Washington State Health Care Authority
Health Technology Assessment

Catheter Ablation Procedures For Supraventricular Tachyarrhythmia Including Atrial Flutter & Atrial Fibrillation

Clinical Expert

Ramakota K. Reddy, MD

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.	X	
2.	Equity interests such as stocks, stock options or other ownership interests.		X
3.	Status or position as an officer, board member, trustee, owner.		X
4.	Loan or intellectual property rights.		X
5.	Research funding.	X	
6.	Any other relationship, including travel arrangements.		X

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Boerincher - Ingleheim, speaking fees
Research Funding: Medtronic, St. Jude,

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

If yes to #7, provide name and funding Sources: _____

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ 4/22/13 _____ RAMAKOTA REDDY

Signature *Date* *Print Name*

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Curriculum Vitae

RAMAKOTA K. REDDY, M.D.

PERSONAL DATA: Birth: Kitchner-Waterloo, Ontario, Canada
Born: August 12, 1965

CURRENT ADDRESS: 3455 Spring Blvd
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email: rreddy@oregoncardiology.com
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LICENSURE TO PRACTICE:

State of Washington, MD0030878, Aug 12, 1993
State of Ohio, 73467, Sept 26, 1997
State of Oregon, MD23163, July 13, 2001

BOARD CERTIFICATION:

American Board of Internal Medicine, 1993, Certificate Number 152998.
American Board of Cardiovascular Disease, 1997, 2007, Certificate Number 152998
ABIM Special Certification in Clinical Cardiac Electrophysiology, 1998, 2008, Certificate Number152998

EDUCATION:

1986-1990 University of Pennsylvania Medical School
M.D. Degree, May 1990

1982-1986 University of Iowa
B.S.E. Degree, Biomedical Engineering with Highest Distinction
Minor, Computer Science

POSTGRADUATE TRAINING:

1993-1997 University of Washington Cardiology Fellowship, Seattle, WA
1993-1996 - General cardiology including non-invasive and invasive techniques, Catherine M. Otto, MD and J. Ward Kennedy, MD.
1995-1997 - Clinical electrophysiology laboratory, Peter J. Kudenchuk, MD and Gust H. Bardy, MD.

1990-1993 Wilford Hall USAF Medical Center, San Antonio, TX
Internal Medicine Residency (Phillip Perucca, MD)

CLINICAL CARDIOLOGY POSITIONS:

2001-present Oregon Cardiology, Electrophysiologist. Practice in:
Sacred Heart Medical Center, Eugene, OR
Mackenzie-Willamette Hospital, Springfield, OR
Good Samaritan Hospital, Corvalis, OR
Peacehealth Hospital, Florence, OR

1997-2001 Wright Patterson Air Force Base Medical Center, Dayton OH
Chief of Cardiology, 2000-2001
Director of Electrophysiology, 1997-2001
Director of Clinical Research, 1998-2001
Committee appointments: Education, Clinical Informatics
Clinical Research: SCD-HeFT (top 5 enrollee), BiCARD

1998-2001 F. Edward Hebert School of Medicine
Uniformed Services University of the Health Sciences
Associate Professor of Medicine
Department of Medicine

POSITIONS HELD PRIOR TO MEDICAL DEGREE:

1988-1990 University of Pennsylvania, Department of Radiology,
Research Assistant & Computer Programmer
Magnetic resonance imaging techniques and flow imaging
Felix Wehrli, PhD.

1988 Kennedy Space Center NASA, Cape Canaveral, Florida,
Instructor: Space Life Sciences Training Program

1984-1986 University of Iowa, Cardiac Image Processing Laboratory
Research Assistant & Computer Programmer
Quantitative Angiography, Fast CT and MRI cardiac Imaging
David Skoton, MD & Steve Collins, PhD.

1984-85Palmer College of Chiropractic
Developed a complete billing system for National Direct Student Loans using dBase II and dBase III on IBM-PC's

INVESTIGATOR INITIATED RESEARCH PROTOCOLS (COMPETITIVE GRANT SUPPORTED):

North American Society of Pacing and Electrophysiology (NASPE) Fellowship Grant, 1996-97
"The Effect of Transthoracic Shock Waveform Shape on Cardiac Mechanics in Humans Measured in the *Non*-fibrillating Heart"

American Heart Association Fellowship Grant, 1996-97
"Intravenous Bolus Lidocaine for Chemical Cardioversion of Atrial Fibrillation"

American Heart Association Fellowship Grant, 1995-96.
"Prospective Comparison of Biphasic and Monophasic Shock Waveforms on Cardiac Function after Transthoracic Defibrillation"

MULTICENTER RESEARCH PROTOCOL PARTICIPATION:

SCD-HeFT: Sudden Cardiac Death in Heart Failure Trial, 1998-2001.
Primary Investigator, Wright Patterson Air Force Base.
Patients randomized: 49 (7^{th} highest in study). Member of EGM reading committee.

Bi-CARD Study, Biphasic vs Monophasic waveforms for conversion of atrial fib, 1999-2000..
Primary Investigator, Wright Patterson Air Force Base

Intrinsic-RV Study, Guidant Corporation, 2003-2005.
Co-Primary Investigator, Sacred Heart Medical Center

MAVERIC Study, Medtronic Corporation, 2003-2006.
Primary Investigator, Sacred Heart Medical Center

PAVE: Post AV Node Ablation Evaluation, St. Jude Corporation, 2003-2005.
Primary Investigator, Sacred Heart Medical Center

ORGANIZATIONS:

American College of Cardiology, Fellow
North American Society of Pacing and Electrophysiology, Member
American College of Physicians, Member
Aerospace Medical Association, Member
Society of Air Force Physicians, Member

HONORS:

Omicron Delta Kappa, Collegiate honor society, 1985-present
Tau Beta Pi, Engineering Collegiate honor society, 1984-present
Phi Eta Sigma, Collegiate honor society, 1983-present
National Merit Scholar, 1982

SCHOLARSHIPS:

Air Force Health Professions Scholarship, 1986-90
3M Engineering Merit Scholarship, 1984-86
Archie Alaxander Scholarship, 1983-84
University of Iowa Biomedical Engineering Scholarship, 1982-83

PUBLICATIONS

ABSTRACTS:

1. Reddy RK, Saad TF: Occult Pulmonary Hypertension in a Patient Awaiting Liver Transplantation. *Society of Air Force Physicians*, San Antonio, TX, 1992.

2. Reddy RK, Dooley DP: Disseminated Coccidioidomycosis Presenting as a Unique Omental Mass, *Society of Air Force Physicians*, St. Louis, MO, 1993.

3. Reddy RK, Grimwood RE: Autoantibody to an Unknown Basement Membrane Protein Presenting as a Bullous Eruption, *Society of Air Force Physicians*, St Louis, MO, 1993.

4. Reddy RK, Gleva MJ, Dolack GL, Kudenchuk PJ, Poole, JE, Gliner BE, Bardy GH: Biphasic truncated waveform transthoracic defibrillation results in less post-shock ECG ST segment changes than standard damped sine wave shocks. *JACC* February:405A, 1995.

5. DeRook FA, Lewis DH, Muzzarelli JR, Reddy RK, Comess KA: Imaging and Lab Studies for Myocardial Ischemia and Injury. 1997 Annual Western Regional Meeting of the Society of Nuclear Medicine.

6. Casciello M, Sawyer R, Reddy RK: Persistent Atrial Flutter Caused by Electrical Injury. *Society of Air Force Physicians*, San Antonio, TX, 2000.

7. Casciello M, Pierce RH, Reddy RK: A Rare Case of Enterococcus Faecalis Pericarditis. *Society of Air Force Physicians*, San Antonio, TX, 2000.

8. Lorenzo HN, Reddy RK: Diagnosis of a Wide Complex Tachycardia in a Patient with a 15 Year History of Presyncope and Palpitations after Insertion of an Implantable Loop Recorder. *Society of Air Force Physicians*, San Antonio, TX, 2000.

9. Shalaby A, Adler S, Bailin S, Barsohn M, Reddy RK, Remole S, Weiss R, Munneke D: Can Novel Digital Processing Technology Enable Successful Device Classification of Atrial Tachyarrhythmias. *Heart Rhythm*, 2:S124, May 2005.

10. Poole JE, Johnson GW, Callans DJ, Raitt MH, Yee R, Reddy RK, Wilber DJ, Guarnieri T, Talajic M, Marchlinski FE, Anderson J, Lee KL, Bardy GH: Rhythm Precursors in Those Treated for Ventricular Tachycardia or Ventricular Fibrillation in SCD-HeFT.. *Heart Rhythm*, 2:S39-40, May 2005.

11. Costin KM, Burke BO, Seagrave S, Reddy RK, McClelland JH: Catheter Reprocessing: A Prospective Study. *Heart Rhythm*, 3:S138-9, May 2006.

12. Poole JE, Johnson GW, Hellkamp AS, Anderson J, Callans DJ, Raitt MH, Reddy RK, Marchlinski FE, Yee R, Guarnieri T, Wilbur DJ, Talajic M, Mark DB, Lee KL, Bardy GH; the SCD-HeFT Investigators. Mortality after appropriate and inappropriate shocks in SCD-HeFT. *Heart Rhythm*, 3: S40. May 2006.

13. Patton K, Poole J, Gold M, Wang T, Johnson G, Hellkamp A, Anderson J, Callans D, Raitt M, Reddy RK, Marchlinski FE, Yee R, Guarnieri T, Wilber DJ, Talajic M, Mark DB, Lee KL, Bardy GH: Septadian variation in life-threatening ventricular arrhythmias in SCD-HeFT. *Heart Rhythm*, 3:S161-70, May 2006.

14. Patton K, Poole J, Gold M, Wang T, Johnson G, Hellkamp A, Anderson J, Callans D, Raitt M, Reddy RK, Marchlinski FE, Yee R, Guarnieri T, Wilber DJ, Talajic M, Mark DB, Lee KL, Bardy GH: Circadian variation of ventricular arrhythmias in SCD-HeFT. *Heart Rhythm*, 3:S164-5, May 2006.

15. Blatt JA, Poole JE, Johnson GW, Callans DJ, Raitt MH, Reddy RK, Marchlinski FE, Yee R, Guarnieri T, Talajic M, Wilber DJ, Mark DB, Lee KL, Bardy GH: No Benefit From DFT Testing in the Sudden Cardiac Death in Heart Failure Trial. *Heart Rhythm*, 4:S81, May 2007.

BOOK CHAPTERS:

1. Reddy RK, Bardy GH: Implantable Dual Chamber Defibrillators for Atrial Defibrillation. In Murgatroyd FD, Camm AJ (eds): Nonpharmacological Management of Atrial Fibrillation. Futura Publishing Co., Armonk, NY. 1997.

2. Reddy RK, Jones, GK, Bardy GH: Implantable Cardioverter-Defibrillator Implantation Techniques. In Singer I, Barold SS, Camm AJ (eds): Nonpharmacological Therapy of Arrhythmias for the 21st Century: The State of the Art. Futura Publishing Co, Armonk, NY. 1998.

ARTICLES:

1. Dooley DP, Reddy RK, Smith CE, Coccidioidomycosis Presenting as an Omental Mass. *Clinical Infectious Diseases* 19:802-3, 1994

2. Wittkowsky AK, Reddy RK, Bardy GH. Oral mucosal ulceration from disopyramide. *Annals of Pharmacotherapy* 29:1299, 1995.

3. Bardy GH, Marchlinski FE, Sharma AD, Worley SJ, Luceri RM, Yee R, Halperin BD, Fellows CL, Ahern TS, Chilson DA, Packer DL, Wilber DJ, Mattioni TA, Reddy R, Kronmal RA, Lazzara R, for the Investigators: Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation. *Circulation* 94:2507-14, 1996.

4. Reddy RK, Bardy GH. Experience with Unipolar Pectoral Defibrillation. *Herzschrittmachertherapie und Elecktrophysiologie* 8:32-38, 1997.

5. Reddy RK, Bardy GH. Unipolar Pectoral Defibrillation Systems. *PACE* 20[Pt. II]:600-606, 1997.

6. Kudenchuk, PJ, Bardy GH, Poole JE, Dolack GL, Gleva MJ, Reddy RK, Jones GK, Troutman C, Anderson J, Johnson G. Malignant Sustained Ventricular Tachyarrhythmias in Women: Characteristics and Outcome of Treatment with an Implantable Cardioverter Defibrillator. *J Cardiovasc Electrophysiol* 8:2-10, 1997.

7. Reddy RK, Poole JE. Pharmacological Therapy of Ventricular Arrhythmias. *ACC Journal Review*, 6(4):43-7, 1997.

8. Reddy RK, Gleva MJ, Gliner BE, Dolack GL, Kudenchuk PJ, Poole JE, Bardy GH: Biphasic Transthoracic Defibrillation Causes Fewer ECG ST Segment Changes After Shock. *Annals of Emergency Medicine.* 30(2):127-134, 1997.

9. Ender PT, Durning SJ, Woelk WK, Brockett RM, Astorga A, Reddy R, Meier PA: Pseudo-outbreak of methicillin-resistant Staphylococcus aureus. *Mayo Clinic Proc*. 74(9):885-9, 1999.

10. Marrouche NF, Reddy RK, Wittkowski AK, Riddle C, Bardy GH: High Dose Bolus Lidocaine For Chemical Cardioversion of Atrial Fibrillation: A Prospective Randomized Double-Blind Crossover Trial. *American Heart Journal*, 139(6):8e-11e, 2000.

11. Page RL, Kerber RE, Russel JK, Trouton T, Waktare J, Gallik D, Olgin JE, Ricard P, Dalzell GW, Reddy RK, Lazzara R, Lee K, Carlson M, Halperin B, Bardy GH: Biphasic Versus Monophasic Shock Waveform for Conversion of Atrial Fibrillation: The Results of an International Randomized, Double-Blind Multicenter Trial. *JACC*, 39(12):1956-63, 2002.

12. McClelland JH, Duke D, Reddy R: Preliminary Results of a Limited Thoracotomy: New Approach to Treat Atrial Fibrillation. *J Cardiovasc Electrophysiology*, 18(12):1289-95, 2007.

13. Blatt JA, Poole JE, Johnson GW, Callans DJ, Raitt MH, Reddy RK, Marchlinski FE, Yee R, Guarnieri T, Talajic M, Wilber DJ, Andersen J, Chung K, Wonk WS, Mark DB, Lee KL, Bardy GH: No Benefit From Defibrillation Threshold Testing in the SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial). *JACC*, 52(7):551-556, 2008.

14. Poole JE, Johnson GW, Hellkamp AS, Anderson J, Callans DJ, Raitt MH, Reddy RK, Marchlinski FE, Yee R, Guarnieri T, Talajic M, Wilber DJ, Fishbein DP, Packer DL, Mark DB, Lee KL, Bardy GH: Prognositc Importance of Defibrillator Shocks in Patients with Heart Failure. *NEJM*, 359(10):1009-17, 2008

Washington State Health Care Authority
Health Technology Assessment

Catheter Ablation Procedures for SVTA

Order of Scheduled Presentations

	Name	Representing
1	Jeanne Poole, MD	Director, Electrophysiology Division of Cardiology, University of Washington
2	Gerhard H. Muelheims, MD, FACC	Spokane Cardiology

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		X
2.	Equity interests such as stocks, stock options or other ownership interests.	X	
3.	Status or position as an officer, board member, trustee, owner.	X	
4.	Loan or intellectual property rights.		X
5.	Research funding.	X	
6.	Any other relationship, including travel arrangements.	X	

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

consulting for Physio control, equity options Cameron Health
Advisory board Boston Scientific
Educational talks for Medtronic, ST. JUDE, Boston Scientific and BIOTRONIK, Research NHI/NHLBI

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).	✓	

If yes to #7, provide name and funding Sources: unrestricted educational grants for fellowship training from Medtronic and Boston Scientific.

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ 4/26/2013 Jeanne E. Poole

Signature *Date* *Print Name*

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Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		✓
2.	Equity interests such as stocks, stock options or other ownership interests.		✓
3.	Status or position as an officer, board member, trustee, owner.		✓
4.	Loan or intellectual property rights.		✓
5.	Research funding.		✓
6.	Any other relationship, including travel arrangements.		✓

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		✓

If yes to #7, provide name and funding Sources:

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X _____ 5/1/13 Gerhard Muellheims

Signature *Date* *Print Name*

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(FAX 586-3545)

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		X
2.	Equity interests such as stocks, stock options or other ownership interests.		X
3.	Status or position as an officer, board member, trustee, owner.		X
4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.		X

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).	X	

If yes to #7, provide name and funding Sources: I represent myself and the University of Washington as my employer.

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X [signature] 5/17/2013 Mohan Viswanathan, MD

Signature *Date* *Print Name*

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Washington State Health Care Authority

Catheter Ablation Procedures for Supraventricular Tachyarrhythmia

Agency Medical Directors' Comments

G. Steven Hammond PhD, MD, MHA
Chief Medical Officer
Department of Corrections
May 17, 2013

Background:

Catheter ablation for supraventricular tachyarrhythmia is intended to control or cure various types of cardiac arrhythmias originating above the ventricles. It is an alternative to medication and surgical treatments.

AMDG Concerns:

- Benefits of catheter ablation in various types of supraventricular arrhythmia uncertain
- Safety of procedures uncertain
- Cost of procedure very high (billed outpatient hospital charges exceed $100K per procedure)
- Must be compared to alternative management including: medication treatment, surgical treatment, or no active treatment

Catheter Ablation Procedures
State Agency Experience

Topic Selection

AMDG Criteria Rankings at Selection:

Efficacy – **High**
Safety – **Medium**
Cost – **High**

AMDG Criteria Rankings After Review of Evidence Report:

Efficacy – **High** for some arrhythmias; **Medium** for others
Safety – **Medium**
Cost – **High**

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Catheter Ablation Procedures
State Agency Experience

AMDG Perspective:

- When is catheter ablation the procedure of choice to manage various supraventricular arrhythmias?
  - How does management by catheter ablation compare to management with medication (anti-arrhythmic drugs or AADs)
    or even no treatment?
  - In what patients is catheter ablation the procedure of choice (Symptomatic patients? Patients who have failed medication treatment? For particular types of arrhythmia?)
- Are catheter ablation procedures safe?
- Are catheter ablation procedures cost-effective?

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Washington State Health Care Authority

Catheter Ablation Procedures
State Agency Experience

Agency	Catheter Ablation Procedures
Labor & Industries: • *Note:* Rarely performed under L&I • Prior authorization required	**Covers**
PEBB-UMP: • No prior authorization required	**Covers**
Medicaid: • No prior authorization required	**Covers**
Dept. of Corrections: • Prior authorization required	**Covers**

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Catheter Ablation Procedures
State Agency Experience

Agency/Year **PEBB-UMP**	2008	2009	2010	2011	4-Yr Overall	Avg % Change	
Patient Count	113	143	147	135	484	5.8%	*
Procedure Count	119	153	154	135	559	4.1%	*
Amount Paid	$2.01M	$2.72M	$2.6M	$2.36M	$9.7M	5.8%	*
Per Procedure Average	$16,864	$17,796	$16,906	$17,476	$17,277		
Medicaid							
Patient Count	60	47	63	93	263	16.5%	*
Procedure Count	65	48	65	95	273	15.0%	*
Amount Paid	$589K	$401K	$471K	$588K	$2.05M	0.4%	*
Per Procedure Average	$9063	$8355	$7481	$6998	$7882		

* Population adjusted growth rate
NOTE: Procedure amounts include related charges on the day of service or for the duration of hospitalization.

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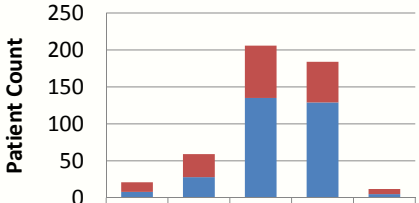
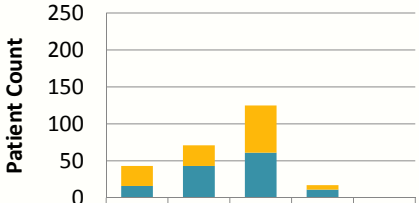
Catheter Ablation Procedures
State Agency Experience

PEBB-UMP Ablation Patients by Age and Gender, 2008-2011



	21-35	36-50	51-65	66-80	80+
Female	13	31	71	55	7
Male	8	28	135	129	5

Medicaid Ablation Patients by Age and Gender, 2008-2011



	21-35	36-50	51-65	66-80	80+
Female	27	28	64	6	1
Male	16	43	61	11	0

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Catheter Ablation Procedures
State Agency Experience

Per Procedure Average Allowed Amount

Agency/Payer	UMP Primary		UMP Medicare		Medicaid		Medicaid Medicare
In or Outpatient (Count)	In (n=118)	Out (n=188)	In (n=94)	Out (n=137)	In (n=28)	Out (n=207)	Out (n=38)
Breakdown 1							
Professional Services	$3823	$2676	$1758	$1535	$1490	$1299	$76
Facility	$27,444	$22,699	$53,547	$44,322	$13,088	$8098	$12,447
Breakdown 2							
Equipment/Supplies	$369	$791	$1231	$2100	$0	$3	$241
Ablation Procedure	$1836	$3048	$1635	$3291	$542	$2454	$397
Heart Function Test	$8408	$20,423	$6107	$15,643	$731	$5264	$10,466
Other Charges	$1153	$614	$1094	$2121	$228	$317	$1411
Hospital	$19,501	$498	$45,238	$22,703	$13,077	$59	$0
Avg Allowed	**$31,267**	**$25,375**	**$55,305**	**$45,857**	**$14,579**	**$8098**	**$12,523**

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Catheter Ablation Procedures
State Agency Experience

Medicare:

No national coverage determination (NCD)

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Catheter Ablation Procedures
State Agency Experience

The Evidence Shows:

- **Atrial Fibrillation**
  CA efficacy may be superior to medication (AADs) in preventing recurrence
  (In those failing AADs? Most suitable for symptomatic patients?)
- **Atrial Flutter**
  CA efficacy appears superior to AADs in preventing recurrence
  (After failure of cardioversion, electrical or drug-induced?)
- **AVNRT and AVRT (Other Than WPW)**
  Data limited and insufficient to determine whether CA yields better outcomes than AADs, surgery, or no treatment
- **Wolff-Parkinson-White Syndrome (WPW)**
  CA efficacy appears superior to no treatment in reducing recurrence rate
- **Sinus tachycardia, atrial tachycardia, focal junctional ectopic tachycardia, and nonparoxysmal junctional tachycardia**
  No evidence specific to these arrhythmia types

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Catheter Ablation Procedures
State Agency Experience

AMDG Summary View

- Evidence best supports efficacy in symptomatic, drug-resistant atrial fibrillation, atrial flutter, and WPW syndrome
- Evidence to support efficacy in other AVNRT and AVRT is sparse and low-grade
- Evidence is lacking to support efficacy in sinus tachycardia, atrial tachycardia, focal junctional ectopic tachycardia, and nonparoxysmal junctional tachycardia

Washington State Health Care Authority

Catheter Ablation Procedures
State Agency Experience

AMDG Summary View

- Safety is equivalent to non-CA interventions
- Cost-effectiveness can only be argued for symptomatic, drug-resistant atrial fibrillation, atrial flutter, and WPW syndrome where efficacy is reasonably well established

Washington State Health Care Authority

Catheter Ablation Procedures
State Agency Experience

AMDG Recommendation

Cover with Conditions:

- Catheter ablation procedures for atrial fibrillation, atrial flutter, WPW syndrome, and AVNRT/AVRT, Symptomatic and Drug-Resistant

Not Covered:

- Catheter ablation procedures for sinus tachycardia, atrial tachycardia, focal junctional ectopic tachycardia, and nonparoxysmal junctional tachycardia

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Catheter Ablation Procedures
State Agency Experience

Questions?

More Information: hta.hca.wa.gov/svta.html

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Washington State Health Care Authority

Catheter ablation procedures for SVTA including atrial flutter and atrial fibrillation

May 17, 2013

HEALTH TECHNOLOGY ASSESSMENT
prepared by:

Robin Hashimoto, PhD
Annie Raich, MPH
Mark Junge, BS
Andrea Skelly, PhD, MPH

Spectrum Research, Inc., Tacoma, WA

Background

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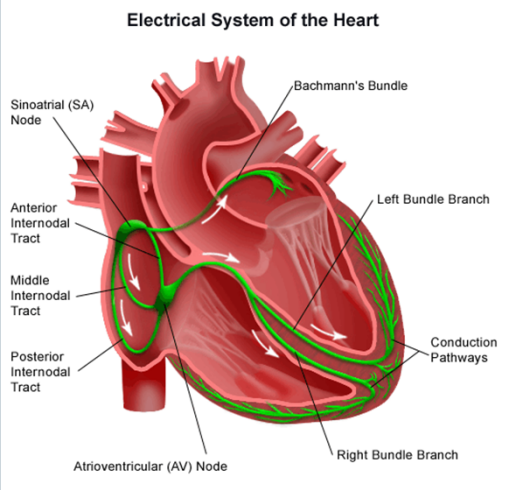

Image from www.chop.edu

Background:
Supraventricular tachyarrhythmias

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- Rapid heart rhythm
- Caused by disorders of impulse initiation ("automatic") or by abnormalities of impulse conduction ("reentrant")
- Originate above the ventricles
- Causes and severity vary with age, sex, and associated comorbidity
- Categorized by the origin of the tachyarrhythmia:
  - Atrial fibrillation (AF)
  - Atrial flutter
  - Supraventricular tachycardias (SVTs)
    - Various specific arrhythmias within this subgroup

Background:
Atrial fibrillation

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- Most common supraventricular tachyarrhythmia
  - ~1/3 of hospitalizations for cardiac dysrhythmia
  - Prevalence: ~0.4 -1.0%
  - Risk increases with age, male sex, obesity, smoking, diabetes, hypertension
- Increases long-term risk of stroke, heart failure, and all-cause mortality; impairs quality of life
- Recurrent if 2+ episodes
- Classifications:
  - paroxysmal (terminates spontaneously)
  - persistent (lasts more than 7 days)
  - Permanent
- Characterized by uncoordinated atrial activation with consequent deterioration of atrial mechanical function.
- Disorganized impulses that cause the heart to quiver thought to originate in/near pulmonary veins

Guidelines:
Atrial fibrillation

5

Recommendation	ACC/AHA/HRS (2011)	HRS/EHRA/ECAS (2012)
Class I	AADs	Ablation for paroxysmal AF refractory to 1+ AAD
Class IIa	Ablation when refractory to 1+ AAD (or AAD not tolerated)	Ablation for persistent AF refractory to 1+ AAD Ablation for paroxysmal AF
Class IIb		Ablation for longstanding persistent refractory to 1+ AAD Ablation for persistent or longstanding persistent

Background:
Atrial flutter

6

- Macroreentrant atrial tachycardia
- Characterized by an organized atrial rhythm with a reentrant circuit that typically involves the cavotricuspid isthmus, causing the impulse to move in a self-perpetuating loop through the right atrium
- Heart rate: 250-350 bpm
- Symptoms: palpitations, dyspnea, fatigue, chest pain
- Risk factors include increased age and male sex

Guidelines:
Atrial flutter

7

Recommendation	ACC/AHA/ESC (2003)	HRS (2003)
Class I	Ablation: Recurrent and well-tolerated flutter; OR poorly tolerated flutter; OR flutter refractory to AADs. Cardioversion: First episode and well-tolerated flutter.	Ablation: Considered initial therapy for typical flutter.
Class IIa	Ablation: First episode and well-tolerated flutter. Dofetilide: Recurrent and well-tolerated flutter.	Ablation: Considered for atypical flutter refractory to AAD(s).
Class IIb	AADs (other than dofetilide): Recurrent and well-tolerated flutter.	

Background:
Supraventricular tachycardias (SVTs)

8

- Sinus tachycardia
  - Inappropriate sinus tachycardia
  - Sinus nodal reentrant tachycardia
- Atrioventricular reentrant tachycardia (AVRT)
  - Includes Wolff-Parkinson-White (WPW) Syndrome
- Atrioventricular nodal reentrant tachycardia (AVNRT)
- Atrial tachycardia
- Focal junctional ectopic tachycardia
- Nonparoxysmal junctional tachycardia

Background:
Supraventricular tachycardias (SVTs)

9

- Supraventricular tachycardias (SVTs)
  - Atrioventricular reentrant tachycardia (AVRT)
    - Characterized by the presence of accessory pathways which can conduct impulses in an anterograde manner, retrograde manner, or both.
    - Includes Wolff-Parkinson-White (WPW) Syndrome
      - Characterized by pre-excitation combined with tachyarrhythmias
  - Atrioventricular nodal reentrant tachycardia (AVNRT)
    - Most common form of SVT
    - Caused by conduction down a slow AV nodal pathway and up the fast AV nodal pathway, leads to an almost simultaneous conduction up to the atria and down to the ventricles

Guidelines:
SVTs

10

Arrhythmia	ACC/AHA/ESC (2003), Class I recommendations
• Regular tachycardia	Specific AADs
• AVNRT	Ablation
• WPW Syndrome	Ablation
• AVRT (poorly tolerated)	Ablation
• AVRT (single episode or infrequent)	No treatment, or vagal maneuvers, or pill-in-the pocket

Technology: catheter ablation

11

- Performed in a cardiac catheterization laboratory
- Guided insertion of catheters from arm, groin, or neck into the heart
- Radiofrequency energy sent through the catheters to the focal point in the heart that is believed to be the source of the arrhythmia.
- Cryoablation uses pressurized refrigerant to freeze the focal point.
- The energy ablates very small areas of the heart to eliminate the cause of the abnormal electrical energy
- May be used in conjunction with antiarrhythmic drugs
- Typically used with long-term anticoagulants to prevent stroke

Technology: catheter ablation

12

- **Pulmonary vein isolation shown**

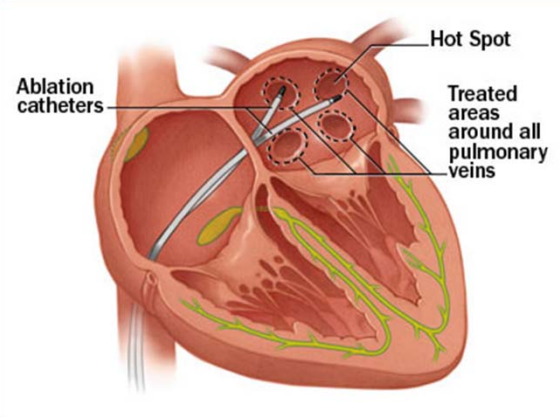


Image from www.cardiologist.org

Technology: catheter ablation

13

- **Atrial fibrillation:** the areas around and inside the pulmonary veins are targeted (pulmonary vein isolation (PVI))
  - Various additional approaches can be used to treat AF (additional lines, wide area circumferential ablation, complex fractionated atrial electrograms, etc.)
- **Atrial flutter:** target is typically between the tricuspid annulus and inferior vena cava
- **SVTs:** target varies by diagnosis

FDA-approved devices

14

- 18 approved radiofrequency ablation catheter devices, manufactured by:
  - Boston Scientific
  - Medtronic
  - Cordis
  - St. Jude Medical
  - Biosense Webseter
  - CR Bard
  - Irvine Biomedical
  - Stereotaxis
  - Atricure
- 3 approved cryoablation catheter devices, manufactured by:
  - Medtronic Cryocath
  - Boston Scientific

Ong, KL et al. Spine 35:1794 (2010)

Comparators

15

- **Antiarrhythmic drugs**

Table 20. Typical Doses of Drugs Used to Maintain Sinus Rhythm in Patients With Atrial Fibrillation*

Drug†	Daily Dosage	Potential Adverse Effects
Amiodarone‡	100 to 400 mg	Photosensitivity, pulmonary toxicity, polyneuropathy, GI upset, bradycardia, torsades de pointes (rare), hepatic toxicity, thyroid dysfunction, eye complications
Disopyramide	400 to 750 mg	Torsades de pointes, HF, glaucoma, urinary retention, dry mouth
Dofetilide§	500 to 1000 mcg	Torsades de pointes
Flecainide	200 to 300 mg	Ventricular tachycardia, HF, conversion to atrial flutter with rapid conduction through the AV node
Propafenone	450 to 900 mg	Ventricular tachycardia, HF, conversion to atrial flutter with rapid conduction through the AV node
Sotalol§	160 to 320 mg	Torsades de pointes, HF, bradycardia, exacerbation of chronic obstructive or bronchospastic lung disease

*Drugs and doses given here have been determined by consensus on the basis of published studies.
†Drugs are listed alphabetically.
‡A loading dose of 600 mg per day is usually given for one month or 1000 mg per day for 1 week.
§Dose should be adjusted for renal function and QT-interval response during in-hospital initiation phase.
AF indicates atrial fibrillation; AV, atrioventricular; GI, gastrointestinal; and HF, heart failure.

- **Surgery**
  - **Cox-Maze infrequently used**

ACC/AHA/HRS guidelines 2011: Circulation 123:e269

Key Questions

16

- **KQ1.** Efficacy and effectiveness
- **KQ1a.** Efficacy and effectiveness of different types of ablation (eg, radiofrequency vs. cryoablation)
- **KQ2.** Efficacy of various PVI approaches for AF
- **KQ3.** Safety
- **KQ4.** Differential efficacy or safety issues in subpopulations
- **KQ5.** Cost effectiveness

Inclusion criteria (PICO)

17

- **Participants.** Adults with supraventricular tachyarrhythmia, including atrial fibrillation, atrial flutter, and supraventricular tachycardia
- **Intervention.** Catheter ablation (for AF, will consider only pulmonary vein isolation)
- **Comparators.** Medical therapy, surgery, other strategies to control rhythm

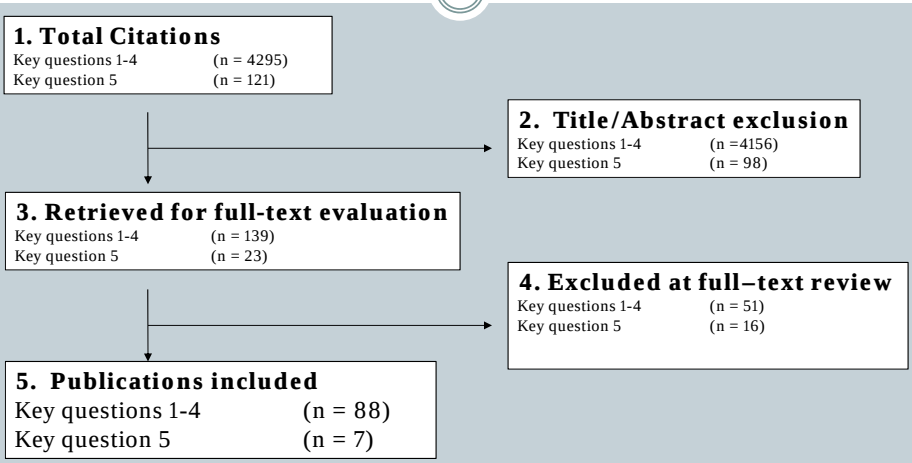
Inclusion criteria (PICO)

18

- **Outcomes.**
  - **Efficacy and effectiveness:**
    - Primary outcomes: freedom from recurrence; mortality or myocardial infarction not caused by the procedure
    - Secondary outcomes: improvement of symptoms, quality of life, maintenance of sinus rhythm, hospitalization/readmission, repeat ablation, measures of cardiac function
  - **Safety:**
    - Procedure-related mortality, stroke, congestive heart failure
    - Other complications/adverse events

Literature search

19



Strength of evidence (SoE)

20

SoE	Interpretation
High	High confidence that the evidence reflects the true effect.
Moderate	Moderate confidence that the evidence reflects the true effect; further research may impact results.
Low	Low confidence that the evidence reflects the true effect; further research likely to impact results.
Insufficient	Evidence does not permit a conclusion or is unavailable.

Results: KQ1

21

KQ1. What is the evidence of efficacy and effectiveness of:

a. **PVI for atrial fibrillation (AF)?**
b. **catheter ablation for atrial flutter?**
c. **catheter ablation for supraventricular tachycardias (SVTs), including :**
   - sinus tachycardia, atrioventricular reentrant tachycardia (AVRT) (including Wolff-Parkinson-White (WPW) Syndrome), atrioventricular nodal reentrant tachycardia (AVNRT), atrial tachycardia, focal junctional ectopic tachycardia, and nonparoxysmal junctional tachycardia

KQ1: Efficacy
(AF: RF PVI versus AADs)

22

Evidence base: 8 RCTs
N = 30 – 198 patients
Intervention:
Radiofrequency (RF) PVI versus antiarrhythmic drugs (AADs)

RCT	N	Symptomatic?	Duration of symptoms	Refractory to AAD(s)?	New AAD(s) given?	AF classification
Wazni (2005)	70	Yes	0.4 yrs.	No	n/a	Paroxysmal or persistent
Forleo (2009)*	70	Yes	3.3 yrs.	Yes	Yes	Paroxysmal or persistent
Jais (2008)	112	Yes	5.5 yrs.	NR	Yes	Paroxysmal
Krittayaphong (2003)	30	Yes	4.7 yrs.	Yes	Yes	Paroxysmal or persistent
Pappone (2006/ 2011)	198	NR	6 yrs.	Yes	Yes	Paroxysmal
Stabile (2006)	62	NR	6.1 yrs.	Yes	No	Paroxysmal
Wilber (2010)	167	Yes	5.7 yrs.	Yes	Yes	NR

* Diabetes mellitus type 2 patients

KQ1: Efficacy
(AF: RF PVI versus AADs)

23

- **Evidence base: 8 RCTs**
  - Cumulative freedom from recurrence

	PRIMARY OUTCOMES:	
	Freedom from recurrence (6-12 mos.)	**Freedom from recurrence (48 mos.)**
Overall SoE	*moderate*	*moderate*
Favors	PVI	PVI
Effect	RD: 50% (95% CI, 43%, 58%) NNT: 2	RD: 61% (95% CI, 48%, 70%) NNT: 2
# studies (# patients)	7 (N = 714)	1 (N = 198)

"=" similar between treatment groups

KQ1: Efficacy
(AF: RF PVI versus AADs)

24

- **Freedom from recurrence: 6 to 12 months**

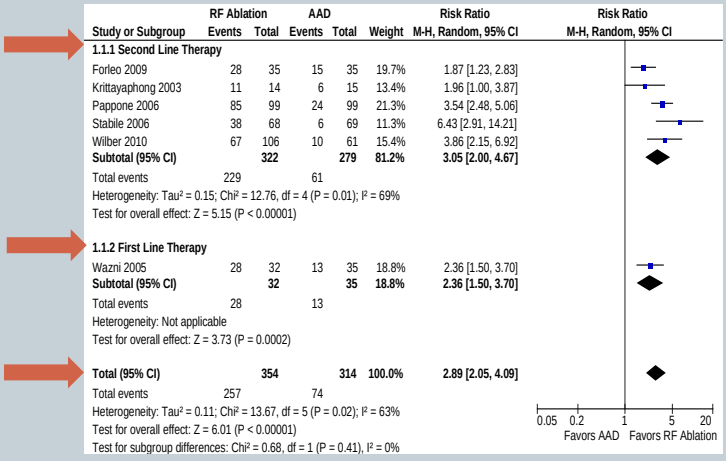


Figure 3 in report: meta-analysis of 6 studies

KQ1: Efficacy
(AF: RF PVI versus AADs)

25

- **Evidence base: 8 RCTs**
  - **N = 30– 198 patients**
  - **Intervention:**
    - Radiofrequency (RF) PVI versus antiarrhythmic drugs (AADs)
  - **Follow-up: 12 months (majority of studies); 48 months (1 study)**

	PRIMARY OUTCOMES (continued)		
	Mortality (not procedure-related) (12 mos.)	**Stroke** (not procedure-related) (12 mos.)	**Congestive heart failure** (not procedure-related) (12 mos.)
Overall SoE	*low*	*low*	*low*
Favors	=	=	=
Effect	RD: 2% (NS)	RD: 0%	RD: 0%
# studies (# patients)	1 (N = 137)	2 (N = 140)	1 (N = 198)

"=" similar between treatment groups

KQ1: Efficacy
(AF: Cryo-PVI versus AADs)

26

- **Evidence base: 1 RCT (Pivotal Trial from FDA SSED)**
- **N = 245 patients**
  - **Intervention:**
    - Cryoablation PVI versus antiarrhythmic drugs (AADs)
  - **Follow-up: 12 months**

	PRIMARY OUTCOMES:			
	Freedom from recurrence	**Mortality** (not procedure-related)	**Stroke** (not procedure-related)	**Congestive heart failure** (not procedure-related)
Overall SoE	*low*	*low*	*low*	*low*
Favors	CryoPVI	=	=	=
Effect	RD: 63% (95% CI, 52%, 70%) NNT: 2	RD:-0.6% (NS)	RD: 0.6% (NS)	RD: 0.6% (NS)
# studies (# patients)	1 (N = 245)	1 (N = 245)	1 (N = 245)	1 (N = 245)

"=" similar between treatment groups

KQ1: Effectiveness
(AF: RF PVI versus Cox-Maze Surgery)

27

- **Evidence base: 1 retrospective cohort study**
- **N = 289 patients**
  - **Intervention:**
    - RF PVI versus antiarrhythmic drugs (AADs)
  - **Follow-up: mean of 54 months**

	PRIMARY OUTCOMES:		
	Freedom from recurrence (in presence of AADS)	**Freedom from recurrence** (in absence of AADS)	**Stroke** (not procedure-related)
Overall SoE	*insufficient*	*low*	*low*
Favors	=	Surgery	=
Effect	RD: 10% (NS)	RD: 26%	RD: 0.3% (NS)
# studies (# patients)	1 (N = 289)	1 (N = 289)	1 (N = 289)

"=" similar between treatment groups

KQ1: Efficacy
(Atrial flutter: RF ablation versus AADs)

28

- **Evidence base: 1 RCT**
- **N = 104 patients**
  - **Intervention:**
    - Radiofrequency ablation versus antiarrhythmic drugs (AADs)
  - **Follow-up: 13 ± 6 months**

	PRIMARY OUTCOMES:	
	Freedom from recurrence	**Mortality** (not procedure-related)
Overall SoE	*moderate*	*low*
Favors	Ablation	=
Effect	RD: 26% (95% CI, 13%, 41%) NNT: 4	RD: 5% (NS)
# studies (# patients)	1 (N = 104)	1 (N = 104)

"=" similar between treatment groups

KQ1: Effectiveness
(SVT (AVNRT): RF ablation versus comparator)

29

- **Evidence base: cohort studies**

	PRIMARY OUTCOMES:		
	Freedom from recurrence (1-8 yrs)	**Freedom from recurrence (14 yrs in 1 study, NR by other)**	**Freedom from recurrence**
Comparator	AADs	Open perinodal dissection surgery	No treatment
Overall SoE	*insufficient*	*insufficient*	*insufficient*
Favors	Ablation	=	Ablation
Effect	RD: 39-55%	RD: 5.2% (NS)	RD: 64%
# studies (# patients)	1 (N = 93)	2 (N = 242)	1 (N = 27)

"=" similar between treatment groups

KQ1: Effectiveness
(SVT (AVRT): RF ablation versus comparator)

30

- **Evidence base: 1 cohort study**

	SECONDARY OUTCOMES:	
	Improvement of symptoms (ablation: 8 mos.) (AADs: 58 mos.)	**Improvement of symptoms (ablation: 8 mos.) (surgery: 54 mos.)**
Comparator	AADs	Surgery
Overall SoE	*insufficient*	*insufficient*
Favors	Ablation	=
Effect	RD: 82%	RD: 10% (NS)
# studies (# patients)	1 (N = 32)	1 (N = 40)

"=" similar between treatment groups

KQ1: Efficacy

(SVT (WPW): RF ablation versus no treatment)

31

- **Evidence base: 1 RCT**
- **N = 76 patients**
  - **Intervention:**
    - Radiofrequency ablation versus no treatment
  - **Follow-up: 24, 48 months**

	PRIMARY OUTCOMES:		
	Freedom from recurrence (24 mos.)	**Freedom from recurrence** (48 mos.)	**Mortality** (not procedure-related) (24 mos.)
Overall SoE	*moderate*	*moderate*	*low*
Favors	Ablation	Ablation	=
Effect	RD: 55% 95% CI, 35%, 70%) NNT: 2	RD: 55% 95% CI, 34%, 70%) NNT: 2	RD: 0%
# studies (# patients)	1 (N = 76)	1 (N = 72)	1 (N = 76)

"=" similar between treatment groups

Results: KQ1a

32

KQ1a. If catheter ablation is efficacious compared with other treatment options, is there differential efficacy between the different types of ablation (e.g., radiofrequency ablation versus cryoablation)?

a. **PVI for atrial fibrillation (AF)?**
b. **catheter ablation for atrial flutter?**
c. **catheter ablation for supraventricular tachycardias (SVTs), including :**
   - sinus tachycardia, atrioventricular reentrant tachycardia (AVRT) (including Wolff-Parkinson-White (WPW) Syndrome), atrioventricular nodal reentrant tachycardia (AVNRT), atrial tachycardia, focal junctional ectopic tachycardia, and nonparoxysmal junctional tachycardia

KQ1a: Efficacy
(Atrial flutter: RF ablation versus cryoablation)

33

- **Evidence base: 4 RCTs**
- **N = 325 patients**
  - **Intervention:**
    - Radiofrequency ablation versus cryoablation
  - **Follow-up: 3 to mean of 15 months**

	PRIMARY OUTCOMES:	
	Freedom from recurrence (5-15 mos.)	**Persistent bidirectional conduction block** (3mos.)
Overall SoE	*low*	*low*
Favors	=	Favors RF ablation
Effect	RD: 6% (NS)	RD: 19% (95% CI, 4%, 33%) NNT: 5
# studies (# patients)	3 (N = 134)	1 (N = 191)

"=" similar between treatment groups

KQ1a: Efficacy
(SVT (AVNRT): RF ablation versus cryoablation)

34

- **Evidence base: 4 RCTs**
- **N = 802 patients**
  - **Intervention:**
    - Radiofrequency ablation versus cryoablation
  - **Follow-up: 6-12 months**

	PRIMARY OUTCOMES:
	Freedom from recurrence
Overall SoE	*moderate*
Favors	RF ablation
Effect	RD: 5% (95% CI, 1%, 9%) NNT: 21
# studies (# patients)	3 (N = 739)

"=" similar between treatment group

Results: KQ2

35

KQ2. What is the evidence regarding the comparative efficacy of various approaches to radiofrequency PVI for atrial fibrillation?

KQ2: Efficacy

(AF: RF PVI versus other approaches to RF PVI)

36

- **Evidence base: 35 RCTs**

	PRIMARY OUTCOMES:			
	Freedom from recurrence (3-15 mos.)	**Freedom from recurrence** (7-36 mos.)	**Freedom from recurrence** (8-12 mos.)	**Freedom from recurrence** (12-23 mos.)
Comparator	WACA	PVI + additional left-sided lines	PVI + additional right-sided lines	PVI + CFE
Overall SoE	*low*	*moderate*	*moderate*	*moderate*
Favors	Favors WACA	=	=	Favors PVI + CFE
Effect	RD: 10% (95% CI, 1%, 18%) NNT: 10	RD: 4.8% (NS)	RD: 2.6% (NS)	RD: 17% (95% CI, 9%, 25%) NNT: 6
# studies (# patients)	5 (N = 500)	8 (N = 1243)	4 (N = 683)	6 (N = 587)

"=" similar between treatment groups

Results: KQ3

37

KQ3. What is the evidence regarding the safety of:

a. **PVI for atrial fibrillation (AF)?**
b. **catheter ablation for atrial flutter?**
c. **catheter ablation for supraventricular tachycardias (SVTs), including :**
   - sinus tachycardia, atrioventricular reentrant tachycardia (AVRT) (including Wolff-Parkinson-White (WPW) Syndrome), atrioventricular nodal reentrant tachycardia (AVNRT), atrial tachycardia, focal junctional ectopic tachycardia, and nonparoxysmal junctional tachycardia

KQ3: Safety
(AF: RF PVI versus AADs)

38

- **Evidence base: 8 RCTs**
  - **N = 30 – 198 patients**
  - **Intervention:**
    - Radiofrequency (RF) PVI versus antiarrhythmic drugs (AADs)
  - **Follow-up: 12 months (majority of studies); 48 months (1 study)**

	Mortality (12 mos.)	Stroke (2-15 mos.)	Pericardial effusion or cardiac tamponade (1-12 mos.)	Pulmonary vein stenosis (2-15 mos.)
Overall SoE	*low*	*low*	*low*	*low*
Favors	=	=	=	=
Effect	RD: 0%	RD: 0.1% (NS)	RD: 0.5% (NS)	RD: 2.8% (NS)
# studies (# patients)	1 (N = 112)	3 (N = 310)	2 (N = 279)	3 (N = 223)

"=" similar between treatment groups

KQ3: Safety
(AF: Cryo-PVI versus AADs)

39

- **Evidence base: 1 RCT (Pivotal Trial from FDA SSED)**
- **N = 245 patients**
  - **Intervention:**
    - Cryo-PVI versus antiarrhythmic drugs (AADs)
  - **Follow-up: 12 months**

	Pericardial effusion or cardiac tamponade (0-1 mos.)	Pulmonary vein stenosis (0-1 mos.)
Overall SoE	*low*	*low*
Favors	=	=
Effect	RD: 0.4% (NS)	RD: 0.4% (NS)
# studies (# patients)	1 (N = 245)	1 (N = 245)

"=" similar between treatment groups

KQ3: Safety
(Atrial flutter: RF ablation versus AADs)

40

- **Evidence base: 1 RCT**
- **N = 104 patients**
  - **Intervention:**
    - Radiofrequency ablation versus antiarrhythmic drugs (AADs)
  - **Follow-up: 13 ± 6 months**

	Mortality (13 ± 6 mos.)
Overall SoE	*low*
Favors	=
Effect	RD: 0%
# studies (# patients)	1 (N = 104)

"=" similar between treatment groups

KQ3: Safety
(SVT (AVNRT): RF ablation versus perinodal dissection surgery)

41

- **Evidence base: 1 cohort study**

	Persistent AV block (1 mos.)	Pacemaker implantation (1 mos.)
Comparator	Open perinodal dissection surgery	Open perinodal dissection surgery
Overall SoE	*insufficient*	*insufficient*
Favors	Surgery	=
Effect	RD: 19%	RD: 0.1% (NS)
# studies (# patients)	1 (N = 120)	1 (N = 120)

"=" similar between treatment groups

Results: KQ4

42

KQ4. Differential efficacy and safety

Does catheter ablation have any differential efficacy or safety compared with other treatment options in subpopulations?

KQ4: Differential efficacy and safety in subpopulations

43

- **Evidence base: all subpopulation data from comparative studies included in KQ1 were reported. No additional comparative studies were identified.**
- **Insufficient (no) evidence on differential effectiveness for the following subpopulations:**
  - Age
  - Sex
  - Race
  - Ethnicity
  - Disability
  - Comorbidities

Results: KQ5

44

KQ5. Cost-effectiveness

What is the evidence of cost-effectiveness of catheter ablation compared with alternative treatment options in the short- and long-term for

a. **atrial fibrillation (AF)?**
b. **atrial flutter?**
c. **supraventricular tachycardias (SVTs)?**

KQ5: Cost-effectiveness
(AF: RF PVI versus AADs)

45

Five-year time horizon

- 3 cost-utility analyses
  - Population: hypothetical cohorts of patients with paroxysmal AF who were refractory to AADs
  - Countries: USA, Canada, UK
  - Funding: USA & Canada (no direct funding but relationships with device manufacturers); UK (NIHR HTA program)
  - Models: Markov decision analysis
  - ICER: $51,400 - $59,200 per QALY (2 studies)
  - ICER: $33,200 - $44,200 per QALY, decreasing with increasing stroke risk (1 study)
  - **Conclusion: PVI may be more cost-effective than AADs depending on how much society is willing to pay per quality-adjusted life year. (moderate quality evidence)**

KQ5: Cost-effectiveness
(AF: RF PVI versus AADs)

46

Lifetime horizon

- 3 cost-utility analyses
  - Population: hypothetical cohorts of patients with paroxysmal or persistent AF with low to moderate stroke risks
  - Countries: USA, Sweden, UK
  - Funding: USA (no direct funding but relationships with device manufacturers); UK (NIHR HTA program); Sweden (NR)
  - ICER: $12,400 - $29,100 per QALY (2 studies)
  - ICER: PVI dominated AADs
  - **Conclusion: PVI may be more cost-effective than AADs depending on how much society is willing to pay per quality-adjusted life year. In general, ablation is more cost-effective in the lifetime horizon due to long-term costs associated with AAD therapy. (moderate quality evidence)**

KQ5: Cost-effectiveness
(SVTs: RF ablation versus AADs)

47

Lifetime horizon

- 1 cost-utility analysis
  - Population: hypothetical cohorts of patients 40 years of age with either highly symptomatic WPW Syndrome
  - Countries: USA
  - ICER: Ablation dominated AADs
  - **Conclusion: There is low quality evidence that ablation may be more cost-effective than AADs. Ablation dominated AADs (thus ablation was associated with less cost and more QALYs compared with AADs).**

Summary and implications

48

Summary: Atrial fibrillation

49

- **Efficacy and effectiveness**

Summary	Overall Strength of Evidence
Radiofrequency PVI results in greater freedom from recurrence compared with AADs in the short- and long-term.	Moderate
Cryo-PVI results in greater freedom from recurrence compared with AADs in the short-term .	Low
Patients treated with radiofrequency or cryo-PVI have low rates of mortality, stroke, and congestive heart failure; similar to AADs.	Low
Different approaches (WACA, PVI + CFE) may be superior to PVI alone. The addition of left- or right-sided lines had no impact on freedom from recurrence.	Low to moderate

Summary: Atrial fibrillation

50

Summary	Overall Strength of Evidence
SAFETY: • No difference in procedure- or treatment-related mortality, stroke, pericardial effusion/cardiac tamponade or pulmonary vein stenosis following RF PVI versus AADs (low SoE). • Data from cohort studies support this evidence • Data from large case series support very low incidence of complications (including mortality (0.044% (2/4589) and stroke (0.525% (74/14,093)) following PVI	Low
COST-EFFECTIVENESS: • PVI may be more cost-effective than AADs depending on how much society is willing to pay per quality-adjusted life year. PVI more cost-effective when evaluated for a lifetime horizon because of the long-term cost associated with AAD use.	Moderate

Summary: Atrial flutter

51

- **Efficacy and effectiveness**

Summary	Overall Strength of Evidence
Catheter ablation results in greater freedom from recurrence in the short-term compared with AADs.	Moderate
Radiofrequency catheter ablation results in greater freedom from recurrence in the short-term compared with cryoablation.	Low

Summary: Atrial flutter

52

Summary	Overall Strength of Evidence
SAFETY • No difference in procedure- or treatment-related mortality following ablation versus AADs. • Data from large case series support very low (< 1%) incidence of complications (including mortality, stroke, pericardial effusion/cardiac tamponade, deep vein thrombosis) following ablation.	Low
COST-EFFECTIVENESS: • No studies identified.	Insufficient

Summary: SVTs (WPW)

53

Summary	Overall Strength of Evidence
In patients with WPW Syndrome, catheter ablation results in greater freedom from recurrence in the short- and long-term compared with no treatment .	Moderate
In patients with WPW Syndrome, catheter ablation and AADs result in similarly low rates of mortality (not attributed to the treatment).	Moderate
COST-EFFECTIVENESS: • Ablation may be more cost-effective than AADs (ablation was associated with less cost and more QALYs compared with AADs).	Low

Summary: SVTs (AVNRT)

54

Summary	Overall Strength of Evidence
Radiofrequency catheter ablation results in greater freedom from recurrence in the short-term compared with cryoablation .	Moderate

Thank you.

55

Questions?

KQ1: Efficacy
(AF: RF PVI versus AADs)

56

Evidence base: 8 RCTs

N = 30 – 198 patients

Intervention:

Radiofrequency (RF) PVI versus antiarrhythmic drugs (AADs)

RCT	N	Symptomatic?	Duration of symptoms	Refractory to AAD(s)?	New AAD(s) given?	AF classification
Wazni (2005)	70	Yes	0.4 yrs.	No	n/a	Paroxysmal or persistent
Forleo (2009)*	70	Yes	3.3 yrs.	Yes	Yes	Paroxysmal or persistent
Jais (2008)	112	Yes	5.5 yrs.	NR	Yes	Paroxysmal
Krittayaphong (2003)	30	Yes	4.7 yrs.	Yes	Yes	Paroxysmal or persistent
Pappone (2006/ 2011)	198	NR	6 yrs.	Yes	Yes	Paroxysmal
Stabile (2006)	62	NR	6.1 yrs.	Yes	No	Paroxysmal
Wilber (2010)	167	Yes	5.7 yrs.	Yes	Yes	NR

* Diabetes mellitus type 2 patients

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence-Based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations Result in Health Benefits

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

Using Evidence as the Basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. *Availability of Evidence:*

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. *Sufficiency of the Evidence:*

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence.

3. *Factors for Consideration - Importance*

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

Medicare Coverage and Guidelines, (Page 115, Final Report)

Medicare

The Centers for Medicare and Medicaid Services does not have a NCD for catheter ablation of supraventricular tachyarryhthmias. A search of the Medicare Coverage Database (MCD) (http://www.cms.gov/medicare-coverage-database/overview-and-quicksearch.aspx) for all National Coverage Determinations was conducted on September 5, 2012. Search term used: "ablation".

Table 1. Clinical Guidelines (Page 57, Final Report)

Assessment (Year)	Lit Search Dates	Procedure(s) Evaluated	Evidence Base Available	Recommendation	Comments
Atrial Fibrillation (AF)					

Heart Rhythm Society /European Heart Rhythm Association/ European Cardiac Arrhythmia Society (2012)[110]
 	
Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation: Recommendations for Patient Selection, Procedural Techniques, Patient Management and Follow-up, Definitions, Endpoints, and Research Trial Design.
	NR	Catheter ablation of AF	NR	Grading system and Class Recommendations adapted from the American College of Cardiology and the American Heart Association*.
				
				<u>Class I Recommendations</u>
				• Symptomatic AF refractory or intolerant to ≥1 Class 1 or 3 antiarrhythmic medication:
				  • Paroxysmal: Catheter ablation is recommended. LOE A
				
				<u>Class IIa Recommendations</u>
				• Symptomatic AF refractory or intolerant to ≥1 Class 1 or 3 antiarrhythmic medication:
				  • Persistent: Catheter ablation is reasonable. LOE B
				• Symptomatic AF prior to initiation of antiarrhythmic drug therapy with Class 1 or 3 antiarrhythmic agent:
				  • Paroxysmal: Catheter ablation is reasonable. LOE B
				
				<u>Class IIb Recommendations</u>
				• Symptomatic AF refractory or intolerant to ≥1 Class 1 or 3 antiarrhythmic medication:
				  • Longstanding Persistent: Catheter ablation may be considered. LOE B
				• Symptomatic AF prior to initiation of antiarrhythmic drug therapy with Class 1 or 3 antiarrhythmic agent:
				  • Persistent: Catheter ablation may be considered. LOE C
				  • Longstanding Persistent: Catheter ablation may be considered. LOE C
					This document is a consensus statement, not a guideline.

National Institute for Health and Clinical Excellence (2012) [114] *Percutaneous balloon cryoablation for pulmonary vein isolation in atrial fibrillation*	NR	Percutaneous balloon cryoablation for AF	NR	Class of Recommendation and LOE NR Ablation procedures may be used for atrial fibrillation when drug therapy is either not tolerated or ineffective.	

Assessment (Year)	Lit Search Dates	Procedure(s) Evaluated	Evidence Base Available	Recommendation	Comments
American College of Cardiology/ American Heart Association (2011)[125] *Guideline for the Diagnosis and Treatment of Hypertrophic Cardiomyopathy*	Through January 2011	Various treatments for coexistent hypertrophic cardio-myopathy (HCM) and AF	NR	Class of Recommendation and LOE categorized in ACC/AHA format.* <u>Class IIa recommendations</u> • Radiofrequency ablation for AF can be beneficial in patients with HCM who have refractory symptoms or who are unable to take antiarrhythmic drugs. LOE B	
American College of Cardiology/ American Heart Association/ European Society of Cardiology (2011/2006)[124] *Focused Updates Incorporated Into the 2006 Guidelines for the Management of Patients With Atrial Fibrillation.*	2001 - 2006	Various treatments for AF	NR	Class of Recommendation and LOE categorized in ACC/AHA format.* <u>Class IIa recommendations</u> • It is reasonable to use ablation of the AV node or accessory pathway for AF to control heart rate when pharmacological therapy is insufficient or associated with side effects. LOE B • Catheter ablation is a reasonable alternative to pharmacological therapy to prevent recurrent AF in symptomatic patients with little or no LA enlargement. LOE C <u>Class IIb recommendations</u> • When the rate cannot be controlled with pharmacological agents, catheter-directed ablation of the AV node may be considered in patients with AF to control the heart rate. LOE C <u>Class III recommendations</u> • Catheter ablation of the AV node should not be attempted without a prior trial of medication to control the ventricular rate in patients with AF. LOE C	
National Institute for Health and Clinical Excellence (2011) [113] *Percutaneous Endoscopic Catheter Laser Balloon Pulmonary Vein Isolation for Atrial Fibrillation*	NR	Percutaneous endoscopic catheter laser balloon pulmonary vein isolation for AF	NR	Class of Recommendation and LOE NR Ablation procedures may be used when drug therapy is either not tolerated or is ineffective.	
Canadian Cardiovascular Society (2010)[106] *Atrial Fibrillation Guidelines: Catheter Ablation for Atrial Fibrillation/ Atrial Flutter.*	NR	Catheter ablation for AF	NR	Class of Recommendation and LOE categorized in CCS format.† <u>Strong Recommendations</u> • Catheter ablation of AF recommended in patients who remain symptomatic following adequate trials of anti-arrhythmic drug therapy and in whom a rhythm control strategy remains desired. LOE Moderate Quality <u>Conditional Recommendations</u> • Catheter ablation recommended to maintain sinus rhythm as first-line therapy for relief of symptoms in highly selected patients with symptomatic, paroxysmal	

Assessment (Year)	Lit Search Dates	Procedure(s) Evaluated	Evidence Base Available	Recommendation	Comments
				AF. LOE Low Quality • Catheter ablation recommended in young patients with lone, paroxysmal AF, electrophysiological study to exclude a reentrant tachycardia as a cause of AF; if present, curative ablation of tachycardia recommended. LOE Very Low Quality	
Canadian Cardiovascular Society (2010)[111] *Atrial Fibrillation Guidelines: Rate and Rhythm Management.*	NR	Catheter ablation for AF and atrial flutter	NR	Class of Recommendation and LOE categorized in CCS format.† <u>Strong Recommendations</u> • AV junction ablation or PV ablation and implantation of permanent pacemaker recommended in symptomatic patients with uncontrolled ventricular rates during AF despite maximally tolerated combination pharmacologic therapy. LOE Moderate Quality • Radiofrequency ablation of AF recommended in patients who remain symptomatic following adequate trials of antiarrhythmic drug therapy and in whom a rhythm-control strategy remains desired. LOE Moderate Quality	-
European Society of Cardiology (2010)[109] *Guidelines for the Management of Atrial Fibrillation.*	NR	Various treatments for AF	NR	Class of Recommendation and LOE categorized in ESC format.‡ <u>Class IIa Recommendations</u> • Catheter left atrial ablation for paroxysmal AF should be considered in symptomatic patients who have previously failed trial of antiarrhythmic medication. LOE A • Left atrial ablation of persistent symptomatic AF refractory to antiarrhythmic therapy should be considered. LOE B • Ablation of AV node to control heart rate should be considered when rate cannot be controlled with pharmacological agents and when AF cannot be prevented by antiarrhythmic therapy or is associated with intolerable side effects, and direct catheter-based or surgical ablation of AF is not indicated, has failed, or is rejected. LOE B • Ablation of the AV node should be considered for patients with permanent AF and indication for CRT (NYHA functional class III or ambulatory class IV symptoms despite optimal medical therapy, LVEF ≤35%, QRS width ≥130 ms). LOE B • Ablation of the AV node should be considered for CRT nonresponders in whom AF prevents effective biventricular stimulation and amiodarone is ineffective or contraindicated. LOE C <u>Class IIb Recommendations</u> • Catheter ablation of AF in patients with heart failure may be considered when antiarrhythmic medication, including amiodarone, fails to control symptoms. LOE B • Catheter ablation of AF may be considered prior to antiarrhythmic drug therapy in symptomatic patients despite adequate rate control with paroxysmal symptomatic AF and no significant underlying heart disease. LOE B • Catheter ablation of AF may be considered in patients with symptomatic long-standing persistent AF refractory	

Assessment (Year)	Lit Search Dates	Procedure(s) Evaluated	Evidence Base Available	Recommendation	Comments
				to antiarrhythmic drugs. LOE B • Ablation of AV node with consecutive implantation of CRT device may be considered in patients with permanent AF, LVEF ≤35%, and NYHA functional class I or II symptoms on optimal medical therapy to control heart rate when pharmacological therapy is insufficient or associated with side effects. LOE C <u>Class III Recommendations</u> • Catheter ablation of AV node should not be attempted without prior trial of medication or catheter ablation of AF, to control AF. LOE C	
Scottish Intercollegiate Guidelines Network (2007)[108] *Cardiac Arrhythmias in Coronary Heart Disease.*	1999 - 2005	Various treatments for AF	NR	Class of Recommendation and LOE categorized in SIGN format.§ <u>Class B Recommendations</u> • Ablation and pacing should be considered for patients with AF who remain severely symptomatic in association with poor rate control or intolerance to rate control medication. LOE 2^{+}, 4, 1^{+}	
National Institute for Health and Clinical Excellence (2006)[107] *The Management of Atrial Fibrillation*	NR	Various treatments for AF	NR	Class of Recommendation and LOE adapted from Scottish Intercollegiate Guidelines Network (SIGN 50).§ <u>Class B Recommendations:</u> Referral for further specialist intervention (e.g., for, atrioventricular junction catheter ablation) after electrical or pharmacological cardioversion should be considered in the following AF patients: • those in whom pharmacological therapy has failed. • those with lone AF. (not defined)	
National Institute for Health and Clinical Excellence (2006) [112] *Percutaneous Radiofrequency Ablation for Atrial Fibrillation*	NR	Percutaneous radio-frequency ablation for AF	NR	Class of Recommendation and LOE NR Percutaneous radiofrequency ablation is a treatment option for symptomatic patients with atrial fibrillation refractory to anti-arrhythmic drug therapy or where medical therapy is contraindicated because of co-morbidity or intolerance.	
Heart Rhythm Society (2003/1992)[122] *NASPE Policy Statement on Catheter Ablation: Personnel, Policy, Procedures, and Therapeutic Recommendations.*	NR	Ablation for AF	NR	Class of Recommendation and LOE categorized in ACC/AHA format.* <u>Class IIb Recommendations</u> • Atrial fibrillation: accumulated evidence is insufficient to determine complications and long-term outcome. Ablation considered for patients after appropriate trial of antiarrhythmic therapy; patients with permanent atrial fibrillation should be referred to centers with experience in performing more complex procedures. LOE B, C	

Assessment (Year)	Lit Search Dates	Procedure(s) Evaluated	Evidence Base Available	Recommendation	Comments
Atrial Flutter					
Canadian Cardiovascular Society (2010)[106] *Atrial Fibrillation Guidelines: Catheter Ablation for Atrial Fibrillation/ Atrial Flutter.*	See above	Catheter ablation for atrial flutter	See above	Class of Recommendation and LOE categorized in CCS format.† <u>Strong Recommendations</u> • Curative catheter ablation recommended for symptomatic patients with typical atrial flutter as first line therapy or as a reasonable alternative to pharmacologic rhythm or rate control therapy. LOE Moderate Quality	
European Society of Cardiology (2010)[109] *Guidelines for the Management of Atrial Fibrillation.*	See above	Various treatments for atrial flutter	See above	Class of Recommendation and LOE categorized in ESC format.‡ <u>Class I Recommendations</u> • Left atrial ablation of common atrial flutter is recommended as part of AF ablation procedure if documented prior to ablation procedure or occurring during AF ablation. LOE B	
Heart Rhythm Society (2003/1992)[122] *NASPE Policy Statement on Catheter Ablation: Personnel, Policy, Procedures, and Therapeutic Recommendations.*	See above	Ablation for atrial flutter	See above	Class of Recommendation and LOE categorized in ACC/AHA format.* <u>Class I Recommendations</u> • Isthmus dependent atrial flutter: ablation can be considered initial therapy. LOE A	
American College of Cardiology/ American Heart Association/ European Society of Cardiology (2003)[123] *Guidelines for the Management of Patients With Supraventricular Arrhythmias.*	NR	Various treatments for supra-ventricular arrhythmias	NR	Class of Recommendation and LOE categorized in ACC/AHA format.* <u>Class I Recommendations</u> • Catheter ablation recommended as long-term management of recurrent and well-tolerated or poorly tolerated atrial flutter. LOE B • Catheter ablation recommended as long-term management of atrial flutter appearing after use of Ic agents or amiodarone for treatment of AF. LOE B • Catheter ablation of flutter isthmus combined with closure of ASD recommended as treatment of SVT for congenital heart disease in unrepaired hemodynamically significant ASD with atrial flutter. LOE C <u>Class IIa Recommendations</u> • Catheter ablation recommended as long-term management of first episode well-tolerated atrial flutter. LOE B • Catheter Ablation recommended as prophylactic therapy for nonsustained and as long-term management of symptomatic non-CTI dependent flutter after failed antiarrhythmic therapy. LOE B	

Assessment (Year)	Lit Search Dates	Procedure(s) Evaluated	Evidence Base Available	Recommendation	Comments
Barcelona Discussion Group (1999)[117] *Report of a Study Group on Ablate and Pace Therapy for Paroxysmal Atrial Fibrillation.*	NR	Catheter Ablation and pace therapy for atrial flutter	NR	Class of Recommendations and LOE: NR • Catheter Ablation recommended as long-term management of First episode and well-tolerated, recurrent and well-tolerated, poorly tolerated Atrial Flutter, Atrial Flutter appearing after use of class Ic agents or amiodarone for treatment of AF, or Symptomatic non-CTI-dependent flutter after failed antiarrhythmic drug therapy.	
Supraventricular tachycardias (SVT)					
Canadian Cardiovascular Society (2010)[106] *Atrial Fibrillation Guidelines: Catheter Ablation for Atrial Fibrillation/ Atrial Flutter.*	See above	Catheter ablation for AVNRT	See above	Class of Recommendation and LOE categorized in CCS format.† <u>Conditional Recommendations</u> • Catheter ablation recommended in young patients with lone, paroxysmal AF, electrophysiological study to exclude a reentrant tachycardia as a cause of AF; if present, curative ablation of tachycardia recommended. LOE Very Low Quality	
European Society of Cardiology (2010)[109] *Guidelines for the Management of Atrial Fibrillation.*	See above	Various treatments for supra-ventricular tachy-arrhthmias	See above	Class of Recommendation and LOE categorized in ESC format.‡ <u>Class IIb Recommendations</u> • Ablation of AV node to control heart rate may be considered when tachycardia-mediated cardiomyopathy is suspected and rate cannot be controlled with pharmacological agents, and direct ablation of AF is not indicated, has failed, or is rejected. LOE C	

Heart Rhythm Society (2003/1992)[122]
 	
NASPE Policy Statement on Catheter Ablation: Personnel, Policy, Procedures, and Therapeutic Recommendations.
	See above	Catheter ablation for supra-ventricular tachy-arrhthmias	See above	Class of Recommendation and LOE categorized in ACC/AHA format.*
				
				<u>Class I Recommendations</u>
				• AV junction: ablation with subsequent complete heart block recommended for patients with atrial tachycardias, particularly persistent or permanent atrial fibrillation in which ventricular response rate not adequately controlled with AV nodal blocking agents. LOE A
				• Focal atrial tachycardia: patients should receive at least one trial of antiarrhythmic drug therapy prior to ablation; ablation can be offered as initial therapeutic approach when therapy to suppress arrhythmia is required. LOE B
				• AV node reentry
				  ○ Slow pathway ablation: initial therapy option for patients needing AVNRT; recommended for patients who have failed ≥1 antiarrhythmic drug or have significant side effects to drug therapy. LOE B
				  ○ Fast pathway ablation: due to risk of complete heart block, reserve for patients who have failed drug therapy and prior attempts at slow pathway ablation. LOE NR
				• AV reentry: for patients with accessory pathway mediated SVT, same recommendation as for AV node reentry; exception: patients with atrial fibrillation and	

Assessment (Year)	Lit Search Dates	Procedure(s) Evaluated	Evidence Base Available	Recommendation	Comments
				rapid ventricular response should undergo ablation as initial therapy. Patients with anteroseptal pathways deserve special consideration because increased risk of complete heart block from catheter ablation reduces benefit/risk balance. LOE B <u>Class IIa Recommendations</u> • Nonisthmus-dependent macroreentrant atrial tachycardias: ablation recommended only after trial of drug therapy because of potential complexity of these reentrant circuits. LOE B, C <u>Class IIb Recommendations</u> • Catheter ablation recommended as prophylactic therapy of SVT during pregnancy. LOE C • Inappropriate sinus tachycardia: ablation considered only after trials of drug therapy (including β-blockers) because of high recurrence rate and persistence of nonspecific symptomatology postablation. LOE C <u>Class III Recommendations</u> • Asymptomatic pre-excitation: accessory pathway ablation recommended (except possible extenuating circumstances relating to pediatric population or high-risk occupational situations). LOE NR	
American College of Cardiology/ American Heart Association/ European Society of Cardiology (2003)[123] *Guidelines for the Management of Patients With Supraventricular Arrhythmias.*	See above	Various treatments for supra-ventricular tachy-arrhthmias	See above	Class of Recommendation and LOE categorized in ACC/AHA format.* <u>Class I Recommendations</u> • Catheter ablation recommended for documented PSVT with only dual AV-nodal pathways or single echo beats demonstrated during electrophysiological study and no other identified cause of arrhythmia. LOE B • Catheter Ablation recommended as prophylactic therapy for recurrent symptomatic focal AT, asymptomatic or symptomatic incessant ATs. LOE B • Catheter ablation recommended as treatment of SVT for CHD after failed antiarrhythmic drugs and symptomatic repaired ASD. LOE C • Catheter ablation recommended as treatment of SVT for congenital heart disease after failed antiarrhythmic drugs and symptomatic Mustard or Senning repair of transposition of great vessels. LOE C • Catheter ablation of flutter isthmus combined with closure of ASD recommended as treatment of SVT for congenital heart disease in unrepaired hemodynamically significant ASD with atrial flutter. LOE C • Catheter Ablation recommended as long-term treatment of patients with recurrent AVNRT: with poorly tolerated AVNRT with hemodynamic intolerance or recurrent symptomatic AVNRT. LOE B • Catheter ablation recommended for recurrent AVNRT with infrequent or single episode in patients who desire complete control of arrhythmia. LOE B • Catheter ablation recommended for infrequent, well-tolerated AVNRT. LOE B	

Assessment (Year)	Lit Search Dates	Procedure(s) Evaluated	Evidence Base Available	Recommendation	Comments
				Class IIa Recommendations • Catheter Ablation recommended as long-term therapy of single or infrequent AVRT episode(s) (no pre-excitation). LOE B • Catheter Ablation recommended as long-term therapy of pre-excitation, asymptomatic accessory pathway–mediated arrhythmias. LOE B • Catheter Ablation recommended as treatment of Focal Junctional Tachycardia. LOE C Class IIb Recommendations • Catheter ablation recommended as prophylactic therapy of SVT during pregnancy. LOE C • Catheter Ablation-sinus node modification/elimination recommended as interventional treatment of Inappropriate Sinus Tachycardia. LOE C Class III Recommendations • Catheter ablation recommended for focal nonsustained asymptomatic AT. LOE C	
Barcelona Discussion Group (1999)[117] *Report of a Study Group on Ablate and Pace Therapy for Paroxysmal Atrial Fibrillation.*	See above	Catheter ablation and pace therapy for supra-ventricular tachy-arrhthmias	See above	Class of Recommendations and LOE: NR • Catheter Ablation recommended as prophylactic therapy for SVT during pregnancy. • Catheter Ablation recommended in experienced center as treatment of SVT in adults with failed antiarrhythmic drugs and symptomatic repaired ASD or Mustard or Senning repair of transposition of the great vessels. • Catheter ablation recommended as alternative to drug therapy for patients with tachycardia–bradycardia syndrome who have bradycardia indication for pacemaker. It is probably most appropriate to undertake trial period of pacing therapy before proceeding to AVJ ablation or these patients may receive AVJ ablation and pacemaker at single session (i.e. one-step procedure). • Catheter Ablation recommended as prophylactic therapy for SVT during pregnancy. • Catheter Ablation recommended in experienced center as treatment of SVT in adults with failed antiarrhythmic drugs and symptomatic repaired ASD or Mustard or Senning repair of transposition of the great vessels. • Catheter ablation recommended as alternative to drug therapy for patients with tachycardia–bradycardia syndrome who have bradycardia indication for pacemaker. It is probably most appropriate to undertake trial period of pacing therapy before proceeding to AVJ ablation or these patients may receive AVJ ablation and pacemaker at single session (i.e. one-step procedure).	
American College of Cardiology/ American Heart Association/ European Society of Cardiology (2011/2006)[124] *Focused Updates Incorporated Into the*	See above	Various treatments for AF, including a few supra-ventricular tachy-arrhthmias	See above	Class of Recommendation and LOE categorized in ACC/AHA format.* Class I recommendations • Catheter ablation of accessory pathway recommended in symptomatic patients with AF who have WPW, particularly those with syncope due to rapid heart rate or those with short bypass tract refractory period. LOE B	

Assessment (Year)	Lit Search Dates	Procedure(s) Evaluated	Evidence Base Available	Recommendation	Comments
2006 Guidelines for the Management of Patients with Atrial Fibrillation.				• Catheter Ablation recommended as long-term therapy of WPW syndrome (well tolerated pre-excitation and symptomatic arrhythmias, AF and rapid-conduction, or poorly tolerated AVRT). LOE B • Catheter Ablation recommended as long-term therapy of AVRT, poorly tolerated (no pre-excitation). LOE B	
Institute for Clinical Systems Improvement (2011)[118] *Heart Failure in Adults*	See above	Catheter ablation for AVRT	See above	Class of Recommendation: NR Quality of evidence: GRADE system (all RCTs and cohort studies evaluated using GRADE system, other studies evaluated using transitional system from ICSI and GRADE). Details of grading NR Radiofrequency catheter ablation may be indicated in patients with heart failure and "reciprocating tachycardias" or selected patients with atrial fibrillation.	

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

Safety Outcomes	Safety Evidence
Mortality	
Thromboembolic events	
Pericardial effusion or cardiac tamponade	
Pulmonary vein stenosis	
Pacemaker implantation	

Efficacy – Effectiveness Outcomes	Efficacy / Effectiveness Evidence
Freedom from Recurrence	
Freedom from Recurrence	
Mortality	
Stroke	

Congestive heart failure	
Persistent bidirectional conduction block	
	Special Population Evidence
Age	
Gender	
Race	
Ethnicity	
Disability	
Cost	**Cost Evidence**
Cost-effectiveness	

Clinical Committee Evidence Votes

First Voting Question
The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective				
Safe				
Cost-effective				

Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote
Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not Covered _____ Covered Unconditionally _____ Covered Under Certain Conditions

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions
If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   - What are the known conditions/criteria and evidence state
   - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
    - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
    - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?