

# SCOPE STATEMENT FOR HERC COVERAGE GUIDANCE

## BREAST CANCER SCREENING IN WOMEN AT ABOVE-AVERAGE RISK

<b>Population description</b>	<p>Women at above average age-adjusted risk of breast cancer or who have dense breasts</p> <p><i>Population scoping notes: Includes women with pre-existing breast cancer, 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 (<math>\geq 20</math> Gy) before age 30 years.</i></p>
<b>Intervention(s)</b>	<p>Standard digital (2-D) mammography, digital breast tomosynthesis (3-D/2-D), breast ultrasound, breast MRI, PET CT, self-exam, clinical exam, breast-specific gamma imaging, screening regimens involving combinations or alternating use of the above tests at various intervals</p> <p><i>Intervention exclusions: None</i></p>
<b>Comparator(s)</b>	<p>No screening, average risk screening regimens, comparisons of above tests to each other</p>
<b>Outcome(s) (up to five)</b>	<p><b>Critical:</b> All-cause mortality, breast cancer morbidity</p> <p><b>Important:</b> Test performance characteristics, cancer stage at diagnosis, recall rate/false-positive test results</p> <p><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></p>

<b>Key Questions</b>	<ol style="list-style-type: none"> <li>1. What is the comparative effectiveness of enhanced strategies for breast cancer screening in women with above average risk?</li> <li>2. Does the comparative effectiveness of enhanced strategies for breast cancer screening in women above average risk vary by: <ol style="list-style-type: none"> <li>a. Reason for above average risk</li> <li>b. Age</li> <li>c. Race or ethnicity</li> <li>d. Breast density</li> </ol> </li> <li>3. What are the harms of enhanced screening strategies for breast cancer in women with above average risk?</li> <li>4. What is the optimal screening interval in above-average risk women? Does the optimal screening interval vary by the: <ol style="list-style-type: none"> <li>a. Characteristics listed in Key Question 2?</li> <li>b. Screening modality?</li> </ol> </li> </ol>
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## CHANGE LOG

Date	Change	Rationale
6/30/2016	<p>In population description, align risk factors to exclude populations covered by the US Preventive Services Task force general requirements for screening, but specifically include women with dense breasts. Add breast-specific gamma imaging as an intervention. Change references to 'adults' to 'women' throughout.</p> <p>Align outcomes with separate coverage guidance for digital breast tomosynthesis (DBT) for consistency. Align outcome scoping notes with changes in the population regarding prior ductal carcinoma in situ. Include breast cancer morbidity rather than cancer-specific mortality.</p> <p>Align key questions with coverage guidance on DBT, and treat breast density as a factor which may affect effectiveness.</p>	<p>Revisions to align this coverage guidance with the scope statement for the coverage guidance on digital breast tomosynthesis and recommendations from the United States Preventive Services Task Force (USPSTF).</p> <p>Clarify references to digital breast tomosynthesis, that they would be used in conjunction with 2-D images.</p> <p>Clarify treatment of dense breasts.</p>