Washington State Health Care Authority

November 17, 2023 Meeting Materials
Health Technology Clinical Committee

Previous meeting business

Contents

Washington State Health Care Authority

Health Technology Clinical Committee

Date: July 21, 2023
Time: 8:00 a.m. – 1:30 p.m.
Location: Webinar
Adopted: Pending

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

HTCC Minutes

Members present: John Bramhall, MD, PhD; Clinton Daniels, DC, MS; Janna Friedly, MD, MPH; Chris Hearne, DNP, MPH; Conor Kleweno, MD; Christoph Lee, MD, MS; Laurie Mischley, ND, MPH, PhD; Sheila Rege, MD; Jonathan Sham, MD; Tony Yen, MD
Clinical expert: Brian Liem, MD

HTCC Formal Action

1. **Welcome and Chair remarks:** Dr. Rege, chair, called the meeting to order; members present constituted a quorum.
2. **HTA program updates:** Josh Morse, program director, presented HTCC meeting protocols and guidelines.
3. **Hyaluronic acid/platelet-rich plasma**
   - *For Agency Medical Director presentation, vendor report, and HTCC initial voting information on HA/PRP, view July 21 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 HA and PRP for knee and hip osteoarthritis. The committee decided that the current evidence on HA and PRP for knee and hip osteoarthritis was sufficient to determine non-coverage. 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 not cover HA/PRP for knee or hip osteoarthritis.

	Not covered	Covered under certain conditions	Covered unconditionally
HA for knee osteoarthritis	9	0	0

HA for hip osteoarthritis	9	0	0
PRP for knee osteoarthritis	5	4	0
PRP for hip osteoarthritis	9	0	0

Discussion

The committee reviewed and discussed the available studies for use of HA and PRP for knee and hip osteoarthritis. Details of study design, inclusion criteria, outcomes and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that use of HA and PRP for knee and hip osteoarthritis to be unproven for being safer, more effective, or more cost-effective than comparators.

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 hyaluronic acid or platelet-rich plasma for the treatment of knee or hip osteoarthritis.

The committee discussed clinical guidelines identified from the following organizations:

- American Academy of Orthopaedic Surgeons, 2022, *Management of Osteoarthritis of the Knee (Nonarthroplasty), Third Edition*
- American College of Rheumatology (ACR), 2020, *Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee*
- Veterans Affairs/Department of Defense, 2020, *Clinical practice guideline for the non-surgical management of hip & knee osteoarthritis*
- Phillips et al., 2021, *A Systematic Review of Current Clinical Practice Guidelines on Intra-articular Hyaluronic Acid, Corticosteroid, and Platelet-Rich Plasma Injection for Knee Osteoarthritis*

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 HA/PRP for the treatment of knee and hip osteoarthritis for public comment to be followed by consideration for final approval at the next committee meeting.

4. Previous meeting business:

Vote on stereotactic body radiation therapy findings and decision:

Action: Six committee members voted on draft SBRT findings and decision with renal cancer language removed, which will be discussed further at a future HTCC meeting.

June 23, 2023 meeting minutes: Draft minutes reviewed. Motion made and seconded to approve the minutes as written.

Action: Seven committee members approved the June 23, 2023 meeting minutes.

5. Meeting adjourned

Washington State Health Care Authority

Hyaluronic acid/platelet-rich plasma

Draft findings and decision
Timeline, overview and comments

Timeline

Phase	Date	Public Comment Days
Selected technologies published	July 2022	
Public comments	July 10 to August 8, 2022	**30**
Draft key questions published	October 13, 2022	
Public comments	October 13 to 27, 2022	**15**
Final key questions published	November 29, 2022	
Draft report published	May 11, 2023	
Public comments	May 11 to June 12, 2023	**33**
Final report published	June 26, 2023	
Public meeting	July 21, 2023	
Draft findings & decision published	July 27, 2023	
Public comments	July 27 to August 10, 2023	**15**

Overview

Category	Comment Period *July 27 to August 10 2023*	Cited Evidence
Patient, relative, and citizen		
Legislator and public official		
Health care professional		
Industry & manufacturer		
Professional society & advocacy organization		
	Total **0**	

Washington State Health Care Authority

Health Technology Clinical Committee
DRAFT Findings and Decision

Topic: Hyaluronic acid (HA)/Platelet-rich plasma (PRP)
Meeting date: July 21, 2023
Final adoption: Pending

Number and coverage topic:
20230721A – Hyaluronic acid/platelet-rich plasma for knee or hip osteoarthritis

HTCC coverage determination:
HA for treatment of knee and hip osteoarthritis is **not a covered benefit**

PRP for treatment of knee and hip osteoarthritis is **not a covered benefit**

HTCC reimbursement determination:
Limitations of coverage: N/A

Non-covered indicators: N/A

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 HA and PRP for knee and hip osteoarthritis. The committee decided that the current evidence on HA and PRP for knee and hip osteoarthritis was sufficient to determine non-coverage. 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 not cover HA/PRP for knee or hip osteoarthritis.

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PRP for hip osteoarthritis	9	0	0

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Action

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- Veterans Affairs/Department of Defense, 2020, *Clinical practice guideline for the non-surgical management of hip & knee osteoarthritis*
- Phillips et al., 2021, *A Systematic Review of Current Clinical Practice Guidelines on Intra-articular Hyaluronic Acid, Corticosteroid, and Platelet-Rich Plasma Injection for Knee Osteoarthritis*

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 HA/PRP for the treatment of knee and hip osteoarthritis 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.

Washington State Health Care Authority

Stereotactic body radiation therapy

Draft findings and decision
Overview and comments

Comments received on SBRT for renal cancer draft findings and decision

	Respondents	Representing	Cited Evidence
1.	Andrew Barbour	University of Washington and Fred Hutch Cancer Center	Yes
2.	Patrick Zaki		Yes

Summary of above comments:

Takeaway:

- Studies cited related to SBRT: Siva et al. 2022, Uhlig et al. 2023. Other studies cited in Zaki comments were not related to SBRT.
- Both studies cited in comments were already addressed in the evidence report and presentation. Therefore, no new evidence was presented in the received comments. *We identified 1 eligible comparative study and 1 noncomparative study reporting on the use SBRT in renal cell carcinoma (From report).*
    - Siva et al. 2022
        - is a small study that looks only at patients who received SBRT. There is no control group, it is not a comparative study. Thus the study was included in the evidence report looking at harms, but not at effectiveness of SBRT/SABR.
        - *We assessed the noncomparative study as being at high risk-of-bias because of the lack of a comparator of interest.*
    - Uhlig et al. 2023
        - *We assessed the comparative study to be at low risk-of-bias as it was a complex analytic study using data from large, national databases.*

Table 15. Summary Study Characteristics of Comparative Studies in Renal Cancer

Citation Setting NCT or Other Trial ID	Duration Risk-of-bias	Patient Characteristics	Description of Intervention	Description of Comparator(s)
Uhlig et al., 2020[180] National Cancer Database (2004 to 2015) NR	Retrospective database analysis (propensity-matched) Median follow-up of 58 months Low risk-of-bias	Total N = 91,965 people with stage I RCC, comprising 174 in SBRT group, 3,432 in RFA group, 5,446 in CA group, and 82,913 in PN group	• SBRT ○ Median dose of 40 Gy (IQR, 32 to 48) in median of 3 fractions (IQR, 2 to 4)	• RFA • CA • PN

Abbreviations. CA: cryoablation; Gy: Gray; PN: partial nephrectomy; RCC: renal cell carcinoma; RFA: radiofrequency ablation; SBRT: stereotactic body radiation therapy.

Table 16. Summary Study Characteristics of Noncomparative Studies in Renal Cancer

Citation Setting NCT or Other Trial ID	Study Design and Duration Risk-of-bias	Patient Characteristics	Description of Intervention
Siva et al., 2022[181] 12 sites in 5 countries NR	Retrospective and prospective data analysis Minimum of 2 years follow-up High risk-of-bias	Total N = 190 people with primary renal cell carcinoma	• SBRT ○ Single or multiple fractions of greater than 5 Gy

Abbreviations. Gy: Gray; NR: not reported; SBRT: stereotactic body radiation therapy

Slide from OHSU CEbP presentation:

Renal Cell Carcinoma

- Based on the studies included in this review, we conclude that SBRT:
  - May be less effective than ablation (RFA, microwave, or cryoablation) or surgery for stage 1 renal cell carcinoma (low CoE, based on 1 comparative NRS)
  - May be more effective than chemotherapy or intensity-modulated radiation therapy for stage 1 renal cell carcinoma (low CoE, based on 1 comparative NRS)
- No economic evidence identified

Next steps:

- Discuss and vote based on these comments with the understanding that cited evidence was previously considered by the committee during the initial 5/19/23 meeting on SBRT.

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: 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

4. Ramadan S, Quan K, Schnarr K, et al. Impact of stereotactic body radiotherapy (SBRT) in oligoprogressive metastatic disease. *Acta Oncol*. 2022;61(6):705-713. doi:10.1080/0284186X.2022.2063067

5. Cheung P, Patel S, North SA, et al. Stereotactic Radiotherapy for Oligoprogression in Metastatic Renal Cell Cancer Patients Receiving Tyrosine Kinase Inhibitor Therapy: A Phase 2 Prospective Multicenter Study. *Eur Urol*. 2021;80(6):693-700. doi:10.1016/j.eururo.2021.07.026

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9. Brookman-Amissah S, Kendel F, Spivak I, et al. Impact of clinical variables on predicting disease-free survival of patients with surgically resected renal cell carcinoma. *BJU Int*. 2009;103(10):1375-1380. doi:10.1111/j.1464-410X.2008.08233.x

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11. Lamb GWA, Bromwich EJ, Vasey P, Aitchison M. Management of renal masses in patients medically unsuitable for nephrectomy—natural history, complications, and outcome. *Urology*. 2004;64(5):909-913. doi:10.1016/j.urology.2004.05.039

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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.

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.