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Comments and Responses Regarding Draft Local Coverage Determination: Mammography/Breast Echography (Sonography)/Breast MRI/Ductography

As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Mammography/Breast Echography (Sonography)/Breast MRI/Ductography LCD. The official notice period for the final LCD begins on April 15, 2009 and the final determination will become effective on July 1, 2009.

Comment: A commenter asked if a radiologist had to be on site for a screening mammography as this might limit care in rural areas where a radiologist may not be present.

Response: It is stated in the section on Diagnostic Mammography in the American College of Radiology (ACR) Guidelines:

Diagnostic mammography is a radiographic examination performed to evaluate patients who have signs and/or symptoms of breast disease, imaging findings of concern, or prior imaging findings requiring specific follow-up. Diagnostic mammography requires direct supervision.

Direct supervision is defined as the physician being present and immediately available to furnish assistance and direction throughout the performance of the procedure. Direct supervision may also be accomplished via telemedicine as long as the interpreting physician is immediately available.

Diagnostic mammography may include MLO, CC, and/or additional views to evaluate an area of clinical or radiographic concern. Additional mammographic views might include spot compression, spot compression with magnification, tangential views, or other special views.

These decisions must be made by the radiologist.

Comment: A commenter questioned the reason a mammography is not covered by a portable x-ray supplier.

Response: Based on the Centers for Medicare & Medicaid Services' regulations, portable x-ray providers are not allowed to perform screening mammography.

Diagnostic mammography may be covered if the approved portable x-ray supplier, as defined in 42 CFR part 486, subpart C, meets the certification requirements of section 354 of the Public Health Services Act, as implemented by 21 CFR part 900, subpart B.

Comment: A commenter asked if radiologists can perform additional studies without primary care physician consent.

Response: This depends on where the service is being performed. An outpatient office setting requires primary care physician order. However, if performed in an inpatient setting, no primary care physician order is required.

Comment: A commenter requested we consider the addition of ICD-9-CM code V71.1 (Observation for suspected malignant neoplasm for CPT codes 77058 and 77059. They use this ICD-9-CM code when metastatic adenocarcinoma is found in the axillary lymph nodes, the lung, the liver, the skeleton, or other organs and suspect that the primary tumor may be in the breast. Breast MRI is the most accurate method, short of mastectomy, to diagnose breast cancer. The identification of the primary tumor frequently guides therapy, which affects quality of life and survival.

Response: ICD-9-CM code V71.1 was removed from the "ICD-9-CM Codes that Support Medical Necessity" section for MRI due to the fact that other ICD-9-CM codes could be used to define the reason for the MRI.

For example:

- Metastatic adenocarcinoma in axillary lymph nodes - 196.3 (Secondary and unspecified malignant neoplasm of lymph nodes of axilla and upper limb);
- The skeleton - 239.2 (Neoplasm of unspecified nature of bone soft tissue and skin).

The contractor will add ICD-9-CM code 199.1 (Malignant neoplasm without specification of site) to cover the indication for a patient diagnosed with metastatic cancer but the primary site is unknown.

Comment: A commenter requested the addition of ICD-9-CM code V15.89 for a diagnostic mammography for benign biopsy proven breast disease. The commenter also requested the addition of the following ICD-9-CM codes for a diagnostic mammography: V10.43 (Personal history of ovarian cancer), V10.42 (Personal history of endometrial cancer), V10.05, V10.06 (Personal history of colon cancer), 611.83 (Capsular contracture of breast implant), 172.5, 173.5 (Other breast neoplasms), 153.0 - 153.9 (Neoplasm colon), 182.0 - 182.8 (Neoplasm body of uterus), 239.1 (Unspecified neoplasm respiratory system), 239.6 (Unspecified neoplasm, brain) and 238.2 (Uncertain behavior neoplasm, skin of breast).

Response: Diagnostic mammography, as defined in the Code of Federal Regulations 42 Section 410.34, is a radiologic procedure furnished to a man or woman with signs or symptoms of breast disease, or a personal history of breast cancer or a personal history of biopsy-proven benign breast disease, including a physician's interpretation of the results.

Therefore, ICD-9-CM codes V10.42, V10.43, V10.05, V10.06, 172.5, 173.5, 153.0 - 153.9, 182.0 - 182.8, 239.1 and 239.6 would be appropriate for a screening mammography as a secondary diagnosis but are not as the sole diagnosis (indication) for a diagnostic mammography.

The contractor agrees and will add the following ICD-9-CM codes to the "ICD-9-CM Codes that Support Medical Necessity" section of the LCD for a diagnostic mammography: 238.2, 611.83 and V15.89 for benign biopsy proven breast disease.

Comment: A commenter asked if a BRAC abnormality could be included.

Response: A BRAC abnormality would fall under screening which would have to be mandated by Congress to be covered.

Comment: A commenter indicated that the American Cancer Society recommends a breast MRI as a screening tool. New evidence on breast Magnetic Resonance Imaging (MRI) screening has become available since the American Cancer Society (ACS) last issued guidelines for the early detection of breast cancer in 2003.

Response: The contractor agrees with the commenter. However, there is no Medicare benefit which allows for coverage of a screening MRI.