

# Local Coverage Article: MoIDX: FDA-Approved BRAF Tests (A54018)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Palmetto GBA	A and B MAC	10111 - MAC A	J - J	Alabama
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10211 - MAC A	J - J	Georgia
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10311 - MAC A	J - J	Tennessee
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11201 - MAC A	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11301 - MAC A	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11401 - MAC A	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11501 - MAC A	J - M	North Carolina
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

## Article Information

### General Information

**Article ID**

A54018

**Original Effective Date**

10/01/2015

**Article Title**

MoIDX: FDA-Approved BRAF Tests

**Revision Effective Date**

10/01/2018

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

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**Revision Ending Date**

N/A

**Retirement Date**

N/A

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## Article Guidance

### Article Text:

Two tests have met the FDA criteria for BRAF 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 BRAF V600 test kit service, please 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 837I electronic claim
  - Block 80 for the UB04 claim form
- Select the appropriate ICD-10-CM diagnosis.

NOTE: MoIDX 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 McKesson Diagnostics Exchange™: <https://app.mckessondex.com/#/login>

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

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## Coding Information

### 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 policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy 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 policy, 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 policy should be assumed to apply equally to all Revenue Codes.

N/A

### CPT/HCPCS Codes

N/A

## ICD-10 Codes that are Covered

### Group 1 Paragraph:

N/A

### Group 1 Codes:

ICD-10 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

ICD-10 CODE	DESCRIPTION
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
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 Codes that are Not Covered

N/A

## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
10/01/2018	R10	Added the following ICD-10 Codes to <b>Covered ICD-10 Codes Group 1: Codes</b> C43.111, C43.112, C43.121, C43.122, D03.111, D03.112, D03.121, D03.122. The following codes were deleted from <b>Covered ICD-10 Codes Group 1: Codes:</b> C43.11, C43.12, D03.11, D03.12. This update is result of the 2018 Annual ICD-10 Updates.
02/26/2018	R9	The Jurisdiction "J" Part B Contracts for Alabama (10112), Georgia (10212) and Tennessee (10312) are now being serviced by Palmetto GBA. The notice period for this article begins on 12/14/17 and ends on 02/25/18. Effective 02/26/18, these three contract numbers are being added to this article. No coverage, coding or other substantive changes (beyond the addition of the 3 Part B contract numbers) have been completed in this revision.
01/29/2018	R8	The Jurisdiction "J" Part A Contracts for Alabama (10111), Georgia (10211) and Tennessee (10311) are now being serviced by Palmetto GBA. The notice period for

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		this article begins on 12/14/17 and ends on 01/28/18. Effective 01/29/18, these three contract numbers are being added to this article. No coverage, coding or other substantive changes (beyond the addition of the 3 Part A contract numbers) have been completed in this revision.
12/14/2017	R7	Removed modifier 22 references.
01/19/2017	R6	Annual review completed, updated article with part a clm submission info and added new trademark for McKesson Z-code ID.
02/24/2016	R5	Added statement that MoIDX will approve all future FDA-approved indications to the end of article.
01/14/2016	R4	Annual review completed, no changes needed.
12/10/2015	R3	Reverted back to SV101-7 and for trade mark purposes, replaced ID/MoIDX identifier/Z-Code to read Z-Code™ Identifier
11/19/2015	R2	Replaced SV101-7 with MID, and removed 2014 coding references
10/01/2015	R1	Removed ICD-9 and ICD-10 codes from the article text.

## Associated Documents

### Related Local Coverage Document(s)

LCD(s)

L35025 - MoIDX: Molecular Diagnostic Tests (MDT)

### Related National Coverage Document(s)

N/A

### Statutory Requirements URL(s)

N/A

### Rules and Regulations URL(s)

N/A

### CMS Manual Explanations URL(s)

N/A

### Other URL(s)

N/A

### Public Version(s)

Updated on 08/30/2018 with effective dates 10/01/2018 - N/A

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

# Keywords

N/A