

**Final Topic Refinement Document**  
**Catheter Ablation for Atrial Fibrillation - Project ID: CRDT0913**

**Date:** 05/29/2014

**Topic:** Catheter Ablation for Atrial Fibrillation – Project ID: CRDT0913

**EPC:** Pacific Northwest EPC

**AHRQ Task Order Officer:** Kim Wittenberg

**Partner:** CMS

## Final Topic Refinement Document

### Key Questions

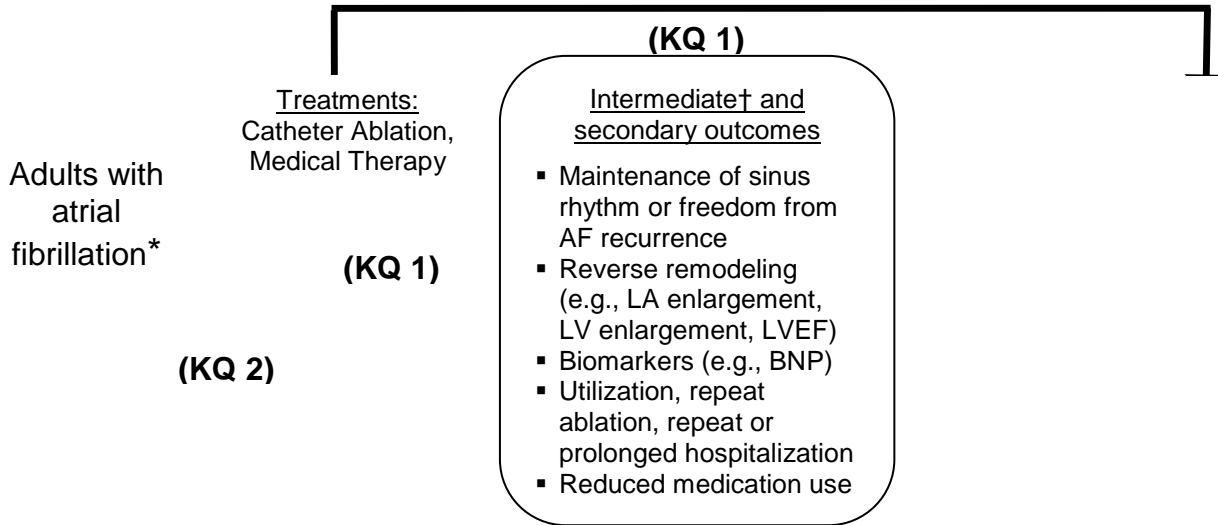
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**Figure 1. DRAFT analytic framework:  
Catheter Ablation for Atrial Fibrillation**



**KQ 3:** Differential efficacy, effectiveness, or harms based on population characteristics (e.g., age, sex)



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PICOTS	Include	Exclude
<p><b>Interventions</b></p>	<ul style="list-style-type: none"> <li>o CHADS<sub>2</sub> or CHA<sub>2</sub>DS<sub>2</sub>VASc criteria) and history of prior stroke</li> <li>o Obesity</li> <li>o Patients with atrial fibrosis</li> <li>x Catheter ablation:               <ul style="list-style-type: none"> <li>o Devices available for use in the U.S.</li> <li>o Main focus on pulmonary vein isolation (PVI) alone; however, PVI with additional lines, PVI plus cavotricuspid isthmus ablation vs. PVI only will also be included – targeting of the pulmonary vein antrum and use of irrigated or 8 mm catheter tips</li> <li>o Ablation (including standalone radiofrequency ablation) of complex fractionated atrial electrograms (CFAE) and linear ablations</li> <li>o Ablation of ganglionated plexi)</li> <li>o Wide area circumferential ablation (WACA)</li> <li>o PVAC (pulmonary vein ablation catheter) system; multi-electrode RF catheter</li> <li>o Michel Haissaguerre approach</li> <li>o Ablation of non-pulmonary vein foci</li> <li>o Cryoablation</li> <li>o Cryoballoon ablation</li> <li>o Laser balloon</li> <li>o Ablating rotors/FIRM (focal impulse and rotor modulation)</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>x Ablation as an adjunct to surgery, intraoperative ablation</li> <li>x Right atrial ablation for atrial flutter</li> <li>x Use of non-Food and Drug Administration (FDA) approved devices or devices not im RiÅe»no</li> </ul>

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PICOTS	Include	Exclude
	<ul style="list-style-type: none"><li>x Freedom from recurrence of AF</li><li>x Maintenance of sinus rhythm,</li><li>x Parameters suggesting reverse remodeling (e.g., LA size, LV size, LV ejection fraction)</li><li>x Effect on biomarkers (e.g., brain natriuretic peptide)</li><li>x Health care utilization</li><li>x Reduced medication use (e.g., need for anticoagulants, antiarrhythmic drugs)</li></ul>	
	<p><u>Harms or adverse events (procedure or treatment related)</u></p>	
	<ul style="list-style-type: none"><li>x In-hospital and 30-day mortality (all-cause, cardiovascular)</li><li>x In-hospital and 30-day stroke (any, by type), TIA</li><li>x In-hospital and 30-day embolic events</li></ul>	]



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PICOTS	Include	Exclude
	journals, published health technology assessments, or publicly available FDA reports x Gray literature (e.g., ongoing or unpublished clinical trial data)	2005 (to exclude outdated technologies) x Single reports from multicenter trials x Duplicate publications of the same study which do not report on unique outcomes

**Definition of Terms**

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and Accessory Cables (P960016)		
Stinger™ Ablation Catheter and TempLink™ Extension Cable (P000020)	2000	C.R. Bard, Inc., Bard Electrophysiology Division
NAVISTAR™ Diagnostic/Ablation Deflectable Tip Catheter (P990025)	2000	Biosense Webster, Inc.