

SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

DIGITAL BREAST TOMOSYNTHESIS (3-D MAMMOGRAPHY) FOR BREAST CANCER SCREENING IN AVERAGE RISK WOMEN

Population description	Women between the ages of 40 and 74 years referred for breast cancer screening <i>Population scoping notes: Excludes women with a personal history of breast cancer, clinically significant BRCA gene mutations, Li-Fraumeni syndrome, Cowden syndrome, hereditary diffuse gastric cancer or other familial breast cancer syndromes, high-risk lesions (ductal or lobular carcinoma in situ, atypical ductal or lobular hyperplasia), or previous large doses of chest radiation therapy (≥ 20 Gy) before age 30 years.</i>
Intervention(s)	Digital breast tomosynthesis (3-D mammography) in conjunction with standard 2-D digital mammography <i>Intervention exclusions: None</i>
Comparator(s)	Standard 2-D mammography with or without computer-aided diagnosis <i>Considered but not selected: No screening, MRI, ultrasound</i>
Outcome(s) (up to five)	Critical: All-cause mortality, breast cancer morbidity Important: Test performance characteristics, cancer stage at diagnosis, recall rate/false positive test results <i>Considered but not selected for GRADE Table: cancer-specific mortality, radiation exposure PPV for recalls, PPV for biopsies, cancer detection rate, and invasive cancer detection rate</i>

Key Questions	<ol style="list-style-type: none">1. What is the comparative effectiveness of digital breast tomosynthesis (DBT) as a primary screening modality in women referred for breast cancer screening?2. Does the comparative effectiveness of DBT vary by the following characteristics:<ol style="list-style-type: none">a. Ageb. Race or ethnicityc. Breast density3. In a screening population, how do the test characteristics of 3-D/2-D mammography compare to those of standard 2-D mammography?4. What are the harms of 3-D/2-D mammography compared to standard 2-D mammography alone?5. If DBT is used as a primary screening modality, what is the optimal screening interval, and does that interval vary according to the characteristics listed in Key Question 2?
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CHANGE LOG

Date	Change	Rationale
1/26/2016	Changed interventions to digital breast tomosynthesis (3-D mammography) with or without standard digital mammography. Reworded for brevity and clarity but chose not to limit scope at this time.	Public comment suggested removing DBT alone from interventions.
6/27/2016	<p>Aligned population scoping notes to match US Preventive Services Task Force (USPSTF) definitions of average risk population.</p> <p>Changed outcomes to align with separate planned coverage guidance on breast cancer screening for women at above-average risk.</p> <p>Add race and ethnicity to the characteristics examined. Break the discussion of screening intervals into a separate key question, #4.</p>	<p>Align with USPSTF population, as coverage of mammography in general is governed by this definition.</p> <p>Align coverage guidances so that they do not overlap and cover the necessary subject area.</p>