

Washington State  
**Health Care Authority**  
*Health Technology Assessment*

## Program Overview

Josh Morse, Director  
Health Technology Assessment Program  
*March 20, 2015*



WA - Health Technology Assessment

## Program Updates

**Today:**

- Testosterone Testing

**May 15, 2015:**

- Bariatric Surgery
- Imaging for Rhinosinusitis

Washington State  
Health Care Authority

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## Background

- The Health Technology Assessment Program (HTA) is located within the Health Care Authority (HCA)
- 2006 legislation designed HTA program to use evidence reports and a panel of clinicians to make coverage decisions for certain medical procedures and tests based on evidence of:
  - Safety
  - Efficacy/ Effectiveness
  - Cost-Effectiveness

Washington State Health Care Authority

WA - Health Technology Assessment

## Background

- Multiple state agency programs participate to identify topics and implement policy decisions:
  - Health Care Authority
    - Uniform Medical Plan
    - Medicaid
  - Labor and Industries
  - Corrections
- Implementation:

Agencies implement determinations of the HTA program within their existing statutory framework.

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Washington State Health Care Authority

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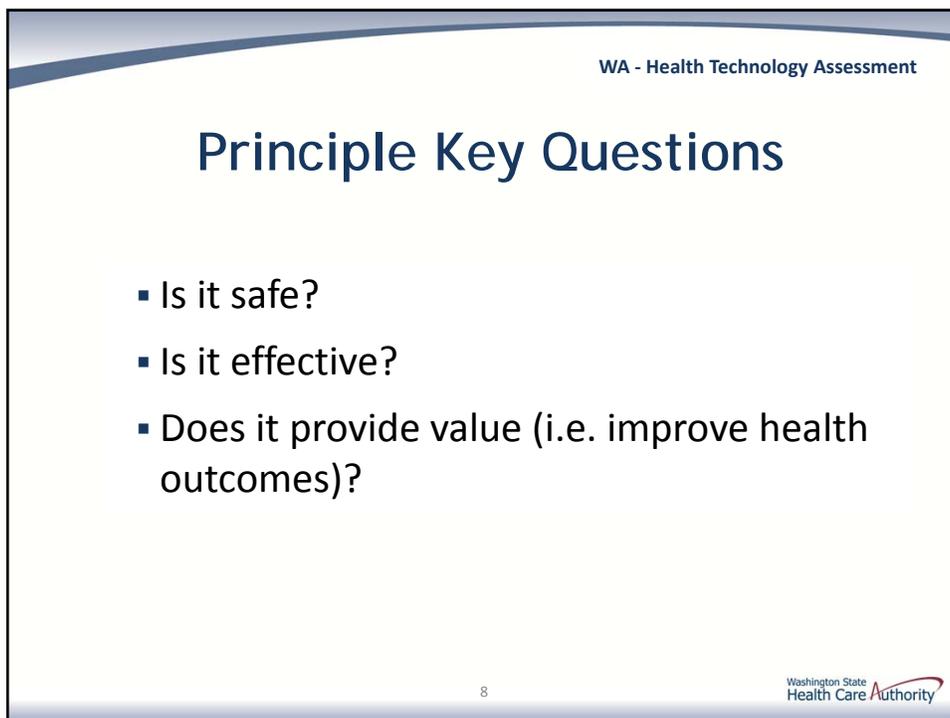
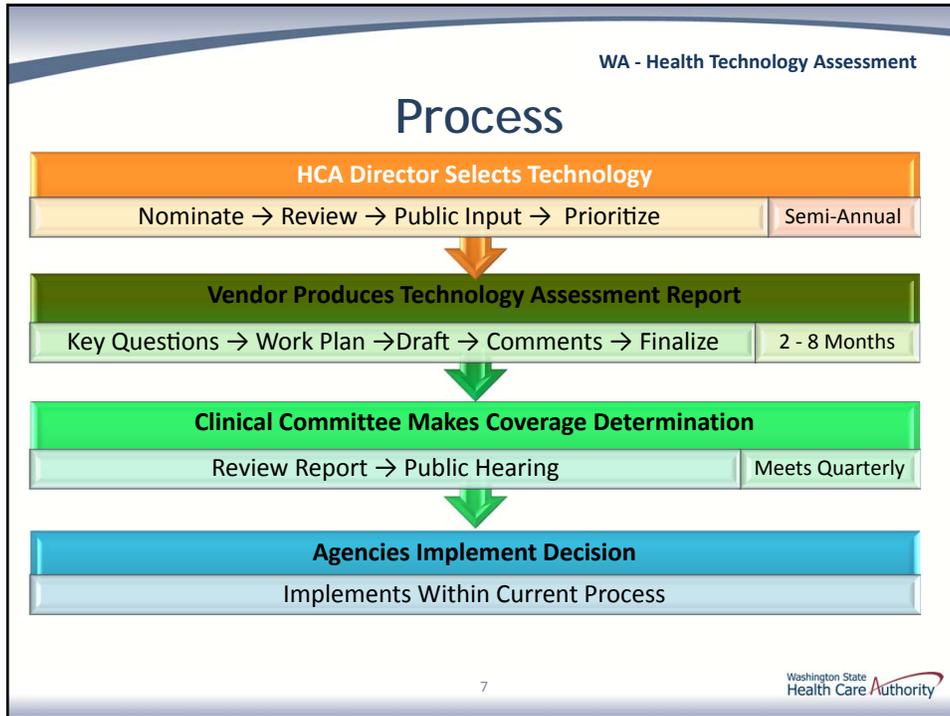
## Purpose: Pay for What Works

Ensure medical treatments, devices and services paid for with state health care dollars are safe and proven to work.

- Provide resources for state agencies purchasing health care
- Develop scientific, evidence-based reports on medical devices, procedures, and tests.
- Facilitate an independent clinical committee of health care practitioners to determine which medical devices, procedures, or tests meet safety, efficacy, and cost tests.

Washington State Health Care Authority 5





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## Values

**Transparency:** Publish topics, criteria, reports, conduct open meetings

**Best Evidence:** Formal, systematic process for review of selected health care technologies.

**Independent Decisions:**  
Committee of practicing clinicians make decisions that are scientifically based, transparent, and consistent across state health care purchasing agencies.

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## Decision Basis

Clinical Committee decisions must give greatest weight to most valid and reliable evidence.

- Objective factors for evidence consideration
  - Nature and source of evidence
  - Empirical characteristics of the studies or trials upon which evidence is based
  - Consistency of outcomes with comparable studies
- Additional evaluation factors
  - **Recency** (date of information)
  - **Relevance** (applicability of information to the key questions presented or participating agency programs and clients)
  - **Bias** (conflict of interest)

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## Technology Topics 2015

- Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment
- Appropriate Imaging for Breast Cancer Screening in Special Populations
- ★ Testosterone Testing
- Imaging for Rhinosinusitis
- Bariatric Surgery for Overweight and Obese
- Tympanostomy Tubes
- Lumbar Fusion (Re-review)

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## How To Participate

- Visit the HTA Web site: <http://www.hca.wa.gov/hta>
- Join the HTA stakeholder distribution list: [shtap@hca.wa.gov](mailto:shtap@hca.wa.gov)  
Stakeholders notified of all program publications and meetings.
- Comment on:
  - Proposed topics
  - Key questions
  - Draft & final reports
  - Draft decisions
- Attend HTCC public meetings.  
All meeting materials posted on the web.
- Present comments at Clinical Committee meetings.
- Nominate health technologies for review.

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## Meeting Reminders

- Meeting is being recorded.
- Transcript will be made available on HTA website:  
[www.hca.wa.gov/hta](http://www.hca.wa.gov/hta).
- When participating in discussions, please:
  - State your name; and
  - Use the microphone.
- To provide public comment during today's meeting:
  - Sign-up on clipboard located on table outside this meeting room; and
  - Complete a Participant Conflict Disclosure form.

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## Contact Information

**Josh Morse, Program Director**  
(360) 725-0839  
[Josh.Morse@hca.wa.gov](mailto:Josh.Morse@hca.wa.gov)

HTA web address: [hca.wa.gov/hta](http://hca.wa.gov/hta)

HTA program email: [shtap@hca.wa.gov](mailto:shtap@hca.wa.gov)

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Health Care Authority



## Health Technology Clinical Committee

Date: January 16, 2015

Time: 8:00 am – 5:00 pm

Location: SeaTac Conference Center, SeaTac, WA

Adopted:

Meeting materials and transcript are available on the HTA website at:

[www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx](http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterials.aspx)

### HTCC DRAFT MINUTES

**Members Present:** C. Craig Blackmore, MD, MPH; Marie-Annette Brown, PhD, RN; Joann Elmore, MD MPH; David K. McCulloch, MD, FRCP; Carson E. Odegard, DC, MPH; Richard C. Phillips, MD, MS, MPH; Michelle Simon, PhD, ND; Michael Souter, MB, Ch-B, DA, Christopher Standaert, MD; Kevin Walsh, MD

### HTCC FORMAL ACTION

- 1. Call to Order:** Dr. Blackmore, Chair, called the meeting to order. Sufficient members were present to constitute a quorum.
- 2. November 21, 2014, Meeting Minutes:** Chair referred members to the draft minutes; motion to approve and second, and adopted by the committee.

*Action:* Eight committee members approved the November 21, 2014 meeting minutes. One member abstained.

- 3. Screening for Osteopenia/ Osteoporosis Draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion. Three comments were received on the draft decision. Committee discussed and clarified decision language based on the previous meeting discussion and public comments received addressing the draft language.

*Action:* Eight committee members voted to approve the Screening for Osteopenia/ Osteoporosis Draft Findings & Decision Draft Findings & Decision document. One member voted not to approve and one member abstained.

#### 4. Neuroimaging for Dementia

##### Agency Utilization and Outcomes:

Gary Franklin, MD, MPH, Medical Director, Washington Department of Labor and Industries presented the state agency utilization rates for Neuroimaging for Dementia to the committee. The full presentation is published with [January 16 meeting materials](#).

Draft

**Scheduled and Open Public Comments:**

The Chair called for public comments. Open public comments were presented by:

- Bruce Smith, MD, Regence

**Vendor Report and HTCC Q & A:**

The Chair introduced the clinical expert for Neuroimaging for Dementia, Lisa C. Silbert, MD, MCR, Director, Dementia Clinic, Portland Veteran’s Affairs Medical Center.

Robin Hashimoto, PhD, Spectrum Research, Inc. presented the evidence review addressing Neuroimaging for Dementia. The full presentation is published with [January 16 meeting materials](#).

**HTCC Coverage Vote and Formal Action:**

***Committee Decision***

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence on Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Functional Magnetic Resonance Imaging (fMRI) or Arterial Spin Labeling (ASL) demonstrates that there is sufficient evidence to not cover.

The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to not cover Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Functional Magnetic Resonance Imaging (fMRI) or Arterial Spin Labeling (ASL) for functional neuroimaging for primary degenerative dementia or mild cognitive impairment. [See transcript for full committee deliberations.]

**HTCC Committee Coverage Determination Vote:**

	<b>Not Covered</b>	<b>Covered Under Certain Conditions</b>	<b>Covered Unconditionally</b>
Functional neuroimaging with PET, SPECT, fMRI or fMRI with ASL	10	0	0

***Discussion***

The chair called for discussion of conditions and evidence related to functional neuroimaging. The committee identified potential conditions and moved to vote. The committee voted to not cover these technologies for primary degenerative dementia and mild cognitive impairment.

***Action***

The committee checked for availability of Medicare national coverage decisions (NCDs). There are NCDs that include coverage for FDG-PET scanning and SPECT scanning for dementia, mild cognitive impairment and other conditions. The committee discussed the basis for these decisions and the date of evidence review supporting the decisions. The Chair cited lack of evidence supporting improved outcomes with use of functional imaging tests. No NCD for fMRI was identified.

The committee discussed the availability of a number of guidelines. The committee did not identify data supporting clinical outcomes or changes in treatment or caregiver benefits to support coverage.

The committee Chair directed HTA staff to prepare a Findings and Decision document on Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment reflective of the majority vote for final approval at the next public meeting.

## **5. Appropriate Imaging for Breast Cancer Screening in Special Populations**

### **Agency Utilization and Outcomes:**

Daniel Lessler, MD, MHA, Chief Medical Officer, Washington Health Care Authority presented the state agency utilization rates for Appropriate Imaging for Breast Cancer Screening in Special Populations to the committee. The full presentation is published with [January 16 meeting materials](#).

### **Scheduled and Open Public Comments:**

The Chair called for public comments. Open public comments were presented by:

- Nadia Salama, MD, MPH, Phd, Group Health Cooperative

### **Vendor Report and HTCC Q & A:**

The Chair introduced the clinical expert for Breast Cancer Screening, Christoph I. Lee, MD, MSHS, Director, Breast Imaging Fellowship, University of Washington School of Medicine. Daniel A. Ollendorf, MPH, Institute for Clinical and Economic Research, presented the evidence review addressing Appropriate Imaging for Breast Cancer Screening. The full presentation is published with [January 16 meeting materials](#)

### **HTCC Coverage Vote and Formal Action:**

#### ***Committee Decision***

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the evidence is sufficient and to cover digital breast tomosynthesis (DBT) for breast cancer screening for woman aged 40 to 74 who are candidates for screening mammography. The committee concluded that the available evidence is not sufficient to support coverage for magnetic resonance imaging (MRI), Hand Held Ultrasound (HHUS) and Automated Breast Ultrasound (ABUS) for supplementary screening following mammography.

The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to cover DBT for woman aged 40 to 74 who are candidates for screening mammography. Separately, the committee voted to not cover MRI, HHUS and ABUS for supplementary screening following mammography. [See transcript for full committee deliberations.]

**HTCC Committee Coverage Determination Vote:**

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Digital Breast Tomosynthesis	4	0	6
Magnetic Resonance Imaging, Hand Held Ultrasound or Automated Breast Ultrasound	10	0	0

**Discussion**

The chair called for discussion of conditions and evidence related to DBT for screening. Coverage without conditions was approved by a majority of the committee. Discussion of the evidence and conditions for use of MRI, HHUS and ABUS were discussed by the committee. The committee voted to not cover these technologies for adjunctive screening for women with dense breast tissue.

**Limitations of Coverage:**

Magnetic Resonance Imaging, Hand-Held Ultrasound and Automated Breast Ultrasound supplementary to screening mammography in women with dense breast tissue is **not covered**.

**Action**

The committee checked for availability of Medicare national coverage decisions (NCDs). There are NCDs for hand held ultrasound, automated breast ultrasound and MRI national coverage, but these NCDs do not address the use of the technologies for screening. No NCD for digital breast tomosynthesis was identified. A recent Medicare payment policy rule was identified, discussed and considered by the committee determination for digital breast tomosynthesis.

The committee reviewed and considered available guidelines including those by the American Cancer Society, National Comprehensive Cancer Network (NCCN), American College of Radiology, American Society of Breast Disease, Society for Breast Imaging, Washington State Radiological Society and European Society of Breast Imaging.

The committee Chair directed HTA staff to prepare a Findings and Decision document on Appropriate Imaging for Breast Cancer Screening in Special Populations reflective of the majority vote for final approval at the next public meeting.

6. Josh Morse, HTA Program Director presented information regarding the five HTA reviews currently in progress.
7. **Meeting adjourned.**

**Health Technology Clinical Committee  
Draft Findings and Decision**

**Topic:** Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment  
**Meeting Date:** January 16, 2015  
**Final Adoption:**

Meeting materials and transcript are available on the HTA website:  
[www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterial](http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterial)

**Number and Coverage Topic:**

20150116A – Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment

**HTCC Coverage Determination:**

Functional neuroimaging for primary degenerative dementia or mild cognitive impairment is **not covered**.

**HTCC Reimbursement Determination:**

**Limitations of Coverage:** N/A

**Non-covered Indicators:**

*Functional* imaging technologies including: fludeoxyglucose (FDG) Positron Emission Tomography (PET), (11)C-dihydrotrabenazine (C-DTBZ) PET, Single Photon Emission Computed Tomography (SPECT), Functional Magnetic Resonance Imaging (fMRI) for the diagnosis of primary degenerative dementia or mild cognitive impairment.

**Agency Contact Information:**

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

**Draft**

**HTCC Coverage Vote and Formal Action**

***Committee Decision***

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the current evidence on Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Functional Magnetic Resonance Imaging (fMRI) or Arterial Spin Labeling (ASL) demonstrates that there is sufficient evidence to not cover.

The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to not cover Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Functional Magnetic Resonance Imaging (fMRI) or Arterial Spin Labeling (ASL) for functional neuroimaging for primary degenerative dementia or mild cognitive impairment.

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Functional neuroimaging with PET, SPECT, fMRI or fMRI with ASL	10	0	0

***Discussion***

The chair called for discussion of conditions and evidence related to functional neuroimaging. The committee identified potential conditions and moved to vote. The committee voted to not cover these technologies for primary degenerative dementia and mild cognitive impairment.

***Action***

The committee checked for availability of Medicare national coverage decisions (NCDs). There are NCDs for that include coverage for FDG-PET scanning and SPECT scanning for dementia, mild cognitive impairment and other conditions. The committee discussed the basis for these decisions and the date of evidence review supporting the decisions. The chair cited lack of evidence supporting improved outcomes with use of functional imaging tests. No NCD for fMRI was identified.

The committee discussed the availability of a number of guidelines. The committee did not identify data supporting clinical outcomes or changes in treatment or caregiver benefits to support coverage.

The committee Chair directed HTA staff to prepare a Findings and Decision document on Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment reflective of the majority vote for final approval at the next public meeting.

**Health Technology Clinical Committee Authority:**

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.



## Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment

### Findings & Decision Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment.

Category	Comment Period	
	February 10 – 24, 2015	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	1	1
Professional society & advocacy organization	1	1
<b>Total</b>	<b>2</b>	<b>2</b>

Technology Assessment Timeline		
Study Stage	Date	Public Comment Days
Technology Recommendations published	November 19, 2012	
<b>Public comments</b>	November 19 - December 3, 2012	<b>15</b>
Selected Technologies published	December 6, 2012	
<b>Public comments</b>	December 6, 2012 - January 7, 2013	<b>32</b>
Draft Key Questions published	May 19, 2014	
<b>Public comments</b>	May 19 – June 2, 2014	<b>15</b>
Final Key Questions published	June 6, 2014	
Draft Report published	October 20, 2014	
<b>Public comments</b>	October 20 – November 20, 2014	<b>32</b>
Final Report published	December 15, 2014	
Public Meeting	January 16, 2015	
Draft Findings & Decision published	February 10, 2015	
<b>Public comments</b>	February 10 – 24, 2015	<b>14</b>
	<b>Total</b>	<b>108</b>

**Public Comments on Draft Findings & Decision**

***Functional Neuroimaging for Primary Degenerative Dementia***

	<b>Name</b>	<b>Representing</b>	<b>Cited Evidence</b>
1	William Abbott, VP Operations - America	Piramal Pharma Inc, 15 Court Square, Suite 1000 Boston MA 02108 (617) 725 0070	Yes
2	Gail Rodriguez, Executive Director	Medical Imaging & Technology Alliance	Yes

February 24, 2015

Dorothy F. Teeter, M.H.A.  
Director, Health Technology Assessment Program  
P.O. Box 42712  
Olympia, WA 98504-2712

Submitted electronically via: [shtap@hcs.wa.gov](mailto:shtap@hcs.wa.gov)

RE: Washington State Health Care Authority Health Technology Assessment draft findings and decision on Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment

Dear Director Teeter:

Thank you for the opportunity to submit comments on the Washington State Health Care Authority (HCA) Health Technology Assessment (HTA) Draft Findings and Decision on Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment.

Piramal Imaging is an emerging leader in the field of molecular imaging, and is dedicated to the development and global commercialization of innovative molecular imaging agents. Our US operations are based in Boston. Our flagship agent, Neuraceq™ (florbetaben F18 injection) is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease (AD) and other causes of cognitive decline. A negative Neuraceq scan indicates sparse to no neuritic plaques and is inconsistent with a neuropathological diagnosis of AS at the time of image acquisition; a negative scan reduces the likelihood that a patient's cognitive impairment is due to AD. A positive Neuraceq scan indicates moderate to frequent amyloid neuritic plaques; neuropathological examination has shown this amount of amyloid neuritic plaque is present in patients with AD, but may also be present in patients with other types of neurologic conditions as well as older people with normal cognition. Neuraceq is an adjunct to other diagnostic evaluations.<sup>1</sup>

Our comments address a clarification in your draft decision related to the committee's non-consideration of beta-amyloid PET imaging during the deliberations. Specifically, we think that the following paragraph in the Draft Findings and Decision memo should be edited to clarify that the committee did not consider evidence related to the clinical utility of beta-amyloid PET imaging, and therefore, the decision does not apply to that modality:

*The committee considered all of the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to not cover fludeoxyglucose Positron Emission Tomography (FDG-PET), Single Photon Emission Computed Tomography (SPECT), Functional Magnetic Resonance Imaging (fMRI) or Arterial Spin Labeling (ASL) for functional neuroimaging for primary degenerative dementia or mild cognitive impairment. Evidence surrounding the clinical utility of beta-amyloid PET imaging is outside the scope of this report, and was therefore not considered by the committee at this time.*

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<sup>1</sup> Full prescribing information for Neuraceq may be found here:  
[http://www.neuraceq.com/images/Neuraceq\\_PI\\_031814.pdf](http://www.neuraceq.com/images/Neuraceq_PI_031814.pdf).

Thank you again for the opportunity to provide these comments. If you have any additional questions, please do not hesitate to contact Susan De Santi, Senior Director, Health of Medical Affairs, USA at 617-595-7745 or [Susan.De-santi@piramail.com](mailto:Susan.De-santi@piramail.com).

Sincerely,



William Abbott  
Vice President of Operations, Americas  
Piramal Imaging



1300 North 17<sup>th</sup> Street • Suite 900  
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February 24, 2015

Dorothy F. Teeter, M.H.A.  
Director  
Health Technology Assessment Program  
P.O. Box 42712  
Olympia, WA 98504-2712

RE: Washington State Health Care Authority Health Technology Assessment draft findings and decision on Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment

Dear Director Teeter:

The Medical Imaging & Technology Alliance (MITA) is pleased to submit a comment on the Washington State Health Care Authority (HCA) Health Technology Assessment (HTA) Draft Findings and Decision on Functional Neuroimaging for Primary Degenerative Dementia or Mild Cognitive Impairment.

As the leading trade association representing medical imaging, radiotherapy, and radiopharmaceutical manufacturers, we have in-depth knowledge of the significant benefits to the health of Americans that medical imaging and radiotherapy provide. We support efforts that foster appropriate use of these technologies for the early detection, diagnosis, staging, therapy monitoring, and surveillance of many diseases.

Medical imaging encompasses X-ray imaging, computed tomography (CT) scans, related image acquisitions, diagnostic ultrasound, nuclear medicine imaging (including positron emission tomography (PET)), and magnetic resonance imaging (MRI). Medical imaging is used to diagnose patients with disease, often reducing the need for costly medical services and invasive surgical procedures.<sup>1</sup> In addition, medical imaging equipment often is used to select, guide, and facilitate effective treatment, for example, by using image guidance for surgical or radiotherapeutic interventions.<sup>2</sup> MITA's members also develop and manufacture innovative radiopharmaceuticals to help in the diagnosis and staging of disease.

Our comment addresses functional neuroimaging of primary degenerative dementia or mild cognitive impairment. We understand that the committee has ruled that the current evidence on

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<sup>1</sup> See, e.g., Perrier, A et al. "Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism." *New England Journal of Medicine*, 352 (2005) No 17: 1760-1768.

<sup>2</sup> See, e.g., Jelinek, JS et al. "Diagnosis of Primary Bone Tumors with Image Guided Percutaneous Biopsy: Experience with 110 Tumors." *Radiology*. 223 (2002): 731-737.

Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT) Functional Magnetic Resonance Imaging (fMRI,) or Arterial Spin Labeling (ASL) “demonstrates that there is sufficient evidence to not cover.”

We believe these tools offer great potential for patients. A better understanding of the development and progression of these diseases could lead to better treatments and help patients and caregivers to plan for important decisions. New studies continue to refine our understanding of the disease progression, and in turn help us to develop more appropriate clinical trials in this space. Considering these ongoing studies, MITA recommends that in the final coverage decision the Committee changes the language to read “currently there is insufficient evidence to cover these functional imaging tests.” Additionally, MITA requests that the Committee schedule a re-review as additional evidence becomes available.

\* \* \* \*

MITA appreciates this opportunity to comment on the draft decision. We would be pleased to answer any questions you might have about these comments. Please contact me at (703) 841-3235 if MITA can be of any assistance.

Sincerely,

A black rectangular redaction box covers the signature of Gail Rodriguez.

Gail Rodriguez, Ph.D.  
Executive Director, MITA

**Health Technology Clinical Committee  
Draft Findings and Decision**

**Topic:** Appropriate Imaging for Breast Cancer Screening in Special Populations  
**Meeting Date:** January 16, 2015  
**Final Adoption:**

Meeting materials and transcript are available on the HTA website:  
[www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterial](http://www.hca.wa.gov/hta/meetingmaterials/Forms/ExtMeetingMaterial)

**Number and Coverage Topic:**

20150116B – Appropriate Imaging for Breast Cancer Screening in Special Populations

**HTCC Coverage Determination:**

**Digital Breast Tomosynthesis**

Digital breast tomosynthesis (DBT) is a **covered benefit** supplementary to digital mammography in woman aged 40 to 74 who are candidates for screening mammography.

**Supplemental Screening Modalities for Breast Cancer Screening**

Supplementary screening with Magnetic Resonance Imaging (MRI), Hand Held Ultrasound (HHUS), or Automated Breast Ultrasound (ABUS) is **not covered**.

**HTCC Reimbursement Determination:**

**Limitations of Coverage: N/A**

**Non-Covered Indicators:**

Magnetic Resonance Imaging (MRI) supplementary to screening mammography in women with dense breasts (applies to **non-high risk populations**)

Hand Held Ultrasound (HHUS) supplementary to screening mammography in women with dense breasts (applies to **high risk and non-high risk populations**)

Automated Breast Ultrasound (ABUS) supplementary to screening mammography in women with dense breasts (applies to **high risk and non-high risk populations**)

**Agency Contact Information:**

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

**Draft**

## HTCC Coverage Vote and Formal Action

### *Committee Decision*

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee concluded that the evidence is sufficient and to cover digital breast tomosynthesis (DBT) for breast cancer screening for woman aged 40 to 74 who are candidates for screening mammography. The committee concluded that the available evidence is not sufficient to support coverage for magnetic resonance imaging (MRI), Hand Held Ultrasound (HHUS) and Automated Breast Ultrasound (ABUS) for supplementary screening following mammography.

The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. Based on these findings, the committee voted to cover DBT for woman aged 40 to 74 who are candidates for screening mammography. Separately, the committee voted to not cover MRI, HHUS and ABUS for supplementary screening following mammography.

### HTCC Committee Coverage Determination Vote

	Not Covered	Covered Under Certain Conditions	Covered Unconditionally
Digital Breast Tomosynthesis	4	0	6
Magnetic Resonance Imaging, Hand Held Ultrasound or Automated Breast Ultrasound	10	0	0

### *Discussion*

The chair called for discussion of conditions and evidence related to DBT for screening. Coverage without conditions was approved by a majority of the committee. Discussion of the evidence and conditions for use of MRI, HHUS and ABUS were discussed by the committee. The committee voted to not cover these technologies for adjunctive screening for women with dense breast tissue.

### Limitations of Coverage:

Magnetic Resonance Imaging, Hand-Held Ultrasound and Automated Breast Ultrasound supplementary to screening mammography in women with dense breast tissue is not covered.

The committee determined Magnetic Resonance Imaging, Hand-Held Ultrasound and Automated Breast Ultrasound were **not covered** benefits.

### *Action*

The committee checked for availability of Medicare national coverage decisions (NCDs). There are NCDs for hand held ultrasound, automated breast ultrasound and MRI national coverage, but these NCDs do not address the use of the technologies for screening. No NCD for digital breast tomosynthesis was identified. A recent Medicare payment policy rule was identified, discussed and considered by the committee determination for digital breast tomosynthesis.

**Draft**

The committee reviewed and considered available guidelines including those by the American Cancer Society, National Comprehensive Cancer Network (NCCN), American College of Radiology, American Society of Breast Disease, Society for Breast Imaging, Washington State Radiological Society and European Society of Breast Imaging.

The committee Chair directed HTA staff to prepare a Findings and Decision document on Appropriate Imaging for Breast Screening in Special Populations reflective of the majority vote for final approval at the next public meeting.

### **Health Technology Clinical Committee Authority:**

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Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.



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**From:** Scott Huntley <sphuntley@tractuscorp.com>  
**Sent:** Thursday, February 12, 2015 7:37 AM  
**To:** HCA ST Health Tech Assessment Prog  
**Subject:** Appropriate Imaging for Breast Cancer Screening in Special Populations

**Follow Up Flag:** Follow up  
**Flag Status:** Completed

I urge the Health Care Authority Health Technology Assessment Committee to support supplemental screening (particularly ultrasound screening) for dense breasted patients. Doing so, with an appropriate workflow, will result in a reduction in mortality and overall cost savings by dramatically reducing the size of cancers at the time of discovery.

The literature (Kelly & Weigert) has demonstrated that screening dense-breasted (BIRADS C and BIRADS D) patients can double (100% increase) in sensitivity when the sensitivity increase for digital breast tomosynthesis in that group is 30% to 40% (Hologic's FDA PMA study showed NO increase in sensitivity). The additional cancers found by supplemental ultrasound tended to be invasive, and sub-centimeter (the very size that results in a high survival rate and low treatment cost).

The primary complaint against screening breast ultrasound is that too many unnecessary biopsies result from the procedure. The literature supports (Kelly) that this is a function of workflow, not intrinsic to the technology of ultrasound. As was the case with mammography in the 1970s and early 1980s, applying a diagnostic workflow with a diagnostic mindset (i.e., can I rule out cancer, or should I send her to biopsy) to asymptomatic patients results in biopsy PPVs of less than 10% while using a screening protocol (as introduced by Tabar – is she normal, or should I bring her back for more thorough non-invasive studies) results in a biopsy PPVs in the 30% to 40% range. Applying a screening protocol to ultrasound screening (Kelly) results in a biopsy PPV in the 30% to 40% range.

Thank you for considering these comments.

Scott Huntley

#### **BACKGROUND:**

##### Unnecessary biopsies:

Ultrasound screening for breast cancer is effective. It has been demonstrated, undeniably, in the literature (Kelly(1), Weigert (2) and others) that adding ultrasound screening to mammography can find 3-4 additional cancers per thousand women screened. These results exceed the improvement reported for tomosynthesis by three-fold. In addition, those mammographically-occult cancers tend to be small (averaging less than 1cm), earlier stage (typically before they spread to the lymph nodes), and the types of cancers (invasive or Grade III DCIS) which, if left untreated will develop into a cancer which will kill the patient – and, although there have been no randomized controlled trials directly studying survivability, the typically sub-centimeter, node-negative mammographically-occult cancers typical for ultrasound screening tend to have a much higher survivability rate than the average for mammographically-discovered cancers.

The primary concerns about ultrasound screening have been claims that the positive biopsy rates resulting from the practice are too low. Fortunately, these objections are incorrect, and result from the fact that we have forgotten the lessons learned in the 1980s when mammography transitioned from a diagnostic to screening modality.

Mammography was initially a diagnostic tool, used to follow up symptoms such as palpable lumps or bloody nipple discharges. The purpose of the mammogram was to determine whether the patient might have cancer and should proceed to biopsy. In those days biopsy meant surgery, and consent to biopsy also meant consent to mastectomy in the same procedure, should the results show positive for cancer. In those days it was not uncommon for radiologist to agonize for 10 minutes or more when interpreting those mammograms because of the serious negatives associated with either a missed cancer, or an unnecessary surgery. Never-the-less, overcalls were common and the positive biopsy rates were often less than 10%. In addition, the time requirements to review the mammograms limited its utility for large screening populations. Thus, mammography was an ineffective screening tool because it was too time consuming and resulted in too many biopsies.

In the 1980s Tabar, and others, pioneered the use of mammography as a true screening tool, and did so primarily by redefining the screening protocol. The results allowed wider access to mammographic screening, but also improved the positive biopsy rate – by adding the intermediate step of the callback. Instead of looking for cancers and sending 50 of every 1000 women to biopsy, the new screening protocol required that radiologists take only a few minutes to look for normal patients. No additional time was spent on the abnormal patients because they were not being referred to biopsy. Instead, they were recalled for a full battery of more extensive, non-invasive exams. This allowed mammography to be used as a true screening tool. Primarily, radiologists could read more exams, extending the offering to more women and saving more lives. Callbacks were added to the protocol. The callbacks were performed on non-normal patients and represented approximately 100 per 1000 women screened, or 100 for every 3-4 cancers discovered. One could argue that this is a poor positive predictive value – but the callback only involved more, and more thorough, noninvasive testing. This allowed more time, and more information so that there are only about 10 biopsies for every 3-4 cancers found.

Ultrasound has, traditionally, been one of those follow-up exams, after a patient has been classified as not normal. It has been used in the phase where the clinical team is looking for cancer and not for normal. The failure of ultrasound as a screening tool is that many clinicians cannot break that pattern, and continue to use it as they have. In other words, they use ultrasound to look for cancer, not normal, and perform a diagnostic exam on asymptomatic women. In other words, they use the exact same workflow protocol that was used for mammography in the 1980s – and they have the exact same results. They find many additional cancers, but they refer too many women to biopsy.

This thesis has been tested clinically and published in the literature. Kelly(3) performed ultrasound screening exams on 6425 women using an automated technique where the initial exam was recorded by a technologist and read later by a radiologist. Reviewers were looking for normal and non-normal patients in both the mammography and ultrasound arms. The non-normal patients were recalled for standard recall workups. During that recall thorough diagnostic ultrasound exams were performed on the patients recalled because of non-normal ultrasound results in the same manner that diagnostic mammography exams were performed on patients recalled because of non-normal mammograms. The recalled patients, whether recalled for ultrasound or mammography, or both, experienced essentially identical diagnostic workups. The positive biopsy rates were also essentially identical, 38.3% for ultrasound-discovered cancers and 39% for mammographically-discovered patients.

The results were that the screening ultrasound exams were read in just a few minutes – making the screening procedure viable for large volumes of patients, and the positive biopsy rate acceptable by most clinical measures. It should be noted that ALL of the hand-held ultrasound exams, even those that found many more cancers, had positive biopsy rates of less than 10%. It can be argued that the mental process one projects during a hand-held exam is basically diagnostic and that the results match the diagnostic mindset.

The effective screen involves a quick review of the entirety of the breast to determine whether it is normal or not. The non-normal patient is called back for further study. No further study, no Doppler or transverse or

coronal views are necessary in the initial screen. Those only take more time, making the screen less efficient, and can be performed during the diagnostic. The effective screen probably involves an automated device, which is essentially just a video recorder with special mapping capabilities, in order to save the physician all of the non-procedural time involved in the exam (walking to and from the exam room, interacting with the patient, etc.) – and to make it easier to execute a true screening protocol where the physician’s decision is restricted to calling the patient back, or not, and does not involve a consideration of whether or not a biopsy is warranted.

Ultrasound breast cancer screening is here to stay. More states will pass laws, more patients will demand it. Most importantly, the clinical literature will continue to show that adding ultrasound to mammography, even tomosynthesis, finds significantly more sub-centimeter, node-negative, invasive and Grade III DCIS cancers – the very types of cancers we want to find as breast imagers. However, the clinical community will not be able to effectively comply with this demand unless we relearn the lessons of mammography in the 1980s. A screen is a screen on an asymptomatic patient and a diagnostic exam is for diagnosis of some symptom.

### Reduction in Mortality and overall costs

Contrary to what many in the radiological community have said, Mammography is not the only method proven in randomized clinical trials to reduce mortality. Duffy and Tabar (4) demonstrated that 20-year survival after detection of breast cancer was dramatically improved by finding invasive cancers smaller was directly correlated to size at time of discovery, REGARDLESS OF HOW THOSE CANCERS WERE DISCOVERED. More than 60% of women whose cancers were discovered when they were larger than 5cm were alive 20 years after the initial detection (dead by any cause, not just breast cancer) while only 12% of those women whose cancers were found smaller than 1cm were dead after 20 years. Weigert and others have demonstrated that ultrasound screening tends to find cancers that are much smaller (typically less than 1cm) than those found by digital mammography.

Tumor size is also a major factor in determining treatment protocols. Women with smaller cancers typically have less expensive treatments, and are often able to forego chemotherapy entirely, than those with larger tumors.

### REFERENCES

- (1) Kelly, “Breast cancer detection using automated whole breast ultrasound and mammography in radiographically dense breasts”, *Eur Radiol* (2010) 20: 734–742
- (2) Weigert, “The Connecticut Experiment: The Role of Ultrasound in the Screening of Women With Dense Breasts”, *The Breast Journal*, Volume 18 Number 6, 2012 517–522
- (3) Kelly, “Breast cancer detection: radiologists’ performance using mammography with and without automated whole-breast Ultrasound”, *Eur Radiol* (2010) 20: 2557–2564
- (4) Duffy and Tabar, “Tumor Size and Breast Cancer Detection: What Might Be the Effect of a Less Sensitive Screening Tool Than Mammography?”, *The Fred Hutchinson Cancer Research Center*, 1075-122X/06 and *republished in The Breast Journal*, Volume 12 Suppl. 1, 2006 S91–S95

Pooja Voria, MD, MBA  
Vice President, Washington State Radiological Society (WSRS)  
2001 6th Ave., Suite 2700  
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February 23, 2015

Washington State Health Care Authority  
Health Technology Assessment  
626 8th Avenue SE  
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Dear members of the HTA committee,

Thank you for your thorough review, assessment and consideration of *Appropriate Imaging for Breast Cancer Screening in Special Populations*. On behalf of the Washington State Radiological Society (WSRS), I want to express strong endorsement of your decision to designate breast tomosynthesis as a covered benefit supplementary to digital mammography for women. The radiologists in Washington State strongly support your decision to cover breast tomosynthesis “unconditionally.” This outcome aligns with the WSRS Digital Breast Tomosynthesis (DBT) position statement as well as the data demonstrating the strengths of tomosynthesis. This also validates the significant efforts made by imaging facilities to help make breast tomosynthesis widely available to patients over the past three years.

I believe your approach towards evaluating the available clinical and economic data was justifiably conservative and that the emerging evidence on breast tomosynthesis will only serve to further substantiate your current supportive position. With that in mind, I offer the following supplemental information for the HTA research team’s consideration.

1. While it is true there is no Medicare National Coverage Decision (NCD) for breast tomosynthesis, the 2015 Medicare Physician Fee Schedule clearly states that breast tomosynthesis is definitively covered.<sup>1</sup> Further, because CMS has categorized breast tomosynthesis as a mammography service, the same “B” rating from the USPSTF is attributed, and no National Coverage Determination or Local Coverage Determination is necessary.<sup>1</sup>
  - a. CMS describes its coverage position as, “The same policies that are applicable to other mammography should be applicable to CPT code 77063.”<sup>2</sup> In other words, since digital mammography is a covered service, so is breast tomosynthesis.
2. Your report references the most recent statement from the American College of Radiology (ACR), but one key section ought to be highlighted, “To be clear: tomosynthesis is no longer investigational. Tomosynthesis has been shown to improve key screening parameters compared to digital mammography.”<sup>3</sup>
3. Given the benefits screening mammography provides to women over the age of 74, I would encourage you to consider expanding your recommendation to cover women of over the age of 74.

I am also in agreement with the decision not to cover Magnetic Resonance Imaging, Hand Held Ultrasound or Automated Breast Ultrasound for screening women at average risk for breast cancer with dense breasts given the available data at this time. If new data becomes available, we are interested in having these modalities reviewed in the future.

Once again, thank you for your efforts. We look forward to a positive majority vote for final approval at the next public meeting.

Sincerely,

Pooja Voria, MD, MBA  
Radiologist, Breast Imaging Subspecialty  
Vice President, Washington State Radiological Society (WSRS)  
Swedish Breast Centers  
Radia Inc., PS

<sup>1</sup> CMS, Medicare Physician Fee Schedule Final Rule CY 2015 [CMS 1612-FC], released October 31, 2014.

<sup>2</sup> CMS Manual System. Transmittal 3160. Pub 100-04 Medicare Claims Processing. Jan 7, 2015: Medicare.gov.

<sup>3</sup> American College of Radiology. Position Statements: ACR Statement on Breast Tomosynthesis. Nov 24, 2014: ACR.org

To: WASHINGTON STATE HEALTH CARE AUTHORITY

From: Jennifer E. Shook MD, PhD

Re: Decision on Coverage of Digital Breast Tomosynthesis

Date: February 23, 2015

First, I want to thank you for reviewing the scientific evidence and for considering my professional opinion that Digital Breast Tomosynthesis (DBT) is the best evidence-based tool for the detection of breast cancer in women. Comprehensive review of the clinical and economic database was an enormous task. One made even more difficult by knowing the great impact of your decision on the health and well being of the women of Washington while minding the ultimate effect on our state's health care budget. I thank you and applaud you for your accomplishment.

If approved, your decision to recommend coverage for DBT unconditionally will provide access to this game changing technology to women in need throughout our state, and not just in the more populous areas with stronger economic bases and donations from generous benefactors. I hope that you will continue your work to ensure that insurance deductibles and coinsurance fees for DBT (CPT code 77063) will be waived as already mandated by The Affordable Care Act for analog and digital mammography. We must do everything possible to remove all barriers to access to DBT.

Based on my clinical practice and the scientific evidence, I believe that DBT is truly a game changing technology in the early detection of breast cancer and I find it frustrating that so many of the negative reports about mammography in the news are based on outdated mammographic technologies. Now is the time more than ever to encourage women to get screened and to provide them access to DBT, the best screening test available for early detection at the least cost.

Thank you again,

Jennifer E. Shook MD, PhD  
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February 24, 2015

Dorothy F. Teeter, M.H.A  
Director  
Health Technology Assessment Program  
P.O. Box 42712  
Olympia, WA 98504-2712

RE: Washington State Health Care Authority Health Technology Assessment draft decision on Appropriate Imaging for Breast Cancer Screening in Special Populations.

Dear Director Teeter:

The Medical Imaging & Technology Alliance (MITA) is pleased to submit comments on the Washington State Health Care Authority (HCA) Health Technology Assessment (HTA) Draft decision on Appropriate Imaging for Breast Cancer Screening in Special Populations.

Every woman has specific screening needs based on a variety of factors including age, risk factors and family history. It is of the utmost importance that access to the most appropriate screening technology remains intact. This access to screening options based on evidence is a key factor in achieving optimal quality of care and outcomes.

As the leading trade association representing medical imaging, radiotherapy, and radiopharmaceutical manufacturers, we have in-depth knowledge of the significant benefits to the health of Americans that medical imaging and radiotherapy provide. We support efforts that foster appropriate use of these technologies for the early detection, diagnosis, staging, therapy monitoring, and surveillance of many diseases.

Breast cancer is the most common cancer diagnosed in women, affecting 1 in 8 women in their lifetimes; almost 300,000 women were diagnosed with breast cancer in 2013.<sup>1</sup> Since the introduction of mammography screening, mortality from breast cancer has decreased by 30 percent;<sup>2</sup> however it is still the second most common cause of cancer death in women, killing almost 40,000 in 2013.<sup>3</sup>

According to The National Breast Cancer Foundation, 98 percent of breast cancer patients survive – if detection occurs early. There are multiple factors contributing to breast cancer in women. Today, thanks to innovation in imaging, women benefit from a variety of screening options that tailor screening to the

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<sup>1</sup> American Cancer Society. Cancer Facts and Figures 2013-2014 <http://www.cancer.org/research/cancerfactsstatistics/allcancerfactsfigures/index>

<sup>2</sup> Tabar L, Vitak B, Chen HH, et al. The Swedish Two-County Trial twenty years later. Updated mortality results and new insights from long-term follow-up. *Radiol Clin North Am.* Jul 2000;38(4):625-651.

<sup>3</sup> American Cancer Society. Cancer Facts and Figures 2013-2014 <http://www.cancer.org/research/cancerfactsstatistics/allcancerfactsfigures/index>

patient's unique needs, rather than taking a one-size-fits-all approach. In addition, for cancers that are detected, imaging informs staging and treatment for improved care.

MITA supports the proposed positive coverage decision for digital breast tomosynthesis (DBT) as a covered benefit mammography service in women ages 40-74 who are candidates for screening mammography.

Breast tomosynthesis is a three-dimensional imaging technology that involves acquiring images of a stationary compressed breast at multiple angles during a short scan. The individual images are then reconstructed into a series of thin high-resolution slices that can be displayed individually or in a dynamic ciné mode. Reconstructed tomosynthesis slices reduce or eliminate the problems caused by tissue overlap and structure noise in single slice two-dimensional mammography imaging.

Breast tomosynthesis is an advance in mammography technology that significantly improves the screening of women in all age brackets and addresses some of the current limitations of 2D mammography. This is especially useful for women with dense breasts because the technology has the ability to visualize areas of tissue superimposition. As a front-line screening tool, it will do this through two key clinical benefits that have been shown in studies published in peer-reviewed journals. Large-scale, peer-reviewed clinical research shows that breast cancer screening with breast tomosynthesis finds up to 40 percent more invasive cancers than conventional 2D mammography.<sup>4</sup> Additionally, breast tomosynthesis increases diagnostic accuracy and reduces unnecessary callbacks up to 40 percent.<sup>5</sup>

These findings were recently validated in a study published in the *Journal of the American Medical Association (JAMA)*, the largest study to date with a total of 454,850 examinations (281,187 conventional mammograms compared to 173,663 3D mammography exams). The results confirmed that breast tomosynthesis finds significantly more invasive cancers than a traditional mammogram – an improvement of 41 percent.<sup>6</sup> The researchers also found that 3D mammography reduces the number of women called back for unnecessary testing due to false alarms by 15 percent. That reduces anxiety, as well as health care costs.

Further evidence demonstrates that breast tomosynthesis is effective in all age groups and breast densities in reducing the recall rate. In the Rose study, while the average reduction in false positive results is 37 percent, all age populations realized in improvement in the recall rate as follows:

< 50 years old	37.2 percent
50-64 years old	32.9 percent
≥ 65 years old	46.6 percent

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<sup>4</sup> Skaane P, Bandos A, Gullien R, et al. "Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program." *Radiology*. 2013 Apr; 267(1):47-56. Epub 2013 Jan 7. 2013.

<sup>5</sup> Rose S, Tidwell A, Bujnock L, et al. "Implementation of Breast Tomosynthesis in a Routine Screening Practice: An Observational Study." *American Journal of Roentgenology*. 2013 Jun; 200(6): 1401-1408. Epub 2013 May 22

<sup>6</sup> Friedewald S, Rafferty E, et al. "Breast Cancer Screening Using Tomosynthesis in Combination with Digital Mammography." *Journal of the American Medical Association*. 2014 Jun; 311(24): 2499-2507.

In the draft decision, the committee also determined that “the available evidence is not sufficient to support coverage for Magnetic Resonance Imaging (MRI), hand held ultrasound (HHUS), and Automated Breast Ultrasound (ABUS) for supplementary screening following mammography.”

New technologies continue to improve the diagnostic options for breast cancer, and new studies continue to hone our understanding of the disease. Although published evidence is limited for automated breast ultrasound (ABUS), it consistently indicates improved cancer detection compared to mammography alone. In the most recent publication of a large population study (N=15,318), Brem cited increased cancer detection of 1.9 per / 1,000 women screened but a reduction in specificity of 13.4%, representing a valid concern for increased false-positive recalls. Follow-on ABUS studies are likely to more fully address this potential harm but unpublished FDA pre-market approval (PMA) data indicates that specificity reductions may be significantly less with more formalized reader training. Information reported in PMA 11006 indicates specificity reductions between -4.2% to -2.1% for mammography + ABUS compared to mammography alone for mammo-negative patients with BI-RADS 3 & 4 breast density. These results were obtained when the PMA readers were trained, which is now mandated by FDA in the approval letter.<sup>7</sup>

Considering there are ongoing studies of diagnostic imaging for breast cancer with technologies such as ultrasound and MRI, MITA recommends that in the final coverage decision the Committee changes the language to read “currently there is insufficient evidence to cover Magnetic Resonance Imaging (MRI), hand held ultrasound (HHUS), and Automated Breast Ultrasound (ABUS) for supplementary screening following mammography.” In addition, MITA recommends that the Committee re-review this decision as evidence becomes available in the future.

MITA appreciates this opportunity to comment on the draft decision. We would be pleased to answer any questions you might have about these comments. Please contact me at (703) 841-3235 if MITA can be of any assistance.

Sincerely,

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<sup>7</sup> Brem RF, Tabár L, Duffy SW, Inciardi MF, Guingrich JA, Hashimoto BE, Lander MR, Lapidus RL, Peterson MK, Rapelyea JA, Roux S, Schilling KJ, Shah BA, Torrente J, Wynn RT, Miller DP, Assessing Improvement in Detection of Breast Cancer with Three-dimensional Automated Breast US in Women with Dense Breast Tissue: The SonoInsight Study, Radiology, Oct 2014

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Gail Rodriguez, Ph.D.  
Executive Director, MITA

**From:** Khai Tran [mailto:[KTran@tranow.com](mailto:KTran@tranow.com)]  
**Sent:** Tuesday, February 24, 2015 2:49 PM  
**To:** HCA ST Health Tech Assessment Prog  
**Subject:** Breast tomosynthesis

Washington Health Technology Assessment Program

February 23, 2015

To Whom It May Concern:

I want to first take the opportunity to express my deepest gratitude to your committee for taking on such an important topic and evaluating the available data with great fortitude. Your findings support the vast published clinical compendium and broad clinical practice experience in the state of Washington with digital breast tomosynthesis, showing a reduction in unnecessary recalls and an increase in cancer detection. A majority vote by your committee will serve to enhance the clinical outcomes achieved by radiologists, like myself, through reducing unnecessary anxiety for women and identifying cancer earlier and more accurately. Ultimately, your positive vote will support the goal of making DBT available to all women in Washington State.

I have a few comments that pertain exclusively to the digital breast tomosynthesis aspect of your report that will hopefully address any remaining uncertainties.

First, it appears as if there is some confusion around Medicare coverage of DBT. The Final Evidence Report noted that CMS published billing codes and payment rates for DBT, but did not explicitly discuss the mandated coverage as outlined in the Final Rule for 2015. CMS considers DBT a "mammography service" and thus, CPT 77063 falls under the same coverage rules of other mammography services, like digital mammography or analog mammography. In addition, the local Medicare Administrative Contractor for Washington, Noridian, published a transmittal that explained coverage of DBT for all claims effective January 1, 2015.

Second, reading time is certainly longer for DBT than digital mammography on its own. However, my personal experience after reading DBT for more than 18 months has shown that we radiologists adjust and improve over time. Currently, actual reading time is approximately 40% higher for DBT. In speaking with colleagues in the state who have similar DBT experience, this is consistent in their practice as well.

Finally, the structure of a DBT exam is such that it can only enhance the performance of digital mammography. This is because both the digital mammography 2D images and the 3D images are included in every DBT exam. Therefore, it is impossible for DBT to ever perform inferior to 2D digital mammography alone; 2D images are included with every exam. This fact supports your C+ rating and I believe that longer-term evidence on DBT will continue to show improvements over digital mammography alone. With this in mind, when evaluating interval cancers, it is important to remember that there are cases when both digital mammography *and* DBT can miss the same lesion during screening. However, because of the structure of a DBT exam, it is not possible for there ever to be a case when digital mammography finds a lesion that DBT missed. Every interval cancer missed in the screening round is missed by both digital mammography and DBT. The superior clinical benefit of DBT is that it finds up to 41% more invasive cancer that standard 2D digital mammography misses, thus enhancing the performance of mammography as a whole.

Thank you for considering my comments and I look forward to a positive final vote that upholds your current position in the Draft Findings and Decisions describing DBT as a covered benefit.

Khai Tran, MD  
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