Digital Breast Tomosynthesis (DBT)

Policy Number:	**M20170619023**
Effective Date:	**8/1/2017**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒ MediSource Connect; ☒Child Health Plus ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To communicate coverage for **digital breast tomosynthesis (DBT)** for Independent Health members.

Policy:

Commercial, Self-Funded, Medicare Advantage, MediSource, MediSource Connect, Essential Plan 1, Essential Plan 2, Essential Plan 3 and Essential Plan 4:
Digital breast tomosynthesis is covered for members as a screening or diagnostic option when performed in conjunction with mammography.

Child Health Plus:
Child Health Plus does not cover digital breast tomosynthesis.

Background:
Digital breast tomosynthesis produces 3-D images which are intended to reveal the inner architecture of the breast, free from distortion typically caused by tissue shadowing or density. Tomosynthesis images are captured while the patient is in a compression for the regular 2-D images, scanning through the entire breast. After the images are reconstructed on a computer, they are displayed for the radiologist as a series of thin high-resolution slices that provide mapping of any abnormalities including size, contour, and the relationship with the surrounding breast tissue. On February 11, 2011, the Food and Drug Administration (FDA) approved Hologic, Inc. to market its Selenia® Dimensions® 2-D Full Field Mammography and Digital Breast Tomosynthesis System.

The American College of Obstetrics and Gynecology Technical Assessment titled Digital Breast Tomosynthesis (2013) states "Clinical data suggest that digital mammography with tomosynthesis produces a better image, improved accuracy, and lower recall rates compared with digital mammography alone. Further study will be necessary to confirm whether digital mammography with tomosynthesis is a cost-effective approach capable of replacing digital mammography alone as the first-line screening modality of choice for breast cancer screening." This Technical Assessment was reaffirmed in 2015, 2018 and in 2020.

The National Comprehensive Cancer Network (NCCN) guideline titled Breast Cancer Screening and Diagnosis (2016) states "Multiple studies show a combined use of digital mammography and tomosynthesis appears to improve cancer detection and decreased call back rates. Of note, most studies used double the dose of radiation. The radiation dose can be minimized by synthetic 2-D reconstruction." In addition, the NCCN advises that DBT should be considered when an annual screening mammogram is recommended.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☐ No ☒

Pre-authorization is not required at the present time. Criteria above will be utilized upon retro-review.

Definitions

Digital breast tomosynthesis (DBT), also known as "3-D mammography", is a modification of digital mammography and uses a moving x-ray source and digital detector. A three-dimensional volume of data is acquired and reconstructed using computer algorithms to generate thin sections of images. In the diagnostic setting, tomosynthesis improves lesion characterization, increasing rates of cancer detection, and according to most studies, decreasing the false negative rate. Tomosynthesis is typically performed in conjunction with a conventional mammogram and has a longer exposure time per acquisition; therefore, the patient is exposed to more radiation (approximately twice the usual radiation dose, which can be even greater if the patient has dense or thick breasts).

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

American College of Obstetrics and Gynecology (ACOG) [web site]. Digital Breast Tomosynthesis Technology Assessment in Obstetrics and Gynecology Number 9, June 2013 (Reaffirmed 2024) Available at: https://www.acog.org/clinical/clinical-guidance/technology-assessment/articles/2013/06/digital-breast-tomosynthesis Accessed March 13, 2024.

Hayes, Inc., Medical Technology Directory Report. Digital Breast Tomosynthesis for Breast Cancer Diagnosis and Screening. Lansdale, PA: October 2017.

National Comprehensive Cancer Network (NCCN) [web site]. Breast Cancer Screening and DiagnosisVersion 3.2023 — October 31, 2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast-screening.pdf Accessed March 13, 2024.

Nguyen T, Levy G, Poncelet E, et al. Overview of digital breast tomosynthesis: Clinical cases, benefits, and disadvantages. Diagn Interv Imaging. 2015 Sep;96(9):843-59.

Regulatory References

Centers for Medicare and Medicaid (CMS) [web site]. CMS Manual System –Medicare Claims Processing. Pub 100-04 Medicare Claims Processing Transmittal 3160. January 7, 2015. Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3160CP.pdf Accessed March 14, 2024.

New York State Department of Financial Services. Supplement No. 1 to Insurance Circular Letter No. 2 (2016). Health Insurance Coverage for Breast Tomosynthesis and Prohibitions Against Copayments. New York State Department of Health [web site]. Available at: https://www.dfs.ny.gov/industry_guidance/circular_letters/cl2017_cl2016_02_s01 Accessed March 13, 2024.

New York State Medicaid Program Physician Procedure Codes. Section 4 - Radiology. April 2023 . Available at: https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect5.pdf Accessed March 13, 2024.

New York State Medicaid Update [web site]; Volume 33; Number 8; August 2017: p.3. Available at: https://www.health.ny.gov/health_care/medicaid/program/update/2017/aug17_mu.pdf Accessed March 13, 2024.

United States Food and Drug Administration (FDA) [web site]. Premarket Approval (PMA). Selenia Dimensions Full Field Digital Mammography System. P080003. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P080003 Accessed March 13, 2024.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
5/1/2024	Health Care Services	Reviewed
1/1/2024	Health Care Services	Revised
6/1/2023	Health Care Services	Reviewed
6/1/2022	Health Care Services	Reviewed
7/1/2021	Health Care Services	Reviewed
7/1/2020	Health Care Services	Reviewed
8/1/2019	Medical Management	Revised
10/1/2018	Medical Management	Revised
11/1/2017	Medical Management	Revised