

# Article - Billing and Coding: MolDX: FDA-Approved BRAF Tests (A54420)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02101 - MAC A	J - F	Alaska
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02102 - MAC B	J - F	Alaska
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02201 - MAC A	J - F	Idaho
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02202 - MAC B	J - F	Idaho
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02301 - MAC A	J - F	Oregon
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02302 - MAC B	J - F	Oregon
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02401 - MAC A	J - F	Washington
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	02402 - MAC B	J - F	Washington
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03101 - MAC A	J - F	Arizona
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03102 - MAC B	J - F	Arizona
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03201 - MAC A	J - F	Montana
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03202 - MAC B	J - F	Montana
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03301 - MAC A	J - F	North Dakota
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03302 - MAC B	J - F	North Dakota
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03401 - MAC A	J - F	South Dakota
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03402 - MAC B	J - F	South Dakota
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03501 - MAC A	J - F	Utah
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03502 - MAC B	J - F	Utah
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03601 - MAC A	J - F	Wyoming
<a href="#">Noridian Healthcare Solutions, LLC</a>	A and B MAC	03602 - MAC B	J - F	Wyoming

## Article Information

### General Information

**Article ID**  
A54420

**Article Title**

**AMA CPT / ADA CDT / AHA NUBC Copyright Statement**

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## Article Type

Billing and Coding

## Original Effective Date

10/01/2015

## Revision Effective Date

03/03/2022

## Revision Ending Date

N/A

## Retirement Date

N/A

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## CMS National Coverage Policy

Title XVIII of the Social Security Act, §1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

## Article Guidance

### Article Text

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

1. Effective 09/07/2012

**cobas<sup>®</sup> 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<sup>™</sup>(vemurafenib), a treatment indicated for a melanoma that cannot be surgically excised or has spread in the body.

2. Effective 5/29/13

**ThxID<sup>™</sup> 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<sup>®</sup>] and as an aid in selecting melanoma patients whose tumors carry the BRAF V600E or V600K mutation for treatment with trametinib [Mekinist<sup>™</sup>].

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
  - 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
- Select the appropriate ICD-10-CM diagnosis.

**NOTE:** MolDX will apply NPI to ID editing on FDA approved BRAF kits. All labs that submit claims for a BRAF V600 test kit **MUST** register the test and confirm the **UNMODIFIED** use of the kit. Tests may be registered on the DEX™ Diagnostics Exchange: <https://app.dexzcodes.com/login>.

This article reflects the FDA-approved indications on article creation date. MolDX will allow future FDA approved and amended indications for these tests.

## Coding Information

### CPT/HCPCS Codes

#### Group 1 Paragraph:

N/A

#### Group 1 Codes: (1 Code)

CODE	DESCRIPTION
81210	BRAF (B-RAF PROTO-ONCOGENE, SERINE/THREONINE KINASE) (EG, COLON CANCER, MELANOMA), GENE ANALYSIS, V600 VARIANT(S)

### CPT/HCPCS Modifiers

#### Group 1 Paragraph:

N/A

#### Group 1 Codes:

N/A

### ICD-10-CM Codes that Support Medical Necessity

#### Group 1 Paragraph:

N/A

#### Group 1 Codes: (38 Codes)

CODE	DESCRIPTION
C43.0	Malignant melanoma of lip
C43.111	Malignant melanoma of right upper eyelid, including canthus
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
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C79.2	Secondary malignant neoplasm of skin
D03.0	Melanoma in situ of lip
D03.111	Melanoma in situ of right upper eyelid, including canthus
D03.112	Melanoma in situ of right lower eyelid, including canthus
D03.121	Melanoma in situ of left upper eyelid, including canthus
D03.122	Melanoma in situ of left lower eyelid, including canthus
D03.21	Melanoma in situ of right ear and external auricular canal
D03.22	Melanoma in situ of left ear and external auricular canal
D03.39	Melanoma in situ of other parts of face
D03.4	Melanoma in situ of scalp and neck
D03.51	Melanoma in situ of anal skin
D03.52	Melanoma in situ of breast (skin) (soft tissue)
D03.59	Melanoma in situ of other part of trunk

CODE	DESCRIPTION
D03.61	Melanoma in situ of right upper limb, including shoulder
D03.62	Melanoma in situ of left upper limb, including shoulder
D03.71	Melanoma in situ of right lower limb, including hip
D03.72	Melanoma in situ of left lower limb, including hip
D03.8	Melanoma in situ of other sites
D03.9	Melanoma in situ, unspecified

**ICD-10-CM Codes that DO NOT Support Medical Necessity**

**Group 1 Paragraph:**

N/A

**Group 1 Codes:**

N/A

**ICD-10-PCS Codes**

**Group 1 Paragraph:**

N/A

**Group 1 Codes:**

N/A

**Additional ICD-10 Information**

N/A

**Bill Type Codes**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

**Revenue Codes**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report

this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

### Other Coding Information

#### Group 1 Paragraph:

N/A

#### Group 1 Codes:

N/A

## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
03/03/2022	R5	Under CMS National Coverage Policy added regulation, Title XVIII of the Social Security Act, §1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim. Under Article Text, revised sentence to read, "To report an FDA approved or laboratory developed test (LDT) BRAF V600 test kit service, please submit the following claim information. " This revision is effective on 03/03/2022.
11/01/2019	R4	11/01/2019: This article is being revised in order to adhere to CMS requirements per Chapter 13, Section 13.5.1 of the Program Integrity Manual, to remove all coding from LCDs and incorporate into related Billing and Coding Articles.  Under <b>CPT/HCPCS Codes Group 1: Codes</b> added CPT <sup>®</sup> code 81210.  CPT <sup>®</sup> was inserted throughout the article where applicable
11/01/2019	R3	As required by CR 10901 article is converted to a formal billing and coding type article. There is no change in coverage.
10/01/2018	R2	Article is revised to add the following ICD-10 codes per the 2019 Annual Update: C43.111, C43.112, C43.121, C43.122, D03.111, D03.112, D03.121, D03.122.  The following codes are deleted:C43.11, C43.12, D03.11, D03.12.

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
12/14/2017	R1	<p>Article is updated for consistency with the MolDX Contractor: to remove modifier 22 instructions; added Part A claim filing instructions and correct reference to and website address for DEX™ Diagnostics Exchange.</p> <p>Article number A54419 for Jurisdiction F Part A (JFA) was retired on January 29, 2018, and combined into Jurisdiction F Part B (JFB) article number A54420. JFA and JFB contract numbers will have the same final MCD article number.</p>

## Associated Documents

### Related Local Coverage Documents

#### LCDs

[L36256 - MolDX: Molecular Diagnostic Tests \(MDT\)](#)

### Related National Coverage Documents

N/A

### Statutory Requirements URLs

N/A

### Rules and Regulations URLs

N/A

### CMS Manual Explanations URLs

N/A

### Other URLs

N/A

### Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
02/28/2022	03/03/2022 - N/A	Currently in Effect (This Version)
12/04/2019	11/01/2019 - 03/02/2022	Superseded
10/16/2019	11/01/2019 - N/A	Superseded

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## Keywords

N/A