

Washington State
Health Care Authority
Health Technology Assessment

Health Technology Assessment

Program Overview

Josh Morse, Program Director
Health Technology Assessment
March 22, 2013

Presentation Overview

Today's Topics:

- Hyperbaric Oxygen Therapy for Tissue Damage, Including Wound Care and Treatment of Central Nervous System Conditions
- Cervical Spinal Fusion For Degenerative Disc Disease
- HTA Program Overview

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HTA 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

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HTA Background

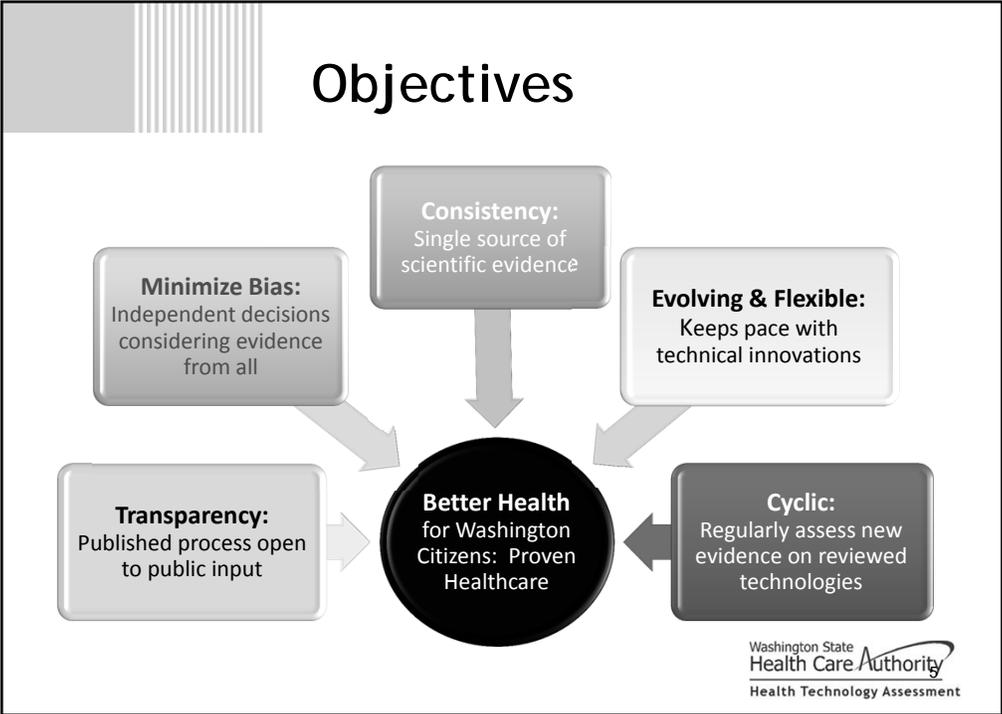
- Multiple state agency programs participate to identify topics and implement policy decisions:
 - Health Care Authority
 - Uniform Medical Plan
 - Medicaid
 - Labor and Industries
 - Corrections
- Implementation:
 - Agencies implement determinations of the HTA program within their existing statutory framework.

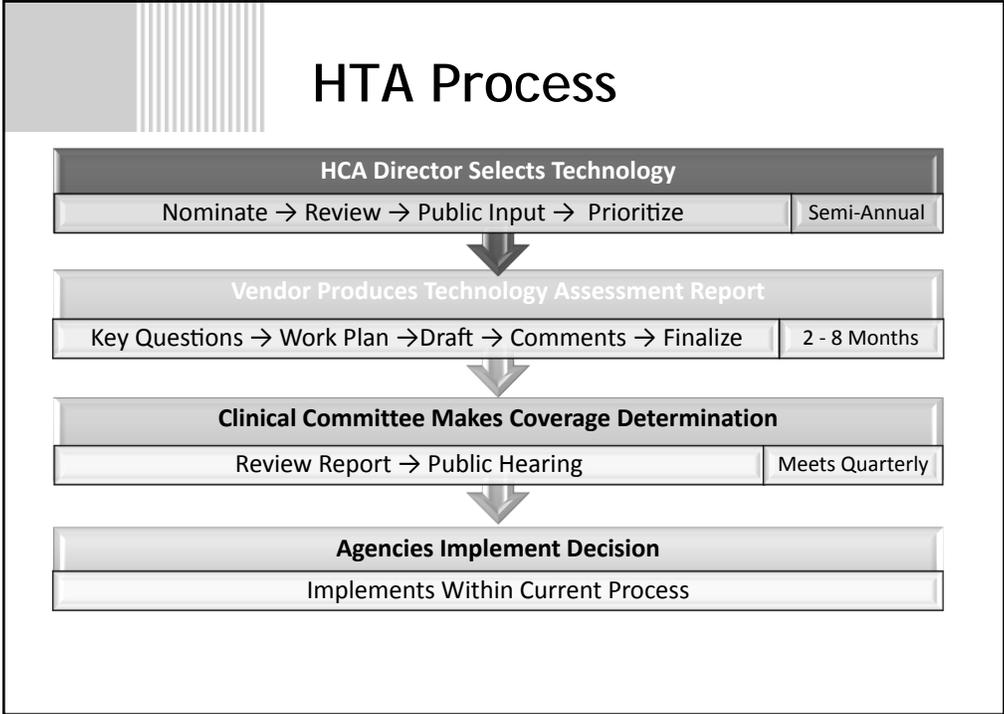
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Purpose: Pay for What Works

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.



Key Questions

- Is it safe?
- Is it effective?
- Does it provide value (i.e. improve health outcomes)?

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HTA 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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HTCC 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 or political considerations)

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Technology Topics 2013

- ❖ Hyperbaric Oxygen Therapy for Wound Care and Brain Injury
- ❖ Cervical Level Fusion for Degenerative Disk Disease
- Ablation Procedures for Supraventricular Tachycardia
- Cochlear Implants: Bi- versus Unilateral
- Carotid Artery Stenting
- Cardiac Nuclear Imaging
- Hyaluronic Acid/Viscosupplementation (update)
- Hip Resurfacing (update)

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How To Participate

- **Visit** the HTA Web site: www.hta.wa.gov
- **Join** the HTA stakeholder distribution list: shtap@hta.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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HTA Contact Information

Email Distribution List: shtap@hca.wa.gov

HTA Web Pages: hta.hca.wa.gov/

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Thank you!

Washington State
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Health Technology Assessment

Health Technology Clinical Committee

Date: November 16, 2012

Time: 8:00 am – 5:00 pm

Location: SeaTac Airport Conference Center

Adopted:

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

http://www.hta.hca.wa.gov/past_materials.html

HTCC MINUTES

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

Members Absent: None

HTCC FORMAL ACTION

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

Action: Eleven committee members approved the September 21, 2012 meeting minutes.

- 3. Intensity Modulated Radiation Therapy Draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion or objection.

The Intensity Modulated Radiation Therapy Draft Findings & Decision was approved and adopted by the committee.

Action: Eleven committee members approved the Intensity Modulated Radiation Therapy Draft Findings & Decision document.

- 4. Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy**

Scheduled and Open Public Comments: The Chair called for public comments.

Scheduled Public Comments: Four individuals scheduled time for public comments.

- o John Rieke, MD, American Society of Radiation Oncology

Not Officially Adopted

- Trent Tredway, MD, Washington State Association of Neurological Surgeons
- Sandra Vermeulen, MD, Executive Director Swedish Radiosurgery Center
- Ed Y. Kim, MD, University of Washington School of Medicine, Department of Radiation Oncology presenting for Shilpen Patel, MD, University of Washington School of Medicine, Department of Radiation Oncology.

Presentation materials and conflict of interest forms are available with [November 16 meeting materials](#).

No open public comments were presented.

Agency Utilization and Outcomes:

Kerilyn Nobuhara MD, MHA, Senior Medical Consultant, Health Care Authority, presented the state agency utilization rates for Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy to the committee. The full presentation is published with [November 16 meeting materials](#).

Vendor Report and HTCC Q & A:

The Chair introduced the clinical expert, Martin Fuss, MD, professor and Vice Chair, Director Program in Image-guided Radiation Therapy, Department of Radiation Medicine, Oregon Health & Science University.

Martha Gerrity, MD, MPH, PhD, of the Center for Evidence-based Policy, Oregon Health & Science University, presented the evidence review addressing Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy. The full presentation is published with [November 16 meeting materials](#).

Committee Discussion and Decision

The HTCC reviewed and considered the Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy technology assessment report and information provided by the state agencies. They also heard comments from the evidence reviewer, the clinical expert, the public, and agency medical directors. 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.

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Stereotactic Radiation Surgery	0	0	11
Stereotactic Body Radiation Therapy	0	0	11

Not Officially Adopted

- Discussion: The Chair called for discussion of conditions of coverage for Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:
- Limitations of Coverage:
 - Stereotactic Radiation Surgery covered for tumors with conditions:
 - Functional status- Karnofsky score greater than or equal to 50, and
 - Multidisciplinary team analysis, including surgical input
 - Stereotactic Body Radiation Therapy (SBRT) is a covered with conditions:
 - Cancers of spine/paraspinal structures, or
 - non-small cell lung cancer, stage 1 inoperable, and
 - Multidisciplinary team analysis, including surgical input.All other indications: Not covered

The committee checked for availability of a Medicare decision. There is no national coverage determination (NCD) for Stereotactic Radiation Surgery or Stereotactic Body Radiation Therapy.

Chair directed HTA staff to a prepare draft coverage determination document for the topic.

5. Vitamin D Screening and Testing:

Scheduled and Open Public Comments: The Chair called for public comments.

Two individuals scheduled time for public comments:

- Eugene F. May, MD, NW Alliance of Multiple Sclerosis Centers
- Nesanet Mitku, MD, NW Alliance of Multiple Sclerosis Centers

Presentation materials and conflict of interest forms are available with [November 16 meeting materials](#).

No open public comments were presented.

Agency Utilization and Outcomes:

G. Steven Hammond MD, MHA, PhD, Chief Medical Officer, Department of Corrections, presented the state agency utilization rates for Vitamin D Screening and Testing to the committee. The full presentation is published with [November 16 meeting materials](#).

Vendor Report and HTCC Q & A:

The Chair introduced the clinical expert, Susan Ott, MD, University of Washington Adjunct Professor, Department of Medicine; Radiology, Pathology and Orthopedics.

Not Officially Adopted

Theresa Rogstad, MPH, Senior Medical Research Analyst for Hayes, Inc., presented the evidence review addressing Vitamin D Screening and Testing. The full presentation is published with [November 16 meeting materials](#).

Committee Discussion and Decision

The HTCC reviewed and considered the Vitamin D Screening and Testing technology assessment report and information provided by the state agencies. They also heard comments from the evidence reviewer, the clinical expert, the public, and agency medical directors. 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.

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Vitamin D Screening and Testing	0	0	11

- Discussion: The Chair called for discussion of conditions of coverage for Vitamin D Screening and Testing following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:
 - Limitations of Coverage:
 - Not covered as a part of **routine screening**
 - **Testing** is covered in individuals with:
 - A disease or condition known to cause, or be caused by, Vitamin D abnormality; or
 - Radiologic or laboratory findings that are positive for markers of Vitamin D abnormality.

The committee checked for availability of a Medicare decision. The Centers for Medicare and Medicaid Services have no published national coverage determinations (NCD) for Vitamin D testing and screening.

Chair directed HTA staff to a prepare draft coverage determination document for the topic.

6. The Chair called for further comments. No further comments on review of Vitamin D Testing and Screening.

Not Officially Adopted

7. Review of draft key questions open for public comment: Cochlear Implants: Bi- versus Unilateral. HTA staff reminded committee members of the open comment period for key questions; committee reviewed draft key questions.
8. Meeting adjourned.

Health Technology Clinical Committee Draft Findings and Decision

Topic: Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy
Meeting Date: November 16, 2012
Final Adoption:

Number and Coverage Topic:

20121116A – Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy

HTCC Coverage Determination:

Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy are **covered benefits with conditions** consistent with the criteria identified in the reimbursement determination.

HTCC Reimbursement Determination:

Limitations of Coverage

- Stereotactic Radiation Surgery for Central Nervous System (CNS) primary and metastatic tumors is a covered benefit for adults and children when the following criteria are met:
 - Patient functional status score, i.e., Karnofsky score, is greater than or equal to 50, and
 - Evaluation includes multidisciplinary team analysis (e.g., tumor board), including surgical input.

- Stereotactic Body Radiation Therapy (SBRT) is ~~a~~-covered for adults and children for the following conditions when the following ~~coverage~~ criteria are met:
 - For cancers of spine/paraspinal structures, or
 - For inoperable non-small cell lung cancer, stage 1, ~~inoperable~~, and
 - Evaluation includes multidisciplinary team analysis (e.g., tumor board), including surgical input.

~~For all other indications: Not covered~~

Non-Covered Indicators

- ~~For a~~All other indications: Not covered
- ~~See above~~

Not officially adopted.

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

HTCC Coverage Vote And Formal Action

Meeting materials and transcript are available on the HTA website at:
http://www.hta.hca.wa.gov/past_materials.html

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 agency and state utilization information. The committee concluded that the current evidence on Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy demonstrates that there is sufficient evidence to cover with conditions. 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 with conditions Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy.

Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy Coverage Vote:

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Stereotactic Radiation Surgery	0	0	11
Stereotactic Body Radiation Therapy	0	0	11

- **Discussion:** The Chair called for discussion of conditions of coverage for Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy following the majority voting for coverage under certain conditions. The following conditions were discussed and approved by a majority of the clinical committee:

Not officially adopted.

- Limitations of Coverage:
 - Stereotactic Radiation Surgery covered for tumors with conditions:
 - Functional status- Karnofsky score greater than or equal to 50, and
 - Multidisciplinary team analysis, including surgical input
 - Stereotactic Body Radiation Therapy (SBRT) is a covered with conditions:
 - Cancers of spine/paraspinal structures, or
 - non-small cell lung cancer, stage 1 inoperable, and
 - Multidisciplinary team analysis, including surgical input.All other indications: Not covered

Action

The committee Chair directed HTA staff to prepare a Findings and Decision document on Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy reflective of the majority vote for final approval at the next public meeting.

The committee reviewed the evidence report for existing clinical guidelines and Centers for Medicare & Medicaid Services (CMS) decisions. CMS does not have a national coverage determination (NCD) for Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy.

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.

Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy

Draft 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 Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy.

Category	Comment Period <i>December 7 – 21, 2012</i>	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	1	1
Industry & manufacturer	0	0
Professional society & advocacy organization	1	1
Total	2	2

Comments With Evidence:

Physician and health care professional comments

Robert Meier, MD, Medical Director Radiation Oncology, Swedish Radiosurgery Center

Comments Without Evidence:

Professional society & advocacy organization

Charles Mick, MD, President, North American Spine Society

Technology Assessment Timeline

Study Stage	Date	Public Comment Days
Technology recommendations published	November 3, 2010	
Public comments due	November 16, 2010	15
Selected technologies published	December 17, 2010	
Public comments due	January 17, 2011	31
Draft Key Questions published	June 18, 2012	
Public comments due	July 2, 2012	15
Final Key Questions published	July 17, 2012	

Technology Assessment Timeline

Study Stage	Date	Public Comment Days
Draft report published	August 31, 2012	
Public comments due	October 1, 2012	32
Final report published	October 15, 2012	
Public meeting date	November 18, 2012	
Findings & decision published	December 7, 2012	
Public comments due	December 21, 2012	15

December 20, 2012

Health Technology Assessment Program (HTA)
Washington State Health Care Authority
PO Box 42712
Olympia, WA 98504-2712

To Whom It May Concern,

I am writing this letter to express my disappointment with the Health Technology **Clinical Commissions' draft decision for SRS/SBRT. After reviewing this document, I** believe that it is one of the most restrictive policies that I am aware of and runs counter to the trends we see with other payers who expand coverage as the published clinical data continues to support the safety and efficacy of this treatment option.

Based on comments within the draft decision announcement, it appears that your committee requested Medicare coverage information; however, determined that:

“CMS does not have a national coverage determination (NCD) for Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy”.

This statement may have been accurate at the time the technology assessment was conducted; however, effective 12/03/12 Medicare has finalized a local coverage determination **for SRS/SBRT. Medicare's coverage policy** provides a more comprehensive list of covered indications than the list compiled by the Health Technology Clinical Commission. The complete list of Medicare covered diagnoses is provided in Appendix A and can also be found on **CMS' website at the following html** address: [http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=32234&ContrId=247&ver=8&ContrVer=1&CtrctrSelected=247*1&Ctrctr=247&name=Noridian+Administrative+Services%2c+LLC+\(02402%2c+MAC+-+Part+B\)&s=56&bc=AggAAAIAAAA&](http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=32234&ContrId=247&ver=8&ContrVer=1&CtrctrSelected=247*1&Ctrctr=247&name=Noridian+Administrative+Services%2c+LLC+(02402%2c+MAC+-+Part+B)&s=56&bc=AggAAAIAAAA&)

Specifically, I would like to make this committee aware that Noridian (Washington State's Medicare Administrative Contractor) provides coverage for prostate cancer, a diagnoses that SBRT is well suited to treat. This decision is consistent with other Medicare contractor and private payer policies and represents a culmination of scientific data that supports this treatment option.

The following table provides an overview of Medicare coverage availability for SRBT to treat prostate cancer:

Medicare Contractor	Jurisdiction	Published Policy	Prostate Cancer Covered	LCD ID Number
Palmetto GBA	J1 (CA, HI, NV) J11 (NC, SC, VA, WV)	Yes (J1), No (J11)	Yes Yes	L28301 NA
TrailBlazer/Novitas	JH (AR, CO, LA, MS, NM, OK, TX)	Yes (Both MACs)	Yes	TB= L26838 (Ret.) Novitas = L32671
Novitas	J12 (DE, DC, MD, NJ, PA)	Yes	Yes	L30277
Wisconsin Physician Services	J5 (IA, KS, MO, NE), J8 (IN,MI), National Part A FI, Legacy Part B Contractor (IL, MN, WI)	Yes	Yes	L28366 (same ID # for all WPS Jurisdictions)
FCSO	J9 (FL)	Yes	Yes	L30366
Noridian	JF (AK, AZ, UT, OR, WA, ID, WY, MT, ND, SD)	Yes	Yes	L32234
CGS	J15 (KY, OH)	No	Yes (Subject to reasonable and necessary)	NA
National Government Services	J13 (CT, NY)	No	Yes (Subject to reasonable and necessary)	NA
NHIC	J14 (MA, ME, NH, RI, VT)	No	Yes (Subject to reasonable and necessary)	NA

As you can see, SBRT for prostate cancer is an option for all Medicare beneficiaries across the country either through medical policy or in the absence of formal policy. Several other payers including **private payers and the Veteran's Administration** have also finalized similar policies covering prostate cancer or have retired previously restrictive policies. Appendix B provides a list of payers who have published favorable coverage policies for SBRT to treat prostate cancer.

It is also worth mentioning the data presented at the 2012 American Society for Radiation Oncology (ASTRO) meeting in October. Appendix C provides the abstracts from these studies which demonstrated excellent efficacy with minimal side effects for men undergoing SBRT for prostate cancer.

In conclusion, the outcomes data for SBRT to treat prostate cancer is maturing rapidly and continues to provide convincing evidence of its safety and efficacy. As a testament to the strength of this data, SBRT is a treatment option for Medicare beneficiaries and is covered by **the Veteran's Administration and other third party payers across the country** for the treatment of their prostate cancer. We are convinced that these positive local coverage determinations made over the past few years appropriately reflect the evidence that SBRT is as safe, effective, less expensive, and much more patient friendly than other forms of radiation treatments. **It is my hope that after reviewing Medicare's**

coverage policy for SRS/SBRT, the Health Technology Assessment Committee will revise its draft coverage decision and expand the current list of indication to be more in line with medical standards of care.

Sincerely,

Robert Meier, MD
Medical Director of Radiation Oncology
Swedish Radiosurgery Center
550 17th Avenue
Suite A-10
Seattle, WA 98122

Appendix A

147.0	MALIGNANT NEOPLASM OF SUPERIOR WALL OF NASOPHARYNX
147.1	MALIGNANT NEOPLASM OF POSTERIOR WALL OF NASOPHARYNX
147.2	MALIGNANT NEOPLASM OF LATERAL WALL OF NASOPHARYNX
147.3	MALIGNANT NEOPLASM OF ANTERIOR WALL OF NASOPHARYNX
147.8	MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF NASOPHARYNX
147.9	MALIGNANT NEOPLASM OF NASOPHARYNX UNSPECIFIED SITE
160.0	MALIGNANT NEOPLASM OF NASAL CAVITIES
160.1	MALIGNANT NEOPLASM OF AUDITORY TUBE MIDDLE EAR AND MASTOID AIR CELLS
160.2	MALIGNANT NEOPLASM OF MAXILLARY SINUS
160.3	MALIGNANT NEOPLASM OF ETHMOIDAL SINUS
160.4	MALIGNANT NEOPLASM OF FRONTAL SINUS
160.5	MALIGNANT NEOPLASM OF SPHENOIDAL SINUS
160.8	MALIGNANT NEOPLASM OF OTHER ACCESSORY SINUSES
160.9	MALIGNANT NEOPLASM OF ACCESSORY SINUS UNSPECIFIED
191.0	MALIGNANT NEOPLASM OF CEREBRUM EXCEPT LOBES AND VENTRICLES
191.1	MALIGNANT NEOPLASM OF FRONTAL LOBE
191.2	MALIGNANT NEOPLASM OF TEMPORAL LOBE
191.3	MALIGNANT NEOPLASM OF PARIETAL LOBE
191.4	MALIGNANT NEOPLASM OF OCCIPITAL LOBE
191.5	MALIGNANT NEOPLASM OF VENTRICLES
191.6	MALIGNANT NEOPLASM OF CEREBELLUM NOS
191.7	MALIGNANT NEOPLASM OF BRAIN STEM
191.8	MALIGNANT NEOPLASM OF OTHER PARTS OF BRAIN
191.9	MALIGNANT NEOPLASM OF BRAIN UNSPECIFIED SITE
192.0	MALIGNANT NEOPLASM OF CRANIAL NERVES
192.1	MALIGNANT NEOPLASM OF CEREBRAL MENINGES
194.3	MALIGNANT NEOPLASM OF PITUITARY GLAND AND CRANIOPHARYNGEAL DUCT
194.4	MALIGNANT NEOPLASM OF PINEAL GLAND
194.6	MALIGNANT NEOPLASM OF AORTIC BODY AND OTHER PARAGANGLIA
198.3	SECONDARY MALIGNANT NEOPLASM OF BRAIN AND SPINAL CORD
198.4*	SECONDARY MALIGNANT NEOPLASM OF OTHER PARTS OF NERVOUS SYSTEM
198.5*	SECONDARY MALIGNANT NEOPLASM OF BONE AND BONE MARROW
198.89*	SECONDARY MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES
225.0	BENIGN NEOPLASM OF BRAIN
225.1	BENIGN NEOPLASM OF CRANIAL NERVES
225.2	BENIGN NEOPLASM OF CEREBRAL MENINGES
227.3	BENIGN NEOPLASM OF PITUITARY GLAND AND CRANIOPHARYNGEAL DUCT
227.4	BENIGN NEOPLASM OF PINEAL GLAND
227.5	BENIGN NEOPLASM OF CAROTID BODY
227.6*	BENIGN NEOPLASM OF AORTIC BODY AND OTHER PARAGANGLIA
228.02	HEMANGIOMA OF INTRACRANIAL STRUCTURES
237.0	NEOPLASM OF UNCERTAIN BEHAVIOR OF PITUITARY GLAND AND CRANIOPHARYNGEAL DUCT
237.1	NEOPLASM OF UNCERTAIN BEHAVIOR OF PINEAL GLAND

237.3* NEOPLASM OF UNCERTAIN BEHAVIOR OF PARAGANGLIA
 237.5* NEOPLASM OF UNCERTAIN BEHAVIOR OF BRAIN AND SPINAL CORD
 237.6* NEOPLASM OF UNCERTAIN BEHAVIOR OF MENINGES
 239.6* NEOPLASM OF UNSPECIFIED NATURE OF BRAIN
 239.7* NEOPLASM OF UNSPECIFIED NATURE OF ENDOCRINE GLANDS AND OTHER PARTS OF NERVOUS SYSTEM
 332.0* PARALYSIS AGITANS
 345.11 GENERALIZED CONVULSIVE EPILEPSY WITH INTRACTABLE EPILEPSY
 345.3 GRAND MAL STATUS EPILEPTIC
 345.91 EPILEPSY UNSPECIFIED WITH INTRACTABLE EPILEPSY
 350.1 TRIGEMINAL NEURALGIA
 350.8 OTHER SPECIFIED TRIGEMINAL NERVE DISORDERS
 350.9 TRIGEMINAL NERVE DISORDER UNSPECIFIED
 351.0 BELL'S PALSY
 351.1 GENICULATE GANGLIONITIS
 351.8 OTHER FACIAL NERVE DISORDERS
 351.9 FACIAL NERVE DISORDER UNSPECIFIED
 352.0* DISORDERS OF OLFACTORY (1ST) NERVE
 352.1* GLOSSOPHARYNGEAL NEURALGIA
 352.2* OTHER DISORDERS OF GLOSSOPHARYNGEAL (9TH) NERVE
 352.3* DISORDERS OF PNEUMOGASTRIC (10TH) NERVE
 352.4* DISORDERS OF ACCESSORY (11TH) NERVE
 352.5* DISORDERS OF HYPOGLOSSAL (12TH) NERVE
 352.6* MULTIPLE CRANIAL NERVE PALSIES
 352.9* UNSPECIFIED DISORDER OF CRANIAL NERVES
 747.81* CONGENITAL ANOMALIES OF CEREBROVASCULAR SYSTEM
 990* EFFECTS OF RADIATION UNSPECIFIED

* ICD-9-CM Codes 198.4, 198.5, 198.89, 227.6, 237.3, 237.5, 237.6, 239.6, 239.7, 352.0, 352.1, 352.2, 352.3, 352.4, 352.5, 352.6, 352.9 and 747.81 are all limited to use for lesions occurring either above the neck or in the spine.

* ICD-9-CM Code 332.0 is limited to the patient who cannot be controlled with medication, has major systemic disease or coagulopathy, and who is unwilling or unsuited for open surgery.

*ICD-9-CM Code 990 may only be used where prior radiation therapy to the site is the governing factor necessitating SRS in lieu of other radiotherapy. An ICD-9-CM code for the anatomic diagnosis must also be used.

Stereotactic Body Radiation Therapy (SBRT) Services (CPT 77373, 77435, G0339, and G0340:

140.0* MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER
 140.1* MALIGNANT NEOPLASM OF LOWER LIP VERMILION BORDER
 140.3* MALIGNANT NEOPLASM OF UPPER LIP INNER ASPECT
 140.4* MALIGNANT NEOPLASM OF LOWER LIP INNER ASPECT
 140.5* MALIGNANT NEOPLASM OF LIP UNSPECIFIED INNER ASPECT
 140.6* MALIGNANT NEOPLASM OF COMMISSURE OF LIP
 140.8* MALIGNANT NEOPLASM OF OTHER SITES OF LIP
 140.9* MALIGNANT NEOPLASM OF LIP UNSPECIFIED VERMILION BORDER
 141.0* MALIGNANT NEOPLASM OF BASE OF TONGUE
 141.1* MALIGNANT NEOPLASM OF DORSAL SURFACE OF TONGUE
 141.2* MALIGNANT NEOPLASM OF TIP AND LATERAL BORDER OF TONGUE
 141.3* MALIGNANT NEOPLASM OF VENTRAL SURFACE OF TONGUE
 141.4* MALIGNANT NEOPLASM OF ANTERIOR TWO-THIRDS OF TONGUE PART UNSPECIFIED
 141.5* MALIGNANT NEOPLASM OF JUNCTIONAL ZONE OF TONGUE
 141.6* MALIGNANT NEOPLASM OF LINGUAL TONSIL
 141.8* MALIGNANT NEOPLASM OF OTHER SITES OF TONGUE
 141.9* MALIGNANT NEOPLASM OF TONGUE UNSPECIFIED
 142.0* MALIGNANT NEOPLASM OF PAROTID GLAND
 142.1* MALIGNANT NEOPLASM OF SUBMANDIBULAR GLAND
 142.2* MALIGNANT NEOPLASM OF SUBLINGUAL GLAND
 142.8* MALIGNANT NEOPLASM OF OTHER MAJOR SALIVARY GLANDS
 142.9* MALIGNANT NEOPLASM OF SALIVARY GLAND UNSPECIFIED
 143.0* MALIGNANT NEOPLASM OF UPPER GUM

143.1* MALIGNANT NEOPLASM OF LOWER GUM
143.8* MALIGNANT NEOPLASM OF OTHER SITES OF GUM
143.9* MALIGNANT NEOPLASM OF GUM UNSPECIFIED
144.0* MALIGNANT NEOPLASM OF ANTERIOR PORTION OF FLOOR OF MOUTH
144.1* MALIGNANT NEOPLASM OF LATERAL PORTION OF FLOOR OF MOUTH
144.8* MALIGNANT NEOPLASM OF OTHER SITES OF FLOOR OF MOUTH
144.9* MALIGNANT NEOPLASM OF FLOOR OF MOUTH PART UNSPECIFIED
145.0* MALIGNANT NEOPLASM OF CHEEK MUCOSA
145.1* MALIGNANT NEOPLASM OF VESTIBULE OF MOUTH
145.2* MALIGNANT NEOPLASM OF HARD PALATE
145.3* MALIGNANT NEOPLASM OF SOFT PALATE
145.4* MALIGNANT NEOPLASM OF UVULA
145.5* MALIGNANT NEOPLASM OF PALATE UNSPECIFIED
145.6* MALIGNANT NEOPLASM OF RETROMOLAR AREA
145.8* MALIGNANT NEOPLASM OF OTHER SPECIFIED PARTS OF MOUTH
145.9* MALIGNANT NEOPLASM OF MOUTH UNSPECIFIED
146.0* MALIGNANT NEOPLASM OF TONSIL
146.1* MALIGNANT NEOPLASM OF TONSILLAR FOSSA
146.2* MALIGNANT NEOPLASM OF TONSILLAR PILLARS (ANTERIOR) (POSTERIOR)
146.3* MALIGNANT NEOPLASM OF VALLECULA EPIGLOTTICA
146.4* MALIGNANT NEOPLASM OF ANTERIOR ASPECT OF EPIGLOTTIS
146.5* MALIGNANT NEOPLASM OF JUNCTIONAL REGION OF OROPHARYNX
146.6* MALIGNANT NEOPLASM OF LATERAL WALL OF OROPHARYNX
146.7* MALIGNANT NEOPLASM OF POSTERIOR WALL OF OROPHARYNX
146.8* MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF OROPHARYNX
146.9* MALIGNANT NEOPLASM OF OROPHARYNX UNSPECIFIED SITE
155.0 MALIGNANT NEOPLASM OF LIVER PRIMARY
155.1 MALIGNANT NEOPLASM OF INTRAHEPATIC BILE DUCTS
155.2 MALIGNANT NEOPLASM OF LIVER NOT SPECIFIED AS PRIMARY OR SECONDARY
157.0 MALIGNANT NEOPLASM OF HEAD OF PANCREAS
157.1 MALIGNANT NEOPLASM OF BODY OF PANCREAS
157.2 MALIGNANT NEOPLASM OF TAIL OF PANCREAS
157.3 MALIGNANT NEOPLASM OF PANCREATIC DUCT
157.4 MALIGNANT NEOPLASM OF ISLETS OF LANGERHANS
157.8 MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES OF PANCREAS
157.9 MALIGNANT NEOPLASM OF PANCREAS PART UNSPECIFIED
162.2 MALIGNANT NEOPLASM OF MAIN BRONCHUS
162.3 MALIGNANT NEOPLASM OF UPPER LOBE BRONCHUS OR LUNG
162.4 MALIGNANT NEOPLASM OF MIDDLE LOBE BRONCHUS OR LUNG
162.5 MALIGNANT NEOPLASM OF LOWER LOBE BRONCHUS OR LUNG
162.8 MALIGNANT NEOPLASM OF OTHER PARTS OF BRONCHUS OR LUNG
162.9 MALIGNANT NEOPLASM OF BRONCHUS AND LUNG UNSPECIFIED
185 MALIGNANT NEOPLASM OF PROSTATE
189.0 MALIGNANT NEOPLASM OF KIDNEY EXCEPT PELVIS
189.1 MALIGNANT NEOPLASM OF RENAL PELVIS
194.0 MALIGNANT NEOPLASM OF ADRENAL GLAND
194.6 MALIGNANT NEOPLASM OF AORTIC BODY AND OTHER PARAGANGLIA
196.1 SECONDARY AND UNSPECIFIED MALIGNANT NEOPLASM OF INTRATHORACIC LYMPH NODES
197.0 SECONDARY MALIGNANT NEOPLASM OF LUNG
197.7 MALIGNANT NEOPLASM OF LIVER SECONDARY
198.0 SECONDARY MALIGNANT NEOPLASM OF KIDNEY
198.7 SECONDARY MALIGNANT NEOPLASM OF ADRENAL GLAND
990* EFFECTS OF RADIATION UNSPECIFIED

*ICD-9-CM Codes 140.0-146.9 and 990 due to recurrence after prior conventional fractionated RT.

Appendix B - Coverage Policies

Medicare Contractors

Noridian Administrative Services

- Medicare Administrative Contractor for Jurisdiction F (Alaska, Arizona, Utah, Oregon, Washington, Idaho, Wyoming, Montana, North Dakota, and South Dakota)
- LCD L32234: Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT)
- Effective 12/03/12 Noridian implemented its final SRS/SBRT LCD at the end of an open public comment period. Coverage of SBRT for prostate cancer and more than three metastatic brain lesions were included in the final LCD under the following criteria:
 - Low or intermediate risk prostate cancer may be covered when the patient is enrolled in an IRB-approved clinical trial and which clinical trial meets **the “standards of scientific integrity and relevance to the Medicare population” described in IOM 100-03, National Coverage Determinations Manual, Chap 1, Part 1, section 20.32, B3a-k (with I-m desirable).** Similarly, enrollment in a clinical registry compliant with the principles established in **AHRQ’s “Registries for Evaluating Patient Outcomes: A User’s Guide”, such as the *Registry for Prostate Cancer Radiosurgery (RPCR)***, may qualify the treatment for coverage.
 - Patients with more than 3 primary or metastatic brain lesions who are enrolled in an IRB-approved clinical trial and which clinical trial meets the **“standards of scientific integrity and relevance to the Medicare population” described in IOM 100-03, National Coverage Determinations Manual, Chap 1, Part 1, section 20.32, B3a-k (with I-m desirable).**
 - Patients with more than 3 primary or metastatic brain lesions who are enrolled in a clinical registry compliant with the principles established in **AHRQ’s “Registries for Evaluating Patient Outcomes: A User’s Guide”.** (See bibliography.)
 - Patients whose pre-treatment imaging/work-up demonstrated 3 or fewer lesions but who are discovered to have greater than three (3) lesions at the time of treatment delivery. However, ongoing coverage after the first treatment requires enrollment in a clinical trial or registry as described in #7 and 8 "Indications".

Novitas (formerly Highmark Medicare Services)

- Medicare Administrative Contractor for Jurisdiction 12 (Delaware, Maryland, New Jersey, Pennsylvania, Virginia, and the District of Columbia)
- LCD L30277: Stereotactic Body Radiation Therapy Local Coverage Determination
- On 10/28/09 Highmark implemented its final SBRT LCD at the end of an open public comment period. Coverage of SBRT for prostate cancer was included in the final LCD under the following criteria:

- Physician documentation of patient selection criteria (stage and other factors);
- Documentation and verification that the patient was informed of the range of therapy choices, including risks and benefits, AND
- Documentation of the specific reasons why SBRT was the treatment of choice for the specific patient.
- Other factors considered favorable for coverage include enrollment of the patient in an appropriate *clinical registry* for planned assessment and publication (emphasis added).

First Coast Service Options

- Medicare Administrative Contractor for Jurisdiction 9 (Florida, Puerto Rico, and the U.S. Virgin Islands)
- LCD L30366: Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy Local Coverage Determination
- On October 5, 2009 First Coast implemented its final SBRT LCD at the end of an **open public comment period. FCSOs' policy covering SBRT for prostate cancer treatment incorporates coverage with evidence collection. FSCO's approach is similar to Highmark's**, in that it covers SBRT for prostate cancer with the identical patient selection criteria, but on a case-by-case basis. The documentation required by FCSO includes the explanation of patient selection, verification that the patient was informed of the range of therapy choices (including the risks and benefits of SBRT -- especially the risk of long term toxicities), and the rationale for SBRT as a treatment choice for the patient. In its response to comments on the original draft of this LCD, FCSO stated that **"Other factors considered favorable for payment of the treatment delivery include enrollment of the patient in an appropriate clinical registry (that includes tracking of late toxicities) for planned assessment and publication."** Individual coverage of SBRT for prostate cancer is considered under the same criteria included in the Highmark final LCD.

Wisconsin Physicians Services

- Medicare Legacy Part B contractor (Illinois, Michigan, Minnesota, and Wisconsin)
 - LCD L28366: Stereotactic Body Radiation Therapy Local Coverage Determinations
 - Wisconsin Physicians Services released a draft LCD in January, 2008 and took it through an open comment period including review and input from the WPS Carrier Advisory Committee (CAC).
 - On 07/16/08 WPS finalized its policy and inserted SBRT coverage for low risk to low/intermediate risk prostate cancer patients.
- Medicare Legacy Part A (previously under Mutual of Omaha) for all states where it operates as the fiscal intermediary.
 - LCD L28366: Stereotactic Body Radiation Therapy Local Coverage Determinations
 - **Following the MAC award to WPS, Mutual of Omaha's Medicare Part A business was transferred to WPS on November 5, 2007.**

- Effective 07/01/11, WPS updated its LCD to include coverage for prostate cancer in states where it operates as the Part A Fiscal Intermediary: Alaska, Alabama, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, North Dakota, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia, and Wyoming.
- Medicare Administrative Contractor for Jurisdiction 5 (Iowa, Missouri, Kansas, and Nebraska)
 - LCD L28366: Stereotactic Body Radiation Therapy Local Coverage Determinations
 - Revision History Number/Explanation ((effective 7/1/08) for IA, MO, NE, KS)
 - Added ECOG scale and Part A information; added coverage for prostate cancer
- Medicare Administrative Contractor for Jurisdiction 8 (Indiana and Michigan)
 - LCD L28366
 - Policy effective 08/20/12

Palmetto GBA

- Medicare Administrative Contractor for Jurisdiction 1 (California, Hawaii, and Nevada)
- LCD L28301: Stereotactic Body Radiation Therapy Local Coverage Determination
- Effective 03/23/09 Palmetto GBA provided coverage in its LCD, following an open public comment for prostate cancer for patients meeting specific criteria OR those patients enrolled in clinical trials registered on clinicaltrials.gov.

Pinnacle Business Solutions

- Legacy Part B contractor for Arkansas and Louisiana
- LCD AC-06-004 (Retired): Stereotactic Radiotherapy/Stereotactic Body Radiation Therapy Local Coverage Determination
- Effective 6/19/07, retired 9/1/2009 prostate (185) added as a covered indication.

Other Government Payers

Veteran's Administration

- CHAMPVA Policy Manual Stereotactic Radiosurgery / Radiotherapy (Updated 2/29/08)
- Like Aetna, the Veteran's Administration provides coverage of the Cyberknife® System consistent with its FDA clearance and is indicated for treatment planning

and image-guided stereotactic radiosurgery and precision radiotherapy for lesions, tumors, and conditions anywhere in the body when radiation treatment is indicated.

National Commercial Payers

Aetna

- National third party payer
- Stereotactic Radiosurgery Policy
- Consistent with its FDA clearance, Aetna considers stereotactic body radiation therapy (SBRT) with a Gamma Knife, CyberKnife, or linear accelerator (LINAC) medically necessary for localized malignant conditions within the body where highly precise application of high dose radiotherapy is required.

Cigna

- National third party payer
- Policy Title: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT)
- Effective 06/15/12 Cigna revised its policy to include coverage of low to intermediate risk prostate cancer

United HealthCare

- National third party payer
- Effective January 2011, SBRT policy retired. Coverage subject to medical necessity.

Appendix C

Title: Five-year Biochemical Control Rates for Stereotactic Body Radiotherapy for Organ Confined Prostate Cancer: A Multi-institutional Pooled Analysis

Authors: Alan Katz MD JD, Deborah Freeman MD, Irving Kaplan MD, Donald Fuller MD, Giampaolo Bolzicco MD, Sean Collins MD, Robert Meier MD, Jason Wang PhD, Michael Steinberg MD, Christopher King MD PhD

Purpose: To report the 5-year biochemical relapse-free survival (bRFS) rates from a pooled multi-institutional dataset of a large number of localized prostate cancer patients treated with stereotactic body radiotherapy (SBRT).

Materials and Methods: The outcome data from 1101 patients with localized adenocarcinoma of the prostate were pooled from 8 institutions. Patients were treated between 2003 and 2011. The distribution by stage was 92% T1-2a and 8% T2b-3. The distribution by Gleason score (GS) was 72% Gleason 6, 20% Gleason 7 and 8% Gleason

8-10. The distribution by risk was 59% low, 30% intermediate- and 11% high-risk. Median baseline PSA was 5.4 ng/ml; 88% of PSAs were <10 ng/ml, 10% were 10-20 ng/ml and 2% were > 20 ng/ml. All patients had CyberKnife SBRT as the radiotherapeutic modality. The median dose was 36.25 Gy (35-40 Gy range) delivered either with 4 or 5 fractions; this is equivalent to a range of 90-112 Gy in conventional fractionation, assuming an alpha/beta ratio of 1.5 Gy. In most cases, the PTV was the GTV expanded by 5mm, 3mm posteriorly. This was created by expanding the CTV from the GTV by 3 mm, 1 mm posteriorly; the PTV was the CTV plus 2 mm to account for errors in target definition and delivery. Androgen deprivation therapy was given to 146 (14%) patients. Biochemical relapse, defined as a rise > 2 ng/ml above nadir, was determined in a total of 49 failures. Of the 49, 9 had resolution of the rise (i.e. the >2 ng/ml rise was a large bounce). However, outcome analyses were performed on all 49 cases; no cases were excluded.

Results: The median follow-up for all 1101 cases was 36 months (range 1 to 66). For all patients, the biochemical relapse-free actuarial survival (bRFS) rate at 5 years was 93%. The 5-year actuarial bRFS rates for Gleason score ≤ 6 , Gleason score 7 and Gleason score ≥ 8 were 95%, 83% and 78%, respectively ($p=0.001$). The 5-year actuarial bRFS rates for iPSA ≤ 4 , iPSA 4-10, iPSA 10-20, and iPSA > 20 were 96%, 94%, 82% and 73%, respectively ($p=0.001$). The 5-year actuarial bRFS rates for low-, intermediate- and high-risk patients were 95%, 90%, and 80%, respectively ($p<0.001$). No difference in bRFS was observed with the use of androgen deprivation ($p=0.76$). A PSA bounce of > 0.20 ng/ml was observed in 16% of the patients at a median of 36 months (range 6-60). The median bounce magnitude was 0.50 ng/ml (range 0.2-5.29). For the 335 cases with a minimum of 4 years of follow-up (median 53 month), the 5-year bRFS rates for low- and intermediate-risk cases were 97% and 89%, respectively.

Conclusion: With a large cohort of patients treated with stereotactic body radiotherapy, with a reasonably long followup period, excellent efficacy was demonstrated at 5 years. For high risk cases, the results are preliminary, given the small number of cases treated. However, for low and intermediate risk cases, these results compare favorably with other modalities. These results support a low alpha beta ratio for prostate cancer.

Stereotactic Body Radiotherapy for Intermediate-risk Organ-confined Prostate Cancer: Interim Toxicity and Quality of Life Outcomes from a Multi-Institutional Study

Author Block R. Meier¹, I. Kaplan², A. Beckman³, G. Henning⁴, S. Woodhouse⁵, S. Williamson⁶, N. Mohideen⁷, D. Herold⁸, C. Cotrutz¹, M. Sanda², ¹*Swedish Cancer Institute, Seattle, WA*, ²*Beth Israel Deaconess Medical Center, Boston, MA*, ³*Central Baptist Hospital, Lexington, KY*, ⁴*St. Joseph Mercy Hospital System, Ypsilanti, MI*, ⁵*Community Cancer Center, Normal, IL*, ⁶*Capital Health System, Trenton, NJ*, ⁷*Northwest Community Hospital, Arlington Heights, IL*, ⁸*Jupiter Medical Center, Jupiter, FL*

Abstract:

Purpose/Objective(s): A phase II prospective multi-center study* was initiated in 2007 to evaluate the toxicity and efficacy of stereotactic body radiotherapy (SBRT) for organ-confined prostate cancer. The study included 21 institutions and completed accrual in 2011. We report an interim analysis of toxicities, quality of life (QoL) and early PSA outcomes of the intermediate-risk cohort.

Materials/Methods: A total of 129 hormone-naïve intermediate-risk patients (CS T1c-T2b, N0-x, M0-x, with either Gleason = 7 & PSA < 10 ng/ml, or Gleason ≤ 6 & PSA between 10-20) with biopsy proven adenocarcinoma of the prostate were enrolled. MR imaging was used to assist in target localization. All patients were treated with a non-isocentric robotic SBRT platform using real-time tracking of implanted fiducials. The prostate was prescribed 40 Gy in 5 fractions of 8 Gy and seminal vesicles received 36.25 Gy. No patient had androgen deprivation therapy. Toxicities were assessed using CTCAE v3 criteria. QoL for urinary, bowel and sexual function were assessed using the Expanded Prostate Cancer Index Composite (EPIC-26) questionnaire; patients with erections “Firm enough for intercourse” on question 9 were scored as potent. Biochemical failure was defined as a 2 ng/ml rise above nadir.

Results: Median follow-up was 30 months (range 10-42 months). No acute grade 3+ toxicities were reported. Acute Grade 2 GU and GI toxicities occurred in 20% and 8.5% of patients, respectively. One patient required temporary catheter placement for acute urinary retention. Late Grade 2 GU and GI toxicities occurred in 10% and 2% of patients, respectively. One late Grade 3 GU toxicity (bladder neck injury 1 year after treatment) was reported. There were no other Grade 3-5 toxicities. Mean EPIC urinary and bowel scores fell at 1 month and returned to baseline by 24 months. At baseline 52% of patients were potent, declining to 35% at 24 months. Pre-treatment median PSA was 5.93 ng/ml, decreasing to 0.80, 0.38 and 0.20 ng/ml at 1, 2 and 3 years, respectively. One patient had a biochemical failure at 3 months follow-up due to a biopsy-proven nodal metastasis. No other biochemical failures have been observed, resulting in a 3-year Kaplan-Meier biochemical progression-free survival rate of 99.2%.

Conclusions: In a multi-institutional study employing CyberKnife SBRT in intermediate-risk prostate cancer patients, serious acute and late toxicities have been minimal. EPIC urinary, bowel and sexual function responses appear favorable compared to other radiotherapy modalities. Early PSA responses are promising. With further follow-up, this study will help determine whether SBRT provides a therapeutic gain in the treatment of organ-confined prostate cancer.

*ClinicalTrials.gov identifier NCT00643994: supported by a grant from Accuray Inc

Long-Term Outcomes of Stereotactic Body Radiotherapy for Organ-Confined Prostate Cancer

Author Block R. Meier, C. Cotrutz, C. Loiselle, S. Sima, S. Vermeulen, *Swedish Cancer Institute, Seattle, WA*

Abstract:

Purpose/Objective(s): Stereotactic body radiotherapy (SBRT) combines conformal dose delivery and hypofractionation, which theoretically may yield a therapeutic advantage in prostate cancer. Since intrafractional prostatic motion can be substantial, real-time image-guidance provides the precise delivery required with dose-escalation. We prospectively examined toxicity and efficacy of image-guided dose-escalated SBRT for organ-confined prostate cancer, and report long-term outcomes.

Materials/Methods: From 2006 to 2011, 51 patients with AJCC 7th Edition stage I-II biopsy proven adenocarcinoma of the prostate received SBRT. Twenty-nine patients were stage I (D'Amico low-risk) and 22 were stage II (intermediate- or high-risk). The median patient age was 67 years (range, 52-80). Six patients received hormonal ablative therapy for a median 4 months (range, 0.75-14). All patients were treated with a non-isocentric robotic stereotactic SBRT platform, using real-time tracking of implanted fiducials. MR imaging was used to assist in target localization. The prostate was prescribed 40 Gy in 5 fractions of 8 Gy. The intermediate- and high-risk patients concomitantly had 36.25 Gy in 5 fractions delivered to the proximal seminal vesicles plus a 3-5 mm margin. Toxicities were assessed using CTCAE v.3 criteria. Biochemical failure was defined as a 2 ng/ml rise above nadir.

Results: The median follow-up was 36 months (range, 12-66). Acute Grade 2 GU and GI toxicities occurred in 35% and 12% of patients, respectively. Two acute grade 3 urinary frequencies (voiding more than once per hour) occurred within 2 weeks of treatment. Late Grade 2 GU and GI toxicities occurred in 18% and 2% of patients, respectively. One late grade 3 urinary obstruction occurred 20 months post-treatment and resolved following cystoscopy. There were no other grade 3-5 toxicities. No significant differences were observed in toxicity rates between stage I and stage II patients. Two of the three grade 3 urinary toxicities occurred in patients with prostate volumes exceeding 130 cc. The median baseline PSA was 5.9 ng/ml; this declined to 0.2 ng/ml at 36 months. For the 14 patients with 5 or more years follow-up the mean PSA was 0.09 ng/ml (range, undetectable - 0.3). One or more benign PSA rises of greater than 0.2 ng/ml were observed in 21 patients at a mean 15 follow-up months. Three patients had rises greater than 2 ng/ml with subsequent nadirs. No patient demonstrated a biochemical failure.

Conclusions: With 5-year or more follow-up for 14 patients, these results demonstrate the feasibility of dose-escalated SBRT delivered with real-time image guidance. Biochemical control rates are excellent, and acute and late toxicities acceptable. Patient selection may aid in limiting toxicities further. Longer follow-up is needed confirm acceptable toxicities, and to assess quality of life and biochemical outcomes.



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December 19, 2012

Washington State - Health Care Authority
Health Technology Assessment
626 8th Avenue SE
Olympia, WA 98501

RE: Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy

Washington State Health Technology Clinical Committee:

The North American Spine Society appreciates the opportunity to comment on the Washington State Health Care Authority Health Technological Clinical Committee (HTCC) draft findings and decision for Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy. The North American Spine Society was founded in 1984 and currently represents over 6,000 spine care physicians and affiliated health practitioners both nationally and internationally. NASS is dedicated to fostering the highest quality, evidence-based, ethical spine care by promoting education, research and advocacy. NASS members include MDs, DOs and PhDs in 24 spine-related specialties including orthopedics, neurosurgery, physiatry, pain management and other disciplines, including allied health professionals.

On November 16, 2012, the Washington State Health Technology Clinical Committee (HTCC) met to vote on coverage for Stereotactic Radiation Surgery and Stereotactic Body Radiation. Eleven out of eleven voting members voted to cover these treatments but only under the "Certain Conditions" described below:

1. For Stereotactic Radiation Surgery: Functional Status of a Karnofsky Performance Status (KPS) score >50 with multidisciplinary team analysis (including surgeon input).
2. For Stereotactic Body Radiation: Cancers of the spine/paraspinal structures or non-small cell lung CA that is "in-operable" and confined to the lung with multidisciplinary team analysis (including surgeon input)

NASS reviewed the Washington State draft policy and offers the following comments on the use of stereotactic radiation for spinal disease specifically, but does not have a position on stereotactic radiation therapy to other organ systems such as Stage 1 non-small cell lung cancer, or intra-cranial pathologies. The draft decision is in line with evidence that demonstrates the effectiveness and safety of Stereotactic Radiosurgery and Stereotactic Body

Radiation Therapy (SBRT) in the treatment of primary and metastatic tumors of the spinal column. SBRT is safe and effective both when performed alone and when performed as adjunct to surgical treatment of spinal neoplasms. We agree with the decision to cover SBRT for “cancers of the spine and paraspinal structures” as well as the need to involve a multidisciplinary team including spine surgeons.

We recommend that the HTCC utilize more specific clinical terminology in their coverage decision. For example, we recommend that the term neoplasms be utilized instead of cancers, since “cancers” may be interpreted as certain malignant tumors only. Current evidence demonstrates safety and effectiveness of SBRT in treating both intermediate grade and high grade neoplasms originating from spinal nerve roots, meninges, osseous spinal structures, cartilaginous spinal structures, and paraspinal tissues among others.

Also recommended is that coverage not be limited by KPS score >50. KPS is poorly suited for spinal dysfunction. Current draft coverage policy means patients would not be offered effective SBRT for their spinal neoplasm if they “require considerable assistance and frequent medical care” (i.e. KPS 50). Spinal neoplasms that compress the spinal cord may result in moderate myelopathy (more accurately measured by modified Japanese Orthopaedic Association (mJOA) score) and hence a KPS of 50 or lower, that may improve after SBRT, and may represent a patient that may most benefit from SBRT for spinal neoplasms causing cord compression. KPS may be an accurate prognosticator for brain tumors, or systemic malignant tumors, but it should not be utilized as a prognosticator in evidence based spine care.

We submit these comments for your consideration. Do not hesitate to contact us directly with any further questions or concerns.

Sincerely,

A handwritten signature in cursive script that reads "Charles Mick".

Charles Mick, MD, President
North American Spine Society

Health Technology Clinical Committee Draft Findings and Decision

Topic: Vitamin D Screening and Testing
Meeting Date: September 21, 2012
Final Adoption:

Number and Coverage Topic:

20121116B – Vitamin D Screening and Testing

HTCC Coverage Determination:

Vitamin D Screening and Testing is a **covered benefit with conditions** consistent with the criteria identified in the reimbursement determination.

HTCC Reimbursement Determination:

Limitations of Coverage

- Not covered as a part of **routine screening**
- **Testing** is covered in individuals with:
 - A disease or condition known to cause, or be caused by, Vitamin D abnormality; or
 - Radiologic or laboratory findings that are positive for markers of Vitamin D abnormality.

Non-Covered Indicators:

- N/A

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

HTCC Coverage Vote And Formal Action

Meeting materials and transcript are available on the HTA website at:
http://hta.hca.wa.gov/past_materials.html

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 agency and state utilization information. The committee concluded that the current evidence on Vitamin D Screening and Testing demonstrates that there is sufficient evidence to cover with conditions. 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 with conditions Vitamin D Screening and Testing.

Vitamin D Screening and Testing Coverage Vote:

HTCC Committee Coverage Determination Vote			
	Not Covered	Covered Unconditionally	Covered Under Certain Conditions
Vitamin D Screening and Testing	0	0	11

Discussion

The Chair called for discussion on conditions for use of Intensity Vitamin D Screening and Testing due to the majority voting for coverage with conditions. The following conditions were discussed and approved by a majority:

Limitations of Coverage

- Not covered as a part of **routine screening**
- **Testing** is covered in individuals with:
 - A disease or condition known to cause, or be caused by, Vitamin D abnormality; or
 - Radiologic or laboratory findings that are positive for markers of Vitamin D abnormality.

Action

The committee Chair directed HTA staff to prepare a Findings and Decision document on Vitamin D Screening and Testing reflective of the majority vote for final approval at the next public meeting.

The committee reviewed the evidence report for existing clinical guidelines and Centers for Medicare & Medicaid Services (CMS) decisions. CMS does not have a national coverage determination (NCD) for Vitamin D Screening and Testing.

Not officially adopted.

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.

Not officially adopted.

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Vitamin D Screening and Testing
Draft 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 Vitamin D Screening and Testing.

Category	Comment Period <i>December 7 – 21, 2012</i>	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	0	0
Professional society & advocacy organization	0	0
Total	0	0

Comments with Evidence:

No comments.

Comments without Evidence:

No comments.

Technology Assessment Timeline		
Study Stage	Date	Public Comment Days
Technology recommendations published	November 1, 2011	
Public comments due	November 15, 2011	15
Selected technologies published	November 29, 2011	
Public comments due	December 29, 2011	30
Draft Key Questions published	April 27, 2012	
Public comments due	May 14, 2012	18
Final Key Questions published	June 6, 2012	
Draft report published	August 31, 2012	
Public comments due	October 1, 2012	32

Technology Assessment Timeline

Study Stage	Date	Public Comment Days
Final report published	October 8, 2012	
Public meeting date	November 18, 2012	
Findings & decision published	December 7, 2012	
Public comments due	December 21, 2012	15