The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required by the ordering physician if, despite this Protocol’s investigational position, you feel this service is medically necessary; supporting documentation must be submitted to Use Management.* Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Description

Digital breast tomosynthesis uses existing digital mammography equipment to obtain additional radiographic data that are used to reconstruct cross-sectional “slices” of breast tissue. Tomosynthesis may improve the accuracy of digital mammography by reducing problems caused by overlapping tissue. Tomosynthesis involves some additional imaging time and radiation exposure.

Background

Digital breast tomosynthesis (DBT) is being developed as an approach to generate images that may improve the sensitivity and specificity of mammography. Current radiographic approaches to mammography produce two-dimensional (2D) images. These 2D systems can have limitations due to overlapping tissue in the breast that may hide lesions (cancers) or cause benign masses to appear suspicious. DBT may be utilized along with full-field digital mammography (FFDM) in screening for breast cancer and may also be used as a technique for the diagnosis of breast cancer in helping to clarify equivocal mammographic findings.

In evaluating DBT, studies must consider test accuracy (sensitivity and specificity), as well as recall rates. In addition, the incremental value of DBT might be compared to using additional views from traditional mammography. Radiation exposure is also a very important consideration. Finally, issues such as the duration of the examination (breast compression) are also important.

To acquire the three-dimensional (3D) DBT images, the x-ray tube head is moved in a 15 degree arc over the stationary breast acquiring 11 to 21 (typically 15) x-ray projection images. The projection images are reconstructed to produce cross-sectional “slices” through the breast. The nominal thickness of the slices can vary from 0.5 to 10 mm, with 1 mm being the “normal” thickness.

The same detector and x-ray tube are used to acquire both the 2D and 3D images. Images can be acquired in any orientation of the gantry, including the standard cranio-caudal (CC) and mediolateral oblique (MLO) mammography views, which may be useful in comparing new images with older mammography results. The 2D and 3D images can be acquired during a single breast compression, or they can be acquired separately.

Regulatory Status

On February 11, 2011, the U.S. Food and Drug Administration (FDA) approved Hologic, Inc. to market its Selenia Dimensions 2D Full Field Digital Mammography (FFDM) and Digital Breast Tomosynthesis (DBT) system. This DBT is the first mammography system that provides 3D images of the breast for breast cancer screening and
diagnosis. The FDA approved the 2D modality of this system two years ago. Since then, a number of facilities in the U.S. have been using the Selenia Dimensions 2D (with the DBT locked). Facilities that have an accredited (or have applied to be accredited) Selenia Dimensions 2D unit can activate the DBT modality of the unit after applying to and obtaining FDA approval to extend its certificate to include the DBT modality.

Because DBT is a new mammographic modality, facilities wanting to use DBT on patients must meet all Mammography Quality Standards Act (MQSA) applicable requirements: (1) personnel must obtain at least eight hours of DBT training; (2) the unit must undergo a mammography equipment evaluation prior to use; and (3) the facility must follow the manufacturer's recommended quality control procedures.

Currently, the Accreditation Bodies (ABs) do not have the capability to review DBT images, and thus, cannot accredit the DBT modality portion of the unit. Therefore, a facility wanting to use the DBT modality of its accredited (or have applied to be accredited) Selenia Dimensions 2D unit will need to apply to FDA to extend its certification to include the DBT modality.

The Selenia Dimensions 3D DBT is a hardware and software upgrade to the Selenia Dimensions 2D FFDM system, which is FDA approved for conventional mammography imaging (P010025/S013, approved December 22, 2008).

Related Protocol:
Scintimammography/Breast-Specific Gamma Imaging/Molecular Breast Imaging

Corporate Medical Guideline

Digital breast tomosynthesis is considered **investigational** in the screening or diagnosis of breast cancer.

References

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**
