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RE: Washington State Healthcare Authority Medical SBRT Policy

Dear Dr. Zerzan,

The American Society for Radiation Oncology (ASTRO)<sup>1</sup> appreciates the opportunity to comment on the Washington State Health Care Authority Health Technology Assessment report on Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT), last reviewed in 2017. ASTRO is concerned with the limitations outlined in the SRS and SBRT policy.

Currently, SBRT is only covered for cancers of the spine/paraspinal structures or inoperable non-small cell lung cancer, stage 1. All other indications are deemed non-covered. This policy is not in line with current data, best practices, or the ASTRO SBRT Model Policy, which we have attached for your review. The state of Washington's Medicaid patient population is disproportionately represented by patients who are black, indigenous and people of color. Given that these populations experience healthcare disparities, including access to adequate, high-quality care, at higher rates, it is critical that Washington state revise its policy to ensure access to SBRT.

**Indications for SBRT**

ASTRO respectfully disagrees with the current limited indications listed in the Washington State SBRT policy. In our opinion, there is sufficient evidence supporting coverage of extended disease sites. In support of our request for coverage, we offer the following comments and references:

**A. Primary Liver cancer**

Tse and colleagues at the Princess Margaret Hospital treated 41 patients with unresectable hepatocellular carcinoma (HCC) or intrahepatic

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<sup>1</sup> *ASTRO members are medical professionals, who practice at hospitals and cancer treatment centers in the United States and around the globe and make up the radiation therapy treatment teams that are critical in the fight against cancer. These teams often include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers, and treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.*

cholangiocarcinoma (IHC), with SBRT using a dose determined by normal tissue tolerance in adjacent normal liver (median dose, 36.0 Gy)<sup>A1</sup>. No radiation-induced liver disease or treatment-related grade 4/5 toxicity was seen. Median survival of HCC and IHC patients was 11.7 months, which compares favorably with what would be expected to be achieved using more toxic, prolonged regimens.

In more recent studies, meta-analyses of HCC patients receiving SBRT show that both local control (LC) and overall survival (OS) rates are comparable to that of radiofrequency ablation (RFA) or liver resection. Dobrzycka and colleagues reported mean OS rates of 90.9% in Year 1, 67.4% in Year 2, and 73.3% in Year 3 of their meta-analyses that included 16 studies with 973 patients. Mean local control was reported at 94.1% in Year 1, 92.2% in Year 2, and 93.7% in Year 3<sup>A2</sup>. A separate analysis of 32 studies encompassing 1,950 patients pooled results of 1-year, 2-year, and 3-year LC rates were 85.7%, 83.6%, and 83.9%, respectively, and grade  $\geq 3$  complication rates were 4.7% for hepatic and 3.9% for GI<sup>A3</sup>. This demonstrates SBRT as a safe and effective option for treating unresectable HCC offering high LC and OS.

Andolino and colleagues reported a median overall survival of 20.4 months for 37 patients who received SBRT for HCC but did not subsequently proceed to orthotopic liver transplant<sup>A4</sup>. Controlling for the 23 patients who did undergo a transplant, the study found a 90% rate of 2-year local control, favorable to other forms of treatment such as trans arterial chemoembolization and percutaneous ethanol injections. No grade 3 or higher nonhematologic toxicities were reported. **Thus, we believe that SBRT as used in these studies is medically necessary therapy for non-metastatic, unresectable HCC or IHC.**

#### References:

- A1. Tse RV, Hawkins M, Lockwood G, et al. Phase I study of individualized stereotactic body radiotherapy for hepatocellular carcinoma and intrahepatic cholangiocarcinoma. *J Clin Oncol*. 2008. 26(4):657-64.
- A2. M. Dobrzycka, P. Spsychalski, O. Rostkowska, M. Wilczyński, P. Kobiela, M. Grąt, V. Dell'Acqua, M. Høyer & B. A. Jereczek-Fossa (2019) Stereotactic body radiation therapy for early-stage hepatocellular carcinoma – a systematic review on outcome, *Acta Oncologica*, 58:12, 1706-1713
- A3. Chai Hong Rim, Hyun Ju Kim, Jinsil Seong, Clinical feasibility and efficacy of stereotactic body radiotherapy for hepatocellular carcinoma: A systematic review and meta-analysis of observational studies, *Radiotherapy and Oncology*, Volume 131, 2019, Pages 135-144, ISSN 0167-8140
- A4. Andolino DL, Johnson CS, Maluccio M, et al. Stereotactic Body Radiotherapy for Primary Hepatocellular Carcinoma. *Int J Radiat Oncol Biol Phys*. 2011. 81(4): e447-e453.

#### Liver metastases

In a peer-reviewed prospective study, Rusthoven and colleagues treated patients with one to three hepatic lesions and maximum individual tumor diameters less than 6 cm with SBRT (36 Gy to 60 Gy in 3 fractions)<sup>A3</sup>. Forty-seven patients with 63 lesions were treated. Among them, 69% had received at least one prior systemic therapy regimen for metastatic disease (range, 0 to 5 regimens), and 45% had extrahepatic disease at study entry. Only one patient experienced grade 3 or higher toxicity (2%). Actuarial in-field local control rates at one and two years after SBRT were 95% and 92%, respectively. Among lesions with maximal diameter of 3 cm or less, 2-year local control was 100%. Median survival was 20.5 months.

Goodman and colleagues achieved similar results using a single fraction SBRT approach <sup>A4</sup>. **Thus, we believe that SBRT as used in these studies is medically necessary therapy for patients with excellent performance status (Karnofsky Performance Status Scale >70) and limited (1-3) liver metastases.**

References:

- A3. Rusthoven KE, Kavanagh BD, Cardenes H, et al. multi-institutional phase I/II trial of stereotactic body radiation therapy for liver metastases. *J Clin Oncol*. 2009. 27(10): 1572-8.
- A4. Goodman KA, Wiegner EA, Maturen KE, et al. Dose-escalation study of single-fraction stereotactic body radiotherapy for liver malignancies. *Int J Radiat Oncol Biol Phys*. 2010. 78(2):486-93.

## B. Pancreatic Cancer

The following table includes a summary of four recent peer-reviewed studies in which SBRT, either single or multiple fractions, has been used to treat patients with unresectable pancreas cancer. The use of SBRT did not appear to compromise the administration of systemic chemotherapy. Furthermore, the overall survival results achieved for this extremely challenging clinical situation are as good or better than what is commonly achieved in studies involving more toxic conventionally fractionated radiotherapy.

**Thus, we believe that SBRT as used in these studies is medically necessary therapy for non-metastatic, unresectable pancreas cancer:**

	N	Selection	SBRT dose to PTV	Chemo	Grade 3+ late toxicity	1 yr OS
<b>Chang</b> <sup>B1</sup>	77	Unresectable Med. Inoperable Locally recurrent Max 7.5 cm	25 Gy x 1	GEM-based	10%	21%
<b>Rwigema</b> <sup>B2</sup>	71	Unresectable	24 Gy x 1	GEM +/- erlotinib	4%	41%
<b>Mahadevan</b> <sup>B3</sup>	36	Unresectable	8-12 Gy x 3	GEM x 6 mos	14%	61%
<b>Polistina</b> <sup>B4</sup>	23	Unresectable	10 Gy x 3	GEM pre- and post	0%	39%

References:

- B1. Chang DT, Schellenberg D, Shen J, et al. Stereotactic radiotherapy for unresectable adenocarcinoma of the pancreas. *Cancer*. 2009; 115(3):665-72.
- B2. Rwigema JC, Parikh SD, Heron DE, et al. Stereotactic Body Radiotherapy in the Treatment of Advanced Adenocarcinoma of the Pancreas. *Am J Clin Oncol*. 2011; 34(1): 63-9.
- B3. Mahadevan A, Jain S, Goldstein M, et al. Stereotactic Body Radiotherapy and Gemcitabine for Locally Advanced Pancreatic Cancer. *Int J Radiat Oncol Biol Phys*. 2010; 78(3): 735-42.
- B4. Polistina F, Costantin G, Casamassima F, et al. Unresectable Locally Advanced Pancreatic Cancer: A Multimodal Treatment Using Neoadjuvant Chemoradiotherapy (Gemcitabine Plus Stereotactic Radiosurgery) and Subsequent Surgical Exploration. *Ann Surg Oncol*. 2010; 17(8):2092–101.

### C. Kidney Cancer

ASTRO believes the 2012 systematic review completed by Siva and colleagues stands as sufficient proof to the efficacy and therapeutic benefit of stereotactic radiotherapy for renal neoplasms <sup>C1</sup>. With findings of 93.9% weighted local control and less than 4% rate of grade 3 or higher adverse events for a total of 126 patients, we believe this evidence contradicts the draft policy statement that “no impact on patient outcomes can be derived from these data”.

The Karolinska group, reported both retrospective and prospective phase II trials, achieving 90% and 98% local control in 162 and 82 lesions respectively <sup>C2</sup>. Additionally, in 2018, the International Radiosurgery Oncology Consortium for Kidney published the results of a pooled analysis of 223 patients showing 4-year local control, cancer-specific survival, and progression-free survival rates of 97.8%, 91.9%, and 65.4%, respectively with an acceptable impact on renal function <sup>C3</sup>. Based on the results of this study, the Japanese Ministry of Health approved SBRT for primary renal cell carcinoma for all Japanese citizens. A more up-to-date systematic review on SBRT for primary renal cell carcinoma showed the same conclusions<sup>C4</sup>. **Thus, with high levels of local control and acceptable levels of toxicity, we believe that SBRT as used in these studies is medically necessary therapy for neoplasms of the kidney.**

#### References:

- C1. Siva S, Pham D, Gills S, et al. A systematic review of stereotactic radiotherapy ablation for primary renal cell carcinomas. *BJU Int.* 2012; 110(11PtB): E737-43.
- C2. Teh BS, Ishiyama H, Mathews T, et al. Stereotactic Body Radiation Therapy (SBRT) for Genitourinary Malignancies. *Discov Med.* 2010; 10(52):255-62.
- C3. Siva S, Louie AV, Warner A, et al. Pooled analysis of stereotactic ablative radiotherapy for primary renal cell carcinoma: A report from the International Radiosurgery Oncology Consortium for Kidney (IROCK). *Cancer* 2018; 124(5):934-942. doi: 10.1002/cncr.31156. Epub 2017 Dec 20.
- C4. Correa RJM, Louie AV, Zaorsky NG, et al. The Emerging Role of Stereotactic Ablative Radiotherapy for Primary Renal Cell Carcinoma: A Systematic Review and Meta-Analysis *Eur Urol Focus.* 2019 Nov;5(6):958-969. doi: 10.1016/j.euf.2019.06.002. Epub 2019 Jun 24.PMID: 31248849

### D. Adrenal Gland

In the analysis of 34 patients with 36 adrenal metastatic lesions treated with SBRT, median survival was 22 months with actuarial local control rates of 66% at one-year <sup>D1</sup>. Another recent study found a crude local control rate of 100% with no cases of local or marginal failure for 12 of the 13 patients who were evaluable <sup>D2</sup>. While the number of patients included in this analysis may not be overwhelming, we believe the clinical outcomes reported illustrate a good therapeutic treatment option for a relatively uncommon malignancy. **Thus, we believe that SBRT as used in these studies is medically necessary therapy for patients with cancer of the adrenal gland.**

#### References:

- D1. Scorsetti M, Alongi F, Filippi AR, et al. Long-term local control achieved after hypo fractionated stereotactic body radiotherapy for adrenal gland metastases: a retrospective analysis of 34 patients. *Acta Oncol.* 2012; 51(5): 618-23.
- D2. Ahmed KA, Barney BM, Macdonald OK, et al. Stereotactic Body Radiotherapy in the Treatment of Adrenal Metastases. *Am J Clin Oncol.* 2012 Jul 9; [Epub ahead of print].

E. Prostate

The publication of clinical studies, particularly those presenting long term outcome data, demonstrates the efficacy and safety of treating prostate cancer with SBRT. An abstract from the SHARP (Stereotactic Hypofractionated Accurate Radiotherapy of the Prostate) trial provides an update on the original feasibility and toxicity. Pham and colleagues found an overall 5-year (nadir + 2ng/ML) biochemical relapse free survival rate of 93% and only 2.5% grade three late genitourinary toxicity for a total of forty patients <sup>E1</sup>. Freeman also reported a 93% rate of biochemical progression-free survival at a medium follow-up of five years <sup>E2</sup>. The following table summarizes findings from this and other studies that shows excellent biochemical control rates with very low rates of serious toxicity. **Thus, we believe that SBRT is an appropriate alternative for select patients with low to intermediate risk prostate cancer.**

	N	Selection	SBRT dose	Grade 3+ late toxicity	Biochemical progression-free survival	Median Follow-up
<b>Freeman</b> <sup>E2</sup>	41	Low-risk	35-36.26 Gy x 5	0%	93%	60 months
<b>King</b> <sup>E3</sup>	67	Low-risk	36.25 Gy x 5	3%	94% (PSA relapse-free)	32 months
<b>Madsen</b> <sup>E4</sup>	40	Low-risk	33.5 Gy x 5	0%	90%	41 months
<b>Katz</b> <sup>E5</sup>	50; 254	Low, intermediate and high-risk	35 Gy x 5; 36.25 Gy x 5	0%; 0.5%	Low (99%), Int (100%), High (83%)	30; 17 months

## References:

- E1. Pham HT, Song G, Bradiazamani K, et al. Five-year Outcome of Stereotactic Hypofractionated Accurate Radiotherapy of the Prostate (SHARP) for Patients with Low-risk Prostate Cancer. [ASTRO Abstract 122]. *Int J Radiat Oncol Biol Phys.* 2010; 78(suppl): S58.
- E2. Freeman DF, King CR. Stereotactic body radiation for low-risk prostate cancer: five-year outcomes. *Radiat Oncol.* 2011; 6:3.
- E3. King CR, Brooks JD, Gill H, et al. Long-term outcomes from a prospective trial of stereotactic body radiotherapy for low-risk prostate cancer. *Int J Radiat Oncol Biol Phys.* 2012; 82(2); 877-882.
- E4. Madsen BL, Hsi RA, Pham HT, et al. Stereotactic hypofractionated accurate radiotherapy of the prostate (SHARP), 33.5 Gy in five fractions for localized disease: first clinical trial results. *Int J Radiat Oncol Biol Phys.* 2007; 67(4): 1099-1105.
- E5. Katz AJ, Santoro M, Ashley R, et al. Stereotactic body radiotherapy for organ-confined prostate cancer. *BMC Urol.* 2010; 10(1): 1 (doi:10.1186/1471-2490-10-1).

F. Oligometastases

Recent published data supports the conclusion that there exists a subset of patients with a controllable, potentially curable, state of distant cancerous spread for which treatment with SBRT is appropriate. The SABR-COMET trial study assessed the impact of SBRT on overall survival and progression-free survival in patients with a controlled primary tumor and 1-5 metastatic lesions. Both overall survival (OS) and progression-free survival (PFS) rates (42.3% and 17.3%, respectively) were significantly greater in patients that received SBRT treatment compared to those who received palliative standard-of-care treatments (17.7% and PFS rate not reached, respectively) <sup>F1</sup>.

Recent studies show that in patients with oligometastatic non-small cell lung cancer (NCSLC), consolidative SBRT increased both PFS and OS relative to maintenance therapy or observation. PFS

nearly tripled in patients with limited metastatic NSCLC who received consolidative SBRT prior to maintenance chemotherapy, compared with those who received maintenance chemotherapy alone. There was also no observed difference in toxicity<sup>F2, F3</sup>.

Clinical trial data supports the use of SBRT in metastatic renal cell carcinoma patients. Local control of metastatic renal cell carcinoma tumors was high and SBRT extended the duration of the ongoing systemic therapy for patients without undermining quality of life. The use of stereotactic radiotherapy in metastatic kidney cancer delayed the need to change systemic therapies for a median of 1 year and could allow sustained systemic therapy breaks for select patients with oligometastatic kidney cancer<sup>F4, F5, F6</sup>. **Thus, we believe that SBRT is an appropriate alternative for select patients with five or fewer oligometastases and with good clinical performance status.**

References:

- F1. Palma, David A et al. "Stereotactic Ablative Radiotherapy for the Comprehensive Treatment of Oligometastatic Cancers: Long-Term Results of the SABR-COMET Phase II Randomized Trial." *Journal of clinical oncology: official journal of the American Society of Clinical Oncology* vol. 38,25 (2020): 2830-2838.
- F2. Iyengar P, Wardak Z, Gerber DE, et al. Consolidative Radiotherapy for Limited Metastatic Non-Small-Cell Lung Cancer: A Phase 2 Randomized Clinical Trial. *JAMA Oncol.* 2018;4(1):e173501.
- F3. Gomez DR, Tang C, Zhang J, et al. Local Consolidative Therapy Vs. Maintenance Therapy or Observation for Patients With Oligometastatic Non-Small-Cell Lung Cancer: Long-Term Results of a Multi-Institutional, Phase II, Randomized Study. *J Clin Oncol.* 2019;37(18):1558-1565.
- F4. Tang C, Msaouel P, Hara K, et al. Definitive radiotherapy in lieu of systemic therapy for oligometastatic renal cell carcinoma: a single-arm, single-centre, feasibility, phase 2 trial. *Lancet Oncol.* 2021;22(12):1732-1739.
- F5. Hannan R, Christensen M, Hammers H, et al. Phase II Trial of Stereotactic Ablative Radiation for Oligoprogressive Metastatic Kidney Cancer [published online ahead of print, 2021 Dec 28]. *Eur Urol Oncol.* 2021;S2588-9311(21)00218-2.
- F6. 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.

ASTRO urges the Washington State Healthcare Authority to include these indications for its SBRT policy based on the growing clinical data and to align the policy with the ASTRO SBRT Model Policy and NCCN guidelines. Medicaid policies across the country offer SBRT coverage for most, if not all, of these indications discussed. If it would be helpful, ASTRO would be happy to assist in the drafting of an updated SBRT policy. ASTRO appreciates the opportunity to offer comments and recommendations for updating the current policy. If you have any questions and/or feedback, please feel free to contact Emilio Beatley, ASTRO's Health Policy Coordinator, at 703-839-7360 or via email at [Emilio.Beatley@astro.org](mailto:Emilio.Beatley@astro.org).

Sincerely,



Laura I. Thevenot  
Chief Executive Officer

Enclosed: ASTRO SBRT Model Policy