

Local Coverage Article: Billing and Coding: MolDX: PIK3CA Gene Tests (A55597)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

Article Information

General Information

Article ID

Original Effective Date

A55597

08/28/2017

Article Title

Billing and Coding: MoIDX: PIK3CA Gene Tests

Revision Effective Date

01/01/2020

Article Type

Billing and Coding

Revision Ending Date

N/A

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Retirement Date

N/A

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CMS National Coverage Policy

N/A

Article Guidance

Article Text:

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)-positive, 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 a PIK3CA targeted gene sequencing service, please submit the following claim information:

- 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
 - Item 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-BISPHOSPHATE 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

Group 1 Paragraph:

N/A

Group 1 Codes:

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

ICD-10 CODE	DESCRIPTION
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
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
01/01/2020	R4	In Article Text, (HER2)- negative was revised to (HER2)- positive . Under ICD-10 Codes that Support Medical Necessity, Z17.1 was deleted and Z17.0 was added effective 05/24/2019.
01/01/2020	R3	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

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		Annual CPT [®] /HCPCS Code Update and becomes effective on 1/1/20. As required by CR 10901, article is converted to a formal billing and coding type article.
05/24/2019	R2	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. Indications and Limitations were revised. Diagnosis criteria was added. Bill Type 014x was added.
08/28/2017	R1	The following sentences were deleted from the first paragraph: 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.

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 06/02/2020 with effective dates 01/01/2020 - N/A

Updated on 12/11/2019 with effective dates 01/01/2020 - N/A

Updated on 06/07/2019 with effective dates 05/24/2019 - N/A

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Keywords

N/A