Washington State Health Care Authority

July 21, 2023 Meeting Materials
Health Technology Clinical Committee

Previous meeting business

Contents

☐ Meeting minutes: June 23, 2023

☐ Timeline, overview, and comments – Stereotactic body radiation therapy (SBRT)

☐ HTCC instructions for final approval of coverage decision

☐ Draft findings and decision - SBRT

Washington State Health Care Authority

Health Technology Clinical Committee

Date: June 23, 2023
Time: 7:00 a.m. – 8:30 a.m.
Location: Webinar
Adopted: Pending

Meeting materials and transcript are available on the **HTA website.**

HTCC Minutes

Members present: Clinton Daniels, DC, MS; Janna Friedly, MD, MPH; Chris Hearne, DNP, MPH; Christoph Lee, MD, MS; Sheila Rege, MD; Jonathan Sham, MD; Tony Yen, MD
Clinical expert: Simon Lo, MD

HTCC Formal Action

1. **Welcome and Chair remarks:** Dr. Friedly, co-chair, called the meeting to order and presented recap from May 19, 2023 meeting; members present constituted a quorum.
2. **HTA program updates:** Josh Morse, program director, presented HTCC meeting protocols and guidelines.
3. **Previous meeting business:**

   May 19, 2023 meeting minutes: Draft minutes reviewed. Motion made and seconded to approve the minutes as written.

   Action: Five committee members approved the May 19, 2023 meeting minutes.
4. **Stereotactic body radiation therapy continued**

   - *For Agency Medical Director presentation, vendor report, and HTCC initial voting information on SBRT, view May 19 meeting materials.*

   HTCC coverage vote and formal action:

   Committee decision

   Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee discussed and voted separately on the evidence for the use of SBRT for prostate, lung, pancreas, oligometastatic, liver, bone, renal, head and neck, adrenal, melanoma, biliary tract, Merkel cell, breast, ovarian, and cervical cancer types. The committee decided that the current evidence on SBRT for prostate, lung, pancreas, oligometastatic, liver, and biliary tract cancer types is sufficient to determine coverage with conditions. The committee considered the evidence, public comment and expert input, 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 SBRT for prostate, lung, pancreas, oligometastatic, liver, and biliary tract cancer types. Separately, the committee voted not to cover SBRT for bone, renal, head and neck, adrenal, melanoma, Merkel cell, breast, ovarian, and cervical cancer types.

	Not covered	Covered under certain conditions	Covered unconditionally
SBRT for localized prostate cancer, non-small cell lung cancer, small cell lung cancer, pancreatic adenocarcinoma, oligometastatic disease, hepatocellular carcinoma, cholangiocarcinoma	0	5	0
SBRT for bone, renal, head and neck, adrenal, melanoma, breast, Merkel cell, ovarian, and cervical cancer types	5	0	0

Discussion

The committee reviewed and discussed the available studies for use of SBRT for prostate, lung, pancreas, oligometastatic, liver, and biliary tract cancer types. Conditions for coverage were discussed and a draft was started, but not completed by the time the May 19, 2023 meeting was adjourned. On June 23, 2023, the Committee reconvened to continue their work discussing conditions for coverage and a draft was voted on. All committee members present supported the conditions of coverage of SBRT for prostate, lung, pancreas, oligometastatic, liver, and biliary tract cancer types. Details of study design, inclusion criteria, outcomes, cost, cost-effectiveness, and other factors affecting study quality were discussed as well as clinical application.

Committee's draft determination

SBRT is covered with conditions for the following:

- **Localized Prostate cancer when each of the following are met**:
    - Very low, low, and intermediate risk prostate cancer, as defined by NCCN based on stage, Gleason score, and PSA level, and
    - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Non-Small Cell Lung Cancer (NSCLC) when each of the following are met:**
    - Stage I and Stage II (node negative),
    - Tumor is deemed to be unresectable, or patient is deemed too high risk, or declines operative intervention, and
    - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Small Cell Lung Cancer (SCLC) when each of the following are met:**
    - Stage I and Stage II (node negative),
    - Tumor is deemed to be unresectable, or patient is deemed too high risk, or declines operative intervention, and

  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Pancreatic Adenocarcinoma when each of the following are met:**
  - Non-metastatic disease and is either deemed not a candidate for induction chemotherapy or has already undergone induction chemotherapy and at least one of the following:
    - Tumor is deemed to be unresectable.
    - Patient is deemed too high risk for surgery.
    - Operative intervention declined.

  AND

  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Oligometastatic disease when each of the following are met:**
  - Five or fewer total metastatic lesions (maximum 3 per organ),
  - Controlled primary tumor,
  - Life expectancy greater than 6 months, and
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Hepatocellular carcinoma when each of the following are met:**
  - Liver confined disease,
  - Five or fewer lesions,
  - Life expectancy greater than 6 months, and
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Cholangiocarcinoma when each of the following are met:**
  - Non-metastatic disease and at least one of the following:
    - Tumor is deemed to be unresectable.
    - Patient is deemed too high risk for surgery.
    - Operative intervention declined.

  AND

  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.

SBRT is not a covered benefit for treatment of the *primary* tumor of the following cancer types:

- Bone
- Renal
- Head and neck cancers
- Adrenal
- Melanoma
- Merkel Cell
- Breast
- Ovarian
- Cervical

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). Based on the information provided in the systematic review, there is no NCD for stereotactic body radiation therapy.

The committee discussed clinical guidelines identified from the following organizations:

- American Society for Radiation Oncology (ASTRO) *2022 Clinically localized prostate cancer: AUA/ASTRO guideline, part I, part II, and part III*
- Prostate Cancer Guidelines Panel, 2022 EAU - EANM - ESTRO - ESUR - ISU*P* - SIOG guidelines on prostate cancer
- American Society of Clinical Oncology (ASCO) *2021 Radiation therapy for small-cell lung cancer: ASCO guideline endorsement of an ASTRO guideline*
- Society of Interventional Radiology (SIR) *2021 Society of Interventional Radiology multidisciplinary position statement on percutaneous ablation of non-small cell lung cancer and metastatic disease to the lungs: endorsed by the Canadian Association for Interventional Radiology, the Cardiovascular and Interventional Radiological Society of Europe, and the Society of Interventional Oncology*
- European Society for Medical Oncology (ESMO), *2020 Metastatic non-small cell lung cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up and Metastatic Non-Small-Cell Lung Cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up 2020 Update*
- National Institute of Health and Care Excellence (NICE) *2018 Lung cancer: diagnosis and management*
- American Society for Radiation Oncology (ASTRO) *2019 Radiation Therapy for Pancreatic Cancer: Executive Summary of an ASTRO Clinical Practice Guideline*
- American Society for Radiation Oncology (ASTRO) *2022 External beam radiation therapy for primary liver cancers: an ASTRO clinical practice guideline*
- European Society for Medical Oncology (ESMO) *2022 Biliary tract cancer: ESMO clinical practice guideline for diagnosis, treatment and follow-up*
- European Society for Medical Oncology (ESMO) *2018 Hepatocellular carcinoma: ESMO clinical practice guidelines for diagnosis, treatment and follow-up*
- National Comprehensive Cancer Network (NCCN) *2022 Kidney Cancer, Version 3.2022*

HTA staff will prepare a findings and decision document on use of stereotactic body radiation therapy for the treatment of selected conditions for public comment to be followed by consideration for final approval at the next committee meeting.

5. Meeting adjourned

Washington State Health Care Authority

Stereotactic body radiation therapy

Draft findings and decision
Timeline, overview and comments

Timeline

Phase	Date	Public Comment Days
Proposed Topics published	June 2022	
Public comments		-
Selected technologies published	June 14	
Public comments	June 14 to July 13, 2022	**30**
Draft key questions published	July 27, 2022	
Public comments	July 27 to August 12, 2022	**17**
Final key questions published	September 21, 2022	
Draft report published	February 15, 2023	
Public comments	February 15 to March 16, 2023	**30**
Final report published	April 12, 2022	
Public meeting	May 19, 2023	
Public meeting (continued)	June 23, 2023	
Draft findings & decision published	June 30, 2023	
Public comments	June 30 to July 14, 2023	**15**

Overview

Category	Comment Period June 30 to July 14, 2023	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	3	2
Industry & manufacturer	1	0
Professional society & advocacy organization	0	0
Total	**4**	**2**

Comments

	Respondents	Representing	Cited Evidence
☐ 1.	Edward Kim	University of Washington	No
☐ 2.	Andrew Barbour	University of Washington and Fred Hutch Cancer Center	Yes
☐ 3.	Audrey Joyce	Regence Health Plans	No
☐ 4.	Peter Zaki		Yes
☐ 5.			

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: SBRT policy
Date: Friday, June 30, 2023 9:13:50 AM
Attachments: [redacted]

External Email

Hello

Thank you for distributing the draft SBRT coverage policy today.

I would like to clarify one point.

During the public hearing on 5/19/23 I recall that there was discussion that the new policy would not intending to omit indications that were covered in the 2013 policy. The previous policy included coverage for:

- CNS primary and metastatic tumors for adults and children with a KPS 50 or higher with multidisciplinary analysis (including surgical input)
- Cancers of the spine/paraspinal structures with multidisciplinary analysis (including surgical input)

These indications are not included in the new draft report. My understanding (based on panel comments from the 5/19/23 public hearing) is that the intention was to continue coverage for these indications.

Is it possible to include language specifying continued coverage for these indications in the final report to avoid any misunderstandings or unintentional coverage denials?

Best,

Edward Kim, M.D.

Associate Professor of Radiation Oncology
UWMC Radiation Oncology Medical Director | **UW Medicine**
[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: FW: Public comment open on HTCC draft findings and decision
Date: Friday, June 30, 2023 9:26:13 AM

External Email

Hello

Thank you for distributing the draft SBRT coverage policy today. I have a comment on the language of the draft policy.

Page 1 includes the text: "SBRT is not a covered benefit for treatment of bone, renal, head and neck, adrenal, melanoma, Merkel cell, breast, ovarian, and cervical cancer types."

Page 2 includes the following covered indication for SBRT:

Oligometastatic disease for:

- *When each of the following conditions are met:*
  - *Five or fewer total metastatic lesions (maximum 3 per organ)*
  - *Controlled primary tumor*
  - *Life expectancy greater than 6 months*
- *Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist*

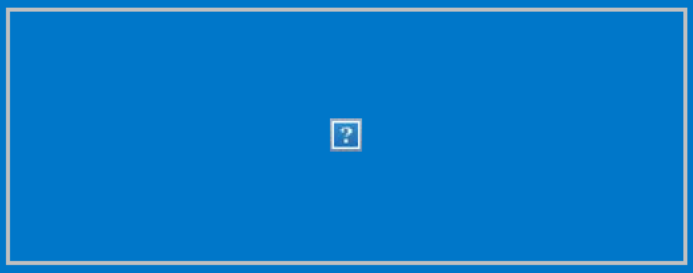
I think the language on page 1 is meant to state that SBRT is not covered for treatment of *primary* bone, renal, head and neck, adrenal, melanoma, Merkel cell, breast, ovarian and cervical cancer types. Is it possible to modify the language on page 1 to clarify this point? (i.e. "SBRT is not a covered benefit for treatment of **primary** bone, renal, head and neck, adrenal, melanoma, Merkel cell, breast, ovarian, and cervical **cancers**."

Otherwise, it is possible that a payor could interpret this to mean that a melanoma or breast cancer oligometastasis would not be covered, even if met the criteria for coverage of oligometastatic disease. Based on my review of the evidence report and discussion at the 5/19/23 public hearing, I do not believe this was the intention of the policy.

Best,

Ed Kim, M.D.
Associate Professor
Medical Director, UWMC Radiation Oncology
Univ of Washington / Seattle Cancer Care Alliance
[redacted]

From: WA - Health Technology Assessment <shtap@public.govdelivery.com>
Sent: Friday, June 30, 2023 8:37 AM
To: [redacted]
Subject: Public comment open on HTCC draft findings and decision



June 30, 2023

Public comment open on HTCC draft findings and decision.

The Health Technology Assessment (HTA) program will accept public comment on the HTCC draft findings and decision for stereotactic body radiation therapy (SBRT) until close of business, July 14, 2023.

Submit all comments to the HCA Health Technology Assessment Program.

About the Health Care Authority (HCA)

The Washington State Health Care Authority (HCA) is committed to health equity, whole-person care, and integrating physical health and behavioral health services for better results and healthier residents.

HCA purchases health care for more than 2.5 million Washington residents through Apple Health (Medicaid), the Public Employees Benefits Board (PEBB) Program, the School Employees Benefits Board (SEBB) Program, and the COFA Islander Health Care Program. As the largest health care purchaser in the state, we lead the effort to transform health care, helping ensure Washington residents have access to better health and better care at a lower cost.

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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: SBRT draft findings and decision, public comment
Date: Friday, June 30, 2023 9:38:05 AM
Attachments: [redacted]

External Email

I wanted to add one comment on the draft finding and decision for SBRT coverage.

SBRT for primary renal cell carcinoma should be 'covered under certain conditions,' instead of 'not covered.' The 'certain conditions' should include: "a patient with a T1-T2N0M0 tumor who has undergone surgical evaluation and has been deemed to be at high risk of surgical morbidity/mortality or deemed inoperable."

When looking at this patient group, the management options include surgery, invasive procedures such as radiofrequency or cryoablation, SBRT, or no treatment. As many of these patients are not candidates for anesthesia due comorbidities leading to high anesthesia risks, that leaves them with the option of SBRT or no treatment. SBRT has been shown to be highly effective and safe after 5-years of follow-up (Siva et al 2022, Lancet https://doi.org/10.1016/S1470-2045(22)00656-8), with a cumulative incidence of local failure at 5 years of 5.5% and a 1% rate of high-grade toxicity.

Failing to provide conditional coverage of SBRT for such patients removes their only treatment option, and therefore, I highly recommend the group reconsider coverage of this indication

Andrew Barbour, MD, PhD

Resident Physician
Radiation Oncology | **UW Medicine - Fred Hutch Cancer Center**
[redacted]
Pronouns | He, Him, His

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Public Comment regarding 20230623A – Stereotactic Body Radiation Therapy
Date: Friday, July 14, 2023 9:27:25 AM
Attachments: [redacted]

External Email

Good morning,

After review of the 2023 HTA draft, 20230623A – Stereotactic Body Radiation Therapy, and the existing 2013 HTA, 20121116A – Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy, and after examining implementation changes that may be needed to support the new 2023 HTA, RBS is unclear regarding the Committee's intent and scope for both the 2013 and 2023 HTAs as they relate to stereotactic radiation surgery (SRS), CNS cancers, and SBRT criteria as it applies to stage 1 inoperable NSCLC and spine, paraspinal structures, bone, and neck cancers.

Regarding SRS and CNS cancer types:

- The 2023 HTA draft determination and its associated evidence do not appear to be applicable to a coverage determination for SCS or CNS cancers per the PICO statement in the 2023 HTA Final Evidence Report which lists non-CNS tumors and included for the 2023 HTA population. Furthermore, per p. 18 of the May 19th, 2023 Meeting Minutes Transcript it appears that SBRT was the only service evaluated as part of this HTCC's re-review, and that SRS is documented as being a type of SBRT that is specific to the brain and the spinal cord and so that coverage decision [2013 HTA] included CNS tumors as well as cancers of the spine and paraspinal structures.
- However, there is documentation suggesting this 2023 HTA re-review was done with the purpose of expanding coverage for SBRT only for cancers not currently covered by the 2013 coverage decision (CNS and a subset of lung cancers), please reference p. 18 of May 19, 2023 Meeting Minutes Transcript as well as p. 306 of May 19, 2023 Meeting Materials for SBRT below.

- Clarification needed from the Committee:
    - Please confirm that SRS and CNS cancers are considered out of scope for the 2023 HTA.
        - If out of scope, is the intent of the Committee that the benefit determination specific to SBRT be referenced in the 2023 HTA and that the benefits determination specific to SRS and CNS cancers remain in effect and applicable to the 2013 HTA?
            - If yes, will the current 2013 HTA be archived and revised to reflect these changes?
            - If no, will the 2013 HTA be archived?

Regarding spine, paraspinal, bone, and neck cancers:

- The 2023 HTA draft indicates that bone and neck cancers are not a covered benefit.
- However, the 2013 HTA includes coverage for spine and paraspinal cancers. It appears that spine and paraspinal cancers were covered in the 2013 HTA due to their correlation with CNS cancers being covered per p. 18 of May 19th, 2023, Meeting Minutes Transcript, which documents that SRS is a type of SBRT that is specific to the brain and the spinal cord and so that coverage decision [2013 HTA] included CNS tumors as well as cancers of the spine and paraspinal structures. Furthermore, documentation within the HTA supporting materials that were reviewed during the public meeting held May 19, 2023, appear to suggest that this HTA re-review was done with the purpose of expanding coverage for SBRT applicable to cancers not currently covered by the 2013 coverage decision (CNS and a subset of lung cancers).

- Clarification needed from the Committee:
    - Are bone and neck cancers in scope for the 2023 HTA re-review given that the 2013 HTA covers spine and paraspinal cancers?
        - If yes, will the 2023 HTA replace to 2013 HTA?
            - If yes, will the 2013 HTA be archived or revised to reflect these changes?
            - If no, will the 2023 HTA be revised to reflect these changes?

Regarding stage 1 inoperable NSCLC:

- Both the 2023 HTA draft and the 2013 HTA document coverage determinations for stage 1 inoperable NSCLC as a covered benefit with conditions consistent with the criteria identified in the reimbursement determination, however the criteria within the respective reimbursement determinations differ. Documentation within the HTA supporting materials that were reviewed during the public meeting held May 19, 2023, appear to suggest that this HTA re-review was done with the purpose of expanding coverage for SBRT applicable to cancers not currently covered by the 2013 coverage decision (CNS and a subset of lung cancers). Furthermore, the PICO statement on p. 26 of the final evidence report lists the included population for the 2023 HTA as adults and children with non-CNS and NSCLC (inoperable, stage 1), however the PICO statement on p. 308 of the May 19, 2023, Meeting Materials for SBRT lists that the included population is adults and children with non-CNS and non-NSCLC (inoperable, stage 1).

- Clarification needed from the Committee:
    - Is stage 1 inoperable NSCLC in scope for the 2023 HTA re-review of SBRT?
        - If yes, will the 2023 HTA replace to 2013 HTA?

- If yes, will the 2013 HTA be archived or revised to reflect these changes?
- If no, will the 2023 HTA be revised to reflect these changes?

References:

- Per p. 18 of May 19, 2023 Meeting Minutes Transcript:
  - this committee reviewed SBRT back in 2012 and in that decision SBRT was covered primarily for inoperable phase one non-small cell lung cancer. This decision also covered stereotactic radiosurgery which is a type of SBRT that is specific to the brain and the spinal cord and so that coverage decision also covered CNS tumors primary and metastatic as well as cancers of the spine and paraspinal structures…. Now in 2022 to 2023 our new evidence report has more data that may suggest expanding use for coverage for different types of cancer. So we reviewed four key questions the first was is there evidence for effectiveness for SBRT and patients with cancers that are not currently covered."

- Per p. 306 of the May 19, 2023 Meeting Materials for SBRT:
  - The objective of the health technology assessment (HTA) is to evaluate the effectiveness, safety, and cost-effectiveness of SBRT in adults and children with cancers not currently covered by the 2012 coverage decision (CNS and a subset of lung cancers). This evidence review will help inform Washington's independent Health Technology Clinical Committee as the committee determines coverage regarding the use of SBRT in adults and children with cancers not currently covered."

- Per p. 26 of the Use for SBRT Final Evidence Report:
  - *Eligible Studies*

    Table 5 summarizes the study inclusion and exclusion criteria.

    Table 5. Key Study Inclusion and Exclusion Criteria for Stereotactic Body Radiation Therapy

Study Component	Inclusion	Exclusion
Populations	• Adults and children with non-CNS and NSCLC (inoperable, stage 1) malignancies where treatment by radiation therapy is appropriate	• Studies in people with noncancer conditions (e.g., trigeminal neuralgia)

- Per p. 308 of the May 19, 2023 Meeting Materials for SBRT:
  - Detailed Inclusion and Exclusion Criteria

Study Component	Inclusion	Exclusion
Populations	• Adults and children with non-CNS and non-NSCLC (inoperable, stage 1) malignancies where treatment by radiation therapy is appropriate	• Studies in people with noncancer conditions (e.g., trigeminal neuralgia)

In addition to the above, it would be greatly appreciated if the Committee could incorporate clarifying language into the 2023 HTA regarding its defined population (e.g. adults and children are in scope for this determination) and conditions excluded from this re-review and determination (e.g. non-cancerous conditions such as Trigeminal Neuralgia)

- Per . 26 of the Use for SBRT Final Evidence Report:
  - Table 5. Key Study Inclusion and Exclusion Criteria for Stereotactic Body Radiation Therapy

Study Component	Inclusion	Exclusion
Populations	• Adults and children with non-CNS and NSCLC (inoperable, stage 1) malignancies where treatment by radiation therapy is appropriate	• Studies in people with noncancer conditions (e.g., trigeminal neuralgia)

Thank you,

Audrey Joyce RN, BSN, CCM
UMP Clinical Program Manager
Regence Health Plans
[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Comments regarding HCA draft for SBRT coverage
Date: Friday, July 14, 2023 9:32:06 PM
Attachments: [redacted]

External Email

Please see attached.

Thank you,
Peter

Dear Health Technology Clinical Committee of the Washington State Health Care Authority,

My name is Peter Zaki, and I am writing to you regarding coverage for appropriate uses of Stereotactic Body Radiation Therapy. For full disclosure, I am a radiation oncology resident physician in my last year of residency at the University of Washington. The following views are my own. Since I am currently a physician trainee and do not plan to work in the state of Washington next year, I do not anticipate any potential conflict of interest. I believe those who could potentially benefit from my comments are the people of Washington which may include you. Firstly I commend the Health Care Authority (HCA) for collecting a comprehensive evidence report to guide their decision-making as well as opening the discussion to the public. There are two major improvements I recommend considering for the proposed plan.

The first potential area of improvement is expanding coverage of oligoprogressive disease under certain conditions (e.g. metastatic lung or renal cancer with ≤ 5 progressive metastases [even when the total number of metastases is > 5], multidisciplinary analysis, and life expectancy greater than 6 months). To clarify, there is a distinction between oligometastatic and oligoprogressive disease. Oligometastatic by definition means ≤ 5 total metastases while oligoprogressive means ≤ 5 progressive metastases. For instance, a patient with ≤ 5 total metastases could have both oligometastatic and oligoprogressive disease but a patient with 10 total metastases and ≤ 5 sites of progression would have oligoprogressive but not oligometastatic disease. While I agree with the HCA proposal to cover oligometastatic disease with the described conditions in the draft, I do not believe the current wording provides enough inclusion of oligoprogressive disease. I would suggest either a separate indication for oligoprogressive disease or expanding the oligometastatic indication to be more inclusive of oligoprogressive disease that does not meet oligometastatic criteria. The evidence report nicely collected sufficient studies on oligometastatic disease and included a few on both oligometastatic and oligoprogressive disease. Therefore, I will refer only to additional studies specific to patients with oligoprogressive disease. Particularly, several studies of SBRT for oligoprogressive patients with metastatic lung or renal cancer, have shown improvement in progression-free-survival and delay in the need to switch systemic therapies.[1–5] Notably, in the studies by Tsai et al and Meyer et al, about half of the patients met oligoprogressive criteria but not oligometastatic definition.[1–3] Since new oncologic drugs can cost up to about $300,000 per year, and a course of SBRT costs less than a tenth of the cost, the state and people of Washington could potentially save money by expanding coverage of SBRT for oligoprogressive disease.[6]

The second potential area of improvement is including coverage for T1-2N0M0 renal cell carcinoma with certain conditions (e.g. when there is a multidisciplinary analysis, life expectancy greater than 6 months, and the patient is either not a candidate for or declined surgery and minimally invasive procedural options). The two main studies included in the HCA evidence report were those by Siva et al and Uhlig et al.[7,8] However, the evidence report failed to mention that the paper by Siva et al found an excellent local control rate of 94.5% at 5 years with SBRT.[7] I will also highlight that only 1 of 190 patients developed grade 3 or higher SBRT-

related toxicity, supporting the safety and efficacy of SBRT.[7] Additionally, while the Uhlig et al paper reported worse 3-year overall survival (76% vs 84%, 87%, and 88%) with SBRT compared to cryoablation, thermal ablation, and partial nephrectomy, respectively, there were significant limitations to this study.[8] To name some: the retrospective non-randomized nature of the study made it prone to selection bias (i.e. patients in the SBRT group may have had worse overall health and not been fit for invasive procedures compared to patients in the other treatment groups), patients in the SBRT group, even after propensity matching, still had larger tumors and older age which we know are both negative prognostic factors in renal cancer patients,[9,10] and disease-specific parameters such as disease-specific survival, local control, or distant control were not reported. To illustrate how overall survival may be affected by a multitude of variables, another study found that patients with localized renal tumors who did not undergo treatment had a 2-year overall survival of 64% and median survival of 9 months, which was worse than the rates reported with treatment in the Uhlig study.[11] Additionally, even if all other variables were controlled and SBRT was shown to be inferior to other treatments, it would be a logical fallacy to not cover SBRT if it was still better than no treatment. In fact, in patients with localized renal cancer that do not receive treatment, tumors have on average of 0.4-1 cm growth per year, although can range from 0.1-4.74 cm per year.[12–14] As mentioned previously, having larger malignant tumors is a worse prognostic indicator, and furthermore, would increase the risk of developing vascular invasion and/or distant metastasis (up to 22% distant metastasis), thereby further compromising disease-specific survival (as low as a median of 3 months and 10% at 1 year) and overall survival (as low as a median of 6 months and 8% at 2 years).[12,14,15] For patients that are not candidates for surgery or ablation but may still benefit from treatment, physicians may still recommend or at least inform them of SBRT as a treatment option out of ethical and/or legal obligations, even if not covered by insurance. Therefore, as a result of lack of insurance coverage, patients that are financially well-off may be more likely to pursue treatment. A decision to not cover evidence-based treatment could unintentionally worsen socioeconomic disparities in cancer outcomes. Moreover, since Black Americans have worse survival compared to non-Black Americans with renal cancer, declining coverage for treatment could potentially worsen racial disparities as well.[10,16,17] I will take this moment to remind the committee that per Tables 2-3 of their evidence report, of the 786 SBRT beneficiaries from 2018 to 2021, only 15 beneficiaries had renal cancer – that is less than 2% of all SBRT beneficiaries. Therefore, by denying coverage for evidence-based treatment of renal cancer patients, the HCA has potentially very little cost-saving benefit in the short-term but potentially a lot to lose.

Thank you for the opportunity to provide comments and your consideration when finalizing your decisions.

Sincerely,
Peter Zaki, MD
Resident Physician
UW Medicine | Department of Radiation Oncology
[redacted]

References:

1. Meyer E, Pasquier D, Bernadou G, et al. Stereotactic radiation therapy in the strategy of treatment of metastatic renal cell carcinoma: A study of the Getug group. *Eur J Cancer*. 2018;98:38-47. doi:10.1016/j.ejca.2018.04.008

2. Tsai CJ, Yang JT, Guttmann DM, et al. Final Analysis of Consolidative Use of Radiotherapy to Block (CURB) Oligoprogression Trial - A Randomized Study of Stereotactic Body Radiotherapy for Oligoprogressive Metastatic Lung and Breast Cancers. *Int J Radiat Oncol*. 2022;114(5):1061. doi:10.1016/j.ijrobp.2022.09.008

3. Tsai CJ, Yang JT, Shaverdian N, et al. *Consolidative Use of Radiotherapy to Block (CURB) Oligoprogression - Randomised Study of Stereotactic Body Radiotherapy in Patients with Oligoprogressive Cancers of the Breast and Lung*. SSRN; 2023. doi:10.2139/ssrn.4477239

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Washington State Health Care Authority

HTCC final approval of coverage decision

Next step: proposed findings and decision and public comment

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

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

Next step: final determination

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

Final vote

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

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome chair will lead discussion to determine next steps.

Washington State Health Care Authority

Health Technology Clinical Committee
DRAFT Findings and Decision

Topic: Stereotactic body radiation therapy (SBRT)
Meeting date: June 23, 2023
Final adoption: Pending

Number and coverage topic:
20230623A – Stereotactic Body Radiation Therapy

HTCC coverage determination:
SBRT is a **covered benefit with conditions** for treatment of localized prostate cancer, non-small cell and small cell lung cancer, pancreatic adenocarcinoma, oligometastatic disease, hepatocellular carcinoma, and cholangiocarcinoma.

SBRT is **not a covered benefit** for treatment of bone, renal, head and neck, adrenal, melanoma, Merkel cell, breast, ovarian, and cervical cancer types.

HTCC reimbursement determination:
Limitations of coverage:

- **Localized Prostate cancer for**:
  - Very low, low, and intermediate risk prostate cancer, as defined by NCCN based on stage, Gleason score, and PSA level, and
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Non-Small Cell Lung Cancer (NSCLC) for:**
  - Stage I and Stage II (node negative), and
  - Tumor is deemed to be unresectable, or patient is deemed too high risk, or declines operative intervention, and
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Small Cell Lung Cancer (SCLC) for:**
  - Stage I and Stage II (node negative) and at least one of the following:
    - Tumor is deemed to be unresectable.
    - Patient is deemed too high risk for surgery.
  - Operative intervention declined, and
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Pancreatic Adenocarcinoma for:**
  - Non-metastatic disease and is either deemed not a candidate for induction chemotherapy or has already undergone induction chemotherapy and at least one of the following:
    - Tumor is deemed to be unresectable.
    - Patient is deemed too high risk for surgery.
    - Operative intervention declined.

  AND

  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Oligometastatic disease for:**
  - When each of the following conditions are met:
    - Five or fewer total metastatic lesions (maximum 3 per organ)
    - Controlled primary tumor
    - Life expectancy greater than 6 months
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Hepatocellular carcinoma for:**
  - When each of the following conditions are met:
    - Liver confined disease
    - Five or fewer lesions
    - Life expectancy greater than 6 months
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Cholangiocarcinoma for:**
  - Non-metastatic disease and at least one of the following:
    - Tumor is deemed to be unresectable.
    - Patient is deemed too high risk for surgery.
    - Operative intervention declined.

    AND
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.

Related documents:

- Final key questions
- Final evidence report
- Meeting materials and transcript

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public and School 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 state agency utilization information. The committee discussed and voted separately on the evidence for the use of SBRT for prostate, lung, pancreas, oligometastatic, liver, bone, renal, head and neck, adrenal, melanoma, biliary tract, Merkel cell, breast, ovarian, and cervical cancer types. The committee decided that the current evidence on SBRT for prostate, lung, pancreas, oligometastatic, liver, and biliary tract cancer types is sufficient to determine coverage with conditions. The committee considered the evidence, public comment and expert input, 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 SBRT for prostate, lung, pancreas, oligometastatic, liver, and biliary tract cancer types. Separately, the committee voted not to cover SBRT for bone, renal, head and neck, adrenal, melanoma, Merkel cell, breast, ovarian, and cervical cancer types.

	Not covered	Covered under certain conditions	Covered unconditionally
SBRT for localized prostate cancer, non-small cell lung cancer, small cell lung cancer, pancreatic adenocarcinoma, oligometastatic disease, hepatocellular carcinoma, cholangiocarcinoma	0	5	0
SBRT for bone, renal, head and neck, adrenal, melanoma, breast, Merkel cell, ovarian, and cervical cancer types	5	0	0

Discussion

The committee reviewed and discussed the available studies for use of SBRT for prostate, lung, pancreas, oligometastatic, liver, and biliary tract cancer types. Conditions for coverage were discussed and a draft was started, but not completed by the time the May 19, 2023 meeting was adjourned. On June 23, 2023, the Committee reconvened to continue their work discussing conditions for coverage and a draft was voted on. All committee members present supported the conditions of coverage of SBRT for prostate, lung, pancreas, oligometastatic, liver, and biliary tract cancer types. Details of study design, inclusion criteria, outcomes, cost, cost-effectiveness, and other factors affecting study quality were discussed as well as clinical application.

Decision

SBRT is covered with conditions for the following:

- **Localized Prostate cancer when each of the following are met**:
    - Very low, low, and intermediate risk prostate cancer, as defined by NCCN based on stage, Gleason score, and PSA level, and
    - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Non-Small Cell Lung Cancer (NSCLC) when each of the following are met:**
    - Stage I and Stage II (node negative),
    - Tumor is deemed to be unresectable, or patient is deemed too high risk, or declines operative intervention, and
    - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Small Cell Lung Cancer (SCLC) when each of the following are met:**
    - Stage I and Stage II (node negative),
    - Tumor is deemed to be unresectable, or patient is deemed too high risk, or declines operative intervention, and

  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Pancreatic Adenocarcinoma when each of the following are met:**
  - Non-metastatic disease and is either deemed not a candidate for induction chemotherapy or has already undergone induction chemotherapy and at least one of the following:
    - Tumor is deemed to be unresectable.
    - Patient is deemed too high risk for surgery.
    - Operative intervention declined.

  AND
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Oligometastatic disease when each of the following are met:**
  - Five or fewer total metastatic lesions (maximum 3 per organ),
  - Controlled primary tumor,
  - Life expectancy greater than 6 months, and
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Hepatocellular carcinoma when each of the following are met:**
  - Liver confined disease,
  - Five or fewer lesions,
  - Life expectancy greater than 6 months, and
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Cholangiocarcinoma when each of the following are met:**
  - Non-metastatic disease and at least one of the following:
    - Tumor is deemed to be unresectable.
    - Patient is deemed too high risk for surgery.
    - Operative intervention declined.

  AND
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.

SBRT is not a covered benefit for treatment of the *primary* tumor of the following cancer types:

- Bone
- Renal
- Head and neck cancers
- Adrenal
- Melanoma
- Merkel Cell
- Breast
- Ovarian
- Cervical

Action

The committee checked for availability of a Centers for Medicare and Medicaid Services (CMS) national coverage decision (NCD). Based on the information provided in the systematic review, there is no NCD for stereotactic body radiation therapy.

The committee discussed clinical guidelines identified from the following organizations:

- American Society for Radiation Oncology (ASTRO) *2022 Clinically localized prostate cancer: AUA/ASTRO guideline, part I, part II, and part III*
- Prostate Cancer Guidelines Panel, 2022 EAU - EANM - ESTRO - ESUR - ISU*P* - SIOG guidelines on prostate cancer
- American Society of Clinical Oncology (ASCO) *2021 Radiation therapy for small-cell lung cancer: ASCO guideline endorsement of an ASTRO guideline*
- Society of Interventional Radiology (SIR) *2021 Society of Interventional Radiology multidisciplinary position statement on percutaneous ablation of non-small cell lung cancer and metastatic disease to the lungs: endorsed by the Canadian Association for Interventional Radiology, the Cardiovascular and Interventional Radiological Society of Europe, and the Society of Interventional Oncology*
- European Society for Medical Oncology (ESMO), *2020 Metastatic non-small cell lung cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up and Metastatic Non-Small-Cell Lung Cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up 2020 Update*
- National Institute of Health and Care Excellence (NICE) *2018 Lung cancer: diagnosis and management*
- American Society for Radiation Oncology (ASTRO) *2019 Radiation Therapy for Pancreatic Cancer: Executive Summary of an ASTRO Clinical Practice Guideline*
- American Society for Radiation Oncology (ASTRO) *2022 External beam radiation therapy for primary liver cancers: an ASTRO clinical practice guideline*
- European Society for Medical Oncology (ESMO) *2022 Biliary tract cancer: ESMO clinical practice guideline for diagnosis, treatment and follow-up*
- European Society for Medical Oncology (ESMO) *2018 Hepatocellular carcinoma: ESMO clinical practice guidelines for diagnosis, treatment and follow-up*
- National Comprehensive Cancer Network (NCCN) *2022 Kidney Cancer, Version 3.2022*

The recommendations of the guidelines vary. The committee's determination is consistent with the noted guidelines.

HTA staff will prepare a findings and decision document on use of stereotactic body radiation therapy for the treatment of selected conditions for public comment to be followed by consideration for final approval at the next committee 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 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 Director.