Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP300

Section: Medical Benefit Policy

Subject: Digital Breast Tomosynthesis

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**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.

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
    b. Extremely dense breast tissue

or

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)
0638T	Computed tomography, breast, including 3D rendering, when performed, bilateral, without contrast, followed by contrast material(s)

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

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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

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

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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. V1.2022

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

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.

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