



# Medical Necessity Tool for Molecular Diagnostic Tests

**MolDX: Molecular Diagnostic  
Tests (MDT): L35025**

# Billing and Coding: MolDX

## Molecular Diagnostic Tests (MDT) — A57526

### Article guidance

The information in this article contains billing, coding, or other guidelines that complement the Local Coverage Determination (LCD) for MolDX: Molecular Diagnostic Tests (MDT) L35160.

To report a Molecular Diagnostic Test service, please submit the following claim information:

- Select appropriate CPT® code
- Enter 1 unit of service (UOS)
- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part B claim field/types:
  - Loop 2400 or SV101-7 for the 5010A1 837P
  - Item 19 for paper claim
- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part A claim field/types:
  - Line SV202-7 for 837I electronic claim
  - Block 80 for the UB04 claim form

### Applicable test codes

81105	81173	81194	81223	81244	81226	81247	81310	81331	81352
81106	81174	81200	81224	81245	81227	81248	81311	81332	81353
81107	81175	81201	81225	81246	81228	81249	81312	81333	81355
81108	81176	81202	81226	81247	81229	81250	81313	81334	81357
81109	81177	81203	81227	81248	81230	81251	81314	81335	81360
81110	81178	81204	81228	81249	81231	81252	81315	81336	81361
81111	81179	81205	81229	81250	81232	81253	81316	81337	81362
81112	81180	81206	81230	81251	81233	81296	81317	81338	81363
81120	81181	81207	81231	81252	81234	81297	81318	81339	81364
81121	81182	81208	81232	81253	81235	81298	81319	81340	81374
81161	81183	81209	81233	81215	81236	81299	81320	81341	81377
81162	81184	81210	81234	81216	81237	81300	81321	81342	81381
81163	81185	81212	81235	81217	81238	81301	81322	81343	81383
81164	81186	81215	81236	81218	81239	81302	81323	81344	81400
81165	81187	81216	81237	81219	81240	81303	81324	81345	81401
81166	81188	81217	81238	81220	81241	81304	81325	81346	81402
81167	81189	81218	81239	81221	81242	81305	81326	81347	81403
81168	81190	81219	81240	81222	81243	81306	81327	81348	81404
81170	81191	81220	81241	81223	81244	81307	81328	81349	81405
81171	81192	81221	81242	81224	81245	81308	81329	81350	81406
81172	81193	81222	81243	81225	81246	81309	81330	81351	81407

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## Molecular Diagnostic Tests (MDT) — A57526

### Applicable test codes (continued)

81408	81451	0016M	0074U	0157U	0200U	0260U	0313U	0371U
81410	81455	0017M	0075U	0158U	0201U	0262U	0314U	0372U
81411	81456	0001U	0076U	0159U	0203U	0264U	0315U	0373U
81412	81460	0005U	0078U	0160U	0204U	0265U	0318U	0374U
81413	81465	0016U	0079U	0161U	0205U	0266U	0319U	0378U
81414	81470	0017U	0084U	0162U	0209U	0267U	0320U	0379U
81415	81471	0018U	0087U	0169U	0211U	0268U	0323U	0380U
81416	81479	0019U	0088U	0170U	0212U	0269U	0326U	0386U
81417	81493	0022U	0089U	0171U	0213U	0270U	0327U	0388U
81418	81504	0023U	0090U	0172U	0214U	0271U	0329U	0389U
81419	81507	0026U	0091U	0173U	0215U	0272U	0330U	0391U
81420	81518	0027U	0094U	0175U	0216U	0273U	0331U	0392U
81422	81519	0029U	0101U	0177U	0217U	0274U	0332U	0395U
81425	81520	0030U	0102U	0179U	0218U	0276U	0333U	0396U
81426	81521	0031U	0103U	0180U	0221U	0277U	0334U	0397U
81427	81522	0032U	0111U	0181U	0222U	0278U	0335U	0398U
81430	81523	0033U	0113U	0182U	0228U	0282U	0336U	0400U
81431	81525	0034U	0114U	0183U	0229U	0285U	0339U	0401U
81432	81528	0036U	0118U	0184U	0230U	0286U	0340U	
81433	81529	0037U	0120U	0185U	0231U	0287U	0341U	
81434	81540	0040U	0129U	0186U	0232U	0288U	0343U	
81435	81541	0045U	0130U	0187U	0233U	0289U	0345U	
81436	81542	0046U	0131U	0188U	0234U	0290U	0347U	
81437	81546	0047U	0132U	0189U	0235U	0291U	0348U	
81438	81551	0048U	0133U	0190U	0236U	0292U	0349U	
81439	81552	0049U	0134U	0191U	0237U	0293U	0350U	
81440	81554	0050U	0135U	0192U	0238U	0294U	0355U	
81441	81595	0055U	0136U	0193U	0239U	0296U	0356U	
81442	0004M	0060U	0137U	0194U	0242U	0297U	0362U	
81443	0006M	0069U	0138U	0195U	0244U	0298U	0363U	
81445	0007M	0070U	0153U	0196U	0245U	0299U	0364U	
81448	0011M	0071U	0154U	0197U	0246U	0300U	0368U	
81449	0012M	0072U	0155U	0198U	0250U	0306U	0369U	
81450	0013M	0073U	0156U	0199U	0258U	0307U	0370U	

# Billing and Coding: MolDX

## Molecular Diagnostic Tests (MDT) — A57526

### Group 2 (24 Codes)

Codes 81599 and 87999 require a Z-Code for DNA/RNA based testing. The remaining molecular microbiology tests, a Z-Code is only required for non-FDA approved/cleared services/tests.

81513	87483	87631	87637	0115U	0240U
81514	87505	87632	87800	0202U	0241U
81599	87506	87633	87801	0223U	0352U
87154	87507	87636	87999	0225U	0353U

# Billing and Coding: MoIDX

## Molecular Diagnostic Tests (MDT) — L35160

### Coverage indications, limitations, and/or medical necessity

#### This coverage policy provides the following information:

- Defines tests required to register for a unique identifier
- Defines tests required to submit a complete technical assessment (TA) for coverage determination
- Defines the payment rules applied to covered tests that are not reported with specific codes from a code set recognized in 45 CFR §162.1002(a)(5), and termed “HIPAA compliant code sets” throughout the remainder of this LCD
- Lists specific covered tests that have completed the registration and TA process and meet Medicare’s reasonable and necessary criteria for coverage.

#### Tests evaluated through the application process and/or technical assessment will be reviewed to answer the following questions:

- Is the test performed in the absence of clinical signs and symptoms of disease?
- Will the test results provide the clinician with information that will improve patient outcomes and/or change physician care and treatment of the patient?
  - Will the test results confirm a diagnosis or known information?
  - Is the test performed to determine risk for developing a disease or condition?
  - Will risk assessment change management of the patient?
  - Is there a diagnosis specific indication to perform the test?
  - Is the test performed to measure the quality of a process or for Quality Control/Quality Assurance (QC/QA), i.e., a test to ensure a tissue specimen matches the patient?

# Billing and Coding: MoIDX

## FDA-approved EGFR tests — A54422

### Applicable CPT code

81235

### Article guidance

Two tests have met the FDA criteria for EGFR genetic testing:

#### 1. EFFECTIVE 6/01/16

**cobas® EGFR Mutation Test** is a real-time PCR test for the qualitative detection of defined mutations of the epidermal growth factor receptor (EGFR) gene in non-small cell lung cancer (NSCLC) patients. Defined EGFR mutations are detected using DNA isolated from formalin-fixed paraffin-embedded tumor tissue (FFPET) or circulating-free tumor DNA (cfDNA) from plasma derived from EDTA anti-coagulated peripheral whole blood.

The test is indicated as a companion diagnostic to aid in selecting NSCLC patients for treatment with the targeted therapies listed in the Table below in accordance with the approved therapeutic product labeling:

Patients with positive cobas EGFR Mutation Test v2 test results using plasma specimens for the presence of EGFR exon 19 deletions or L858R mutations are eligible for treatment with TARCEVA® (erlotinib). Patients who are negative for these mutations by this test should be reflexed to routine biopsy and testing for EGFR mutations with the FFPET sample type.

#### 2. EFFECTIVE 7/12/13

**therascreen® EGFR RGQ** PCR kit for the detection of the epidermal growth factor receptor (EGFR) gene for non-small cell lung cancer (NSCLC) tumor tissue to help select patients with NSCLC for whom GILOTRIF™ (afatinib), an EGFR tyrosine kinase inhibitor (TKI), is indicated.

To report an FDA approved or laboratory developed test (LDT) EGFR test kit service, please submit the following claim information:

- CPT® code 81235
- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part B claim field/types:
  - Loop 2400 or SV101-7 for the 5010A1 837P
  - Item 19 for paper claim
- Enter the appropriate DEX Z-Code identifier adjacent to the CPT code in the comment/narrative field for the following Part A claim field/types:
  - Line SV202-7 for 837I electronic claim
  - Block 80 for the UB04 claim form

### ICD-10-CM codes that support medical necessity

C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung

# Billing and Coding: MolDX

## FDA-approved KRAS tests — A54498

### Applicable CPT Codes

81275

81479

81276

#### Article guidance

The following coding and billing guidance is to be used with its associated Local coverage determination.

#### Two tests have met the Food and Drug Administration (FDA) criteria for KRAS genetic testing:

##### 1. EFFECTIVE 7/06/2012

**therascreen® KRAS** to detect 7 somatic mutations in the human KRAS oncogene was developed to aid in the identification of colorectal cancer (CRC) patients for treatment with Erbitux® (cetuximab).

##### 2. EFFECTIVE 5/7/2015

**cobas® KRAS** to detect mutations in codons 12 and 13 of the KRAS gene was developed to aid in identification of CRC patients for treatment with Erbitux® (cetuximab) or Vectibix® (panitumumab).

To report an FDA approved or laboratory developed test (LDT) KRAS, codon 12 and 13 test kit service, please submit the following claim information:

- Enter CPT® 81275
- Enter the appropriate DEX Z-Code™ Identifier in the comment/narrative field for the following Part B claim field/types:
  - Loop 2400 or SV101-7 for the 5010A1 837P
  - Item 19 for paper claim
- Enter the appropriate DEX Z-Code Identifier in the comment/narrative field for the following Part A claim field/types:
  - Line SV202-7 for the 837I electronic claim
  - Block 80 for the UB04 claim form
- Select the appropriate ICD-10-CM diagnosis.

#### ICD-10-CM codes that support medical necessity

C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
C77.3	Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.1	Secondary malignant neoplasm of mediastinum
C78.2	Secondary malignant neoplasm of pleura
C78.39	Secondary malignant neoplasm of other respiratory organs
C78.4	Secondary malignant neoplasm of small intestine
C78.5	Secondary malignant neoplasm of large intestine and rectum
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C78.80	Secondary malignant neoplasm of unspecified digestive organ

Codes continued on next page »

# Billing and Coding: MoDX

## FDA-approved KRAS tests — A54498

### ICD-10-CM codes that support medical necessity (continued)

C78.89	Secondary malignant neoplasm of other digestive organs
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C79.11	Secondary malignant neoplasm of bladder
C79.19	Secondary malignant neoplasm of other urinary organs
C79.2	Secondary malignant neoplasm of skin
C79.31	Secondary malignant neoplasm of brain
C79.32	Secondary malignant neoplasm of cerebral meninges
C79.49	Secondary malignant neoplasm of other parts of nervous system
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.61	Secondary malignant neoplasm of right ovary
C79.62	Secondary malignant neoplasm of left ovary
C79.63	Secondary malignant neoplasm of bilateral ovaries
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C79.81	Secondary malignant neoplasm of breast
C79.82	Secondary malignant neoplasm of genital organs
C79.89	Secondary malignant neoplasm of other specified sites



# Billing and Coding: MoIDX

## FDA-Approved BRAF Tests (A54418)

### Applicable CPT Code: 81210

81275

#### Article guidance

The following coding and billing guidance is to be used with its associated Local coverage determination.

**Two tests have met the Food and Drug Administration (FDA) criteria for KRAS genetic testing:**

#### 1. EFFECTIVE 09/07/2012

**cobas® 4800 BRAF V600** to detect the presence of a mutation in the BRAF gene in melanoma cells and determine if a patient is eligible for Zelboraf™ (vemurafenib), a treatment indicated for a melanoma that cannot be surgically excised or has spread in the body.

#### 2. EFFECTIVE 5/29/13

**ThxID™ BRAF V600/K** to detect the BRAF V600E and V600K mutations in selecting melanoma patients whose tumors carry the BRAF V600E mutation for treatment with dabrafenib [Tafinlar®] and as an aid in selecting melanoma patients whose tumors carry the BRAF V600E or V600K mutation for treatment with trametinib [Mekinist™].

To report an FDA approved or laboratory developed test (LDT) BRAF V600 test kit service, submit the following claim information:

- CPT® code 81210
- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part B claim field/types:
  - Loop 2400 or SV101-7 for the 5010A1 837P
  - Box 19 for paper claim
- Enter the appropriate DEX Z-Code™ identifier adjacent to the CPT code in the comment/narrative field for the following Part A claim field/types:
  - Line SV202-7 for 8371 electronic claim
  - Block 80 for the UB04 claim form
- Select the appropriate ICD-10-CM diagnosis

#### ICD-10-CM codes that support medical necessity

C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C43.0	Malignant melanoma of lip
C43.111	Malignant melanoma of right upper eyelid, including canthus

Codes continued on next page »

# Billing and Coding: MoIDX

## FDA-Approved BRAF Tests (A54418)

### ICD-10-CM codes that support medical necessity (continued)

C43.112	Malignant melanoma of right lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C91.40	Hairy cell leukemia not having achieved remission
C91.42	Hairy cell leukemia, in relapse

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### Disclaimers

This resource is intended to aid physicians and qualified office staff to identify diagnosis codes (ICD-10 codes) that support medical necessity and is not intended as a substitute for independent medical decision making.

The ICD-10 codes indicated in this guide are based on AMA guidelines and are common codes currently listed as medically supportive, and therefore covered, under Medicare's limited coverage policy.

Services must meet specific medical necessity requirements contained in any applicable statutes, regulations and manuals, as well as criteria defined by National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs). For every service billed, you must indicate the specific sign, symptom, or patient complaint that makes the service reasonable and necessary.

The accuracy and relevance of this information should be verified by reference to the current version of the Coding Manual of the American Medical Association (AMA) and by visiting the Centers for Medicare and Medicaid Services (CMS) Web site at [www.cms.hhs.gov/home/medicare.asp](http://www.cms.hhs.gov/home/medicare.asp). This information is not intended to suggest reimbursement or provide direction for coding and was obtained online at [www.cms.hhs.gov/home/medicare.asp](http://www.cms.hhs.gov/home/medicare.asp). Codes listed are effective as of February 1, 2019. To ensure the accurate and appropriate use of the information, it is recommended that the primary sources (i.e. CMS, MAC publications, notices, and advice) should be consulted periodically since information is often affected by ongoing developments.

All CPT codes provided above are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.



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