

Geisinger Health Plan Policies and Procedure Manual

Policy: MP300

Section: Medical Benefit Policy

Subject: Digital Breast Tomosynthesis

Applicable line of business:

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Commercial	X	Medicaid	X	
Medicare	Х	ACA	X	
CHIP	X			

I. Policy: Digital Breast Tomosynthesis

II. Purpose/Objective:

To provide a policy of coverage regarding Digital Breast Tomosynthesis

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

- 1. Attachment a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
- 2. Exhibit a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
- 3. Devised the date the policy was implemented.
- 4. Revised the date of every revision to the policy, including typographical and grammatical changes.
- 5. Reviewed the date documenting the annual review if the policy has no revisions necessary.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking
 into account both the functional capacity of the Member and those functional capacities that are appropriate for
 Members of the same age

DESCRIPTION:

Digital Breast Tomosynthesis (DBT) is a method for performing high-resolution limited-angle tomography at mammographic dose levels. Digital breast tomosynthesis produces a three dimensional image by taking multiple low-dose images per view along an arc over the breast to improve the sensitivity and specificity of mammography. It has been hypothesized that this technology may be able to decrease the number of false positive and false negative results and decrease recall rates.

INDICATIONS:

Digital breast tomosynthesis is considered a medically necessary imaging option in the screening or diagnosis of breast cancer for any of the following:

- 1. Members having a screening or diagnostic mammogram whose prior mammogram reported a breast density of one of the following:
 - a. Heterogeneously dense breast tissue
 - Extremely dense breast tissue

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2. Members having a baseline mammogram (first mammogram)

FOR MEDICAID BUSINESS SEGMENT:

On October 5, 2015, the Commonwealth of Pennsylvania clarified their existing state mammogram mandate (40 P.S. §764c). Under this state law, digital breast tomosynthesis must be covered at no cost in the same manner as traditional 2D mammography.

LIMITATIONS:

Breast density can change over time. Commonly, breast tissue becomes less dense as a person ages. Therefore, it is possible that breast tomosynthesis may not be medically necessary in future studies.

EXCLUSIONS:

Requests for Digital Breast Tomosynthesis not meeting the criteria listed above will be considered not medically necessary and therefore **NOT COVERED**.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Digital Breast Tomosynthesis

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 77061 Digital breast tomosynthesis; unilateral
- 77062 Digital breast tomosynthesis; bilateral
- 77063 Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)
- G0279 diagnostic digital breast tomosynthesis, unilateral or bilateral
- 0633T Computed tomography, breast, including 3D rendering, when performed, unilateral without contrast material(s)
- 0634T Computed tomography, breast, including 3D rendering, when performed, unilateral, with contract material(s)
- 0635T Computed tomography, breast, including 3D rendering, when performed, unilateral without contrast, followed by contrast material(s)
- 0636T Computed tomography, breast, including 3D rendering, when performed, bilateral, without contrast material(s)
- 0637T Computed tomography, breast, including 3D rendering, when performed, bilateral, with contrast material(s)
- O638T Computed tomography, breast, including 3D rendering, when performed, bilateral, without contrast, followed by contrast material(s)

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Friedewald SM, Rafferty EA, et al. Breast cancer screening using tomosynthesis in combination with digital mammography. JAMA 2014;311(24):2499-2507

Digital Breast Tomosynthesis. The American College of Obstetricians and Gynecologist - Vol. 121, No. 6, June 2013

Rafferty EA, Park JM, et al. Diagnostic Accuracy and Recall Rates for Digital Mammograpy and Digital Mammography Combined with One-View and Two-View Tomosynthesis: Results of an Enriched Reader Study AJR:202, February 2014

Zuley ML, andos AI, et al. Digital Breast Tomosynthesis versus Supplemental Diagnostic Mammographic Views for Evaluation of Noncalcified Breast Lesions Radiology: Volume 266; Number 1 – January 2013

Partyka L, Lourenco AP, et al. Detection of Mammographically Occult Architectural Distortion on Digital Breast Tomosynthesis Screening: Initial Clinical Experience AJR:203, July 2014

Rafferty EA, Park JM, et al. Assessing Radiologist Performance Using Combined Digital Mammography and Breast Tomosynthesis Compared with Digital mammography Alone: Results of a Multicenter, Multireader Trial Radiology: Volume 266: Number 1 – January 2013

Destounis S, Arieno A, Morgan R. Initial Experience with Combination Digital Breast Tomosynthesis Plus Full Field Digital Mammography or Full Field Digital Mammography Alone in the Screening Environment Journal of Clinical Imaging Science/Vol. R/ Issue 1/Jan-Mar 2014

Ciatto S, Houssami N, et al. Integration of 3D Digital Mammography with Tomosynthesis for Population Breast-Cancer Screening (STORM): A Prospective Comparison Study http://dx.doi.org/10.1016/S1470-2045(13)70134-7 www. the lancet.com/oncology

Skaane P, Bandos A, et al. Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program Radiology: Volume 267:Number 1 – April 2013

Greenberg JS, Javitt MC, et al. Clinical Performance Metrics of 3D Digital Breast Tomosynthesis Compared With 2D Digital Mammography for Breast Cancer Screening in Community Practice AJR:203, September 2014

Rose SL, Tidwell AL, et al. Implementation of Breast Tomosynthesis in a Routine Screening Practice: An Observational Study AJR:200, June 2013

Smith A. Breast Tomosynthesis: The Use of Breast Tomosynthesis in a Clinical Setting. Imaging Science, Hologic

Geisinger Technology Assessment Committee. Breast Tomosynthesis. Jan 14, 2015.

Mohindra N, Neyaz Z, Agrawal V, et al. Impact of addition of digital breast tomosynthesis to digital mammography in lesion characterization in breast cancer patients. Int J Appl Basic Med Res. 2018;8(1):33-37

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Breast Cancer Screening and Diagnosis. v2.2024

Armaroli P, Frigerio A, Correale L, et al. A randomised controlled trial of digital breast tomosynthesis vs digital mammography as primary screening tests: Screening results over subsequent episodes of the Proteus Donna study. Int J Cancer. 2022 Nov 15;151(10):1778-1790

Weigel S, Walter H, Hans-Wernter H, et al. Breast Density and Breast Cancer Screening with Digital Breast Tomosynthesis: A TOSYMA Trial Subanalysis. Published Online: Oct 4 2022

This policy will be revised as necessary and reviewed no less than annually.

Devised: 9/15

Revised: 12/15 (clarification), 10/16 (changed language; Added Medicaid Segment)

Reviewed: 10/17, 10/18, 10/19, 10/20, 10/21, 10/22, 10/23, 10/24

CMS UM Oversight Committee Approval: 12/23, 12/24

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endors ement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.