Washington State Health Care Authority

February 16, 2024 Meeting Materials
Health Technology Clinical Committee

Previous meeting business

Contents

Washington State Health Care Authority

Health Technology Clinical Committee

Date: November 17, 2023
Time: 9:00 a.m. – 4:00 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: Joseph Strunk, 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, and an overview of the HTA program.
3. **Previous meeting business:**

   July 21, 2023 meeting minutes: Draft minutes reviewed. Motion made and seconded to approve the minutes as written.

   Action: Nine committee members approved the July 21, 2023 meeting minutes.

   Vote on hyaluronic acid/platelet-rich plasma findings and decision:

   Action: Nine committee members voted on draft HA/PRP findings and decision.

   Vote on stereotactic body radiation therapy for renal cancer findings and decision:

   Action: Six committee members voted on draft SBRT for renal cancer findings and decision.

4. **Spinal cord stimulation**

   Washington State agency utilization and outcomes: Christopher Chen, MD, MBA Medical Director for Medicaid, Health Care Authority, presented the state agency perspective on spinal cord stimulation. Find the full presentation published with the November 17 meeting materials.

   Scheduled and open public comments: Chair called for public comments. Comments were provided by:

   - Julie Pilitsis, MD – President of North American Neuromodulation Society (NANS)
   - Christopher Gharibo, MD – WASIPP/ASIPP (American Society of Interventional Pain Physicians)

- Nilesh Patel, MD – Boston Scientific, Inc. representing manufacturer's group (Medtronic, Saluda Medical, Nevro Corporation, and Abbott)
- Washington State Physicians SCS Workgroup, represented by:
  - Steven Stanos, DO – Executive Medical Director of Rehabilitation and Performance Medicine Swedish Providence Medical Center; Seattle, WA
  - Brett Stacey, MD – Professor; University of Washington; Seattle, WA
  - Fangfang Xing, MD – Swedish Providence Medical Center; Seattle, WA
- Cindy Steinberg – U.S. Pain Foundation

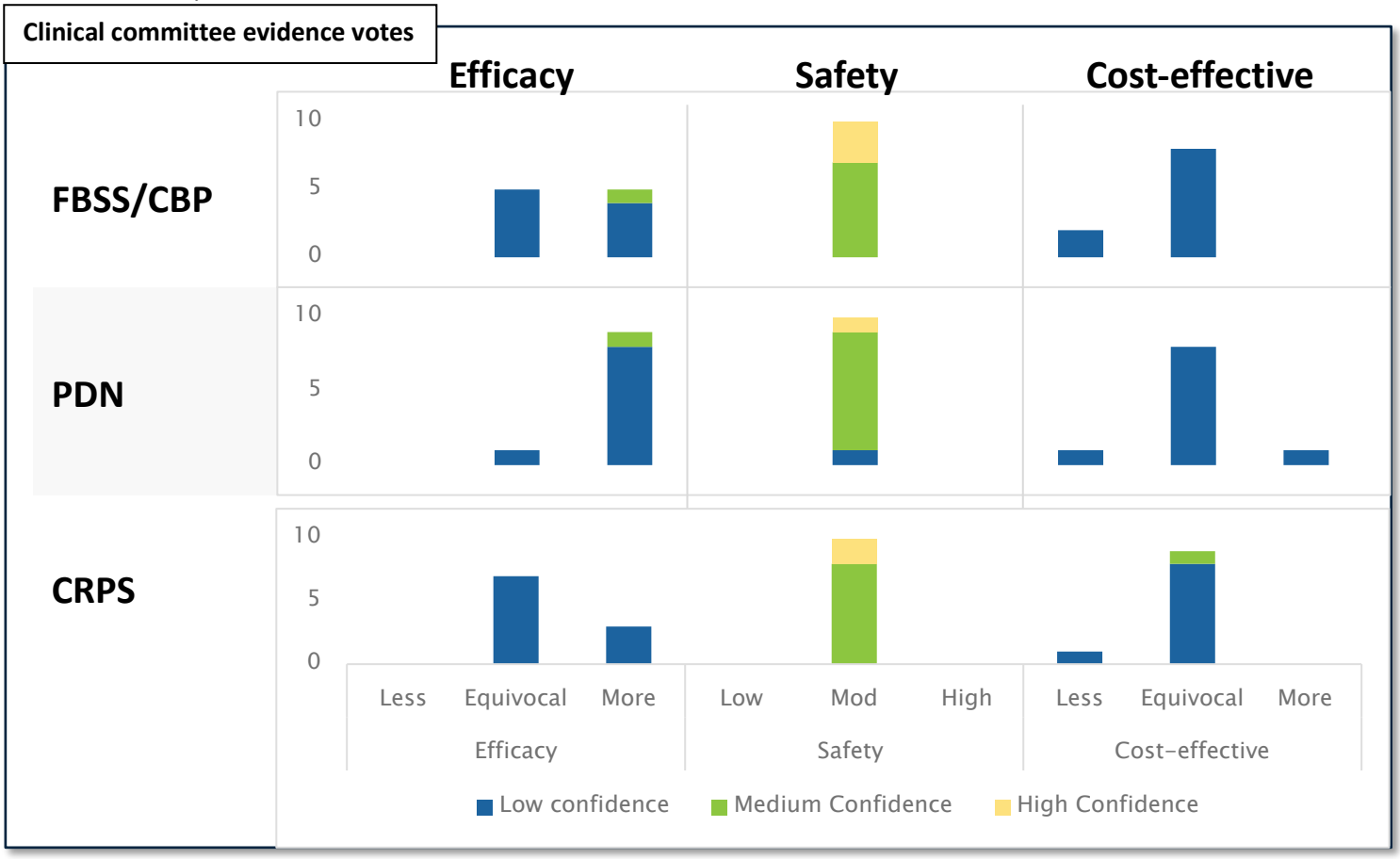
Vendor report/HTCC questions and answers: Andrea Skelly, PhD, MPH Aggregate Analytics, presented the evidence review for spinal cord stimulation. The full presentation is published with the November 17 meeting materials.

HTCC discussion and action:

Discussion

The committee began their review and discuss of available studies for use of SCS for chronic back pain, complex regional pain syndrome (CRPS), and painful diabetic neuropathy (PDN). Committee deliberation included straw poll voting on the evidence using the Decision Aid. The meeting concluded at this point based on time. The agency medical directors were directed to develop draft coverage criteria for consideration and further discussion by the committee at the next HTCC meeting. Coverage on SCS for each condition was discussed, but a formal vote and draft coverage criteria were not completed by the time the meeting was adjourned. Below is the breakdown of the committee's evidence votes for safety, efficacy, and cost effectiveness for each condition:

Clinical committee evidence votes



Action
The committee chair directed HTA staff to establish a follow up meeting and for agency medical directors to develop potential draft coverage criteria to continue discussion on SCS and produce draft findings and decision.

5. Meeting adjourned

Washington State Health Care Authority

Stereotactic body radiation therapy for renal cancer

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 **Public meeting (continued)**	May 19, 2023 June 23, 2023	
Public vote on SBRT for renal	November 17, 2024	
Draft findings & decision on SBRT for renal published	December 14, 2023	
Public comments	December 14 to 27, 2023	**14**

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	0	0
Industry & manufacturer	1	0
Professional society & advocacy organization	0	0
Total	**1**	**0**

Comments

	Respondents	Representing	Cited Evidence
☐ 1.	Audrey Joyce	Regence Blue Sheild	No

From: Joyce, Audrey <[redacted]>
Sent: Friday, January 5, 2024 7:25 AM
To: Nichols, Tonja (HCA)[redacted]
Subject: Please Prioritize_SBRT HTCC implementation compromised
Importance: High

External Email

Good morning Tonja,

I noticed that there is a new draft version of the Stereotactic Body Radiation Therapy HTCC out with edits made to reflect inclusion of the renal cancer criteria without the HTCC ID number being changed. It is crucial that the new draft's HTCC ID number be changed from the original published HTCC's number to mitigate member and provider abrasion as well as confusion for all who work with or rely on HTCCs. Without changing ID numbers for these two HTCCs that have different criteria, HCA and RBS' noncompliance with RCW 70.14.120 is imminent.

Please see attached email for explicit details and prior discussion on this topic in which HCA confirmed a different ID number would be applied to the new HTCC.

Origianl HTCC:

Washington State Health Care Authority

Health Technology Clinical Committee
Final Findings and Decision

Topic: Stereotactic body radiation therapy (SBRT)
Meeting date: June 23, 2023
Final adoption: July 21, 2023

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

New draft HTCC:

Washington State Health Care Authority

Health Technology Clinical Committee
Draft Final Findings and Decision

Topic: Stereotactic body radiation therapy (SBRT)
Meeting date: November 17, 2023
Final adoption: Pending

(highlighted text that is underlined indicates added text, strikethrough ~~removed text~~)

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

Thank you,

Audrey Joyce

Audrey Joyce RN, BSN, CCM
UMP Clinical Programs Manager
Regence Blue Shield
[redacted]
Regence

Upcoming PTO:
Upcoming Holidays:

Washington State Health Care Authority

Health Technology Clinical Committee
Draft Final Findings and Decision

Topic: Stereotactic body radiation therapy (SBRT)
Meeting date: November 17, 2023
Final adoption: Pending

(highlighted text that is underlined indicates added text, strikethrough ~~removed text~~)

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, renal cancer, pancreatic adenocarcinoma, oligometastatic disease, hepatocellular carcinoma, and cholangiocarcinoma.

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

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.
- **Renal cancer**
  - 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*

  *For meeting information on renal cancer decision, see November 17, 2023

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, renal, 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.

Note on final decision: renal cancer was originally excluded from the determination completed at the June 23, 2023 meeting. Based on consideration of comments received prior to the final vote, the committee deferred a final decision on coverage for renal cancer until their November 17 meeting.

June 23, 2023 vote

	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, head and neck, adrenal, melanoma, breast, Merkel cell, ovarian, and cervical cancer types	5	0	0

November 17, 2023 vote on renal cancer

	Not covered	Covered under certain conditions	Covered unconditionally
SBRT for renal cancer	2	4	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. On November 17, 2023, members present at both previous SBRT meetings discussed and voted on a draft findings and decision exclusive to SBRT for renal cancer. A majority of members supported the conditions of coverage of SBRT for renal cancer. 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.
  - Evaluation includes multidisciplinary team analysis (e.g., tumor board) including a surgical specialist and radiation oncologist.
- **Renal cancer**
  - 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.
  - 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
- 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.