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June 25, 2014

Bernice Hecker, MD, MHA, FACC
Contractor Medical Director
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Re: LCD DL35236- Draft LCD for Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT)

Dear Dr. Hecker:

The American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) appreciate the opportunity to comment on the proposed coverage policy entitled "Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT), DL 35236."

Stereotactic radiosurgery is an increasingly important part of the neurosurgical treatment armamentarium for brain metastasis patients. Recent publications have largely invalidated the number of metastasis as a criterion for appropriate selection for SRS. In the most recent guidelines on SRS for brain metastasis published by the American Society for Radiation Oncology (ASTRO), Tsao et al. write "[t]he maximum number or total volume of brain metastases best treated with radiosurgery (or surgery) is unknown. Randomized trials which have examined the use of radiosurgery, included selected patients with up to 4 brain metastases, while retrospective reports document use of radiosurgery that exceed 4 brain metastases." (Tsao et al., 2012). ASTRO noted that the literature supports the use of SRS as an initial management for brain metastasis patients who exhibit good prognosis, an expected survival of 3 months or more, and all brain metastases ≤ 3 to 4 cm (Tsao et al., 2012). In particular, SRS has been demonstrated to afford improved local control and neurocognition for multiple metastases patients (Tsao et al., 2012; Chang et al., 2009).

In a recent study of 251 brain metastases from MD Anderson, the authors concluded that "[t]he number of BM [brain metastasis] is not a strong predictor for clinical outcomes following initial SRS for newly diagnosed BM." (Likhacheva et al., 2013). A study of 103 patients with ≥ 5 brain metastases performed at Yale University demonstrated overall survival in patients with 5 or more brain metastases treated with radiosurgery alone was reasonable and compared well with controls (Raldow et al., 2013). Similar findings have been observed in other studies (Salveti et al., 2013; Rava et al., 2013).

In the largest prospective, multicenter clinical trial performed to date, Yamamoto et al. studied 1194 patients accrued over 3 years at 23 independent sites. When treated with SRS alone as an upfront approach, overall survival did not differ between patients with 2 to 4 brain metastases and those with 5 to 10 metastases (noninferiority < 0.0001) (Yamamoto et al., 2014). In patients with ≤ 10 brain metastases, this study further demonstrates the invalidity of brain metastasis number as a criterion for SRS efficacy.

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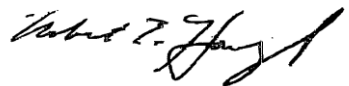
In sum, the literature does not support the continued use of number of brain metastases as a reliable criterion for selection of SRS. SRS has been documented to offer favorable overall survival and low complications for appropriately selected patients with more than 3 brain metastases. Instead, the patient's performance status (e.g. Karnofsky Performance Status) and expected survival as well as size of the brain metastases should be used as selection criteria for SRS.

Regarding the proposed non-covered service for cobalt-60 pallidotomy, we recommend that SRS be used for a patient with movement disorder who cannot be controlled with medical therapy and for whom major comorbidities or coagulopathy preclude open neurosurgery. Coverage should permit unilateral thalamotomy or pallidotomy with SRS. Through stereotactic radiosurgical lesioning of the thalamus or globus pallidus, SRS has been demonstrated to provide significant clinical benefit for patients with Parkinson's disease, essential tremor, and other disabling tremors. In a study of 86 patients with medically refractory tremor treated with SRS, statistically significant improvements in Fahn-Tolosa-Marin mean tremor score, mean handwriting score, and mean drinking score were seen ($p < 0.0001$) (Kooshkabadi et al., 2013). In a prospective, multicenter study of SRS of 72 patients with Parkinson disease or essential tremor, significant tremor improvement on the unified Parkinson's disease rating scale (UPDRS) was shown (Ohye et al., 2012). In another major study of long-term results of SRS for 172 patients with essential tremor, statistically significant improvements in tremor scores for both writing and drawing were demonstrated (Young et al., 2010). Thus, as demonstrated by these studies as well as many others in the literature, SRS is a safe and effective alternative for movement disorder patients who are refractory to medications and not eligible for open neurosurgical procedures, and it should be a covered service.

The AANS and CNS have initiated a national SRS registry focused on clinical quality and outcomes through the NeuroPoint Alliance. We do support the statement emphasizing the importance of clinical science through the enrollment of patients in "a clinical registry compliant with the principles established in AHQR's 'Registries for Evaluating Patient Outcomes: A User's Guide'"; the national SRS registry which will be launched later this year will in fact be AHQR compliant and should provide valuable scientific data on the efficacy and safety of SRS.

Thank you for the opportunity to provide our input on your proposed policy. Please do not hesitate to contact us with any questions regarding SRS, the national registry, or our recommendations.

Sincerely,



Robert E. Harbaugh, MD, President
American Association of Neurological Surgeons



Daniel K. Resnick, MD, President
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