

**Proton Beam Therapy**  
*Draft Findings & Decision*  
*Timeline and Overview of Comments*

The Health Technology Assessment (HTA) program received five comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Proton Beam Therapy.

Category	Comment Period	
	June 2 – 16, 2014	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	3	1
Industry & manufacturer	1	1
Professional society & advocacy organization	1	1
<b>Total</b>	<b>5</b>	<b>3</b>

Technology Assessment Timeline		
Study Stage	Date	Public Comment Days
Technology recommendations published	November 19, 2012	
<b>Public comments due</b>	December 3, 2012	<b>15</b>
Selected technologies published	December 6, 2012	
<b>Public comments due</b>	January 7, 2013	<b>32</b>
Draft Key Questions published	September 20, 2013	
<b>Public comments due</b>	<b>October 7, 2013</b>	<b>18</b>
Final Key Questions published	November 19, 2013	
Draft report published	February 7, 2014	
<b>Public comments due</b>	<b>March 10, 2014</b>	<b>32</b>
Final report published	April 11, 2014	
Public meeting date	May 16, 2014	
Findings & decision published	June 2, 2014	
<b>Public comments due</b>	<b>June 16, 2014</b>	<b>15</b>

**Comments Submitted:**

Name			Cited Evidence
1	Michael Shevach, MD	Medical Director, Department of Radiation Oncology Olympic Medical Cancer Center	No
2	Pat Kulpa, MD, MBA	Medical Director, Regence Group-Healthcare Services	No
3	Gail Rodriguez, PhD	Executive Director, Medical Imaging & Technology Alliance	Yes
4	Laura. I. Thevenot	Chief Executive Officer, American Society for Radiation Onocology	Yes
5	Ramesh Rengan, MD, PhD	Medical Director, Seattle Cancer Care Alliance Proton Therapy Associate Professor, Department of Radiation Oncology, University of Washington, School of Medicine Associate Member, Fred Hutchinson Cancer Research Center	Yes

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

**Topic:** Proton Beam Therapy  
**Meeting Date:** May 16, 2014  
**Final Adoption:**

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)

**Number and Coverage Topic:**

20140516A – Proton Beam Therapy

**HTCC Coverage Determination:**

Proton Beam Therapy is a **covered benefit with conditions** consistent with the criteria identified in the reimbursement determination.

**HTCC Reimbursement Determination:**

**Limitations of Coverage**

Proton Beam Therapy is a **covered benefit with conditions** for:

- Ocular cancers
- Pediatric cancers (e.g., medulloblastoma, retinoblastoma, Ewing’s sarcoma)
- Central nervous system cancers (e.g. brain, spinal, paraspinal tumors)
- Other non-metastatic cancers with the following conditions:
  - Patient has had prior radiation in the expected treatment field with contraindication to all other forms of therapy, and
  - At agency discretion.

**Non-Covered Indicators**

Proton Beam Therapy is **not covered** for all other conditions.

**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*****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 Proton Beam 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 Proton Beam Therapy.

**Proton Beam Therapy**

<b>HTCC Committee Coverage Determination Vote</b>			
	<b>Not Covered</b>	<b>Covered Unconditionally</b>	<b>Covered Under Certain Conditions</b>
Proton Beam Therapy	0	0	10

***Discussion***

The Chair called for discussion of conditions of coverage for Proton Beam Therapy following the majority voting for coverage under certain conditions. Based on review of the information provided in the evidence report, in public comments and state agency utilization information, the following conditions were discussed and approved by a majority of the clinical committee:

**Limitations of Coverage**

Proton Beam Therapy is a **covered benefit with conditions** for:

- Ocular tumors
- Pediatric cancers (e.g., medulloblastoma, retinoblastoma, Ewing's sarcoma)
- Central nervous system tumors (e.g., brain, spinal and paraspinal tumors)
- Other non-metastatic cancers with the following conditions:
  - Patient has had prior radiation in the expected treatment field with contraindication to all other forms of therapy, and
  - At agency discretion.

**Non-Covered Indicators**

Proton Beam Therapy is **not covered** for all other conditions.

**Action**

The committee checked for availability of a Medicare coverage decision. CMS does not have a national coverage determination (NCD) for Proton Beam Therapy, but does have a local coverage determination (LCD). The committee considered the differences between the draft HTCC conditions for coverage and those in other policies. Differences result from the committee's determinations of where the evidence provided is sufficient to support conditional coverage.

The committee reviewed selected clinical guidelines from the National Comprehensive Cancer Network, American Society for Radiation Oncology, American College of Radiology, American Cancer Society and Alberta Health Services. The committee also reviewed training standards published by the American College of Radiology and joint publications with the American Society for Radiation Oncology and the American Association of Physicists in Medicine.

The committee Chair directed HTA staff to prepare a draft Findings and Decision document on Proton Beam Therapy 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.

**Table 1: Summary of Draft Coverage Criteria Comments**

The following table is assembled to highlight aspects of the draft coverage decision addressed in included comment letters.

HTCC DRAFT Coverage Criteria		Summary
<b>DRAFT Conditions</b>	<b>Comments With Specific Suggested Edits</b>	
<b>PROTON BEAM THERAPY is a covered benefit with the following conditions:</b>		
<ul style="list-style-type: none"> <li>• Ocular cancers</li> </ul>	<i>No comments</i>	
<ul style="list-style-type: none"> <li>• Pediatric cancers (e.g., medulloblastoma, retinoblastoma, Ewing’s sarcoma)</li> </ul>	<i>No comments</i>	
<ul style="list-style-type: none"> <li>• Central nervous system cancers (e.g., brain, spinal and paraspinal tumors)</li> </ul>	<p><i>Comment(s) 1: “This, in my judgment, should be clarified and limited to primary (meaning non-metastatic situations) non-lymphomatous/ hematologic CNS malignant tumors or, if metastatic, after conventional external beam radiation (2D, 3D, IMRT) and / or stereotactic radiosurgery have failed, in the absence of other progressive systemic metastasis.”</i></p> <p><i>Comment 2: “clarify whether this implies to both malignant and benign tumors and its intent was for both adults and pediatric population.”</i></p>	
<ul style="list-style-type: none"> <li>• Other non-metastatic cancers with the following conditions:                             <ul style="list-style-type: none"> <li>○ Patient has had prior radiation in the expected treatment field with contraindication to all other forms of therapy, and</li> <li>○ At agency discretion.</li> </ul> </li> </ul>	<i>Comments 3, 4, 5: Refer to complete comments and ASTRO model policy.</i>	
<b>Non-Covered Indicators:</b>		
Proton Beam Therapy is <b>not covered</b> for all other conditions.	<i>Comments 3, 4, 5: Refer to complete comments and ASTRO model policy.</i>	

**Table 2: Technology Assessment Center Responses to Evidence Cited in Comments on Draft Finding and Decision**

Evidence Cited In Comments	
From	ICER Response
<p>Ramesh Rengan, MD, PhD                      Medical Director, SCCA Proton Therapy                      Associate Professor UW School of Medicine                      Associate Member, Fred Hutchinson Cancer Research Center                      UW Department of Radiation Oncology</p>	
<p><b>Lung</b>                      Iwata H, Demizu Y, Fujii O, et. al. Long-term outcome of proton therapy and carbon-therapy for large (T2a-T2bN0M0) non-small-cell lung cancer. <i>J Thorac Oncol.</i> 2013; 8(6); 726-35.]</p> <p><b>Findings:</b> Outcomes study to evaluate protons and carbon ions as alternative to SBRT, which is difficult to use in T2N0M0 NSCLC patients. Local control, overall survival and progression-free survival rates after 4 years were 75%, 58% and 46%, respectively. Both ion types performed favorably. Grade 3 toxicities were only observed in 2 of 70 patients.</p>	<p><i>This was a retrospective comparative cohort study; the article was unavailable in digital archives during the original search. Its inclusion would not change the conclusions of the review, as the study involved a comparison to a modality currently unavailable in the U.S.</i></p>
<p><b>Prostate</b>                      Mendenhall NP, Hoppe BS, Nichols RC, et. al. Five-year outcomes from 3 prospective trials of image-guided proton therapy for prostate cancer. <i>Int J Radiat Oncol Biol Phys.</i> 2014; 88(3): 596-602.</p> <p><b>Findings:</b> Outcomes study of proton therapy for prostate in 3 trials (211 patients with low, intermediate and high risk prostate cancer). Rates of biochemical and clinical freedom from progression were 99% for low and intermediate risk, and 75% in high risk patients. Five-year clinical outcomes with image-guided proton therapy included extremely high efficacy, minimal physician-assessed toxicity, and excellent patient-reported outcomes.</p>	<p><i>Patients were stratified by whether prostate cancer was classified as low, intermediate, or high risk) and followed prospectively. No comparator to proton beam therapy was studied. This study would not change the conclusions of the review, as its focus was primarily on comparative evidence.</i></p>

Evidence Cited In Comments	
From	ICER Response
<p><b>Secondary Cancers</b>                      Sethi RV, Shih HA, Yeap BY, et al. Second nonocular tumors among survivors of retinoblastoma treated with contemporary photon and proton radiotherapy. <i>Cancer</i>. 2014;120:126–133</p> <p><b>Findings:</b> Retinoblastoma is highly responsive to radiation. The central objection to the use of RT, the risk of second malignancy, is based on studies of patients treated with antiquated, relatively nonconformal techniques. The current study is, to the authors’ knowledge, the first to present a series of patients treated with the most conformal of the currently available external-beam RT modalities. Although longer follow-up is necessary, the preliminary data from the current study suggest that proton RT significantly lowers the risk of RT-induced malignancy.</p> <p><b>Proposal:</b> Based upon the new data demonstrating the substantial reduction in risk of second malignancy with proton beam radiotherapy that was NOT included in the initial review (Sethi et al 2014), we would ask the committee to approve coverage for any cancer patient in who is deemed to have a substantial risk of secondary malignancy from exposure to standard photon beam radiotherapy. We would anticipate that any patient with an expected life expectancy of greater than 5 years from their current cancer diagnosis to benefit from reduction of normal tissue exposure as can be achieved with proton beam radiotherapy.</p>	<p><i>This paper <u>was</u> in fact included in the ICER review. The citation was listed as 2013 in the report because an online version of the publication was used. The citation above represents the print version, which became available in 2014, but is identical to the citation used in the report. The findings and concerns regarding the quality of this study were a central component of the discussion at the May meeting.</i></p>



**From:** Michael N. Shevach <mshevach@olympicmedical.org>  
**Sent:** Monday, June 09, 2014 9:11 AM  
**To:** HCA ST Health Tech Assessment Prog  
**Cc:** Rena B. Zimmerman; Scott Kennedy; Ken Berkes  
**Subject:** Proton beam therapy


Under "Limitations of Coverage":

"• Central nervous system tumors (e.g., brain, spinal and paraspinal tumors)"

This, in my judgment, should be clarified and limited to primary (meaning non-metastatic situations) non-lymphomatous CNS malignant tumors or, if metastatic, after conventional external beam radiation (2D, 3D, IMRT) and / or stereotactic radiosurgery have failed, in the absence of other progressive systemic metastasis.

Michael Shevach, MD  
Medical Director Department of Radiation Oncology  
Olympic Medical Cancer Center  
Sequim, WA

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**From:** Michael N. Shevach <mshevach@olympicmedical.org>  
**Sent:** Tuesday, June 10, 2014 12:16 PM  
**To:** HCA ST Health Tech Assessment Prog  
**Subject:** RE: Proton beam therapy

Thanks for your response. I need to clarify my comment. Please change “non-lymphomatous” to read “non-lymphomatous / hematologic”. “CNS” is short hand for central nervous system. Thanks.

Mike Shevach

June 16, 2014

Christine Masters  
Program Specialist  
Health Technology Assessment Program  
626 8th Avenue SE  
Olympia, WA 98501

RE: Health Technology Assessment *Proton Beam Therapy*

Dear Ms. Masters:

Regence recommends that the statement in the draft decision for the HTA *Proton Beam Therapy*: “Central nervous system tumors (e.g., brain, spinal and paraspinal tumors)” be edited **to clarify whether this implies to both malignant and benign tumors and its intent was for both adults and pediatric population.**

HTA - Decision Implementation Group

2014 Proton Beam Therapy DRAFT Decision

**Limitations of Coverage**

Proton Beam Therapy is a **covered benefit with conditions** for:


- Ocular tumors
- Pediatric cancers (e.g., medulloblastoma, retinoblastoma, Ewing’s sarcoma)
- Central nervous system tumors (e.g., brain, spinal and paraspinal tumors)
- Other non-metastatic cancers with the following conditions:
  - Patient has had prior radiation in the expected treatment field with contraindication to all other forms of therapy, and
  - At agency discretion.

**Non-Covered Indicators**

Proton Beam Therapy is **not covered** for all other conditions.

Thank you for your consideration of this request.

Sincerely,

  
Pat Kulpa MD MBA  
Medical Director  
The Regence Group-Healthcare Services



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June 16, 2014

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

Re: Draft Findings and Decision for the Health Technology Assessment program's Proton Beam Therapy technology assessment – 20140516A

Dear Director Teeter,

The Medical Imaging and Technology Alliance (MITA) is pleased to submit comments on The Draft Findings & Decision for the Health Technology Assessment program's Proton Beam Therapy (PBT) technology assessment.

As the leading trade association representing medical imaging, radiotherapy, and radiopharmaceutical manufacturers, MITA has in-depth knowledge of the significant benefits to the health of Americans that radiation therapy provides.

Proton beam therapy, a radiation therapy that uses protons rather than photons to deposit radiation energy, focuses a beam of radiation to the target tumor tissue. This technology delivers a lower dose of radiation to a patient's healthy tissue than other types of radiation therapy,<sup>1</sup> making PBT particularly important in pediatric and neurological cases.

MITA applauds the committee for recognizing the benefits of proton beam therapy and for its determination that PBT should be a covered benefit for the following conditions:

- Ocular cancer
- Pediatric cancer
- Central nervous system cancers
- Other non-metastatic cancers where
  - the patient has had prior radiation in the expected treatment field with contraindication to all other forms of therapy, and
  - at the agency's discretion

We appreciate the opportunity to comment.

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<sup>1</sup> ASTRO. Model Policies: Proton Beam Therapy (PBT). ASTRO: May 20, 2014.

As you know, PBT is not a new technology. However, there have been recent advancements with newer delivery methods referred to as scanning or intensity modulated proton therapy (IMPT). There are studies underway comparing the effectiveness of IMPT to other forms of radiation therapy and traditional scatter proton therapy.

As new evidence accumulates, we encourage you to reevaluate the conditions under which coverage for PBT applies. We strongly support coverage of proton beam therapy and specifically coverage of all other indications not specified as covered under this draft HTA when the patient is enrolled in a clinical trial and/or registry. We hope the decision's flexibility in allowing agency discretion provides a model for future HTA determinations related to radiation therapy.

Please see the attached document, the recently released American Society for Therapeutic Radiology and Oncology (ASTRO) model policy, which addresses coverage for proton beam therapy.

We appreciate your consideration on this matter and look forward to working with you in the future on this and other issues.

Sincerely,

A blue rectangular redaction box covers the signature of Gail Rodriguez. Below the box, the handwritten signature "G. Rodriguez" is partially visible.

Gail Rodriguez, Ph.D.  
Executive Director, MITA



June 16, 2014

Christine Valkyrie Masters  
Program Specialist  
Health Technology Assessment  
Washington State Health Care Authority  
P.O. Box 42712  
Olympia, WA 98504-2712

*BY ELECTRONIC SUBMISSION to [shtap@hca.wa.gov](mailto:shtap@hca.wa.gov)*

Dear Ms. Masters:

The American Society for Radiation Oncology\* (ASTRO), appreciates the opportunity to comment on the Washington State Health Care Authority (HCA) Health Technology Clinical Committee (HTCC) Draft Findings and Decision on Proton Beam Therapy (PBT), Number 20140516A.

On June 4<sup>th</sup>, ASTRO released a new Model Policy for PBT that identifies cancer diagnoses that meet ASTRO's evidence-based standards and should be covered by private insurers and Medicare. This Model Policy recommends two coverage groups for PBT: 1) patients with specific diagnoses for which PBT has been proven to be effective; and 2) patients with cancer diagnoses where there is a need for continued clinical evidence development and comparative effectiveness analyses for the appropriate use of PBT. For the patients in group two, coverage with evidence development is recommended for patients if they are enrolled in clinical trials or a multi-institutional registry to collect data and inform consensus on the role of proton therapy. The HTCC draft findings and decisions are generally in line with our PBT Model Policy. However, we recommend extending coverage for all tumors that approach or are located at the base of the skull and primary hepatocellular cancers treated in a hypofractionated regimen. In addition, ASTRO urges Washington State HCA to cover PBT for patients with difficult-to-treat, rare or highly complex cancer for which the characteristics of PBT offers advantages over other forms of treatment. We also recommend coverage with evidence development for patients with other diagnoses who are enrolled in approved clinical trials or in multi-institutional registries. The Proton Model Policy is enclosed for your review.

*\* ASTRO is the premier radiation oncology society in the world, with more than 10,000 members who are physicians, nurses, biologist, physicists, radiation therapists, dosimetrists and other health care professionals that specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, the Society is dedicated to improving patient care through professional education and training, support for clinical practice and health policy standards, advancement of science and research, and advocacy. ASTRO publishes two medical journals, International Journal of Radiation Oncology, Biology, Physics ([www.redjournal.org](http://www.redjournal.org)) and Practical Radiation Oncology ([www.practicalradonc.org](http://www.practicalradonc.org)); developed and maintains an extensive patient website, [www.rtananswers.org](http://www.rtananswers.org); and created the Radiation Oncology Institute ([www.roinstitute.com](http://www.roinstitute.com)), a non-profit foundation to support research and education efforts around the world that enhance and confirm the critical role of radiation therapy in improving cancer treatment. To learn more about ASTRO, visit [www.astro.org](http://www.astro.org).*

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

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Washington State Health Care Authority Comment Letter

June 16, 2014

Page 2

Thank you for your consideration of our comments. Should you have any questions or wish to discuss our recommendations further, please contact ASTRO's Assistant Director of Health Policy, Anne Hubbard, at (703) 839-7394 or via email at [anneh@astro.org](mailto:anneh@astro.org).

Sincerely,

A blue rectangular redaction box covers the signature of Laura I. Thevenot.

Laura I. Thevenot  
Chief Executive Officer

Enclosures: ASTRO Proton Beam Therapy Model Policy

June 16, 2014

Washington State Health Care Authority  
Health Technology Assessment  
Re: Technology Assessment of Proton Beam Radiotherapy

**Re: Public comments from the UW Department of Radiation Oncology on the “Draft Findings & Decision” for the Health Technology Assessment program’s Proton Beam Therapy (PBT) technology assessment**

Dear Sir/Madam:

We are asking the committee to reconsider its draft recommendations based on new guidelines, new evidence, and to correct a misunderstanding on whether research would be covered if not explicitly cited in the recommendations. Of note, new coverage guidelines were issued by ASTRO on May 20, 2014, and substantial new evidence has been published since the committees’ evidence review of Proton Beam Therapy (PBT). This information was not available when the committee made its initial review. Note that the decision to not address coverage for PBT while in research studies may have been based on inaccurate information.

For each of these new findings, we have proposed changes to the recommendations to address and include the new information received.

**1. New Coverage Guidelines**

On May 20, 2014, the American Society for Radiation Oncology (ASTRO) approved a new Model Policy for proton beam therapy (PBT) that details which cancer diagnoses meet ASTRO’s evidence-based standards and should be covered by private insurers and Medicare. This Model Policy supports PBT coverage for appropriate patients and identifies areas where coverage with evidence development and further research are needed.

ASTRO notes that scientific evidence exists confirming that PBT is particularly useful in a number of pediatric cancers, particularly those in the brain, as well as for certain adult cancers such as ocular melanoma. Additional research on other cancer disease sites, such as breast, prostate and lung, is ongoing with NCI-supported clinical trials currently accruing patients in all three disease sites at the more than 14 proton therapy treatment centers around the country.

**Radiation Oncology**



ASTRO's Model Policy recommends two coverage groups for PBT:

- 1) patients with specific diagnoses for which PBT has been proven to be effective; and
- 2) patients with cancer diagnoses where evidence of effectiveness of PBT is still emerging, and therefore coverage with evidence development is recommended for patients if they are enrolled in clinical trials or a multi-institutional registry to collect data and inform consensus on the role of proton therapy.

This Model Policy is consistent with ASTRO's previous statement on the use of PBT for prostate cancer, as well as ASTRO's *Choosing Wisely* list issued last September. In addition, ASTRO urges private insurers and Medicare to cover PBT for cancer patients with difficult-to-treat, rare or highly complex cases for which the characteristics of PBT offers advantages over other forms of treatment.

**Proposal:** Please consider changing the HTCC "Draft Findings and Decision" on Proton Beam Therapy to follow ASTRO's recommendation that "...coverage with evidence development is recommended for patients if they are enrolled in clinical trials or a multi-institutional registry to collect data and inform consensus on the role of proton therapy." (We have recommended new language in section 3 below.)

## 2. New Evidence Published

Substantial new evidence has been published since the committees' evidence review of Proton Beam Therapy conducted through September 2013. This evidence includes the resources and studies listed below.

### General

1. Coverage with Evidence Development Requirements Position Statement. American Society for Radiation Oncology website. <http://www.astro.org/Practice-Management/Reimbursement/Coverage-Position-Statement.aspx>. Published November 15, 2013. Accessed December 13, 2013.
2. Proton Beam Therapy for Prostate Cancer Position Statement. American Society for Radiation Oncology website. <http://www.astro.org/Practice-Management/Reimbursement/Proton-Beam-Therapy.aspx>. Published November 15, 2013. Accessed April 9, 2014.
3. Proton Beam Therapy (PBT) Model Policy. American Society for Radiation Oncology website. [https://www.astro.org/uploadedFiles/Main\\_Site/Practice\\_Management/Reimbursement/ASTRO%20PBT%20Model%20Policy%20FINAL.pdf](https://www.astro.org/uploadedFiles/Main_Site/Practice_Management/Reimbursement/ASTRO%20PBT%20Model%20Policy%20FINAL.pdf) Approved May 20, 2014.
4. Stereotactic Body Radiation Therapy (SBRT) Model Policy. American Society for Radiation Oncology website. [http://www.astro.org/uploadedFiles/Main-Site/Practice-Management/Reimbursement/2013HPCoding%20guidelines\\_SBRT\\_Final.pdf](http://www.astro.org/uploadedFiles/Main-Site/Practice-Management/Reimbursement/2013HPCoding%20guidelines_SBRT_Final.pdf). Published April 17, 2013. Accessed April 9, 2014.

5. Stereotactic Radiosurgery (SRS) Model Coverage Policy. American Society for Radiation Oncology website. <http://www.astro.org/uploadedFiles/Main-Site/Practice-Management/Reimbursement/SRSMPJuly2011.pdf>. Published July 25, 2011. Accessed April 9, 2014.

## Lung

Iwata H, Demizu Y, Fujii O, et. al. Long-term outcome of proton therapy and carbon-therapy for large (T2a-T2bN0M0) non-small-cell lung cancer. *J Thorac Oncol*. 2013; 8(6); 726-35.]

**Findings:** Outcomes study to evaluate protons and carbon ions as alternative to SBRT, which is difficult to use in T2N0M0 NSCLC patients. Local control, overall survival and progression-free survival rates after 4 years were 75%, 58% and 46%, respectively. Both ion types performed favorably. Grade 3 toxicities were only observed in 2 of 70 patients.

## Prostate

Mendenhall NP, Hoppe BS, Nichols RC, et. al. Five-year outcomes from 3 prospective trials of image-guided proton therapy for prostate cancer. *Int J Radiat Oncol Biol Phys*. 2014; 88(3): 596-602.

**Findings:** Outcomes study of proton therapy for prostate in 3 trials (211 patients with low, intermediate and high risk prostate cancer). Rates of biochemical and clinical freedom from progression were 99% for low and intermediate risk, and 75% in high risk patients. Five-year clinical outcomes with image-guided proton therapy included extremely high efficacy, minimal physician-assessed toxicity, and excellent patient-reported outcomes.

## Secondary Cancers

Sethi RV, Shih HA, Yeap BY, et al. Second nonocular tumors among survivors of retinoblastoma treated with contemporary photon and proton radiotherapy. *Cancer*. 2014;120:126–133

**Findings:** Retinoblastoma is highly responsive to radiation. The central objection to the use of RT, the risk of second malignancy, is based on studies of patients treated with antiquated, relatively nonconformal techniques. The current study is, to the authors' knowledge, the first to present a series of patients treated with the most conformal of the currently available external-beam RT modalities. Although longer follow-up is necessary, the preliminary data from the current study suggest that proton RT significantly lowers the risk of RT-induced malignancy.

**Proposal:** Based upon the new data demonstrating the substantial reduction in risk of second malignancy with proton beam radiotherapy that was NOT included in the initial review (Sethi et al 2014), we would ask the committee to approve coverage for any cancer patient in who is deemed to have a substantial risk of secondary malignancy from exposure to standard photon beam radiotherapy. We would anticipate that any patient with an expected life expectancy of greater than 5 years from their current cancer diagnosis to benefit from reduction of normal tissue exposure as can be achieved with proton beam radiotherapy.

### 3. Coverage for Evidence Collection and Submission

In light of ASTRO's recommendation to cover evidence development while enrolled in clinical trials or a registry, along with the new evidence released (see above), and more evidence expected from a multitude of ongoing with NCI-supported clinical trials, we would ask the committee to explicitly cover proton beam therapy when "undergoing treatment in the context of evidence collection/submission of outcome data" as it did with the Final Findings and Decision for Intensity Modulated Radiation Therapy (IMRT) dated November 2012.

While the committee suggested that payers would cover patients undergoing treatment in the context of evidence collection/submission on a case-by-case basis, it is our understanding that instead no coverage would be available. Instead research would fall under "Non-covered Indicators." Coverage under research was supported by HCA and Dan Lessler, the CMO of the HCA, stated in this testimony on May 16<sup>th</sup> that, "If the decision of the committee is to cover under, for one or other or a number of conditions, our recommendation would be to cover it in the context of evidence collection."

Furthermore, we understand the committee's stated position that "setting a research agenda is beyond the purview of the HTCC". We would highlight that requiring coverage for evidence collection is **NOT** setting a research agenda in any way, shape, or form. The establishment of IRB-approved prospective clinical trials in proton beam radiotherapy is then carried out by investigators who obtain scientific and full regulatory approval for this research at the sponsoring institution. Moreover, financial support for the experimental component of these trials is secured through the standard mechanisms of research funding (i.e. grant funding after competitive peer review in a study section). Payer support for costs associated with clinical treatment delivery is the established standard for technology-based clinical trials. Support of this language embedded within the ASTRO model policy by the HTCC would be consistent with this established standard.

**Proposal:** We recommend that the PBT Draft Findings and Decision be updated to explicitly address coverage of patients in clinical studies using the same language as the November 2012 IMRT recommendation. The new language would state that Proton Beam Therapy is a covered benefit with conditions for "undergoing treatment in the context of evidence collection/submission of outcome data (e.g., registry, observational study)."

Thanks again for allowing us to provide comments,



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