This document was used during the September 21, 2013, Assessment of Options Advisory panel meeting to facilitate the discussion of the research gaps in ductal carcinoma.

Management Strategies for Ductal Carcinoma in Situ (DCIS)

Research Areas	***Notes***
Intervention and Comparator	
3. What are the comparative sensitivity and specificity of breast MRI, mammography and other **preoperative imaging evaluations for detecting occult invasive breast cancer** among DCIS patients originally diagnosed with core needle biopsy? Do differences among these interventions lead to clinically relevant differences in choice of management strategies (including observation/active surveillance)?	
5. Do the comparative safety and effectiveness of management strategies (including observation/active surveillance) for women diagnosed with DCIS differ depending on variation in **clinical, pathologic, and genomic presentations of DCIS** (e.g., grade, topographic nature of tumor, positive margins, pN0(i+) or pN1mic SLN metastases)?	

8. Is it possible to develop and validate **risk stratification models** based on currently available data on patient characteristics, clinical characteristics, and test results that accurately identify subsets of women with DCIS for whom the balance of benefits and harms is relatively clear for specific intervention strategies, including (a) observation/active surveillance only, (b) local excision only, (c) local excision with radiation therapy, and (d) mastectomy?	
11. What are the comparative safety and effectiveness of **a management strategy involving no immediate treatment (i.e., observation/active surveillance)** versus **immediate treatment with surgery, radiation, and/or medical therapy**? For women who choose observation/active surveillance, what is the optimal frequency and length of observation/active surveillance? Are outcomes different for women who elect observation/active surveillance and subsequently have an invasive cancer detected and treated compared to women who choose immediate treatment for DCIS?	
12. What are the comparative safety and effectiveness of **partial breast radiation therapy** versus **whole breast radiation therapy**? What are the comparative safety and effectiveness of different approaches to partial breast radiation therapy (e.g., intra-operative vs. postoperative)?	

15. What is the comparative effectiveness of **different approaches to communicating the diagnosis of DCIS to the patient** (e.g., 'cancer' vs. 'non-invasive cancer' vs. 'pre-cancer,' likelihood of progression to invasive cancer, time frame/urgency for making management decisions) in terms of (a) choices patients make about which specific management strategies (including observation/active surveillance) to use, and when to start them, and (b) outcomes related to these decision, including patient satisfaction, decisional regret, anxiety, distress/confusion, or other key patient-centered outcomes?	
16. What is the comparative effectiveness of **decision making tools** compared to **usual care** in terms of (a) choices patients make about which specific management strategies (including observation/active surveillance) to use, and when to start them, and (b) outcomes related to these decisions, including patient satisfaction, decisional regret, anxiety, distress/confusion, or other key patient-centered outcomes? What are the optimal format, content, and timing for these decision aids? How consistently are these decision tools used in practice?	
Outcomes	
22. What are the **most important patient-centered outcomes** (e.g., breast cancer mortality, symptoms, function, negative affect, wellbeing/quality of life, body image, loss of productivity, time away from work and family, long-term functional status, risk tolerate for uncertainty, peer support) for women diagnosed with DCIS?	

24. What is the impact of DCIS management strategies on **comorbidities**?	
26. What is the impact of DCIS management strategies on rates of **invasive cancers**?	