



**Supplement No. 1 to Insurance Circular Letter
No. 2 (2016)**

February 27, 2017

TO: All Insurers Authorized to Write Accident and Health Insurance in New York State, Article 43 Corporations, Health Maintenance Organizations (“HMOs”), Student Health Plans Certified Pursuant to Insurance Law § 1124, and Municipal Cooperative Health Benefit Plans

RE: Health Insurance Coverage for Breast Tomosynthesis and Prohibitions Against Copayments

STATUTORY REFERENCES: Insurance Law §§ 3216, 3221, and 4303

I. Introduction

The purpose of this circular letter is to provide clarification to insurers authorized to write accident and health insurance in this state, article 43 corporations, health maintenance organizations, student health plans certified pursuant to Insurance Law § 1124, and municipal cooperative health benefit plans (collectively, “issuers”) regarding (1) the coverage of tomosynthesis, or 3D mammograms, and (2) whether the prohibition against annual deductibles and coinsurance for mammography screenings and diagnostic imaging for the detection of breast cancer includes copayments.

II. Discussion

A. Tomosynthesis

Following the issuance of Insurance Circular Letter No. 2 (2016), the Superintendent of Financial Services (“Superintendent”) received inquiries regarding whether the coverage and cost-sharing requirements for mammography applied to tomosynthesis. According to the Mayo Clinic, tomosynthesis uses X-rays to collect multiple images of the breast from several angles and then a computer synthesizes the images to form a 3-D image of the breast.¹ The Mayo Clinic states that digital mammograms, like tomosynthesis, allow for more detailed analysis and are more effective at detecting cancer in dense breast tissue.² Tomosynthesis may be particularly beneficial to Black women as they have been found to have denser breast tissue than White

¹ <http://www.mayoclinic.org/tests-procedures/mammogram/in-depth/dense-breast-tissue/art-20123968?pg=2>.

² Id.

women.³ Early detection may also be particularly important to Black women as they have a high incidence of aggressive breast cancer and the highest breast cancer death rate.⁴

As stated in Insurance Circular Letter No. 2 (2016), Insurance Law §§ 3216(i)(11)(A), 3221(l)(11)(A) and 4303(p)(1) require a policy or contract that provides coverage for hospital, surgical or medical care to provide coverage for mammograms at any age for a covered person that has a prior history of breast cancer or a first degree relative with a prior history of breast cancer when a physician recommends the mammogram. In addition, these sections require a policy or contract to cover a single baseline mammogram for covered persons age 35 through 39, and an annual mammogram for persons age 40 and older.

Insurance Law §§ 3216(i)(11)(C), 3221(l)(11)(C) and 4303(p)(2) define “mammography screening” as an X-ray examination of the breast using dedicated equipment, including X-ray tube, filter, compression device, screens, films and cassettes, with an average glandular radiation dose less than 0.5 rem per view per breast. Tomosynthesis falls under the definition of “mammography screening” and therefore must be covered when medically necessary.

As noted in Insurance Circular Letter No. 2 (2016), Insurance Law §§ 3216(i)(11)(B), 3221(l)(11)(B), and 4303(p)(1)(D) require that issuers cover mammography screenings without annual deductibles or coinsurance for policies and contracts issued, renewed, modified, or amended on or after January 1, 2017 with respect to participating providers in the issuer’s network, or with respect to non-participating providers, if the issuer does not have a participating provider in the in-network benefits portion of its network with the appropriate training and experience to meet the particular health care needs of the insured pursuant to Insurance Law § 3217-d(d) or 4306-c(d), or as applicable, Public Health Law § 4403(6)(a). In addition, Insurance Law §§ 3216(i)(11)(F), 3221(l)(11)(F), and 4303(p)(5) require that screening and diagnostic imaging for the detection of breast cancer, including diagnostic mammograms, breast ultrasounds, or magnetic resonance imaging, covered under the policy or contract, shall not be subject to annual deductibles or coinsurance, effective for policies or contracts that are issued, renewed, modified, or amended on or after January 1, 2017. Tomosynthesis is a screening and diagnostic imaging tool for the detection of breast cancer that is covered by these provisions. Therefore, an issuer must cover tomosynthesis, when medically necessary, without being subject to annual deductibles or coinsurance.

The Superintendent urges each issuer to ensure that its participating providers are aware of the criteria that the issuer uses in determining whether tomosynthesis is medically necessary for a particular patient, including the patient’s family history and whether she has dense breast tissue. Additionally, each issuer should remind participating providers who are prohibited by contract with the issuer from balance billing patients of the contractual hold harmless requirements when services are denied as not medically necessary. Furthermore, issuers should consider the latest scientific evidence when developing medical necessity criteria and when making medical necessity determinations regarding coverage for tomosynthesis. Current

³ See, Anne Marie McCarthy, et al., *Racial Differences in Quantitative Measures of Area and Volumetric Breast Density*, American Association for Cancer Research Annual Meeting (Apr. 20, 2015), *discussed in* 104 J. NAT’L. CANCER INST. 6 (Oct. 2015); *see also*, Rochman, *Study Finds Black Women have Denser Breast Tissue than White Women*, Journal of the National Cancer Institute, Vol 107, No 10 (2015).

⁴ <https://www.cancer.gov/about-nci/organization/crhd/cancer-health-disparities-fact-sheet>; *see also*, *Breast Cancer Rates by Race and Ethnicity*, Centers for Disease Control, www.cdc.gov/cancer/breast/statistics/race.htm (2016).

scientific evidence includes the following: Sarah M. Friedewald, MD, et al., *Breast Cancer Screening Using Tomosynthesis in Combination With Digital Mammography*, 331 JAMA 2499 (June 25, 2014); Melissa A. Durand, MD, et al., *Early Clinical Experience with Digital Breast Tomosynthesis for Screening Mammography*, 274 RADIOLOGY 85 (Jan. 2015); Brian M. Haas, MD, et al., *Comparison of Tomosynthesis Plus Digital Mammography and Digital Mammography Alone for Breast Cancer Screening*, 269 RADIOLOGY 694 (Dec. 2013); Per Skaane, MD, PhD, *Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program*, 267 RADIOLOGY 47 (Apr. 2013). These articles represent a growing body of evidence regarding the effectiveness of tomosynthesis.

B. Prohibition Against Copayments

As stated above, Insurance Law §§3216(i)(11)(B) and (F), 3221(l)(11)(B) and (F), 4303(p)(1)(D) and 4303(p)(5) prohibit issuers from imposing annual deductibles and coinsurance for covered mammography screenings and for diagnostic imaging for the detection of breast cancer. The Superintendent has received inquiries asking whether the prohibition against annual deductibles and coinsurance includes copayments. The answer is “yes.” “Coinsurance,” as used in many sections of the Insurance Law relating to benefits, refers to the share of the claim for which the insured is responsible, whether the share is expressed as a percentage of the claim or a fixed dollar amount. Therefore, the prohibition against annual deductibles and coinsurance includes all cost sharing, including copayments.

III. Conclusion

An issuer must cover tomosynthesis, when medically necessary for the detection of breast cancer, without being subject to annual deductibles, copayments and coinsurance. As a general matter, the prohibition against annual deductibles and coinsurance for mammography screenings and diagnostic imaging for the detection of breast cancer includes all cost sharing, including copayments.

Please direct any questions regarding this circular letter to Thomas Fusco, Supervising Insurance Attorney, Health Bureau, New York State Department of Financial Services, Walter J. Mahoney Office Building, 65 Court Street, Room 7, Buffalo, New York 14202 or by e-mail at thomas.fusco@dfs.ny.gov.

Very truly yours,

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