# HERC Coverage Guidance – Ablation for Atrial Fibrillation
# Disposition of Public Comments

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## Commenters

| Identification | Stakeholder |
|---|---|
| A | Family Physician, Reedsport, OR [*Submitted June 26, 2014*] |
| B | Oregon Chapter of the American College of Cardiology, Portland, OR [*Submitted July 22, 2014*] |
| C | Medtronic, Inc., Mounds View, MN [*Submitted July 21, 2014*] |

# HERC Coverage Guidance – Ablation for Atrial Fibrillation
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## Public Comments

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| A | 1 | Agree with recommendations. They appear to be well-researched. Choosing Wisely recommendation adds weight; these have been researched by others and are endorsed by the specialty society. | Thank you for your comment. |
| B | 1 | The Oregon Chapter of the American College of Cardiology appreciates the opportunity to provide comments on the Health Evidence Review Commission's Coverage Guidance for Ablation for the Treatment of Atrial Fibrillation. We are of the opinion that the coverage guidance is well written and appropriate and agree with the overall conclusions and coverage decisions. However, there are several points worth revising, as detailed below. | Thank you for your comment. |
| B | 2 | Page 1: Box labeled "HERC Coverage Guidance", the third and fourth points are redundant, i.e., PVI at time of other cardiac surgery and surgical MAZE procedure at time of other cardiac surgery are the same. This error is repeated several times in the document. Although Al-Khatib distinguishes these two terms in her paper, these are generally used as synonyms in clinical practice, and thus comparisons between them are not valid. We recommend that the definitions of PVI and MAZE be included in the guidance. | PVI and surgical Maze are discussed separately in the AHRQ review, with different studies informing conclusions. Neither procedure is defined or described in this report. Given that both procedures have similar recommendations, box language changed to the generic term "surgical ablation". |
| B | 3 | Page 2: First paragraph under "clinical background", the term "permanent afib" is now rarely used and signifies afib that is always present and that no attempts are being made to restore sinus rhythm. We suggest clarifying that if attempts are made, then the afib is referred to as "longstanding persistent". | Current description of atrial fibrillation varieties is from the AHRQ report, and states the following:<br><br>"Types of AF include first-detected, paroxysmal (arrhythmia terminates spontaneously within 7 days), persistent (arrhythmia is sustained beyond 7 days), longstanding persistent (usually lasting for more than 1 year when attempts at achieving sinus rhythm are planned or are in progress), and permanent AF (in which cardioversion has failed or has not been attempted)."<br><br>Suggested clarification made to the text. |
| B | 4 | Page 3: Top, "the risk of stroke is up to 8%, depending on other stroke risk factors". To more appropriately classify this risk, we recommend the statement be revised to state a range, such as 1-8%. | Current language is verbatim from the AHRQ report. No citation provided for the range. AHA guideline reports 5X |

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| | | | increase in stroke risk, but does not list an actual %. Sentence deleted. |
| B | 5 | Page 4: Middle, cardiac resynchronization therapy (CRT) is presented as a potential treatment for afib. CRT can be used in conjunction with AV node ablation, but the goal is not to decrease afib burden, as is currently discussed. Existing practice guidelines and current clinical practice do not include CRT as an appropriate treatment for afib, and we recommend removing it as a treatment option. | Language is from the background section and is verbatim from the AHRQ report; there is no evidence pertaining to CRT in the evidence review section. Sentence deleted. |
| B | 6 | Page 5: Top, AV node ablation is always in conjunction with placement of a permanent pacemaker (or previous placement of such). We suggest revision to reflect this. | This language is verbatim from the AHRQ report; four of the six included studies evaluated AV node ablation compared to pharmacologic treatment; all of these included placement of a pacemaker. One of the remaining studies compared two different approaches (anterior and posterior) to "AV junction modification". In this study, no pacemaker was used, as AV node pacing function remained intact. The sixth study compared right ventricular pacing to biventricular pacing.<br><br>Text of document revised to eliminate reference to studies that did not compare a primarily pharmacologic intervention to a primarily procedural intervention; this allows deletion as follows:<br>"All studies included at least one treatment arm with radiofrequency ablation of either the AVN or His bundle, ~~most often~~ in conjunction with pacemaker placement." |
| B | 7 | Page 8: There are separate paragraphs dealing with surgical PVI v. MAZE procedure at time of other cardiac surgery. Again, see page 1 comments above. | See comment #B2. Box language changed to surgical ablation. However, |

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| | | | because these two procedures are addressed discretely in the AHRQ report, with different studies supporting PVI and Maze, text of the document other than the box not revised. |
| B | 8 | Page 9: Bottom, again, surgical PVI and MAZE are the same thing. | See comment #B7 |
| C | 1 | Medtronic appreciates this opportunity to comment on Oregon Health Evidence Review Commission's (HERC's) draft coverage guidance on ablation for atrial fibrillation (AF).[1] Medtronic has extensive clinical expertise and offers innovative products across several areas of cardiovascular care, including AF. We applaud the efforts of HERC to develop evidence-based coverage guidance on treatments for AF. The guidance clearly summarizes and evaluates the robust body of evidence for AF treatment strategies. | Thank you for your comment. |
| C | 2 | To ensure alignment with the clinical guidelines and avoid potential confusion, we request clarification of the term "persistently symptomatic" in the draft coverage language for pulmonary vein isolation (PVI). The coverage guidance currently states:<br>*"Transcatheter pulmonary vein isolation is recommended for coverage for those who are persistently symptomatic despite rate control medications and antiarrhythmic medications (strong recommendation)."*<br><br>This language may suggest coverage is limited to patients with *persistent* AF and does not include patients with *paroxysmal* AF. We believe this may not be HERC's intention as such language would be counter to the prevailing clinical guidelines and clinical trial evidence cited in the coverage guidance document. The 2014 AHA/ACC/HRS Atrial Fibrillation Guideline (referenced on page 13 of the coverage guidance document) strongly recommends PVI for patients with symptomatic paroxysmal or symptomatic persistent AF who are refractory or intolerant to at least 1 class I or III antiarrhythmic medication (January 2014).<br>We propose the following revised coverage language:<br><br>*Transcatheter pulmonary vein isolation is recommended for coverage for those who are symptomatic (paroxysmal AF or persistent AF) despite rate control medications or antiarrhythmic medications (strong recommendation).* | EbGS agrees that the recommendation as written can be confusing and has modified the language to clarify:<br><br>Transcatheter pulmonary vein isolation is recommended for coverage for those who ~~are persistently~~ remain symptomatic from atrial fibrillation despite rate control medications and antiarrhythmic medications (strong recommendation) |
| C | 3 | This revised language will help to ensure alignment with current clinical practice guidelines and that the appropriate patients have access to the right treatment strategies. | EbGS agrees. |

## References Provided by Commenters

| Commenter | References |
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| C | (1) January, C. T., Calkins, H., Murray, K. T., Cigarroa, J. E., & Stevenson, W. G. (2014). 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation. *Circulation*, *129*, 000-00. |