

Local Coverage Article: Billing and Coding: MoIDX: PIK3CA Gene Tests (A53558)

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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

A53558

Original Effective Date

10/01/2015

Article Title

Billing and Coding: MoIDX: PIK3CA Gene Tests

Revision Effective Date

04/01/2020

Article Type

Billing and Coding

Revision Ending Date

N/A

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CPT codes, descriptions and other data only are

Retirement Date

N/A

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CMS National Coverage Policy

N/A

Article Guidance

Article Text:

Effective for dates of service on and after May 24, 2019.

The U.S. Food and Drug Administration (FDA) has approved Piqray (alpelisib) tablets, to be used in combination with the (FDA)-approved endocrine therapy fulvestrant, to treat postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer (as detected by an FDA-approved test) following progression on or after an endocrine-based regimen.

To submit a claim for PIK3CA targeted gene sequencing service, please submit the following claim information:

- Enter the appropriate CPT® code
- Select the appropriate diagnosis for the patient
- Enter 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 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

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

N/A

Group 1 Codes:

| CODE | DESCRIPTION |
|-------|---|
| 81309 | PIK3CA (PHOSPHATIDYLINOSITOL-4, 5-BIPHOSPHATE 3-KINASE, CATALYTIC SUBUNIT ALPHA) (EG, COLORECTAL AND BREAST CANCER) GENE ANALYSIS, TARGETED SEQUENCE ANALYSIS (EG, EXONS 7, 9, 20) |
| 0155U | ONCOLOGY (BREAST CANCER), DNA, PIK3CA (PHOSPHATIDYLINOSITOL-4,5-BIPHOSPHATE 3KINASE, CATALYTIC SUBUNIT ALPHA) (EG, BREAST CANCER) GENE ANALYSIS (IE, P.C420R, P.E542K, P.E545A, P.E545D [G.1635G>T ONLY], P.E545G, P.E545K, P.Q546E, P.Q546R, P.H1047L, P.H1047R, P.H1047Y), UTILIZING FORMALIN-FIXED PARAFFINEMBEDDED BREAST TUMOR TISSUE, REPORTED AS PIK3CA GENE MUTATION STATUS |

CPT/HCPCS Modifiers

N/A

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

The code Z17.0 should be on the claim in addition to one of the following:

Group 1 Codes:

| ICD-10 CODE | DESCRIPTION |
|-------------|---|
| C50.011 | Malignant neoplasm of nipple and areola, right female breast |
| C50.012 | Malignant neoplasm of nipple and areola, left female breast |
| C50.019 | Malignant neoplasm of nipple and areola, unspecified female breast |
| C50.021 | Malignant neoplasm of nipple and areola, right male breast |
| C50.022 | Malignant neoplasm of nipple and areola, left male breast |
| C50.029 | Malignant neoplasm of nipple and areola, unspecified male breast |
| C50.111 | Malignant neoplasm of central portion of right female breast |
| C50.112 | Malignant neoplasm of central portion of left female breast |
| C50.119 | Malignant neoplasm of central portion of unspecified female breast |
| C50.121 | Malignant neoplasm of central portion of right male breast |
| C50.122 | Malignant neoplasm of central portion of left male breast |
| C50.129 | Malignant neoplasm of central portion of unspecified male breast |
| C50.211 | Malignant neoplasm of upper-inner quadrant of right female breast |
| C50.212 | Malignant neoplasm of upper-inner quadrant of left female breast |
| C50.219 | Malignant neoplasm of upper-inner quadrant of unspecified female breast |
| C50.221 | Malignant neoplasm of upper-inner quadrant of right male breast |
| C50.222 | Malignant neoplasm of upper-inner quadrant of left male breast |
| C50.229 | Malignant neoplasm of upper-inner quadrant of unspecified male breast |
| C50.311 | Malignant neoplasm of lower-inner quadrant of right female breast |
| C50.312 | Malignant neoplasm of lower-inner quadrant of left female breast |
| C50.319 | Malignant neoplasm of lower-inner quadrant of unspecified female breast |
| C50.321 | Malignant neoplasm of lower-inner quadrant of right male breast |
| C50.322 | Malignant neoplasm of lower-inner quadrant of left male breast |
| C50.329 | Malignant neoplasm of lower-inner quadrant of unspecified male breast |
| C50.411 | Malignant neoplasm of upper-outer quadrant of right female breast |
| C50.412 | Malignant neoplasm of upper-outer quadrant of left female breast |
| C50.419 | Malignant neoplasm of upper-outer quadrant of unspecified female breast |
| C50.421 | Malignant neoplasm of upper-outer quadrant of right male breast |
| C50.422 | Malignant neoplasm of upper-outer quadrant of left male breast |
| C50.429 | Malignant neoplasm of upper-outer quadrant of unspecified male breast |
| C50.511 | Malignant neoplasm of lower-outer quadrant of right female breast |
| C50.512 | Malignant neoplasm of lower-outer quadrant of left female breast |

| ICD-10 CODE | DESCRIPTION |
|-------------|---|
| C50.519 | Malignant neoplasm of lower-outer quadrant of unspecified female breast |
| C50.521 | Malignant neoplasm of lower-outer quadrant of right male breast |
| C50.522 | Malignant neoplasm of lower-outer quadrant of left male breast |
| C50.529 | Malignant neoplasm of lower-outer quadrant of unspecified male breast |
| C50.611 | Malignant neoplasm of axillary tail of right female breast |
| C50.612 | Malignant neoplasm of axillary tail of left female breast |
| C50.619 | Malignant neoplasm of axillary tail of unspecified female breast |
| C50.621 | Malignant neoplasm of axillary tail of right male breast |
| C50.622 | Malignant neoplasm of axillary tail of left male breast |
| C50.629 | Malignant neoplasm of axillary tail of unspecified male breast |
| C50.811 | Malignant neoplasm of overlapping sites of right female breast |
| C50.812 | Malignant neoplasm of overlapping sites of left female breast |
| C50.819 | Malignant neoplasm of overlapping sites of unspecified female breast |
| C50.821 | Malignant neoplasm of overlapping sites of right male breast |
| C50.822 | Malignant neoplasm of overlapping sites of left male breast |
| C50.829 | Malignant neoplasm of overlapping sites of unspecified male breast |
| C50.911 | Malignant neoplasm of unspecified site of right female breast |
| C50.912 | Malignant neoplasm of unspecified site of left female breast |
| C50.919 | Malignant neoplasm of unspecified site of unspecified female breast |
| C50.921 | Malignant neoplasm of unspecified site of right male breast |
| C50.922 | Malignant neoplasm of unspecified site of left male breast |
| C50.929 | Malignant neoplasm of unspecified site of unspecified male breast |
| Z17.0 | Estrogen receptor positive status [ER+] |

ICD-10 Codes that DO NOT Support Medical Necessity

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 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.

| CODE | DESCRIPTION |
|------|---|
| 014x | Hospital - Laboratory Services Provided to Non-patients |

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

Other Coding Information

N/A

Revision History Information

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION |
|-----------------------|-------------------------|--|
| 04/01/2020 | R14 | Under CPT/HCPCS Codes Group 1: Codes the description was changed for HCPCS code 0155U. This revision is due to the 2 nd Quarter CPT [®] /HCPCS Code Update and is effective on 4/1/20. |
| 03/26/2020 | R13 | Under ICD-10 Codes that Support Medical Necessity - Group 1: Paragraph and Group 1: Codes changed ICD-10 code from Z17.1 to Z17.0. This revision has a retro-effective date of 5/24/19. |
| 01/01/2020 | R12 | Under Article Text replaced the verbiage in the first bulleted sentence that reads "CPT [®] code 81404 – PIK3CA" with the verbiage "Enter the appropriate CPT [®] code". |
| 01/01/2020 | R11 | Under CPT/HCPCS Codes Group 1: Codes added HCPCS code 0155U and CPT [®] code 81309. The CPT [®] code 81404 was deleted. This revision is due to the Annual CPT [®] /HCPCS Code Update and becomes effective on 1/1/20. |

| REVISION HISTORY DATE | REVISION HISTORY NUMBER | REVISION HISTORY EXPLANATION |
|-----------------------|-------------------------|--|
| 10/31/2019 | R10 | Under CPT/HCPCS Codes Group 1: Codes the description was changed for CPT [®] code 81404. This revision is due to 4 th quarter CPT [®] /HCPCS Code update and becomes effective on 10/1/2019. |
| 10/24/2019 | R9 | 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 Article Title changed the title to "Billing and Coding: MoIDX: PIK3CA Gene Tests". Acronyms were inserted where appropriate throughout the LCD. CPT [®] was inserted throughout the article where applicable. |
| 05/24/2019 | R8 | Pik3CA was previously not covered. The FDA approved a new drug for breast cancer that requires PIK3CA testing. This change is effective 5/24/19. |
| 07/19/2018 | R7 | Removed the sentence: "Therefore, the MoIDX Team has determined PIK3CA gene testing is a statutorily excluded service. MoIDX will also deny panels of tests that include the PIK3CA gene." |
| 02/26/2018 | R6 | The Jurisdiction "J" Part A and Part B Contracts for Alabama (10111/10112), Georgia (10211/10212) and Tennessee (10311/10312) are now being serviced by Palmetto GBA. Effective 02/26/18, these 6 contract numbers are being added to this article. No coverage, coding or other substantive changes (beyond the addition of the 6 Part A and B contract numbers) have been completed in this revision. |
| 07/20/2017 | R5 | Updated the DEX Z-Code identifier information. Added the Part A contractor numbers. |
| 07/14/2016 | R4 | Completed annual validation. In the 1st bullet, added the word "targeted" between the words PIK3CA and gene. Corrected CPT code 81403 81404. |
| 11/19/2015 | R3 | Changed MoIDX ID (MID) back to SV101-7 |
| 11/19/2015 | R2 | Replaced SV101-7 with MID, Removed Palmetto GBA reference and replaced with MoIDX. |
| 10/01/2015 | R1 | Completed Annual Validation. Updated CPT code from 81479 to 81403. |

Associated Documents

Related Local Coverage Document(s)

N/A

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 04/21/2020 with effective dates 04/01/2020 - N/A

Updated on 03/26/2020 with effective dates 03/26/2020 - N/A

Updated on 01/06/2020 with effective dates 01/01/2020 - N/A

Updated on 12/09/2019 with effective dates 01/01/2020 - N/A

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Keywords

N/A