Tinnitus: non-invasive, non-pharmacologic treatments

Clinical Expert

Jay T. Rubinstein, MD

Virginia Merrill Bloedel Professor and Director,
Virginia Merrill Bloedel Hearing Research Center, University of Washington School of Medicine

Professor of Otolaryngology – Head and Neck Surgery,
University of Washington School of Medicine

Professor of Bioengineering, University of Washington School of Medicine
Applicant Name: Jay T Rubinstein, MD, PhD
Address: 715 2nd Ave #1802
Seattle, WA 98104

1. Business Activities
(a) If you or a member of your household was **an officer or director of a business** during the immediately preceding calendar year and the current year to date, provide the following:

<table>
<thead>
<tr>
<th>Title</th>
<th>Business Name &amp; Address</th>
<th>Business Type</th>
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</thead>
<tbody>
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</tbody>
</table>

(b) If you or a member of your household **did business under an assumed business name** during the immediately preceding calendar year or the current year to date, provide the following information:

<table>
<thead>
<tr>
<th>Business Name</th>
<th>Business Address</th>
<th>Business Type</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

2. Honorarium
If you **received an honorarium of more than $100** during the immediately preceding calendar year and the current year to date, list all such honoraria:

<table>
<thead>
<tr>
<th>Received From</th>
<th>Organization Address</th>
<th>Service Performed</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

3. Sources of Income
(a) Identify **income source(s) that contributed 10% or more of the combined total gross household income** received by you or a member of your household during the immediately preceding calendar year and the current year to date.

<table>
<thead>
<tr>
<th>Source Name &amp; Address</th>
<th>Received By</th>
<th>Source Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of Washington</td>
<td>me</td>
<td>salary</td>
</tr>
<tr>
<td>WA Dept of Corrections</td>
<td>spouse</td>
<td>salary</td>
</tr>
<tr>
<td>Vacation rental condo</td>
<td>both of us</td>
<td>rent</td>
</tr>
<tr>
<td>Click here to enter text.</td>
<td>Click here to enter text.</td>
<td>Click here to enter text.</td>
</tr>
</tbody>
</table>
(b) Does any income source listed above relate to, or could it reasonably be expected to relate to, business that has, or may, come before the Committee?

☐ Yes  ☒ No

If “yes”, describe:  Click here to enter text.
Click here to enter text.
Click here to enter text.

(c) Does an income source listed above have a legislative or administrative interest in the business of the Committee?

☐ Yes  ☒ No

If “yes”, describe:  Click here to enter text.
Click here to enter text.
Click here to enter text.

4. Business Shared With a Lobbyist

If you or a member of your household shared a partnership, joint venture, or similar substantial economic relationship with a paid lobbyist, were employed by, or employed, a paid lobbyist during please list the following:

(Owning stock in a publicly traded company in which the lobbyist also owns stock is not a relationship which requires disclosure.)

<table>
<thead>
<tr>
<th>Lobbyist Name</th>
<th>Business Name</th>
<th>Type Business Shared</th>
</tr>
</thead>
<tbody>
<tr>
<td>Click here to enter text.</td>
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</tr>
</tbody>
</table>

Provide the information requested in items 5, 6, and 7 below only if:
(a) Your response involves an individual or business if you or a member of your household did business with, or reasonably could be expected to relate to business that has or may come before the Health Technology Clinical Committee.
(b) The information requested involves an individual or business with a legislative or administrative interest in the Committee.

5. Income of More Than $1,000

List each source (not amounts) of income over $1,000, other than a source listed under question 3 above, which you or a member of your household received during the immediately preceding calendar year and the current year to date:

<table>
<thead>
<tr>
<th>Income Source</th>
<th>Address</th>
<th>Description of Income Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fidelity investments</td>
<td>Click here to enter text.</td>
<td>Investment Income</td>
</tr>
<tr>
<td>Bioengineering &amp; medicolegal consulting</td>
<td>715 2nd Ave #1802</td>
<td>Consulting Fees</td>
</tr>
</tbody>
</table>
6. **Business Investments of More Than $1,000**

(Do not list the amount of the investment or include individual items held in a mutual fund or blind trust, a time or demand deposit in a financial institution, shares in a credit union, or the cash surrender value of life insurance.)

If you or a member of your household had a personal, beneficial interest or investment in a business during the immediate preceding calendar year of more than $1,000, list the following:

<table>
<thead>
<tr>
<th>Business Name</th>
<th>Business Address</th>
<th>Description of Business</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

7. **Service Fee of More Than $1,000**

(Do not list fees if you are prohibited from doing so by law or professional ethics.)

List each person for whom you performed a service for a fee of more than $1,000 in the immediate preceding calendar year or the current year to date.

<table>
<thead>
<tr>
<th>Name</th>
<th>Description of Service</th>
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</thead>
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</table>

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

Print Name: Jay T Rubinstein, MD, PhD

Check One:  
☐ Committee Member  
☐ Subgroup Member  
☐ Contractor

Signature:  
Date: 5/7/20
I. EDUCATION AND PROFESSIONAL HISTORY

Education

1981 Sc.B. with Honors  Brown University (Engineering)
1983 Sc.M.  Brown University (Engineering)
1987 M.D. with Honors  University of Washington
1988 Ph.D.  University of Washington (Bioengineering)

Internships and Residencies

1988-89  Intern (Surgery), Beth Israel Hospital, Boston MA
1990-94  Resident (Otolaryngology), Massachusetts Eye & Ear Infirmary, Boston, MA

Clinical and Research Fellowships

1988  Research Fellow, Department of Physiology and Biophysics, University of Washington, Seattle WA
1989-90  Research Fellow, Department of Otology and Laryngology, Harvard Medical School
1994-95  Clinical Fellow in Otology/Neurotology, Department of Otolaryngology, The University of Iowa Hospitals and Clinics, Iowa City IA

Academic Appointments

1989-95  Research Affiliate, Research Laboratory of Electronics, Massachusetts Institute of Technology
1994-95  Fellow Associate, The University of Iowa Hospitals and Clinics, Iowa City IA
1995-00  Assistant Professor, Department of Otolaryngology-Head and Neck Surgery, The University of Iowa Hospitals and Clinics
1997-04  Faculty Appointment, Interdisciplinary Neuroscience PhD Program, The University of Iowa
1996-00  Assistant Professor, Department of Physiology & Biophysics, The University of Iowa
2000-04  Associate Professor with Tenure, Department of Otolaryngology-Head and Neck Surgery, The University of Iowa
2000-04  Associate Professor, Department of Physiology & Biophysics, The University of Iowa
2000-04  Associate Professor, Department of Biomedical Engineering, The University of Iowa
2003-04  Boerhaave Professor, Leiden University, The Netherlands
2004-    Virginia Merrill Bloedel Professor and Director, Virginia Merrill Bloedel Hearing Research Center, University of Washington
2004- Professor of Otolaryngology—Head and Neck Surgery, University of Washington
2004-05 Adjunct Professor of Bioengineering, University of Washington
2005- Professor of Bioengineering, University of Washington
2012- Research Affiliate, Washington National Primate Research Center

Other Employment Pertaining to Current Professional Appointments
1975-77 Software Developer, Telmar Communications Corp., New York NY
1979 Research Assistant, Geoelectromagnetics Laboratory, Department of Geological Sciences, Brown University, Providence RI
1980-81 Research Assistant, Visual Physiology Laboratory, Division of Engineering and Center for Neural Science, Brown University, Providence RI
1980-82 Teaching Assistant, Digital Electronics Laboratory, Division of Engineering, Brown University, Providence RI
1981-82 Research Assistant, Laboratory for Engineering Man/Machine Systems, Division of Engineering, Brown University, Providence RI
1996-04 Attending Surgeon, VA Medical Center, Iowa City, Iowa
2005- Board of Trustees, Listen & Talk School, Seattle, WA
2006-08 Board of Trustees, Executive Committee, Northwest Lions Foundation for Sight and Hearing, Seattle, WA
2006-12 Chairman, Board of Trustees, Audient, LLC, Seattle, WA
2008-12 Board of Directors, SightLife, LLC, Seattle, WA
2010- Medical Advisory Board, National Organization for Hearing Research

Certification and Licensure
Certification
1995 Diplomate, American Board of Otolaryngology—Head and Neck Surgery
2005 Neurotology Certificate of Added Qualifications
2013 Neurotology Certificate renewal

Licensure
1994 Iowa License #29758 (expired)
1994 California License (expired)
1994 Massachusetts License (expired)
2004 Washington License MD00044088 (active)

Honors and Awards
1981 Honorary Undergraduate Teaching Assistantship
1981 Sigma Xi
1984-86 Poncin Scholarship Award
1987 Alpha Omega Alpha
1992 American Academy of Otolaryngology Resident Research Grant
2003-04  Boerhaave Professor, Leiden University, the Netherlands
2005-06  Best Doctors in America
2006    Elected Senior Member of the IEEE
2006    Elected to the Collegium Oto-Rhino-Laryngologicum Amicitaet Sacrum
2007-08  President-elect, American Auditory Society
2007-08  Best Doctors in America
2009    Presidential Citation, American Otologic Society
2009-10  President, American Auditory Society
2009    Honor Award, American Academy of Otolaryngology – HNS
2009-10  Best Doctors in America
2010-11  Best Doctors in America
2012-13  President-elect, Association for Research in Otolaryngology
2012    Seattle Top Doctors
2013-14  President, Association for Research in Otolaryngology
2014-15  Past-President, Association for Research in Otolaryngology
2015    Americas Top Doctors
2016    Seattle Top Doctors
2017    Seattle Top Doctors
2018-21  President-Elect, The Politzer Society
2018    America’s Top Doctors 5 years
2019    Elected Fellow, American Institute of Medical and Biological Engineering

II. TEACHING

Classroom, Seminar, or Teaching Laboratory
1980-82  Teaching Assistant, Digital Electronics Laboratory, Brown University
1994-03  Weekly Neurotology Conference - lectures to otolaryngology residents and supervision of temporal bone dissection.
1994-03  Otolaryngology Basic Science Course
1995-03  Lectures to first & third year medical students on physiology & pathophysiology of the ear.
1997-03  Lectures to neuroscience graduate students on auditory physiology
2000-03  Lectures to primary care physicians on management of tinnitus, dizziness and hearing loss

Clinical Teaching (in ward, clinic, or operating room)
Otolaryngology Residents, Fellows and Medical Students

Teaching Activities Other Than Classroom or Clinical
1991-92  Assisted in undergraduate thesis supervision for Konstantina M. Trbovic, "Modeling of Auditory Nerve Responses to Electrical Stimulation," Department of Physics, Massachusetts Institute of Technology
2000  PhD Committee for Karen Chi, Department of Speech Pathology and Audiology, University of Iowa
2001  PhD Committee for Christina Runge, Department of Speech Pathology and Audiology, University of Iowa
2001-03  Mentor, Doris Duke Clinical Research Fellowship Program, University of Iowa
2003  PhD Committee for Tiffany Johnson, Department of Speech Pathology and Audiology, University of Iowa
2005-07  Research mentor Chad Ruffin, visiting Howard Hughes Fellow.
2005-06  Research mentor Grace Liu, MD visiting medical student.
2005-06  PhD Committee for Lendra Friesen, Department of Speech and Hearing Sciences, University of Washington
2007  PhD Committee for Olivier Macherey, University of Leuven, Belgium, “Effects of Stimulus Waveform on Hearing with Cochlear Implants”
2008-  PhD Committee for Katie Faulkner, Department of Speech and Hearing Sciences, University of Washington

Clinical Activities
A. Inpatient
   Surgery performed 1.5 day per week in operating rooms of UW Medical Center and Seattle Childrens
B. Outpatient
   Patient appointments 1.5 days per week

Master’s and Ph.D. Theses Directed and Postdoctoral Fellows Supervised
1995-96  Charles Miller, PhD - Postdoctoral Fellow. Physiology of electrically stimulated spiral ganglion cells, University of Iowa.
1995-96  Akihiro Matsuoka, MD, PhD. Response of auditory nerve to pulse trains. Dept of Speech Pathology & Audiology, University of Iowa.
1999-02  Nahla Hussein, MD. Doctoral Thesis, Suez Canal University, Egypt
2001-03  Gang Chen, MSE student, Dept. of Electrical Engineering, U. of I.
2002-03  Ron Andreatta, MSE student, Dept of Biomedical Engineering, U. of I.
2002-03  Robert Hong, MD, Doris Duke Fellow, University of Iowa.
2005-07  Jeff Longnion, MD/PhD student in bioengineering, UW
2005-11  Jong Ho Won, PhD student in bioengineering, UW
2005-09  Vasant Dasika, PhD. Postdoctoral fellow, UW.
2005-06  Steven Bierer, PhD. Postdoctoral fellow, UW.
2005-06  Robert Kang, MD, Otolaryngology-HNS resident, UW.
2007-08  Seeyoun Kwon, Visiting bioengineering graduate student, Hanyang University, Seoul.
2007-11  Nikita Imennov, PhD student in bioengineering, UW.
2009-10  Kyu Hwan Jung, MD, Visiting Fellow, Samsung Medical Center, Seoul.
2010-11  Minhyun Park, MD, Seoul National University, Seoul.
2010-11  Akinori Kashio, MD, Tokyo University, Tokyo
2011-12  Hyun-Joon Shim, MD, Seoul National University
2012-14  Il-Joon Moon, MD, Samsung Medical Center, Seoul
2009-12  Gary Jones, PhD, Postdoctoral fellow, UW
2014-16  Elle O’Brien, PhD student in neurobiology, UW
2016-19  Jesse Resnick, MD, PhD student in neurobiology, UW

Clinical Fellows Supervised

1996-98  Paul Gidley, MD. Currently Professor, Department of Head and Neck Surgery, University of Texas MD Anderson Cancer Center,
1998-00  Brian Perry, MD. Currently in private practice, San Antonio, TX
2000-02  Ravi Samy, MD. Currently Associate Professor, Department of Otolaryngology, University of Cincinnati
2002-04  Ted Meyer, MD, PhD. Currently Associate Professor, Medical University of South Carolina
2011-12  Michal Preis, MD. Currently an otolaryngologist at Maimonides Medical Center, Brooklyn, NY
2014-15  Kavita Dedhia, MD. Currently Assistant Professor, Department of Otolaryngology, Emory University, Atlanta GA

III. SCHOLARSHIP

Papers Published


86. Goldwyn JH, Shea-Brown E, Rubinstein JT. Encoding and decoding amplitude


97. Jung KH, Won JH, Drennan WR, Jameyson E, Miyasaki G, Norton SJ,


Papers in press


Papers submitted

Books/Chapters Published


**Selected Abstracts**


Selected NIH Contract Progress Reports


**Other Special Presentations**

**Theses**

**Invited Presentations**
1991 Invited Speaker; Asilomar Conference on Implantable Auditory Prostheses  
1993 Invited Speaker; Bryant College Conference on Cochlear Implants  
1995 Invited Speaker; Asilomar Conference on Implantable Auditory Prostheses  
1995 Chairman, Neural Modeling Session, Biomedical Engineering Society  
1996 Moderator, Cochlear Implant Session, Association for Research in Otolaryngology  
1996 Invited speaker, Bloedel Hearing Research Center, University of Washington  
1997 Invited speaker, 5th International Cochlear Implant Conference, New York, NY  
1997 Invited speaker, Asilomar Conference on Implantable Auditory Prostheses, Pacific Grove, CA  
1998 International Faculty, First International Symposium & Workshop on Objective Measures in Cochlear Implants, Nottingham, U.K.  
1999 Invited speaker, Asilomar Conference on Implantable Auditory Prostheses, Pacific Grove, CA  
2000 Invited speaker, CI 2000, 6th International Cochlear Implant Conference, Miami Beach, Florida  
2000 Invited speaker, 5th European Symposium on Paediatric Cochlear Implantation, Antwerp, Belgium  
2000 Invited speaker, World Congress on Medical Physics & Biomedical Engineering, Chicago, IL  
2000 Invited Speaker, 45th Japan Audiological Society Meeting, Nagoya, Japan  
2001 Moderator, 8th Symposium on Cochlear Implants in Children, Los Angeles, CA
2001  Moderator, Second International Symposium & Workshop on Objective Measures in Cochlear Implants, Lyon, France
2001  Visiting Professor, Hospital of the University of Geneva, Geneva Switzerland
2001  Co-Chair, Asilomar Conference on Implantable Auditory Prostheses, Pacific Grove, CA
2001  Visiting Professor, Department of Otolaryngology, Johns Hopkins School of Medicine, Baltimore, MD
2002  Outreach Faculty, Wireless Integrated MicroSystems Engineering Research Center, University of Michigan, Ann Arbor, MI
2002  Visiting Professor, First International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul, Korea
2002  Invited Speaker, Prentice Bloedel Day, Department of Otolaryngology, University of Washington, Seattle, WA
2002  Visiting Professor, Department of Otolaryngology, Mount Sinai School of Medicine, New York, NY
2002  Invited Speaker, Symposium on frontiers of organ and tissue replacement, American Society for Artificial Internal Organs, New York, NY
2002  International Advisory Member, 7th International Cochlear Implant Conference, Manchester, UK
2002  Visiting Professor, Department of Otolaryngology, University of Cincinnati, Cincinnati, OH
2002  Featured Speaker, Research Study Club, Los Angeles County Otolaryngology Society
2003  Keynote Speaker, NYU Cochlear Implant Course, Department of Otolaryngology, New York University, NY
2002  Invited panel on artificial organs, Third Annual Conference on Regenerative Medicine & DNA Therapies, Washington, D.C.
2003  Faculty Board, 4th International Symposium on Electronic Implants in Otology & Conventional Hearing Aids, Toulouse, France
2003  Guest speaker, American Auditory Society, Scottsdale, AZ
2003  Visiting Professor, Second International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul.
2003  Invited speaker, Asilomar Conference on Implantable Auditory Prostheses, Pacific Grove, CA
2003  Invited speaker, Research Plenary Session, Annual meeting of Self-Help for Hard of Hearing People, Atlanta, GA
2003  Invited Faculty, 9th Symposium on Cochlear Implants in Children, Washington, DC
2003  Invited speaker, Workshop on Cochlear Implants: Perception, Physiology, Models, Association for Research in Otolaryngology, Daytona Beach, FL
2003  Invited speaker, Symposium on Tinnitus: Mechanisms, Models, Therapy, Association for Research in Otolaryngology, Daytona Beach, FL
2003  Visiting Professor, Saint Louis University / Washington University combined grand rounds, Saint Louis, MO.
2003  Visiting Professor, Department of Otolaryngology, University of Texas, Houston, Guest Speaker, Houston Society of Otolaryngology.
2003  Guest Faculty, Third International Symposium on Objective Measures in Cochlear Implantation, Department of Otolaryngology, University of Michigan, Ann Arbor, MI.
2003  Invited Lecturer, Department of Phoniatics and Linguistics, University College London, UK.
2003  Twilight Lecture, The Ear Foundation, University of Nottingham, UK.
2003  Keynote Speaker, Asia-Pacific Symposium on Cochlear Implants, Taipei, Taiwan.
2004  International Advisory Panel, VIII International Cochlear Implant Conference, Indianapolis, IN.
2004  International Faculty, 7th European Symposium on Paediatric Cochlear Implantation, Geneva, Switzerland
2004  Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2004  Invited Lecturer, MRC Cognition and Brain Sciences Unit, University of Cambridge, UK
2004  Visiting Professor, Laboratory of Experimental ORL, University of Leuven, Belgium
2004  Guest Speaker, 204th General Meeting of the Netherlands Union of Otolaryngology, Nieuwegein, Netherlands
2004  Visiting Professor, Third International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul
2004  Guest Professor, University of Michigan Temporal Bone Dissection Course, Ann Arbor, MI
2004  Guest Speaker, Hearing, Balance and Chemical Senses Seminar, Kresge Hearing Research Institute, Ann Arbor, MI
2005  Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2005  Keynote Speaker, Frontiers in Hearing, Breckenridge, CO
2005  Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2005  International Faculty, 5th Asia Pacific Symposium on Cochlear Implant and Related Sciences, Hong Kong.
2006  Visiting Professor, Department of Otolaryngology, University of Florida, Gainesville.
2006  Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2006  Visiting Professor, Department of Otolaryngology, University of Pennsylvania, Philadelphia.
2006  Guest Speaker, Neuroengineering Now, Department of Bioengineering, University of Texas, Dallas, TX
2006  Visiting Professor, Osaka University Department of Otolaryngology, Osaka, Japan
2006  Guest Speaker, Second Annual Cochlear Implant Centres Group Education Day, Sunnybrook Health Sciences Centre, Toronto, Canada
2007  Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2007  Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2007  Howard P House Memorial Lecture, Pacific Coast Oto-Ophthalmologic Society, Oahu, HI
2007  Visiting Professor, Fourth International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul
2007  Guest Professor, Updates in Otology & Neurotology, Cesme, Turkey
2007  International Faculty, Asia Pacific Symposium on Cochlear Implant and Related Sciences, Sydney, Australia
2008  Keynote Speaker, 2nd International Music and Cochlear Implant Symposium, University Hospital of Zurich, Switzerland
2008  Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2008  Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2008  Visiting Professor, Fifth International Temporal Bone Dissection Course, Samsung Medical Center, Sungkyunkwan School of Medicine, Seoul, Korea
2008  Keynote Speaker, 6th Inner Ear Disease and Cochlear Implant Symposium, Izmir Teaching and Research Hospital, Kusadasi, Turkey
2009  Guest Translational Research Lecture, American Auditory Society, Scottsdale, AZ
2009  Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2009  Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2009  Invited Speaker, Nemours Cochlear Implant Symposium, AI duPont Hospital for Children, Wilmington, DE
2009  Invited Speaker, Conference on Implanted Auditory Prostheses, Lake Tahoe, CA
2009  International Faculty, Asia Pacific Symposium on Cochlear Implant and Related Sciences, Singapore
2010  Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2010  International Otologist, Frontiers of Otolaryngology, University of Melbourne, Australia
2010  Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2010  Distinguished speaker, House Ear Institute, Los Angeles
2010  Consulting speaker, IESLab, Ltd, Jinan, China
2010  Guest Professor, Dept of Otolaryngology, Miyazaki University, Japan
2010  Invited Speaker, Sixth International Symposium on Meniere’s disease, Kyoto, Japan
2010  International Faculty, 7th Inner Ear and Cochlear Implantation Symposium, Bodrum, Turkey
2011  Guest Speaker, The Colorado Audiology-Otology Conference, Vail, CO
2011  Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2011  Holy Hour Speaker, Dept ExpORL, Katholieke Universiteit Leuven, Belgium
2011  Willard Fee Lecture, Dept of Otolaryngology, Stanford University, Stanford, CA
2011  Keynote speaker, Korean Otological Society, Jeong-Sun, Korea
2011  Plenary speaker, 8th Asia-Pacific Symposium on Cochlear Implant, Daegu, Korea
2011  Visiting professor, Samsung Medical Center, Seoul, Korea
2011  Guest Professor, Leiden University Cochlear Implant Course, The Netherlands
2011  Guest surgeon, Xijing Hospital, Xi’an, China
2011  Keynote address, 7th International Symposium on Objective Measures in Auditory Implants, Amsterdam, Netherlands
2012  International Faculty, 8th Inner Ear and Cochlear Implantation Symposium, Cappadocia, Turkey
2012  Guest speaker, 16th International Symposium on Audiological Medicine, Beijing
2012  Seminar speaker, Weldon School of Biomedical Engineering, Purdue University, West Lafayette, IN
2013  Visiting Professor, Department of Otolaryngology, Bnai Zion Medical Center, Technion, Haifa, Israel
2013  Schindler Lecture, UC San Francisco Department of Otolaryngology-HNS.
2014  Visiting Surgeon, Global Foundation for Children with Hearing Loss, Childrens’ Hospital #1, Ho Chi Minh City, Hanoi Nat’l Childrens’ Hospital, Vietnam
2014  Guest Faculty, Cochlear Colloquium, Mumbai, India
2015  Keynote speaker, Asia Pacific Symposium on Cochlear Implants, Beijing, China
2015  Invited speaker, Acoustical Society of America, Pittsburgh, PA
2016  Wilson TS Wang Visiting Professor, Department of Otolaryngology, Chinese University of Hong Kong
2016  Invited Speaker, Barany Society, Seoul, Korea
2016  Visiting Professor, Department of Otolaryngology, UT Southwestern, Dallas, TX.
2017  Robert H Mathog MD Memorial Lectureship, Department of Otolaryngology-HNS, Wayne State University, Detroit
2017  Schuknecht Lecture, Massachusetts Eye & Ear, Harvard Medical School, Boston
2017  John Niparko Lecture, Department of Otolaryngology, University of Southern California, Los Angeles
2018  Invited speaker, Crossroads of Music and Technology, Berklee School of Music, Boston, MA
2018  Guest speaker, The Politzer Society, Las Palmas de Gran Canaria, Spain
2018  Guest faculty, Cochlear China surgeons advisory board, Beijing, China
2019  John Daly Lecture, Department of Otolaryngology, New York University
2019  Guest Faculty, Ibero-American Conference on Cochlear Implants, Pamplona
2019  Keynote speaker, Asia-Pacific Conference on Cochlear Implants, Tokyo

Patents Received

Patents Applied For
2. **Jay Rubinstein, James Phillips, Albert Fuchs, Leo Ling, Kaibao Nie, Steven Bierer,** Vestibular Implant Stimuli for the Treatment of Meniere's Disease, 2009

Areas of Research
Functional electrical stimulation of the inner ear
Treatment of hearing loss, tinnitus and vestibular dysfunction
High performance computing for neural modeling
Grants and Contracts

1995-97  San Diego Supercomputer Center.  
         Biophysical Model of Spiral Ganglion Cell and Auditory Nerve  
         Principal Investigator  200 Cray hours quarterly

1996-99  The Whitaker Foundation.  
         Biophysical Model of Type-I Spiral Ganglion Cells  
         Principal Investigator  $210,000

1996-98  NIH, Shannon Award, NO1-R55 DC/ODO2948-01.  
         Comparative Biophysical Model of Spiral Ganglion Cells  
         Principal Investigator  $100,000

         The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation  
         Co-Principal Investigator  $852,000

1997  National Institutes of Health, SBIR R43DC03505  
         Cochlear Electrode with High Channel Selectivity  
         Subcontract PI  $99,550

1998  National Institutes of Health  
         Cochlear Implant Conference  
         Co-Investigator (Shannon, PI)  $25,000

1999-00  Braintronics, Inc.  
         Tinnitus Suppression with Electrical Stimulation  
         Principal Investigator  $150,000

1999-04  National Institutes of Health  1 R01 DC03590  
         Spiral CT for Cochlear Implantation  
         Investigator (Wang, PI)  $1,159,301

1999-02  National Institutes of Health  Contract No. NIH-DC-98-14  
         The Neurophysiological Effects of Simulated Auditory Prosthesis Stimulation  
         Co-Principal Investigator  $1,116,095

         Effects of Remaining Hair Cells on Cochlear Implant Function  
         Co-Investigator (Abbas, PI)  $879,110

2000-03  Tinnitus Research Consortium  
         Electrical Suppression of Tinnitus  
         Principal Investigator  $300,000

2001  National Institutes of Health  1 R13 DC005041-01  
         2001 Conference on Implantable Auditory Prostheses  
         Conference Co-Chair (Shannon, PI)  $30,000

2001-06  National Institutes of Health P50  
         Iowa Cochlear Implant Center IV  
         Co-Director (Gantz, PI)  $10,823,000

2002-06  National Institutes of Health  Contract No. NIH-DC-98-11
Effects of Remaining Hair Cells on Cochlear Implant Function
Co-Investigator (Abbas, PI) $1,522,412
2002-03 Braintronics, Inc
Ear Implant for Tinnitus Suppression
Principal Investigator $250,000
2002 Advanced Bionics Inc.
Dynamic range with high-rate conditioning stimuli
Principal Investigator $30,000
2003 Advanced Bionics Inc.
Frequency discrimination with high-rate conditioning stimuli
Principal Investigator $30,000
2004-08 National Institutes of Health R01 DC05972
Randomized Trial of Tinnitus Retraining Therapy
Investigator (Tyler, PI) $1,768,575
2006 National Organization for Hearing Research Foundation
Measuring and improving hearing in infants with cochlear implants
Role: Mentor (Dasika, PI) $20,000
2005-10 National Institutes of Health R01 DC007525
Optimized Conditioned Processing for Cochlear Implants
Principal Investigator $1,905,126
2006-11 National Institutes of Health R13 DC006616
Building the Next Generation of Clinical Researchers - American Auditory Society
Role: Co-Investigator (Gorga, PI) $133,579
2006-11 National Institutes of Health DC-05-0011 (Phillips, PI)
Neuropsychological Studies of Electrical Stimulation for the Vestibular Nerve
Investigator $2,831,646
2006-07 Cochlear Corporation
Validation of the UW CAMP music test for cochlear implant recipients.
Role: PI $30,000
2007-08 Advanced Bionics Corporation
Validation of the UW CAMP music test for cochlear implant recipients
Role: PI $15,000
2006-08 Cochlear Corporation
Clinical Trial of the Nucleus Hybrid Cochlear Implant
Role: PI $7,500
2008 National Institutes of Health F32 DC008238 (Dasika, PI)
The development of sensitivity to electrical stimulation with cochlear implants.
Role: Mentor $58,898
2009-11 National Institutes of Health F31 DC009755 (Won, PI)
Psychophysics of speech processor modifications in cochlear implants.
Role: Mentor $68,836
2008-09 Cochlear Corporation
Clinical Trial of the Nucleus Hybrid S12 Cochlear Implant
Role: PI $7,500

2009-11 Wallace Coulter Foundation
Clinical Feasibility of a Vestibular Neurostimulator
Role: PI $212,000

2009-11 National Institutes of Health F31 DC010306
A model-based approach for optimizing cochlear implant stimulation
Role: Co-mentor (Goldwyn, PI) $68,836

2010 University of Washington Technology Gap Innovation Fund
Improving speech and music perception with cochlear implants
Role: Investigator (Nie, PI) $50,000

2009-11 National Institutes of Health F31 DC010309 (Faulkner, PI)
Auditory Training to Improve Spectral Resolution in Cochlear Implant Listeners
Role: Co-mentor $41,000

2010-12 National Institutes of Health F32 DC011431 (Jones, PI)
Modeling spectral-ripple discrimination by cochlear implant users
Role: Mentor $80,000

2010-15 National Institutes of Health R01 DC010148 (Drennan, PI)
Improved analysis of cochlear implant sound processing
Role: Investigator $1,875,000

2011 ITHS/National Primate Research Center (Phillips, PI)
Vestibular Prosthesis for Bilateral and Uncompensated Unilateral Loss
Role: Co-investigator $75,000

2011-14 Kranwinkle Family
Clinical Feasibility of a Vestibular Implant for Meniere’s disease
Role: PI $1,004,000

2013-14 American Otologic Society (Horn, PI)
Spectral and Temporal Resolution in Children with Cochlear Implants
Role: Co-mentor $80,000

2014-15 Wallace Coulter Foundation (Atlas, PI)
Tonality in Cochlear Implants
Role: Investigator $100,000

2014-19 National Institutes of Health R01 DC014002
Optimization of a human vestibular implant
Role: PI $2,961,610

2014-19 National Institutes of Health K23 DC013055 (Horn, PI)
Spectral and Temporal Resolution in Children with Cochlear Implants
Role: Co-Mentor $1,151,530

2014 Anderson Family
Operating support for the Bloedel Center
### COLLEGE OF MEDICINE CURRICULUM VITAE

Jay T. Rubinstein, M.D., Ph.D.

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<table>
<thead>
<tr>
<th>Year</th>
<th>Funding Source</th>
<th>Role</th>
<th>Amount</th>
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<tr>
<td>2014-</td>
<td>Bill and Melinda Gates Foundation</td>
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<td>2014-</td>
<td>Bloedel Minigrant Endowment</td>
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<td>NIDCD F31DC017349-01 (Resnick, PI)</td>
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<td>2018-21</td>
<td>Department of Defense DM170556OD (Drennan, PI)</td>
<td>Role: Mentor</td>
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<td>2018-19</td>
<td>Cheney Foundation (Horn, PI)</td>
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<td>Cheney Foundation (Carlson, PI)</td>
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### IV. SERVICE

**Professional Affiliations**

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<tr>
<th>Year</th>
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<tbody>
<tr>
<td>1980-</td>
<td>IEEE Engineering in Medicine and Biology Society</td>
</tr>
<tr>
<td>1986-</td>
<td>Association for Research in Otolaryngology</td>
</tr>
<tr>
<td>1990-</td>
<td>American Academy of Otolaryngology-Head and Neck Surgery</td>
</tr>
<tr>
<td>1992-94</td>
<td>Triological Society Resident Fellow</td>
</tr>
<tr>
<td>1996-</td>
<td>American Neurotology Society - Associate Member</td>
</tr>
<tr>
<td>1999-</td>
<td>American Auditory Society</td>
</tr>
<tr>
<td>2002-</td>
<td>American Otological Society</td>
</tr>
<tr>
<td>2006-</td>
<td>IEEE Senior Member</td>
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<tr>
<td>2006-</td>
<td>Collegium ORLAS</td>
</tr>
<tr>
<td>2007-09</td>
<td>President-elect and Program Chair, American Auditory Society</td>
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<tr>
<td>2008-11</td>
<td>Council, Association for Research in Otolaryngology</td>
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<tr>
<td>2009-10</td>
<td>President, American Auditory Society</td>
</tr>
<tr>
<td>2009-16</td>
<td>Vice-President, CORLAS-US group</td>
</tr>
<tr>
<td>2012-13</td>
<td>President-elect, Association for Research in Otolaryngology</td>
</tr>
<tr>
<td>2013-14</td>
<td>President, Association for Research in Otolaryngology</td>
</tr>
<tr>
<td>2014-15</td>
<td>Past-President, Association for Research in Otolaryngology</td>
</tr>
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</table>
2016-  Treasurer, CORLAS-US group
2019-  College of Fellows, American Institute of Medical and Biological Engineering
2018-22 President-Elect, The Politzer Society

Collegiate, University and National Committees
1992-94  Graduate Medical Education Committee, Massachusetts Eye and Ear Infirmary
1994-00 Committee on Implantable Hearing Devices, American Academy of Otolaryngology--Head and Neck Surgery
1995-  Scientific Advisory Council, NIDCD National Temporal Bone, Hearing and Balance Pathology Resource Registry
1996  Steering Committee, 1997 Asilomar Conference on Implantable Auditory Prostheses
1996  Ad Hoc NIH Site Visitor
1997  IAIMS Task Force, The University of Iowa
1997-  American Neurotology Society Research Committee
1997-  College of Medicine Research Committee
1997  Ad Hoc member NIH Hearing Research Study Section
1997  Ad Hoc member NIH Sensory Disorders SBIR Study Section
1998  Ad Hoc member NIH Hearing SBIR Study Section
1999  Ad Hoc member NIH IFCN Study Section
2000  Ad Hoc Member, NIH IFCN6 SBIR Study Section
2000  Peer reviewer, Conference of Rectors of the Austrian Universities
2000  NIH NINDS Special Emphasis Panel ZNS1 SRB-H(04)
2001  NIH NIDCD Special Emphasis Panel ZDC1 SRB-O
2001  Conference co-chair, Asilomar Conference on Implantable Auditory Prostheses
2001  Steering Committee, NIH/VA International Hearing Aid Conference
2001  Task Force on New Materials, American Board of Otolaryngology
2001  Nominating Committee, Association for Research in Otolaryngology
2001  Peer Reviewer, Hearing Loss Guideline Panel, New York State Department of Health
2002  Steering Committee, 2003 Asilomar Conference on Implantable Auditory Prostheses
2002  Outreach Faculty, Wireless Integrated MicroSystems Engineering Research Center, University of Michigan, Ann Arbor, MI
2002  NIH NIDCD Special Emphasis Panel, ZRG1 IFCN-4(06)
2002  Prosthetic Clinical Management National Workgroup on Cochlear Implants, Department of Veteran Affairs
2002  Ad Hoc Reviewer, Swiss National Science Foundation
2003  NIH NIDCD Special Emphasis Panel ZDC1 SRB-O
2003       Ad Hoc Reviewer, Royal National Institute for the Deaf, UK
2003       NIH NIDCD Special Emphasis Panel ZDC1 SRB-R (42)
2004       Ad hoc member, NIH AUD study section
2005       Ad hoc member, NIH R03 study section
2005-09    Permanent member NIH AUD study section
2005-08    Government Relations Committee, ARO
2006       Guest examiner, American Board of Otolaryngology
2006-07    Program Advisory Committee, American Otologic Society
2007       Guest examiner, American Board of Otolaryngology
2007       Steering committee, Conference on Implantable Auditory Prostheses
2007       Ad Hoc Reviewer, US Department of Energy Retinal Prosthesis Program
2008       Neurotology Examiner, American Board of Otolaryngology
2008-09    Scientific Advisory Panel, NIH Roadmap Nanomedicine Initiative
2009       Guest Examiner, American Board of Otolaryngology
2010       Neurotology Examiner, American Board of Otolaryngology
2010       Chair, nominating committee, American Otologic Society
2010       Program Committee, American Otologic Society
2012       Program Committee, American Otologic Society
2012-13    President-elect, Association for Research in Otolaryngology
2013-14    President, Association for Research in Otolaryngology
2014-15    Past President, Association for Research in Otolaryngology
2018-22    President-Elect, The Politzer Society
2018       Chair, NIDCD Special Emphasis Panel
2019       Chair, NIDCD Special Emphasis Panel
2019       Guest Examiner, American Board of Otolaryngology

Board Memberships
2001-       Scientific Advisory Board, American Tinnitus Association
2002-       Surgical Advisory Board, Cochlear Corporation
2003-       Editorial Board, Otology and Neurotology
2003-       Editorial Board, Hearing Research
2005-08    Associate Editor, Journal of the Association for Research in Otolaryngology
2004-08    Executive Board, American Auditory Society
2005-       Board of Trustees, Listen & Talk School, Seattle, WA
2005-       Surgical Advisory Board, Advanced Bionics Corporation
2006-08    Board of Trustees, Executive Committee, Northwest Lions Foundation for
            Sight and Hearing, Seattle, WA
2006-12    Chairman, Board of Trustees, Audient, LLC, Seattle, WA
2008-11    Council-at-large, Association for Research in Otolaryngology
2008-13    Board of Directors, SightLife, LLC, Seattle, WA
2010-13    Board of Directors, Otology & Neurotology
2010-18    Research Advisory Board, American Otologic Society
2012-17  Board of Scientific Counselors, NIDCD
2015      2017-21 NIDCD Strategic Plan Working Group
2017      Chair, Scientific Advisory Board, American Otologic Society

Ad Hoc Reviewer
Annals of Biomedical Engineering
Annals of Neurology
Annals of Otology, Rhinology & Laryngology
American Journal of Otology
Archives of Otolaryngology
Audiology and Neuro-otology
Ear and Hearing
Hearing Research
Hospital Physician
IEEE Transactions on Biomedical Engineering
Journal of Biomechanics
Journal of Neurophysiology
Journal of Neuroscience
Journal of the Acoustical Society of America
Journal of the Association for Research in Otolaryngology
Laryngoscope
Medical & Biological Engineering & Computing
Nature Medicine
Otology and Neurotology
Science Translational Medicine
The Lancet
Tinnitus: non-invasive, non-pharmacologic treatments

Judy Zerzan, MD, MPH
Chief Medical Officer
Health Care Authority
Friday May 15, 2020

Introduction

• Clinical questions
• Current policies and utilization
• Evidence summary
• Rationale and recommendations
Tinnitus

- Tinnitus = auditory experience of ringing, buzzing, roaring, hissing in the ears
  - Subjective or objective
  - Constant or intermittent
  - Pulsatile or rhythmical
  - One or both ears

- NHANES 7.1-14.6% of the population

- Comorbidities include depression, anxiety, hearing and concentration difficulties, sleep disturbance

Clinical Questions

- What is the effectiveness of non-invasive, non-pharmacologic therapies for the treatment of bothersome, subjective tinnitus?
- What are the harms associated with non-invasive, non-pharmacologic therapies for the treatment of tinnitus?
- What are the costs and cost-effectiveness of non-invasive, non-pharmacologic treatment of tinnitus?
Agency Medical Directors’ Concerns

• Safety: medium
• Efficacy: high
• Cost: high

Non-invasive and Non-pharmacologic Treatments

• Sound Therapies
  – Sound generators, sound maskers, altered auditory stimuli, hearing aids that include sound masking or generating

• Repetitive Transcranial Magnetic Stimulation (rTMS)
  – Delivery of multiple electromagnetic pulses to the scalp

• Cognitive Behavioral Therapy
  – Psychotherapy approach to reduce the distress associated with tinnitus

• Tinnitus Specific Therapies
  – Tinnitus retraining, tinnitus masking plus counseling
Current State Agency Policy

- **Sound Therapies**
  - L&I covers sound masking
- **Repetitive Transcranial Magnetic Stimulation (rTMS)**
  - Not covered for this indication
- **Cognitive Behavioral Therapy**
  - Covered
- **Tinnitus Specific Therapies**
  - No policy or not covered

Coverage Overview

<table>
<thead>
<tr>
<th></th>
<th>Sound Therapies</th>
<th>rTEMS</th>
<th>CBT</th>
<th>Tinnitus Specific Therapies</th>
<th>No Policy</th>
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<tbody>
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<td>Medicare</td>
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<tr>
<td>Aetna</td>
<td>NC</td>
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<td>Cigna</td>
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<tr>
<td>Humana</td>
<td>NC</td>
<td>NC</td>
<td>NC</td>
<td>NC</td>
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<tr>
<td>Kaiser</td>
<td>NC</td>
<td></td>
<td></td>
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<td>Premera</td>
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<td>Tricare</td>
<td>NC</td>
<td></td>
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<td>United</td>
<td>NC</td>
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### WA Utilization Medicaid

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<thead>
<tr>
<th>State health program</th>
<th>Medicaid, fee-for-service population</th>
<th>Medicaid, managed care population</th>
<th>WA Utilization: L&amp;I and UMP</th>
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<tbody>
<tr>
<td>State fiscal year</td>
<td>2017</td>
<td>2018</td>
<td>2019</td>
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<tr>
<td>Unique Individuals</td>
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<td></td>
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<tr>
<td>Medicaid</td>
<td>139,173</td>
<td>111,414</td>
<td>111,222</td>
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<tr>
<td>Fee-for-service</td>
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<tr>
<td>Individuals</td>
<td>139</td>
<td>126</td>
<td>118</td>
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<tr>
<td>with at least one</td>
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<tr>
<td>procedure/service</td>
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<tr>
<td>Number of</td>
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<td>192</td>
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<tr>
<td>procedure-days</td>
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<tr>
<td>Average procedure-days per Individual</td>
<td>1.8</td>
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<td>Max procedure days per Individual</td>
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### WA Utilization: L&I and UMP

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<th>State health program</th>
<th>Washington State Department of Labor and Industries (L&amp;I)</th>
<th>Public Employees Benefit Board Uniform Medical Plan (PEBB/UMP)</th>
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<tr>
<td>State fiscal year</td>
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<td>2018</td>
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<tr>
<td>Unique individuals</td>
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<tr>
<td>Workers' compensation claims by year</td>
<td>126,524</td>
<td>124,081</td>
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<tr>
<td>Individuals with at least one procedure/service</td>
<td>1,171</td>
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<tr>
<td>Number of procedure-days</td>
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Clinical Practice Guidelines

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<tr>
<th>Source</th>
<th>Sound Maskers</th>
<th>rTEMS</th>
<th>CBT</th>
<th>Tinnitus Specific Therapies</th>
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<tr>
<td>Multidisciplinary European guideline (2019)</td>
<td>n/a</td>
<td>Against</td>
<td>Strong recommend</td>
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<td>Assoc. of Scientific Medical Societies – Germany (2015)</td>
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<td>n/a</td>
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<td>American Acad. Of Otolaryngology (2014)</td>
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<tr>
<td>International Federation of Clinical Neurophysiology (2014)</td>
<td>Possible, but partial and transient benefit</td>
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Evidence Summary

- 59 studies reported in 69 articles 1996-2019
- All low or very low quality
- Effectiveness
  - Tinnitus distress and disability (14 instruments, 5 with defined clinical meaningful difference)
  - Psychological measures (18 instruments, 5 with defined clinical meaningful difference)
  - Quality of life (6 instruments, 2 with defined clinically meaningful difference)
Evidence on Sound Therapies

- All very low quality
- Effectiveness
  - Tinnitus distress and disability: no benefit or unable to determine
  - Psychological measures: no benefit or unable to determine
- Harms: no harms
- Cost: not reported

Evidence on rTEMS

- Low or very low quality
- Effectiveness
  - Tinnitus distress and disability: no benefit
  - Psychological measures: no benefit
  - Quality of life: no benefit
- Harms: unable to determine
- Cost: not reported
Evidence on CBT
Therapist led and Internet/book led

- All low quality evidence except very low on QOL
- Effectiveness
  - Tinnitus distress and disability: benefit
  - Psychological measures: benefit
  - Quality of life: no benefit (book led)
- Harms: no harms
- Cost: not reported

Evidence on Tinnitus Specific Therapies

- Mostly very low quality and a few low quality
- Effectiveness
  - Tinnitus distress and disability: benefit in studies that also used CBT principles
  - Psychological measures: unable to determine
  - Quality of life: unable to determine
- Harms: unable to determine
- Cost: unable to determine
AMD Recommendations

- **Sound Therapies**
  - Non coverage (would cover hearing aids if hearing loss is present)

- **Repetitive Transcranial Magnetic Stimulation (rTMS)**
  - Non coverage

- **Cognitive Behavioral Therapy**
  - Cover

- **Tinnitus Specific Therapies**
  - Non coverage

Questions?

More Information:
Order of scheduled presentations:

Tinnitus: non-invasive, non-pharmacologic treatments

<table>
<thead>
<tr>
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<td>2</td>
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<td>3</td>
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No requests were received to provide public comment on this technology assessment.
Overview of Presentation

- Background and policy context
- Methods and search results
- Summary findings and conclusions
- Questions
- Detailed results, as requested by the Committee
Background

Tinnitus refers to the experience of hearing ringing, buzzing, roaring, or hissing in the ears.

- Prevalence ranges from 7.1% to 14.6%.
- Treatment is aimed at reducing the perception of and/or reaction to the tinnitus noise.
- Due to the heterogeneity of the condition, no one treatment may be universally effective.
Background: Therapies & Technologies-Sound Therapies

- **Sound maskers**
  - Introduce sound using ambient or ear-level devices to mask tinnitus sounds, distract user, or both

- **Altered auditory stimuli**
  - Music or other sounds that is altered to emit noise at specific frequencies, often matched to an individual's tinnitus frequency

- **Hearing aids with sound generating or masking**
  - For individuals with hearing loss and tinnitus.

Source: [http://bradentonsertoma.org/speech-hearing](http://bradentonsertoma.org/speech-hearing)

---

Background: Therapies & Technologies-rTMS

**Repetitive transcranial magnetic stimulation (rTMS)**

- Non-invasive neuromodulation intervention
- Multiple electromagnetic pulses targeted to specific brain regions
- Delivered over multiple sessions over the course of days to weeks

Source: [https://brainclinics.com/rtems/](https://brainclinics.com/rtems/)
Background: Therapies & Technologies - CBT

**Cognitive Behavioral Therapy (CBT)**

- Cognitive restructuring and behavior modification
- CBT principals are used to promote changes to reduce the distress associated with tinnitus

![Cognitive Behavioral Therapy Diagram](https://a360-wp-uploads.s3.amazonaws.com/wp-content/uploads/hearingr/2013/05/Tinnitus_fig1.png)

Background: Therapies & Technologies - Tinnitus-specific Therapy

**Tinnitus-specific therapies** describe interventions that use components of sound and psychological therapy in combination to treat tinnitus. These include, among others:

- Tinnitus retraining therapy (TRT)
- Neuromonics tinnitus treatment (NTT)
- Tinnitus activities treatment (TAT)
- Tinnitus-masking counseling
Regulatory Status and Policy Context

• Some of the technologies evaluated in the scope of this HTA are devices regulated by the U.S. Food and Drug Administration
  o 72 FDA-cleared sound devices as of late 2019
  o rTMS approved for treatment-resistant depression, acute migraine headache, obsessive-compulsive disorder

• The State of Washington Health Care Authority selected non-invasive, non-pharmacologic treatments for tinnitus for an HTA because of medium concerns of safety and high concerns for efficacy and cost.

Methods
Key Questions

- **Key Question 1: Effectiveness (Health Outcomes)**
  - What is the effectiveness of non-invasive, non-pharmacologic therapies for the treatment of bothersome, subjective tinnitus?

- **Key Question 2: Safety**
  - What are the harms associated with non-invasive, non-pharmacologic therapies for tinnitus?

- **Key Question 3: Cost**
  - What are the costs and cost-effectiveness of non-invasive, non-pharmacologic therapies for the treatment of tinnitus?

Scope

<table>
<thead>
<tr>
<th>Population</th>
<th>Adults with subjective, idiopathic tinnitus without underlying anatomical conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interventions</td>
<td>Sound therapies; rTMS; Cognitive behavioral therapy; Tinnitus-specific therapies</td>
</tr>
<tr>
<td>Comparators</td>
<td>No treatment, usual care, waitlist or delayed treatment, sham treatment</td>
</tr>
</tbody>
</table>
| Outcomes | • KQ 1 (Effectiveness): validated measures  
  - Tinnitus symptom, severity, distress, disability, or handicap  
  - Psychological measures (e.g., depression, anxiety),  
  - Sleep impact  
  - Health-related quality of life  
  - Functional status  
  • KQ 2 (Safety): adverse events, serious adverse events, side effects  
  • KQ 3 (Cost): Cost, cost-effectiveness |
| Setting | Any primary or specialty care setting in countries categorized as very high on the United Nations’ Human Development Index |
| Study Designs | Randomized controlled trials, controlled trials (all KQ)  
Cohort studies with a concurrent comparator group (KQ2)  
Cost-studies (KQ3) |

**Abbreviations:** KQ=key question; NTT=neuromonics tinnitus treatment; rTMS=repetitive transcranial magnetic stimulation; TAT=tinnitus activities treatment; TRT=tinnitus retraining therapy. *only if at least 3 low or some risk of bias RCTs not available*
Search and Assessment Methods

- PubMed MEDLINE, Embase, Cochrane Library, PsycInfo, Relevant web sites
- Dates: Database inception through September 9, 2019
- ClinicalTrials.gov search for ongoing studies
- Individual study risk of bias assessment
- OpenEpi for ARD, IRR, RR, and CI calculations when not provided
- Modified Grading of Recommendations, Assessments, Development and Evaluation (GRADE) approach for overall certainty of evidence

GRADE

**Outcomes assessed**: tinnitus distress & disability, psychological measures (including sleep), quality of life, adverse events, cost outcomes

<table>
<thead>
<tr>
<th>Certainty Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Very confident that the estimate of effect of intervention on outcome lies close to the true effect.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Moderately confident in estimate of effect of intervention on outcome. True effect is likely close to estimate, but possibly different.</td>
</tr>
<tr>
<td>Low</td>
<td>Little confidence in estimate of effect of intervention on outcome. True effect may be substantially different from estimate.</td>
</tr>
<tr>
<td>Very low</td>
<td>No confidence in estimate of effect of intervention on outcome. True effect is likely substantially different from estimate.</td>
</tr>
</tbody>
</table>

RCTs

Cohorts
# Measures of Tinnitus Distress and Disability

<table>
<thead>
<tr>
<th>Instrument Name</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tinnitus Handicap Inventory</td>
<td>THI</td>
</tr>
<tr>
<td>Tinnitus Questionnaire</td>
<td>TQ and mini-TQ</td>
</tr>
<tr>
<td>Tinnitus Handicap Questionnaire</td>
<td>THQ</td>
</tr>
<tr>
<td>Tinnitus Reaction Questionnaire</td>
<td>TRQ</td>
</tr>
<tr>
<td>Tinnitus Functional Index</td>
<td>TFI</td>
</tr>
<tr>
<td>Visual Analog Scale</td>
<td>VAS</td>
</tr>
<tr>
<td>Tinnitus Experience Questionnaire</td>
<td>TExQ</td>
</tr>
<tr>
<td>Tinnitus Effects Questionnaire</td>
<td>TEIQ</td>
</tr>
<tr>
<td>Tinnitus Cognitions Questionnaire</td>
<td>TCQ</td>
</tr>
<tr>
<td>Tinnitus Disability Questionnaire</td>
<td>TD</td>
</tr>
<tr>
<td>Tinnitus Coping Style Questionnaire</td>
<td>TCSQ</td>
</tr>
<tr>
<td>Tinnitus Severity Index</td>
<td>TSI</td>
</tr>
<tr>
<td>Tinnitus Acceptance Questionnaire</td>
<td>TAQ</td>
</tr>
<tr>
<td>Tinnitus Severity Scale</td>
<td>TSS</td>
</tr>
</tbody>
</table>

Most commonly used

## Summary of Findings
**Summary of Search Yield**

- 3,310 records identified through database searches
- 177 full-text articles assessed for eligibility
- 59 RCTs* eligible for this review
  - 11 sound therapy
  - 19 rTMS
  - 21 CBT
  - 10 Tinnitus-specific

* Some studies reported on multiple interventions across categories

**Evidence Map and Topline Summary**

<table>
<thead>
<tr>
<th>Effectiveness</th>
<th>Favors intervention</th>
<th>No difference</th>
<th>Unable to determine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tinnitus distress and disability</td>
<td>k=21 N=2,689</td>
<td>k=10 N=1,346</td>
<td>k=18 N=760</td>
</tr>
<tr>
<td>Psychological measures</td>
<td>k=19 N=1,884</td>
<td>k=1 N=120</td>
<td>k=2 N=566</td>
</tr>
<tr>
<td>Quality of life</td>
<td>k=3 N=436</td>
<td>k=2 N=566</td>
<td>k=1 N=100</td>
</tr>
<tr>
<td>Safety</td>
<td>k=1 N=492</td>
<td>k=2 N=556</td>
<td>k=1 N=526</td>
</tr>
<tr>
<td>Cost</td>
<td>k=2 N=526</td>
<td>k=1 N=492</td>
<td>k=5 N=247</td>
</tr>
</tbody>
</table>

Legend

- GRADE Certainty of Evidence
  - Very low
  - Low
  - Moderate
  - High

K = number of studies
N = total number of participants

* Tinnitus-specific interventions without sound therapy (k=3, N=409) were given a “very low” certainty of evidence rating.

Note: Placement of shape along the X-axis does not indicate magnitude of effect.
Findings: Cognitive Behavioral Therapy

Study Characteristics: Cognitive Behavioral Therapy

<table>
<thead>
<tr>
<th>21 RCTs</th>
<th>1996 to 2018</th>
<th>N range 20-304</th>
<th>Duration: NR- 6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 U.S.</td>
<td>17 in other countries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 some risk of bias</td>
<td>13 high risk of bias</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 industry support</td>
<td>15 no industry support</td>
<td>3 NR</td>
<td></td>
</tr>
<tr>
<td>12 therapist-led</td>
<td>8 self-directed</td>
<td>1 Both</td>
<td></td>
</tr>
<tr>
<td>3 KQ1</td>
<td>18 KQ1 &amp; KQ2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14 wait list control</td>
<td>7 attention control</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: KQ = key question; NR = not reported; RCT = randomized controlled trial
Cognitive Behavioral Therapy-GRADE Table

<table>
<thead>
<tr>
<th>Intervention (Comparison)</th>
<th>Outcome</th>
<th>No. Studies (No. Participants)</th>
<th>GRADE Certainty of Evidencea</th>
<th>Direction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapist-led individual or group CBT interventions (delayed treatment or attention control)</td>
<td>Tinnitus distress and disability</td>
<td>13 RCTs (1,743)</td>
<td>●●○○</td>
<td>Benefit</td>
</tr>
<tr>
<td></td>
<td>Psychological measures</td>
<td>11 RCTs (1,100)</td>
<td>●●○○</td>
<td>Benefit</td>
</tr>
<tr>
<td></td>
<td>Safety</td>
<td>3 RCTs (436)</td>
<td>●●○○</td>
<td>No harms</td>
</tr>
<tr>
<td>Internet or book-guided CBT interventions (wait list or attention control)</td>
<td>Tinnitus distress and disability</td>
<td>9 RCTs (946)</td>
<td>●●○○</td>
<td>Benefit</td>
</tr>
<tr>
<td></td>
<td>Psychological measures</td>
<td>8 RCTs (784)</td>
<td>●●○○</td>
<td>Benefit</td>
</tr>
<tr>
<td></td>
<td>Quality of life</td>
<td>2 RCTs (120)</td>
<td>●●○○</td>
<td>No benefit</td>
</tr>
</tbody>
</table>

Notes: *Certainty ratings: ●●●● Very low, ●●○○ Low, ●●●○ Moderate, ●●●● High
Abbreviations: CBT = cognitive behavioral therapy; RCT = randomized controlled trial

Additional Detail on Effectiveness of CBT interventions

- Therapist-led interventions
  - Tinnitus distress and disability
    - 7 studies reporting using TQ; primary study outcome in 4 studies
      - Effect sizes(ES) 0.81 to 0.95 based on 3 studies
      - All but 1 also reported other measures (VAS, TDQ, TRQ)
    - 3 studies reported using THI; primary study outcome in 1 study
      - ES 0.38 and 0.98, based on 2 studies
      - All also reported other measures (TFI, TAQ)
    - 3 studies reported measures other than the TQ and THI
      - TRQ: 7.8 to 10.3 larger point improvement for intervention vs. control (statistically significant in 1 study, significance NR by other 2 studies)
      - Other measures reported by 2 of the 3 studies, larger numerical improvements for intervention but no statistical significance testing

Effect Size
1.2 very large
0.8 large
0.5 medium
0.2 small
### Additional Detail on Effectiveness of CBT interventions

- **Self-directed interventions**
  - Tinnitus distress and disability
    - 4 studies reported using THI, primary study aim for 2 studies
      - Effect sizes ranged from 0.56* to 0.70* across the 4 studies
      - Three of the 4 also reported larger improvements on other measures (mini-TQ, TAQ, TRQ, VAS for loudness, VAS for distress)
    - 3 studies reported using TRQ, primary study aim for 2 studies
      - 1 study: ES 0.28 at 6 weeks
      - 1 study: 12.5-point larger improvement*; % achieving meaningful reduction (13% vs. 3%)
      - 1 study: No significant difference at 6 weeks (actual values NR)
    - 1 study reported using TFI, primary study aim
      - ES 0.7 at post-intervention (8 weeks)
    - 1 study reported using TQ, primary study aim
      - Internet-delivered: ES 1.0* at 3 months, 0.66* at 9 months
      - Book-delivered: ES 0.24 at 3 months, 0.39* at 9 months

* Indicates a statistically significant result

### Findings: Tinnitus Specific Therapies
Study Characteristics: Tinnitus-specific Therapies

10 RCTs
- 2004-2017
- N range: 39-492
- Duration: NR-6 months

- 3 U.S.
- 7 in other countries
- 4 some risk of bias
- 6 high risk of bias
- 3 industry support
- 5 no industry support
- 2 NR
- 9 participants with some hearing loss
- 9 KQ1
- 1 required hearing loss
- 1 KQ1 & KQ2 & KQ3
- 3 industry support
- 2 usual care
- 6 waitlist control
- 2 attention control

Abbreviations: KQ = key question; NR = not reported; RCT = randomized controlled trial

Tinnitus-specific therapy-GRADE Table

<table>
<thead>
<tr>
<th>Intervention (Comparison)</th>
<th>Outcome</th>
<th>No. Studies (No. Participants)</th>
<th>GRADE Certainty of Evidence</th>
<th>Direction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tinnitus-specific-interventions with sound therapy (delayed treatment or attention control)</td>
<td>Tinnitus distress and disability</td>
<td>7 RCTs (937)</td>
<td>●●○○</td>
<td>Benefit</td>
</tr>
<tr>
<td></td>
<td>Psychological measures</td>
<td>2 RCTs (556)</td>
<td>●○○○</td>
<td>Unable to determine</td>
</tr>
<tr>
<td></td>
<td>Quality of life</td>
<td>2 RCTs (556)</td>
<td>●○○○</td>
<td>Unable to determine</td>
</tr>
<tr>
<td></td>
<td>Safety</td>
<td>1 RCT (492)</td>
<td>●○○○</td>
<td>Unable to determine</td>
</tr>
<tr>
<td></td>
<td>Cost</td>
<td>1 RCT (492)</td>
<td>●○○○</td>
<td>Unable to determine</td>
</tr>
<tr>
<td>Tinnitus-specific interventions without sound therapy (delayed treatment or attention control)</td>
<td>Tinnitus distress and disability</td>
<td>3 RCTs (409)</td>
<td>●○○○</td>
<td>Benefit</td>
</tr>
<tr>
<td></td>
<td>Psychological measures</td>
<td>1 RCT (90)</td>
<td>●○○○</td>
<td>Unable to determine</td>
</tr>
</tbody>
</table>

Notes: *Certainty ratings: ●○○○ Very low, ●●○○ Low, ●●●○ Moderate, ●●●● High
Abbreviations: RCT = randomized controlled trial
Findings: Sound Therapy

### Study Characteristics: Sound Therapy

<table>
<thead>
<tr>
<th>11 RCTs</th>
<th>1999 to 2018</th>
<th>N range 30-136</th>
<th>Duration: NR to 1 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 U.S.</td>
<td>8 other countries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 some risk of bias</td>
<td>6 high risk of bias</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 industry funding</td>
<td>6 No industry funding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 participants with hearing loss</td>
<td>3 excluded hearing loss</td>
<td>1 NR</td>
<td></td>
</tr>
<tr>
<td>10 KQ 1</td>
<td>1 KQ1 &amp; KQ2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 HA + SG vs. HA alone</td>
<td>4 Altered auditory stimulus vs. placebo stimulus</td>
<td>3 SG + intervention vs. intervention alone</td>
<td>1 game</td>
</tr>
</tbody>
</table>

Abbreviations: HA = hearing aid; KQ = key question; NR = not reported; SG = sound generator
### Sound therapy interventions - GRADE Table

<table>
<thead>
<tr>
<th>Intervention (Comparison)</th>
<th>Outcome</th>
<th>No. Studies (No. Participants)</th>
<th>GRADE Certainty of Evidence&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Direction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hearing aids with sound-generating features (regular hearing aids)</td>
<td>Tinnitus distress and disability</td>
<td>3 RCTs (87)</td>
<td>●●●●</td>
<td>No benefit</td>
</tr>
<tr>
<td>Altered auditory stimulus (control stimulus)</td>
<td>Tinnitus distress and disability</td>
<td>4 RCTs (219)</td>
<td>●●●●</td>
<td>Unable to determine</td>
</tr>
<tr>
<td></td>
<td>Psychological measures</td>
<td>1 RCT (50)</td>
<td>●●●●</td>
<td>No benefit</td>
</tr>
<tr>
<td></td>
<td>Safety</td>
<td>1 RCT (100)</td>
<td>●●●●</td>
<td>No harms</td>
</tr>
<tr>
<td>Sound generators with information, education, counseling (information, education, counseling alone)</td>
<td>Tinnitus distress and disability</td>
<td>3 RCTs (234)</td>
<td>●●●●</td>
<td>No benefit</td>
</tr>
<tr>
<td></td>
<td>Psychological measures</td>
<td>1 RCT (48)</td>
<td>●●●●</td>
<td>Unable to determine</td>
</tr>
<tr>
<td>Auditory Attention Training Game (control game)</td>
<td>Tinnitus distress and disability</td>
<td>1 RCT (31)</td>
<td>●●●●</td>
<td>Unable to determine</td>
</tr>
</tbody>
</table>

<sup>a</sup>Certainty ratings: ●●●● Very low, ●●● Low, ●● Moderate, ●●●● High

Abbreviations: RCT = randomized controlled trial

---

**Findings: rTMS**
Study Characteristics: active rTMS vs. sham rTMS

19 RCTs
- 2007 to 2018
- N range 6-153
- Duration: 1 day to 4 weeks

- 4 U.S.
- 15 other countries

- 1 low
- 13 some risk of bias
- 5 high risk of bias

- 14 no industry support
- 5 funding support NR

- 14 participants with hearing loss
- 3 excluded hearing loss
- 2 NR

- 5 KQ 1
- 1 KQ 2
- 13 KQ1 & KQ2

- 9 cross-over RCT
- 10 parallel-assignment RCT

Abbreviations: KQ = key question; NR = not reported; RCT = randomized controlled trial; rTMS = repetitive transcranial magnetic stimulation

rTMS intervention-GRADE Table

<table>
<thead>
<tr>
<th>Intervention (Comparison)</th>
<th>Outcome</th>
<th>No. Studies (No. Participants)</th>
<th>GRADE Certainty of Evidence*</th>
<th>Direction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active rTMS (sham rTMS)</td>
<td>Tinnitus distress and disability</td>
<td>18 RCTs (760)</td>
<td>●●〇〇</td>
<td>No benefit</td>
</tr>
<tr>
<td></td>
<td>Psychological measures</td>
<td>5 RCTs (247)</td>
<td>●〇〇〇</td>
<td>No benefit</td>
</tr>
<tr>
<td></td>
<td>Quality of life</td>
<td>1 RCT (153)</td>
<td>●〇〇〇</td>
<td>No benefit</td>
</tr>
<tr>
<td></td>
<td>Safety</td>
<td>14 RCTs (526)</td>
<td>●〇〇〇</td>
<td>Unable to determine</td>
</tr>
</tbody>
</table>

Notes: *Certainty ratings: ●〇〇〇 Very low, ●〇〇〇 Low, ●〇〇〇 Moderate, ●〇〇〇 High
Abbreviations: RCT = randomized controlled trial; rTMS = repetitive transcranial magnetic stimulation.
Discussion

Evidence Map - Reprise

Efficacy
- Tinnitus distress and disability
  - Favors intervention
  - No difference
  - Unable to determine

Psychological measures

Quality of life

Safety

Cost

Legend
GRADE Certainty of Evidence
- Very low
- Low
- Moderate
- High

Intervention Type
- Sound
- tTMS
- CST
- Tinnitus-specific

Favors intervention
- No difference
- Unable to determine

Note: Placement of shape along the X-axis does not indicate magnitude of effect

Legend:
- K = number of studies
- N = total number of participants

Table 9
Limitations of the Evidence

- Many high risk of bias studies
- Small sample sizes leading to imprecise effect estimates
- Harms not consistently ascertained
- Heterogeneity of interventions
- Limited evidence for subgroups of interest
  - e.g., Occupational noise exposure
- Only 1 study reporting cost outcomes

Ongoing Studies

- We identified 35 relevant ongoing studies registered in clinicaltrials.gov
  - Most trials were interventional and had less than 100 subjects
  - Ongoing studies fell into the following broad intervention categories
    - 18 neuromodulation studies many but not all are on rTMS
    - 7 sound therapy studies
    - 4 psychological or behavioral studies
    - 4 studies with ≥2 types of therapy
    - 2 studies that address the etiology, diagnosis, and experience of tinnitus
## Clinical Practice Guidelines and Payor Coverage Policies

### Clinical Practice Guidelines

<table>
<thead>
<tr>
<th>CPG, Year</th>
<th>AGREE-II Quality Rating</th>
<th>CBT</th>
<th>Sound Therapy</th>
<th>rTMS</th>
<th>Tinnitus-Specific Therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td>NICE, 2020</td>
<td>7</td>
<td>✓</td>
<td>?</td>
<td>?</td>
<td>?</td>
</tr>
<tr>
<td>European consensus, 2019</td>
<td>6</td>
<td>✓</td>
<td>?</td>
<td>🚫</td>
<td>?</td>
</tr>
<tr>
<td>German Medical Society, 2015</td>
<td>5</td>
<td>✓</td>
<td>?</td>
<td>?</td>
<td>🚫</td>
</tr>
<tr>
<td>AAOHNS, 2014</td>
<td>5</td>
<td>✓</td>
<td>✓ --?</td>
<td>🚫</td>
<td>--</td>
</tr>
</tbody>
</table>

- ✓ Recommend for
- 🚫 Recommend against
- ? No recommendations for or against, more research needed

AgrEE-II: 1=worst possible quality, 7 = best possible quality
Payor Policies

- CMS
  - National Coverage Determination (NCD) prior to 2014 stated that tinnitus masking was considered experimental and was therefore not covered, however, that NCD was removed effective December 18, 2014

- Other Payors

<table>
<thead>
<tr>
<th>Treatment Type</th>
<th>Medicare</th>
<th>Aetna</th>
<th>Cigna</th>
<th>Humana</th>
<th>Kaiser Permanente</th>
<th>Premera Blue Cross</th>
<th>Regence BlueShield</th>
<th>TRICARE</th>
<th>UnitedHealth</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBT</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>rTMS</td>
<td>—</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>X</td>
<td>X</td>
<td>—</td>
<td>X</td>
</tr>
<tr>
<td>Sound Therapy</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Tinnitus-Specific...</td>
<td>—</td>
<td>X</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

Notes: X = not covered; — = no policy identified.

Limitations of the HTA

- Only included peer-reviewed journal publications in English
- Did not evaluate comparative effectiveness of interventions
- Did not evaluate neuromodulation interventions other than rTMS
- Did not evaluate psychological interventions other than CBT unless part of a multicomponent intervention (e.g. tinnitus retraining therapy)
  - Poor study reporting means it’s possible we misclassified some interventions, or excluded some interventions
- HTA not scoped to evaluated medications, lifestyle modifications, alternative and complementary therapies, or invasive interventions
### Conclusions

**LOW certainty**
- CBT, or tinnitus specific interventions that combine psychological counseling with sound therapy, offer some benefit for reducing tinnitus related distress and disability

**VERY LOW to LOW certainty**
- Sound therapy alone and rTMS (as used in studies) may not be effective

**VERY LOW certainty**
- Across the body of evidence, harms were poorly ascertained and reported.
  - May be few to no harms from CBT or sound therapy
  - Insufficient evidence to determine harms from rTMS and tinnitus-specific therapies

### Questions?
Adults with subjective tinnitus that is bothersome

- Serious adverse events
- Adverse events

Non-invasive, non-pharmacologic treatments for tinnitus
- Sound therapies
- rTMS
- CBT
- Tinnitus-specific therapies (e.g. TRT, NTT, TAT)

KQ1
- Tinnitus symptoms
- Depression
- Anxiety
- Sleep
- Health-related quality of life
- Functional status
- Cost
- Cost effectiveness

KQ3
- SQ 1

KQ2
- EQ 1

SQ 1
- EQ 1

CQ 1

Analytic Framework
Table 5. Sound therapy studies (k=11)

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Country</th>
<th>Risk of Bias</th>
<th>Eligible Interventions &amp; Comparators (N randomized)</th>
<th>Total Sample Size</th>
<th>Treatment Duration</th>
<th>Mean Age (SD)</th>
<th>N (%) Female</th>
<th>Outcomes Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davis (2008)</td>
<td>Australia</td>
<td>High</td>
<td>Counseling only (13)</td>
<td>28</td>
<td>1 year</td>
<td>49.8 (15.8)</td>
<td>24 (48.0)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Dineen (1999)</td>
<td>Australia</td>
<td>High</td>
<td>Information only (28) with sound device (20)</td>
<td>48</td>
<td>NR</td>
<td>53.6 (15.0)</td>
<td>28 (58.3)</td>
<td>Tinnitus distress, Psychological</td>
</tr>
<tr>
<td>Henry (2015)</td>
<td>U.S.</td>
<td>Some</td>
<td>Hearing aid only (15) with sound generator (15)</td>
<td>30</td>
<td>3-4 months</td>
<td>67.2 (9.2)</td>
<td>10 (33)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Henry (2017)</td>
<td>U.S.</td>
<td>Some</td>
<td>Hearing aid only (18) with sound generator (19)</td>
<td>37</td>
<td>4-5 months</td>
<td>Mean (Range)</td>
<td>Hearing aid: 4 (22) Hearing aid+sound: 4 (21)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Hiler (2005)</td>
<td>Germany</td>
<td>Some</td>
<td>Tinnitus education without sound generator (36)</td>
<td>136</td>
<td>Education: 4 weeks</td>
<td>Hearing aid: 51.0 (15.3)</td>
<td>Tinnitus distress</td>
<td></td>
</tr>
<tr>
<td>Schad (2018)</td>
<td>U.S.</td>
<td>High</td>
<td>Placebo noise (10) Notched noise (10) Matched noise (10)</td>
<td>30</td>
<td>2 weeks</td>
<td>58 (NR)</td>
<td>10 (33)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Stein (2016)</td>
<td>Germany</td>
<td>Some</td>
<td>Placebo music (50) Notched music (50)</td>
<td>100</td>
<td>3 months</td>
<td>47.5 (10.8)</td>
<td>33 (33)</td>
<td>Tinnitus distress, Safety</td>
</tr>
<tr>
<td>Strauss (2015)</td>
<td>Germany</td>
<td>Some</td>
<td>Hearing aid (10) Hearing aid plus sound generator (10)</td>
<td>20</td>
<td>3 weeks</td>
<td>Hearing aid: 53.5 (4.8)</td>
<td>Hearing aid+sound: 52.7 (5.9)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Wise (2016)</td>
<td>New Zealand</td>
<td>High</td>
<td>Control computer game (16) Attention training computer game (15)</td>
<td>31</td>
<td>20 days</td>
<td>Control: 62.3 (4.6) Attention training: 52.3 (10.6)</td>
<td>Tinnitus distress</td>
<td></td>
</tr>
<tr>
<td>Author (Year)</td>
<td>Country</td>
<td>Risk of Bias</td>
<td>Eligible Interventions &amp; Comparators (N randomized)</td>
<td>Total Sample Size</td>
<td>Treatment Duration</td>
<td>Mean Age (SD)</td>
<td>N (%) Female</td>
<td>Outcomes Reported</td>
</tr>
<tr>
<td>---------------</td>
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<td>--------------</td>
<td>----------------------------------------------------</td>
<td>------------------</td>
<td>-------------------</td>
<td>---------------</td>
<td>-------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Anders (2010)</td>
<td>Czech Republic</td>
<td>High</td>
<td>Sham rTMS (26) rTMS (26)</td>
<td>52</td>
<td>2 weeks</td>
<td>Sham: 50.1 (14.0) rTMS: 48.5 (14.0)</td>
<td>13 (31)</td>
<td>Tinnitus distress, Safety</td>
</tr>
<tr>
<td>Barwood (2013)</td>
<td>Australia</td>
<td>High</td>
<td>Sham rTMS (4) rTMS (4)</td>
<td>8</td>
<td>10 days</td>
<td>42.4 (8.8)</td>
<td>4 (50)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Chung (2012)</td>
<td>Taiwan</td>
<td>Some</td>
<td>Sham rTMS (10) rTMS (12)</td>
<td>22</td>
<td>10 days</td>
<td>53.0 (16.8)</td>
<td>2 (9)</td>
<td>Tinnitus distress, Safety</td>
</tr>
<tr>
<td>Falster (2015)</td>
<td>U.S.</td>
<td>Some</td>
<td>Sham rTMS (35) rTMS (35)</td>
<td>70</td>
<td>2 weeks</td>
<td>Sham: 52.8 (8.3) rTMS: 58.3 (9.6)</td>
<td>13 (20)</td>
<td>Tinnitus distress, Safety</td>
</tr>
<tr>
<td>Formanek (2018)</td>
<td>Czech Republic</td>
<td>Some</td>
<td>Sham rTMS (12) rTMS (20)</td>
<td>22</td>
<td>5 days</td>
<td>Sham: 51.8 (10.3) rTMS: 47.9 (14.3)</td>
<td>9 (28)</td>
<td>Tinnitus distress, Psychological, Safety</td>
</tr>
<tr>
<td>Hookstra (2013)</td>
<td>The Netherlands</td>
<td>Some</td>
<td>Sham rTMS (24) rTMS (26)</td>
<td>52</td>
<td>5 days</td>
<td>Sham: 52 (12)</td>
<td>9 (18)</td>
<td>Tinnitus distress, Safety</td>
</tr>
<tr>
<td>Asplund (2005)</td>
<td>Germany</td>
<td>Some</td>
<td>Sham rTMS (10) rTMS (10)</td>
<td>10</td>
<td>5 days</td>
<td>Sham: 47.6 (13.4)</td>
<td>2 (20)</td>
<td>Tinnitus distress, Safety</td>
</tr>
<tr>
<td>Langguth (2007)</td>
<td>Germany</td>
<td>Low</td>
<td>Sham rTMS (75) rTMS (71)</td>
<td>153</td>
<td>2 weeks</td>
<td>Sham: 49.9 (13.2) rTMS: 48.1 (12.5)</td>
<td>41 (28)</td>
<td>Tinnitus distress, Psychological, Safety, QoL, Safety</td>
</tr>
<tr>
<td>Memmeler (2011)</td>
<td>U.S.</td>
<td>Some</td>
<td>Sham rTMS (21) rTMS (21)</td>
<td>21</td>
<td>1 week</td>
<td>NR</td>
<td>NR</td>
<td>Tinnitus distress, Psychological, Safety, Safety</td>
</tr>
<tr>
<td>Piccirillo (2013)</td>
<td>U.S.</td>
<td>High</td>
<td>Sham rTMS (20) rTMS (20)</td>
<td>20</td>
<td>4 weeks</td>
<td>Median 42 (range 22 to 59)</td>
<td>5 (36)</td>
<td>Tinnitus distress, Safety</td>
</tr>
<tr>
<td>Piccirillo (2011)</td>
<td>U.S.</td>
<td>Some</td>
<td>Sham rTMS (14) rTMS (14)</td>
<td>14</td>
<td>2 weeks</td>
<td>Median 52</td>
<td>4 (29)</td>
<td>Tinnitus distress, Safety</td>
</tr>
<tr>
<td>Plewnia (2012)</td>
<td>Germany</td>
<td>Some</td>
<td>Sham rTMS (16) Secondary auditory cortex rTMS (16)</td>
<td>48</td>
<td>4 weeks</td>
<td>Sham: 45.6 (10.3) Secondary auditory cortex rTMS: 46.4 (13.0) Temporoparietal association cortex rTMS: 55.8 (9.7)</td>
<td>23 (48)</td>
<td>Tinnitus distress, Safety</td>
</tr>
</tbody>
</table>

**Table 6- rTMS studies Part 2 (k=19)**

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Country</th>
<th>Risk of Bias</th>
<th>Eligible Interventions &amp; Comparators (N randomized)</th>
<th>Total Sample Size</th>
<th>Treatment Duration</th>
<th>Mean Age (SD)</th>
<th>N (%) Female</th>
<th>Outcomes Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plewnia (2007)</td>
<td>Germany</td>
<td>Some</td>
<td>Sham rTMS (6) rTMS (6)</td>
<td>6</td>
<td>2 weeks</td>
<td>57.7 (9.9)</td>
<td>1 (17%)</td>
<td>Tinnitus distress, Safety</td>
</tr>
<tr>
<td>Misli (2004)</td>
<td>Italy</td>
<td>Some</td>
<td>Sham rTMS (16) rTMS 1 Hz (16)</td>
<td>16</td>
<td>1 week</td>
<td>52.5 (10.6)</td>
<td>3 (21)</td>
<td>Tinnitus distress, Psychological, Safety, Safety</td>
</tr>
<tr>
<td>Sahlsten (2017)</td>
<td>Finland</td>
<td>Some</td>
<td>Sham rTMS (20) rTMS (22)</td>
<td>42</td>
<td>10 days</td>
<td>Sham: 51.5 (10.7) rTMS: 48.9 (13.1)</td>
<td>12 (31%)</td>
<td>Tinnitus distress, Psychological, Safety, Safety</td>
</tr>
<tr>
<td>Schecklmann (2016)</td>
<td>Germany</td>
<td>Some</td>
<td>Sham cTBS (11) cTBS (12)</td>
<td>23</td>
<td>10 days</td>
<td>Sham: 46.5 (11.5) cTBS: 48.2 (10.7)</td>
<td>9 (39)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Vanneste (2016)</td>
<td>Belgium</td>
<td>High</td>
<td>Study 1 Sham rTMS (21) Study 1 (TMS 1-Hz) (21) Study 2 Sham rTMS-10 Hz (39) Study 2 (TMS 10-Hz (39)</td>
<td>60</td>
<td>1 session</td>
<td>50.1 (11.8)</td>
<td>24 (40%)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Vanneste (2012)</td>
<td>Belgium</td>
<td>Some</td>
<td>Study 1 Sham rTMS (24) Study 1 (1 Hz) (24) Study 1 (10 Hz) (24) Study 2 Sham rTMS (40) Study 2 (1 Hz) (40) Study 2 (5 Hz) (40) Study 2 (10 Hz) (40)</td>
<td>64</td>
<td>1 session</td>
<td>Study 1: 52.2 (8.8) Study 2: 53.7 (7.6)</td>
<td>Study 1: 11 (46%) Study 2: 16 (40%)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Vanneste (2011)</td>
<td>Belgium</td>
<td>High</td>
<td>Sham rTMS (78) rTMS 1-Hz (78) rTMS 3-Hz (78) rTMS 5-Hz (78) rTMS 10-Hz (75) rTMS 20-Hz (78)</td>
<td>78</td>
<td>1 session</td>
<td>53.5 (11.9)</td>
<td>15 (19%)</td>
<td>Tinnitus distress</td>
</tr>
</tbody>
</table>
### Table 7-CBT Studies Part I (k=21)

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Country</th>
<th>Risk of Bias</th>
<th>Eligible Interventions &amp; Comparators (N randomized)</th>
<th>Total Sample Sizea</th>
<th>Treatment</th>
<th>Mean Age (SD)</th>
<th>N (%) Female</th>
<th>Outcomes Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott et al. (2009)</td>
<td>Australia</td>
<td>High</td>
<td>Information-only-control (24) Internet-based CBT (32)</td>
<td>56</td>
<td>NR</td>
<td>Control: 48.7 (8.6) CBT: 50.5 (9.5)</td>
<td>5 (10)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Anderson et al. (2002)</td>
<td>Sweden</td>
<td>High</td>
<td>Waitlist control (64) Group-based CBT (63)</td>
<td>117</td>
<td>NR</td>
<td>Control: 47.2 (15.8) CBT: 48.6 (12.3)</td>
<td>5 (10)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Anderson et al. (2005)</td>
<td>Sweden</td>
<td>High</td>
<td>Waitlist control (15) Internet-based CBT (12)</td>
<td>23</td>
<td>NR</td>
<td>Control: 70.1 (3.9)</td>
<td>11 (47.8)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Beukes et al. (2015)</td>
<td>U.K.</td>
<td>Some</td>
<td>Attention-only control (73) Internet-based CBT (73)</td>
<td>146</td>
<td>8 weeks</td>
<td>55.6 (12.9)</td>
<td>63 (43)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Henry et al. (1998)</td>
<td>Australia</td>
<td>High</td>
<td>Waitlist-control (20) Group-based CBT (20)</td>
<td>60</td>
<td>NR</td>
<td>64.6 (NRI)</td>
<td>8 (13)</td>
<td>Psychological</td>
</tr>
<tr>
<td>Henry et al. (2017)</td>
<td>U.S.</td>
<td>High</td>
<td>Waitlist control (150) Group-based CBT (150)</td>
<td>300</td>
<td>8 weeks</td>
<td>58(13)</td>
<td>15 (5)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Henry et al. (2018)</td>
<td>U.S.</td>
<td>Some</td>
<td>Waitlist control (104) Individual, telephone-based CBT (101)</td>
<td>205</td>
<td>8 weeks</td>
<td>59.0 (10.5)</td>
<td>30 (14)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Hessel et al. (2012)</td>
<td>Sweden</td>
<td>Some</td>
<td>Online discussion forum control (32) Internet-based CBT (32)</td>
<td>64</td>
<td>8 weeks</td>
<td>48.5 (14.7)</td>
<td>43 (43.4)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Jasper et al. (2014)</td>
<td>Germany</td>
<td>Some</td>
<td>Online discussion forum control (44) Group-based CBT (43) Internet-based CBT (41)</td>
<td>128</td>
<td>10 weeks</td>
<td>52.1 (9.0) Group CBT: 50.2 (13.1) Internet CBT: 51.3 (9.8)</td>
<td>31 (44)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Kaldo et al. (2007)</td>
<td>Sweden</td>
<td>Some</td>
<td>Waitlist-control (38) Book-guided CBT (34)</td>
<td>72</td>
<td>NR</td>
<td>Control: 485 (15.7) CBT: 45.9 (13)</td>
<td>5 (8)</td>
<td>Tinnitus distress</td>
</tr>
</tbody>
</table>

### Table 7-CBT Studies Part II (k=21)

<table>
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<tr>
<th>Author (Year)</th>
<th>Country</th>
<th>Risk of Bias</th>
<th>Eligible Interventions &amp; Comparators (N randomized)</th>
<th>Total Sample Sizea</th>
<th>Treatment</th>
<th>Mean Age (SD)</th>
<th>N (%) Female</th>
<th>Outcomes Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maser-Hengg et al. (2003)</td>
<td>Germany</td>
<td>High</td>
<td>Waitlist control (20) Group-based CBT (43)</td>
<td>116</td>
<td>NR</td>
<td>Control: 47.3 (7.9) CBT: 44.7 (12.7)</td>
<td>10 (50) CBT: 24 (55.8)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Mars et al. (2009)</td>
<td>U.S.</td>
<td>High</td>
<td>Waitlist control (19)</td>
<td>20</td>
<td>NR</td>
<td>Control: 57.8 (13.3) CBT: 57.3 (13.7)</td>
<td>72 (44)</td>
<td>Psychological</td>
</tr>
<tr>
<td>Nyenhuis et al. (2013)</td>
<td>Germany</td>
<td>Some</td>
<td>Information-only-control (77) Book-guided CBT (77) Internet-based CBT (79) Group-based CBT (71)</td>
<td>304</td>
<td>8 weeks</td>
<td>Control, book, and internet CBT:12 weeks Group CBT: 4 weeks</td>
<td>132 (43)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Robinson et al. (2008)</td>
<td>U.S.</td>
<td>High</td>
<td>Waitlist control (27) Group-based CBT (38)</td>
<td>65</td>
<td>8 weeks</td>
<td>55.0 (11.3)</td>
<td>31 (48)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Sadler et al. (2006)</td>
<td>U.K.</td>
<td>High</td>
<td>Individual-based CBT (14)</td>
<td>25</td>
<td>NR</td>
<td>Control: 54.3 (15.3) CBT: 50 (14.6)</td>
<td>6 (25)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Wiese et al. (2008)</td>
<td>Germany</td>
<td>Some</td>
<td>Waitlist control (67) Individual-based CBT (63)</td>
<td>130</td>
<td>3 months</td>
<td>Control: 52.9 (11.9) CBT: 49.5 (11.8)</td>
<td>26 (44.2)</td>
<td>Psychological</td>
</tr>
<tr>
<td>Wiese et al. (2018)</td>
<td>Germany</td>
<td>Some</td>
<td>Online discussion forum control (82) Internet-based CBT (62)</td>
<td>124</td>
<td>3 months</td>
<td>Control: 47.5 (14.1) CBT: 47.81 (12.3)</td>
<td>74 (60)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Zachriat et al. (2004)</td>
<td>Germany</td>
<td>High</td>
<td>Education-only control (23) Group-based CBT (29) Tinnitus Retraining Therapy (31)</td>
<td>77</td>
<td>CBT: 12 weeks</td>
<td>TKT: 6 months Control: 56.1 (10.6) CBT: 53.8 (11.8)</td>
<td>5 (20) CBT: 11 (41) TKT: 10 (33)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Zenner et al. (2013)</td>
<td>Germany</td>
<td>High</td>
<td>Waitlist control (120) Individual-based CBT (165)</td>
<td>286</td>
<td>NR</td>
<td>Median 49 (Range 14 to 75)</td>
<td>98 (34)</td>
<td>Tinnitus distress</td>
</tr>
</tbody>
</table>
## Table 8-Tinnitus-specific studies (k=10)

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Country</th>
<th>Risk of Bias</th>
<th>Eligible Interventions &amp; Comparators (N randomized)</th>
<th>Total Sample Size</th>
<th>Treatment Duration</th>
<th>Mean Age (SD)</th>
<th>N (%)</th>
<th>Outcomes Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bauer et al. (2017)</td>
<td>U.S.</td>
<td>Some</td>
<td>Standard care (19) Tinnitus retraining therapy (20)</td>
<td>39</td>
<td>18 months</td>
<td>N (%) in age categories 18 to 50 years: 6 (16%) 51 to 65 years: 25 (66%) 66 to 75 years: 7 (18%)</td>
<td>12 (32%)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Caffier et al. (2006)</td>
<td>Germany</td>
<td>High</td>
<td>Waitlist control (20) Tinnitus retraining therapy (20)</td>
<td>48</td>
<td>12 months</td>
<td></td>
<td>22 (46%)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Cima et al. (2012)</td>
<td>The Netherlands</td>
<td>Some</td>
<td>Usual care (24) Tinnitus retraining therapy + CBT (245)</td>
<td>492</td>
<td>8 months</td>
<td>54.2 (11.5)</td>
<td>184 (37%)</td>
<td>Tinnitus distress Psychological Safety Cost</td>
</tr>
<tr>
<td>Davis et al. (2008)</td>
<td>Australia</td>
<td>High</td>
<td>Counseling only (13) Neuromonics (22)</td>
<td>69</td>
<td>12 months</td>
<td>49.8 (15.8)</td>
<td>24 (48.0%)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Henry et al. (2018)</td>
<td>U.S.</td>
<td>Some</td>
<td>Tinnitus education (39) Tinnitus retraining therapy (34) Tinnitus masking (42)</td>
<td>148</td>
<td>18 months</td>
<td>61.7 (9.8)</td>
<td>4 (2.7%)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Henry et al. (2007)</td>
<td>U.S.</td>
<td>High</td>
<td>No treatment (91) Traditional support (94) Tinnitus retraining therapy (94)</td>
<td>269</td>
<td>4 weeks</td>
<td>61.6 (9.9)</td>
<td>9 (3%)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Kock et al. (2013)</td>
<td>Germany</td>
<td>High</td>
<td>Waitlist control (25) Tinnitus retraining-based music therapy (25)</td>
<td>50</td>
<td>1 week</td>
<td>Control: 42.6 (11.5) Music therapy: 43.9 (10.4)</td>
<td>Control: 9 (41%) Music therapy: 9 (44%)</td>
<td>Tinnitus distress</td>
</tr>
<tr>
<td>Seydel et al. (2016)</td>
<td>Germany</td>
<td>High</td>
<td>Waitlist control (45) Tinnitus retraining therapy (45)</td>
<td>90</td>
<td>7 days</td>
<td>51 (NR)</td>
<td>119 (50%)</td>
<td>Tinnitus distress Psychological</td>
</tr>
<tr>
<td>Westin (2011)</td>
<td>Sweden</td>
<td>Some</td>
<td>Waitlist control (22) Tinnitus retraining therapy (20)</td>
<td>64</td>
<td>18 months</td>
<td>Control: 49.6 (11.9) Tinnitus retraining therapy: 49.0 (14.5)</td>
<td>Control: 8 (36) Tinnitus retraining therapy: 8 (40)</td>
<td>Tinnitus distress Psychological QoL</td>
</tr>
<tr>
<td>Zachariats (2004)</td>
<td>Germany</td>
<td>High</td>
<td>Education-only (23) Tinnitus retraining therapy (31)</td>
<td>77</td>
<td>24 weeks</td>
<td>Control: 56.1 (10.6) Tinnitus retraining therapy: 51.6 (11.0)</td>
<td>Control: 5 (26%) Tinnitus retraining therapy: 10 (33%)</td>
<td>Tinnitus distress</td>
</tr>
</tbody>
</table>

### Cost Outcome

- One study comparing TRT to usual care over 8 months duration reported that the mean total health care costs per patient in 2009 USD over the duration of the intervention was $3,875 for usual care and $4,023 for TRT, resulting in a difference of $152 (95% CI, $-333 to $643).
- The cost per quality-adjusted life year (QALY) gained from health care payor perspective was $10,456 (95% CI, NR) for the TRT intervention compared to usual care.
- Given a willingness-to-pay threshold of $45,000, there was a 68% probability that TRT is cost-effective.
- With regard to societal costs, the cost per patient over the duration of the intervention was $7,027 for usual care and $7,380 for TRT, resulting in a difference of $357 (95% CI, $-1,034 to $1,782).
- The cost per QALY gained from societal perspective was $24,580 (95% CI, NR) for the TRT intervention compared to usual care.
- Given a willingness-to-pay threshold of $45,000, there was a 58% probability that TRT is cost-effective.76
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 three 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 as expressed by the following standards:

- 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 benefit

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

- 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.

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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
• 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.

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**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.

<table>
<thead>
<tr>
<th>Not Confident</th>
<th>Confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.</td>
<td>Very certain of evidentiary support. Further information is unlikely to change confidence</td>
</tr>
</tbody>
</table>

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

Clinical committee findings and decisions

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?

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.
**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.

**Discussion document:** What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

<table>
<thead>
<tr>
<th>Safety outcomes</th>
<th>Importance of outcome</th>
<th>Safety evidence/ confidence in evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious adverse events</td>
<td></td>
<td></td>
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<tr>
<td>adverse events</td>
<td></td>
<td></td>
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<tr>
<td>side effects including device-related complications</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Efficacy – effectiveness outcomes</th>
<th>Importance of outcome</th>
<th>Efficacy / Effectiveness evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Validated tinnitus symptom severity or handicap</td>
<td></td>
<td></td>
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<tr>
<td>depression</td>
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<td></td>
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<tr>
<td>anxiety</td>
<td></td>
<td></td>
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<tr>
<td>sleep</td>
<td></td>
<td></td>
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<tr>
<td>health-related quality of life</td>
<td></td>
<td></td>
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<tr>
<td>functional status</td>
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<td></td>
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</tbody>
</table>
## Cost outcomes

<table>
<thead>
<tr>
<th>Importance of outcome</th>
<th>Cost evidence</th>
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<table>
<thead>
<tr>
<th>Cost outcomes</th>
<th>Importance of outcome</th>
<th>Cost evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost effectiveness</td>
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<td></td>
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</tbody>
</table>

## Special population / Considerations outcomes

<table>
<thead>
<tr>
<th>Importance of outcome</th>
<th>Special populations/ Considerations evidence</th>
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<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Special population / Considerations outcomes</th>
<th>Importance of outcome</th>
<th>Special populations/ Considerations evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
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<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
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<tr>
<td>Ethnicity</td>
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</tbody>
</table>

### For safety:

Is there sufficient evidence that the technology is safe for the indications considered?

<table>
<thead>
<tr>
<th>Unproven (no)</th>
<th>Less (yes)</th>
<th>Equivalent (yes)</th>
<th>More in some (yes)</th>
<th>More in all (yes)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

### For efficacy/ effectiveness:

Is there sufficient evidence that the technology has a meaningful impact on patients and patient care?

<table>
<thead>
<tr>
<th>Unproven (no)</th>
<th>Less (yes)</th>
<th>Equivalent (yes)</th>
<th>More in some (yes)</th>
<th>More in all (yes)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

### For cost outcomes/ cost-effectiveness:

Is there sufficient evidence that the technology is cost-effective for the indications considered?

<table>
<thead>
<tr>
<th>Unproven (no)</th>
<th>Less (yes)</th>
<th>Equivalent (yes)</th>
<th>More in some (yes)</th>
<th>More in all (yes)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>
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.

Next step: proposed findings and decision and public comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?
2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next step: final determination

Following review of the proposed findings and decision document and public comments:

Final vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome chair will lead discussion to determine next steps.
Medicare Coverage and Guidelines
[From page 52 of final evidence report]

Prior to 2014, a CMS National Coverage Determination (NCD) stated that tinnitus masking was considered experimental and was therefore not covered. However, effective December 18, 2014, CMS removed the tinnitus NCD. As a result, there is no stated CMS policy on any of the tinnitus treatments considered within the scope of this HTA.

Clinical Practice Guidelines
[From page 50 of final evidence report]

We identified 6 clinical practice guidelines (CPGs) related to tinnitus diagnosis and treatment that evaluated the interventions included within the scope of this HTA; these are summarized in Table 10. We rated the quality of each guideline using the Appraisal of Guidelines for Research & Evaluation II (AGREE-II) instrument. With this instrument 6 domains are assessed and an overall score of 1 (lowest quality) to 7 (best quality) is assigned. In addition to the interventions included within the scope of the HTA, some of the guidelines we identified also included interventions outside of the scope of this HTA, notably medications, herbal supplements, and invasive treatments. Our summary focuses only on the interventions that were in the scope of this HTA.

Table 10. Summary of Clinical Practice Guidelines for the Treatment of Tinnitus

<table>
<thead>
<tr>
<th>Title</th>
<th>Year</th>
<th>Summary</th>
<th>AGREE Rating (1-worst quality to 7-best quality)</th>
</tr>
</thead>
</table>
| National Institutes for Health and Care Excellence (NICE) Guideline: Tinnitus assessment and management (NG 155)[80,81] | 2020 | Recommendation for: CBT (individual face-to-face, group-based, or virtual)  
No recommendation: rTMS, sound therapy, combination therapies; more research needed for these therapies. | 7                                                |
| A multidisciplinary European guideline for tinnitus: diagnostics, assessment, and treatment[82] | 2019 | Strong recommendation for: CBT  
Weak recommendation for: Hearing aids for patients with hearing loss; hearing aids should not be offered to patients with tinnitus in the absence of hearing loss.  
Recommendation against: rTMS  
No recommendation: Transcranial electrical stimulation; vagus nerve stimulation; acoustic coordinated reset neuromodulation; tinnitus retraining therapy; invasive nerve stimulation, sound therapy (including masking, music, environmental sound, Neuromonics) | 6                                                |
| Association of the Scientific Medical Societies in Germany Guideline 01 7/064: Chronic Tinnitus[83] | 2015 | Recommend for: tinnitus-specific CBT (carried out using an evidence-supported and structured therapeutic manual)  
Recommend against: Tinnitus retraining therapy  
No recommendation: Sound therapy, music therapy or acoustic neuromodulation, hearing aids (although hearing aids and middle ear implants can be recommended for the treatment of an appropriate accompanying hearing loss), rTMS, other electromagnetic procedures or other electrical stimulation (e.g., transcutaneous electrical stimulation in the ear or cervical spine areas, vagus nerve stimulation) | 5                                                |
Recommendation for: Hearing aid evaluation for patients with hearing loss and persistent, bothersome tinnitus  
Option (flexible decision making): Sound therapy (including environmental enrichment devices, hearing aids, ear-level sound generators, masking devices, or combination tinnitus instruments)  
Recommendation against: rTMS (for routine treatment) | 5                                                |
<table>
<thead>
<tr>
<th>Title</th>
<th>Year</th>
<th>Summary</th>
<th>AGREE Rating (1-worst quality to 7-best quality)</th>
</tr>
</thead>
<tbody>
<tr>
<td>International Federation of Clinical Neurophysiology: Evidence-based guidelines on the therapeutic use of repetitive transcranial magnetic stimulation[^87]</td>
<td>2014</td>
<td>Low frequency (1 Hz) rTMS single or repeated sessions has possible therapeutic efficacy (Level C recommendation) but the effects are partial and transient. The best method of targeting is not fully validated and there remain numerous uncertainties about its feasibility and usefulness in clinical practice. No recommendations for high frequency rTMS.</td>
<td>4</td>
</tr>
<tr>
<td>VA/DoD Clinical Practice Guidelines: Management of Concussion-mild Traumatic Brain Injury[^199]</td>
<td>2016</td>
<td>There is no evidence to suggest for or against the use of any particular modality for the treatment of tinnitus after mild traumatic brain injury. The strength of this recommendation was not assessed due to limited evidence.</td>
<td>5</td>
</tr>
</tbody>
</table>

Notes: a Authors state, “May be useful for acute relief purposes but is not considered an effective intervention with long-term results.”
b Authors state, “The words routine and routinely are used to avoid setting a legal precedent and to acknowledge that there may be individual circumstances for which clinicians and patients may wish to deviate from the prescribed action in the statement.”

Abbreviations: AAA = American Audiologic Association; AAO-HNSF = American Academy of Otolaryngology—Head and Neck Surgery Foundation; AGREE = Appraisal of Guidelines for Research & Evaluation II instrument; ASMS = Association of the Scientific Medical Societies (Germany); CBT = cognitive behavioral therapy; CR = coordinated reset; DoD = Department of Defense; mTBI = mild traumatic brain injury; NCRAR = National Center for Rehabilitative Auditory Research; NICE = National Institute for Health and Clinical Excellence; rTMS = repetitive transcranial magnetic stimulation; TACS = transcranial alternating current stimulation; tDCS = transcranial direct current stimulation; TRT = Tinnitus retraining therapy; VA = Department of Veterans Affairs; (t)VNS = (transcutaneous) Vagus Nerve Stimulation.

The most recent CPG is from the National Institute for Health and Care Excellence (NICE) in the United Kingdom;\[^200\,201\] we rated this guideline as a “7” on the AGREE-II instrument. This CPG was published in March 2020. With respect to psychological therapies, this guideline recommends use of face-to-face individual, virtual, or group-based CBT. Acceptance and commitment therapy (not included in the scope of this HTA) was also recommended. With respect to sound therapy and neuromodulation therapies (including rTMS), this guideline did not make a recommendation for use of these treatments in practice because of limited evidence for effectiveness. For both therapies, the guideline recommended additional research. The guideline also did not make a recommendation for use in practice for combination therapies, including TRT, and also called for more research on this approach.

Other CPGs include similar recommendations as the NICE guideline. A consensus multidisciplinary European guideline from 2019 included a strong recommendation for CBT, a weak recommendation for hearing aids in patients with hearing loss and tinnitus, and a recommendation against rTMS.\[^93\] The guideline panel made no recommendations on sound therapy, Neuromonics, TRT, and neuromodulation therapy other than rTMS. CPGs issued by the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) in 2014 and the German Association of the Scientific Medical Societies in 2015 made similar recommendations for CBT.\[^94\,95\] The AAO-HNS recommended against rTMS and states that sound therapy is optional,\[^95\] while the German society made no recommendation for or against rTMS or sound therapies but did recommend against TRT.\[^94\] The International Federation of Clinical Neurophysiology issued guidelines in 2014 specific to the use if rTMS across a wide variety of conditions, including tinnitus. They state that low-frequency rTMS may have possible therapeutic efficacy for tinnitus, but results are partial and transient and many uncertainties remain.\[^87\] Lastly, the Department of Veterans Affairs/Department of Defense issued a joint CPG in 2016 for the management of concussion and mild traumatic brain injury in 2016 that included recommendations specific to tinnitus management in this population.\[^199\] This guideline made no recommendation for or against the use of any interventions for tinnitus in this population.