
OR	Operating Room
OSA	Obstructive Sleep Apnea
OSAS	Obstructive Sleep Apnea Syndrome
OSD	Office of the Secretary of Defense
OSHA	Occupational Safety and Health Act
OSS	Office of Strategic Services
OT	Occupational Therapy (Therapist)
OTC	Over-The-Counter
OTCD	Ornithine Transcarbamylase Deficiency
OUSD	Office of the Undersecretary of Defense
OUSD (P&R)	Office of the Undersecretary of Defense (Personnel and Readiness)
P/O	Prosthetic and Orthotics
P&T	Pharmacy And Therapeutics (Committee)
PA	Physician Assistant
PACAB	Port Access Coronary Artery Bypass
PACO ₂	Partial Pressure of Carbon Dioxide
PAO ₂	Partial Pressure of Oxygen
PAK	Pancreas After Kidney (transplant)
PAP	Papanicolaou
PAT	Performance Assessment Tracking
PATH Intl	Professional Association of Therapeutic Horsemanship International
PatID	Patient Identifier
PAVM	Pulmonary Arteriovenous Malformation
PBM	Pharmacy Benefit Manager
PBT	Proton Beam Therapy
PC	Peritoneal Carcinomatosis Personal Computer Professional Component
PCA	Patient Controlled Analgesia
PCDIS	Purchased Care Detail Information System
PCI	Percutaneous Coronary Intervention
PCM	Primary Care Manager
PCMBN	PCM By Name
PCMH	Patient-Centered Medical Home
PCMRA	PCM Research Application
PCMRS	PCM Panel Reassignment (Application) PCM Reassignment System
PCO	Procurement (Procuring) Contracting Officer
PCP	Primary Care Physician Primary Care Provider
PCS	Pelvic Congestion Syndrome Permanent Change of Station

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Acronyms And Abbreviations

PCSIB	Purchased Care Systems Integration Branch
PD	Passport Division
PDA	Patent Ductus Arteriosus Personal Digital Assistant
PDD	Percutaneous (or Plasma) Disc Decompression
PDDBI	Pervasive Developmental Disorders Behavior Inventory
PDDNOS	Pervasive Developmental Disorder Not Otherwise Specified
PDF	Portable Document Format
PDI	Potentially Disqualifying Information
PDQ	Physicians's Data Query
PDR	Person Data Repository
PDS	Person Demographics Service
PDTS	Pharmacy Data Transaction System
PDX	Principal Diagnosis
PE	Physical Examination
PEC	Pharmacoeconomic Center
PEP	Partial Episode Payment
PEPR	Patient Encounter Processing and Reporting
PERMS	Provider Education and Relations Management System
PESA	Percutaneous Epididymal Sperm Aspiration
PET	Positron Emission Tomography
PFCRA	Program Fraud Civil Remedies Act
PPF	Partnership For Peace
PPPWD	Program for Persons with Disabilities
PGD	Preimplantation Genetic Diagnosis
Phen-Fen	Pondimin and Redux
PHI	Protected Health Information
PHIMT	Protected Health Information Management Tool
PHP	Partial Hospitalization Program
PHS	Public Health Service
PI	Program Integrity (Office)
PIA	Privacy Impact Assessment (Online)
PIC	Personnel Investigation Center
PIE	Pulsed Irrigation Evacuation
PII	Personally Identifiable Information
PIN	Personnel Identification Number
PIP	Personal Injury Protection Personnel Identity Protection
PIRFT	Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)
PIT	PCM Information Transfer
PIV	Personal Identity Verification
PK	Public Key

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PKE	Public Key Enabling
PKI	Public Key Infrastructure
PKU	Phenylketonuria
PLS	Preschool Language Scales
PM-DRG	Pediatric Modified-Diagnosis Related Group
PMPM	Per Member Per Month
PMR	Percutaneous Myocardial Laser Revascularization
PNET	Primitive Neuroectodermal Tumors
PNT	Policy Notification Transaction
POA	Power of Attorney Present On Admission
POA&M	Plan of Action and Milestones
POC	Pharmacy Operations Center Plan of Care Point of Contact
POL	May 1996 TRICARE/CHAMPUS Policy Manual 6010.47-M
POS	Point of Sale (Pharmacy only) Point of Service Public Official's Statement
POV	Privately Owned Vehicle
PPACA	Patient Protection and Affordable Care Act
PPC-PCMH	Physician Practice Connections Patient-Centered Medical Home
PPD	Per Patient Day
PPN	Preferred Provider Network
PPO	Preferred Provider Organization
PPP	Purchasing Power Parity
PPS	Prospective Payment System Ports, Protocols and Services
PPSM	Ports, Protocols, and Service Management
PPV	Pneumococcal Polysaccharide Vaccine
PQI	Potential Quality Indicator Potential Quality Issue
PR	Periodic Reinvestigation
PRC	Program Review Committee
PRFA	Percutaneous Radiofrequency Ablation
PRG	Peer Review Group
PRO	Peer Review Organization
ProDUR	Prospective Drug Utilization Review
PROM	Programmable Read-Only Memory
PRP	Personnel Reliability Program
PRPP	Pharmacy Redesign Pilot Project
PSA	Prime Service Area Physician Scarcity Area

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PSAB	Personnel Security Appeals Board
PSCT	Peripheral Stem Cell Transplantation
PSD	Personnel Security Division
PSF	Provider Specific File
PSG	Polysomnography
PSI	Personnel Security Investigation
PST	Pacific Standard Time
PT	Pacific Time Physical Therapist Physical Therapy Prothrombin Time
PTA	Pancreas Transplant Alone Percutaneous Transluminal Angioplasty
PTC	Processed To Completion
PTCA	Percutaneous Transluminal Coronary Angioplasty
PTK	Phototherapeutic Keratectomy
PTNS	Posterior Tibial Nerve Stimulation
PTSD	Post-Traumatic Stress Disorder
PVCs	Premature Ventricular Contractions
QA	Quality Assurance
QC	Quality Control
QI	Quality Improvement Quality Issue
QII	Quality Improvement Initiative
QIO	Quality Improvement Organization
QIP	Quality Improvement Program
QLE	Qualifying Life Event
QM	Quality Management
QUIG	Quality Indicator Group
RA	Radiofrequency Annuloplasty Remittance Advice
RADDP	Remote Active Duty Dental Program
RAM	Random Access Memory
RAP	Request for Anticipated Payment
RAPIDS	Real-Time Automated Personnel Identification System
RARC	Remittance Advice Remark Code
RC	Reserve Component
RCC	Recurring Credit/Debit Charge Renal Cell Carcinoma
RCCPDS	Reserve Component Common Personnel Data System
RCN	Recoupment Case Number Refund Control Number
RCS	Report Control Symbol

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Acronyms And Abbreviations

SPC	Special Processing Code
SPECT	Single Photon Emission Computed Tomography
SPK	Simultaneous Pancreas Kidney (transplant)
SPOC	Service Point of Contact
SPR	SECRET Periodic Reinvestigation
SQL	Structured Query Language
SRE	Serious Reportable Event
SSA	Social Security Act Social Security Administration
SSAA	Social Security Authorization Agreement
SSAN	Social Security Administration Number
SSBI	Single-Scope Background Investigation
SSDI	Social Security Disability Insurance
SSL	Secure Socket Layer
SSM	Site Security Manager
SSN	Social Security Number
SSO	Short-Stay Outlier
ST	Speech Therapy
STF	Specialized Treatment Facility
STS	Specialized Treatment Services
STSF	Specialized Treatment Service Facility
SUBID	Sub-Identifier
SUDRF	Substance Use Disorder Rehabilitation Facility
SVO	SIT Validation Office
SVT	Supraventricular Tachycardia
SWLS	Satisfaction With Life Scale
T-3	TRICARE Third Generation
TAD	Temporary Additional Duty
TAFIM	Technical Architecture Framework for Information Management
TAH	Total Artificial Heart
TAMP	Transitional Assistance Management Program
TAO	TRICARE Alaska Office TRICARE Area Office
TAR	Total Ankle Replacement
TARO	TRICARE Alaska Regional Office
TAVR	Transcatheter Aortic Valve Replacement
TB	Tuberculosis
TBD	To Be Determined
TBE	Tick Borne Encephalitis
TBI	Traumatic Brain Injury
TC	Technical Component
TCMHC	TRICARE Certified Mental Health Counselor

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Acronyms And Abbreviations

TCP/IP	Transmission Control Protocol/Internet Protocol
TCSRC	Transitional Care for Service-Related Conditions
TDD	Targeted Disc Decompression
TDEFIC	TRICARE Dual Eligible Fiscal Intermediary Contract
TDP	TRICARE Dental Program/Plan
TDR	Total Disc Replacement
TDY	Temporary Duty
TED	TRICARE Encounter Data
TEE	Transesophageal Echocardiograph [Echocardiography]
TEFRA	Tax Equity and Fiscal Responsibility Act
TEOB	TRICARE Explanation of Benefits
TEPRC	TRICARE Encounter Pricing (Record)
TEPRV	TRICARE Encounter Provider (Record)
TET	Tubal Embryo Transfer
TF	Transfer Factor
TFL	TRICARE For Life
TFMDP	TRICARE (Active Duty) Family Member Dental Plan
TGRO	TRICARE Global Remote Overseas
TGROHC	TGRO Host Country
TIFF	Tagged Imaged File Format
TIL	Tumor-Infiltrating Lymphocytes
TIMPO	Tri-Service Information Management Program Office
TIN	Taxpayer Identification Number
TIP	Thermal Intradiscal Procedure
TIPS	Transjugular Intrahepatic Portosystemic Shunt
TIS	TRICARE Information Service
TLAC	TRICARE Latin America/Canada
TLC	Total Lung Capacity
TMA	TRICARE Management Activity
TMA-A	TRICARE Management Activity - Aurora
TMAC	TRICARE Maximum Allowable Charge
TMCPA	Temporary Military Contingency Payment Adjustment
TMH	Telemental Health
TMI&S	Technology Management Integration & Standards
TMOP	TRICARE Mail Order Pharmacy
TMR	Transmyocardial Revascularization
TMS	Transcranial Magnetic Stimulation
TNEX	TRICARE Next Generation (MHS Systems)
TNP	Topical Negative Pressure
TOB	Type of Bill
TOE	Target of Evaluation
TOL	TRICARE Online

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