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Subject: Revised Key Questions for Health Technology Assessment of Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiotherapy (SBRT)

Dear Mr. Morse,

The American Association of Neurological Surgeons (AANS), and the Congress of Neurological Surgeons (CNS), would like to thank you and the Washington State Health Care Authority for the opportunity to provide comment on the revised technology assessment questions for the Washington State Health Care Authority Health Technology Clinical Committee consideration of Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiotherapy (SBRT). The AANS and CNS have been actively involved in policy issues surrounding SRS and are eager to work with you to provide appropriate guidance and evidence assessment regarding the efficacy, safety, and cost effectiveness of SRS for selected patients with brain and spine disorders. Neurosurgeons have extensive experience and literature from over 40 years, since a neurosurgeon first introduced SRS care in the United States.

We are concerned that some of the key questions in the “DRAFT Key Questions and Background Stereotactic Radiation Surgery and Stereotactic Body Radiation Therapy” are very general and we are eager to provide more specific details in response to the draft technical assessment expected on July 6, 2012.

KQ1: What is the evidence of effectiveness for stereotactic radiation surgery (SRS) and stereotactic body radiation therapy compared to conventional external beam radiation therapy (EBRT) for the following patients:

- a. Patients with central nervous system (CNS) tumors;

AANS/CNS Comment: Stereotactic radiosurgery (SRS) has been shown to offer a high rate of tumor control and an excellent chance of neurological preservation for many patients with select primary central nervous system tumors, vascular malformations, and functional disorders. Levels of evidence range from Class II to Class V (references below).

- b. Patients with non-central nervous system cancers?

AANS/CNS Comment: The same is true for SRS for non-CNS tumors that have spread to the brain. In particular, SRS has been used Class I through Class V evidence for the safe and effective treatment of patients with brain metastases (references below).

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KQ2: What are the potential harms of SRS and SBRT compared to conventional external beam radiation therapy (EBRT)? What is the incidence of these harms? Include consideration of progression of treatment in unnecessary or inappropriate ways.

AANS/CNS Comment: SRS and EBRT are forms of ionizing radiation, and share the potential for a similar range of side effects. In appropriately selected patients and with careful delivery of SRS, the incidence of serious and irreversible side effects for most indications is under 5%. When weighed against treatment alternatives for benign and malignant CNS tumors, functional disorders, and vascular malformations, the risks of SRS are typically lower than that of other options and certainly of progression or persistence of the CNS pathology. In particular for brain metastases and skull base tumors, SRS has been shown to offer a better chance of neurological and neurocognitive preservation than external beam radiotherapy (EBRT) or surgical resection for select cohorts of patients (Chang et al., 2009; Tooze et al., 2011; Ivan et al., 2011).

KQ3: What is the evidence that SRS and SBRT have differential efficacy or safety issues in sub populations? Including consideration of:

a. Gender

AANS/CNS Comment: There is no appreciable effect of gender on SRS outcomes (references below).

b. Age

AANS/CNS Comment: Age has been shown to be a factor in survival of brain metastasis patients after SRS. Age is an important factor in RPA, GPA, and disease specific GPA indices for brain metastases patient outcomes after SRS (Sperduto et al., 2008; Andrews et al., 2004). For nonmalignant pathologies SRS indications, age can be a favorable prognostic factor for SRS outcomes compared to open surgery or EBRT (Regis et al., 2006; Williams et al., 2011; Dewas et al., 2011).

c. Site and type of cancer; and

d. Stage and grade of cancer

AANS/CNS Comment: Parts c. and d. of Key question 3 are more relevant to body SBRT, and are not considered a significant factor in the evidence of CNS disease.

e. Setting, provider characteristics, equipment, quality assurance standards and procedures.

AANS/CNS Comment: This is a difficult question to answer. In general, outcomes with SRS have not been shown to be device specific. However, they are likely related to SRS team experience, neurosurgeon's technique, and volume (Koga et al., 2011; Kondziolka et al., 1999).

KQ4: What is the evidence of cost and cost-effectiveness of SRS and SBRT compared to EBRT?

AANS/CNS Comment: When appropriately indicated, SRS has been found to be cost effective for patients with brain metastases, spinal metastases, and skull base tumors (Haley et al., 2011; Lal et al., 2012; Banerjee et al., 2008; Rutigliano et al., 1995; Park et al., 2011).

Again, thank you for this opportunity to comment and we look forward to the release of the draft report. If you have any questions, please feel free to contact us.

Sincerely,



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