

**Delfini Conclusions Summary by Considerations:**

**Magnetic Resonance Imaging (MRI) for Diagnosis and Treatment of Women at High Risk For or With a Personal History of Breast Cancer**

<p><b>Values Key:</b>  <b>+ Positive or Use</b>  <b>? Medium Strength to Borderline Uncertainty</b>  <b>— Negative or Avoid</b></p>	<p><b>Considerations</b></p> <p><b>Alternatives</b>  Including evidence quality, effectiveness, safety, cost, QALY assessment</p> <p><b>Patient Perspective</b></p> <ul style="list-style-type: none"> <li>• benefits</li> <li>• harms and risks</li> <li>• costs</li> <li>• uncertainties</li> <li>• applicability</li> <li>• satisfaction</li> <li>• clinical considerations (eg tolerability, ease of use, dependency, abuse potential)</li> <li>• unmet needs, special populations</li> </ul> <p><b>Other Considerations: Examples</b></p> <ul style="list-style-type: none"> <li>• accreditation issues</li> <li>• clinician perspective</li> <li>• community standards</li> <li>• ethical considerations</li> <li>• liability and risk management issues</li> <li>• marketing</li> <li>• media or press issues</li> <li>• medical community impacts</li> <li>• medical-legal</li> <li>• public relations</li> <li>• purchasing issues</li> <li>• regulatory</li> <li>• research realities (eg likelihood that no evidence will be able to answer clinical questions etc.)</li> <li>• utilization (eg impacts of provider change including demand do you have the capacity to support this change impact of substitution etc.)</li> <li>• overall impact on the health care organization or entity</li> </ul>	<p><b>Project Key Questions</b></p> <p>For women at risk of breast cancer based on presentation of with an abnormal mammogram; palpable breast abnormality; or relevant demographic and clinical risk factors:</p> <ol style="list-style-type: none"> <li>1. What is the evidence that breast MRI has the ability to diagnose or exclude breast cancer in women at high risk compared to current tests including mammography? <ol style="list-style-type: none"> <li>a. Describe sensitivity, specificity, and other key test characteristics</li> </ol> </li> <li>2. What is the evidence that breast MRI improves health outcomes for patients with suspected or diagnosed breast cancer? Including consideration of: <ol style="list-style-type: none"> <li>a. reduced need for other tests</li> <li>b. more accurate diagnosis</li> <li>c. change in treatment plan</li> <li>d. reduced mortality and morbidity</li> </ol> </li> <li>3. What is the evidence of the safety of breast MRI in this population?</li> <li>4. What is the evidence that breast MRI has differential efficacy or safety issues in subpopulations? Including consideration of: <ol style="list-style-type: none"> <li>a. Age, breast tissue characteristics; breast implants</li> <li>b. Other patient characteristics or evidence of appropriate patient selection criteria</li> <li>c. Type of scanning machine and software, reader training, and other operational factors</li> <li>d. Provider type, setting or other provider characteristics</li> <li>e. Health care system type, including worker's compensation, Medicaid, state employees</li> </ol> </li> <li>5. What is the evidence about the cost implications and cost effectiveness of breast MRI?</li> </ol>
<p><b>Criteria Key &amp; Notes</b></p> <p><b>Evidence Quality: Therapies [Diagnostics]</b></p> <p>+ Low-risk of bias RCT data [low-risk of bias observational studies meeting critical appraisal criteria for diagnostic testing]  ? Med/borderline-risk of bias RCT data; all-or-none observations with low-risk of confounding [med/borderline-risk of bias observational studies meeting critical appraisal criteria for diagnostic testing]  — RCT data at high-risk of bias, observational studies, opinion [high risk of bias observational studies OR observational studies not meeting critical appraisal criteria for diagnostic testing]</p> <p><b>Clinical Significance (with consideration of size of outcomes)</b></p> <p>+ Morbidity, mortality, symptom relief, emotional/physical functioning, health-related quality of life  ? Intermediate outcomes with proof of direct causal chain to clinically meaningful outcomes  — Intermediate outcomes without proof of direct causal chain or other outcomes</p> <p><b>Size of the Outcomes</b></p> <p>Sufficient size is a judgment depending on context and outcome. Review confidence intervals. <b>No difference may reflect a power issue.</b></p> <p><b>Safety</b></p> <p>NNH is a judgment depending on the harm.  + Sufficient to determine safe  — Borderline or insufficient to determine safe or determined not safe</p> <p><b>Cost Analysis</b></p> <p>+ Low-risk of bias plus reasonable assumptions  ? Medium/borderline risk of bias and/or questionable assumptions  — High risk of bias or questionable or poor assumptions</p>		

Criteria, Considerations, Comparisons & Examples to Inform Decisions & Judgments	Questions: What is the level of confidence that...	Outcome	Level of Confidence	Other Considerations (eg, clinical significance)	Your Judgment "Worksheet"
Likelihood of Outcomes (See above for considerations for Clinical Significance)	1. these outcomes will be achieved, realized or experienced?	Increased detection of breast cancer	HIGH		
		Decreased need for other tests	LOW		
		Changes in treatment plans (e.g., wider excisions, more mastectomies, unnecessary mastectomies)	HIGH		
		Decreased re-excision rates	LOW		
		Decreased recurrence rates	LOW		
		Decreased mortality	LOW		
Size of the Outcomes	2. the estimate is likely to be correct?	2-5 additional cancers detected/100 MRIs, but with uncertain benefit in mortality, potential for risk and increase in cost	HIGH		
Size of the Outcomes	3. the estimate is likely to be correct?	Up to 11 additional benign biopsies/100 MRIs	MEDIUM		
Safety	4. the estimate is correct?	No increase in meaningful adverse psychological outcomes	MEDIUM		
		No increase in adverse outcomes from radiation	HIGH		
Cost	5. the estimate is correct?	Increased cost of technology: MRI 10 times the cost of mammography	HIGH		
QALY: Evidence Quality for Mortality and Methods Overall [Possibly reasonable QALY judgment: + <\$50K, ? \$50-150k, — >\$150K]	6. the estimate is correct?	Cost per QALYs saved: ~\$30,000 to ~\$310,000 depending upon risk and assumptions	LOW		
Alternatives Available	7. the information about alternatives is correct?	Mammography: lower sensitivity, but fewer false positive biopsies	HIGH		

<b>Patient Perspective</b>	If goal is increased detection, MRI is preferred. If goal is assurance that benefits outweigh harms, MRI is not preferred.
<b>Conclusions Regarding Net Benefit</b>	There is no proof of net benefit, and there is potential harm.

**Other Evidentiary Considerations**

1. Intervention or technology is considered to be safe or has low likelihood of harm or the adverse effects are acceptable. The intervention or technology is unlikely to result in other unacceptable untoward effects or unacceptable unintended consequences and is of acceptable cost (e.g., dietary change).  
 Meets criteria
2. No other effective treatments or technologies exist, and adverse clinical outcomes are likely if the condition is not treated.  
 Meets criteria
3. Other related interventions or technologies already in use also have insufficient evidence, and there may be advantages for intervention or technology over alternatives. Caution is urged if assuming "class effect." The criteria for concluding the existence of "class effect" are controversial.  
 Meets criteria
4. Well-designed studies are unlikely (e.g., condition or disease is rare, topic does not lend itself to valid study design or execution and adverse clinical outcomes are likely if the condition is not treated.)  
 Meets criteria
5. There is sufficient evidence of effectiveness and safety in other populations to suggest net clinical benefit in this population.  
 Meets criteria