

April 29, 2021

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RE: United Healthcare Radiation Therapy Commercial Medical Policies: Fractionation, Image-Guidance, and Special Services and Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery

Dear Dr. Malin:

The American Society for Radiation Oncology (ASTRO)¹ wishes to thank United Healthcare (UHC) for the continued dialogue with the Society regarding prior authorization and radiation therapy services. ASTRO appreciates the opportunity to comment on UHC's Fractionation, Image-Guidance, and Special Services policy, as well as the Stereotactic Body Radiation Therapy (SBRT) and Stereotactic Radiosurgery (SRS) policy. Please find outlined below specific differences between ASTRO's recommendations and UHC's policies.

Fractionation, Image-Guidance, and Special Services Policy

UHC concludes in the *Fractionation, Image-Guidance, and Special Services* policy that clinical evidence demonstrates that hypofractionated radiation therapy regimens are equally as effective and safe as standard fractionation for bone metastases, breast cancer, locally advanced non-small cell lung cancer, and prostate cancer. Though ASTRO guidelines generally support hypofractionation for the treatment of these disease sites, the guidelines stress that shared decision making between the physician and patient should come first. **We urge UHC to edit the policy to recognize that some patients have certain clinical characteristics and situations where longer course treatments are appropriate, and that the treatment regimen should be determined through shared decision making between doctors and patients.** Clinical situations that may require longer course treatments include:

- Breast patients with:
 - Triple negative disease.
 - Anatomic conditions, such as pectus excavatum, that require treatment across the heart.
 - Significant cardiopulmonary comorbidities.
 - Variants or pathogenic mutations in genes where there is little data on outcomes.
 - Prior history of radiation.
 - Connective tissue disease.
 - Clinical trial participation.
 - Treatment of supraclavicular and/or internal mammary lymph nodes.

¹ *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.*

- Post-mastectomy radiation therapy.
- Additional consideration *may also be warranted* for patients with:
 - Very young age (<45 yo)
 - History of breast augmentation/reconstruction.
 - Previous taxanes.
 - Post-operative infection.
 - Multiple surgeries required.
 - Oncoplastic rearrangement or reduction is done at the time of surgery.
- Prostate patients with:
 - Prior local prostate treatment, including but not limited to prostatectomy, cryotherapy, prior radiation, etc.
 - History of rectal, urinary bladder, or urethral fistula or abscess.
 - History of anorectal surgery, including but not limited to coloanal anastomosis.
 - Pelvic lymph nodes treatment as part of prostate cancer radiotherapy.
 - Clinical trial participation.
- Additional consideration *may also be warranted* for patients with:
 - History of prior TURP, or similar prostate tissue ablative therapies.
 - Connective tissue disease or inflammatory bowel disease.
 - Prostate size above 80cc.
 - History of bladder outlet obstruction/strictures/dilations.
 - High IPSS scores.
 - Large median lobes.

Additionally, UHC states that for breast cancer, EBRT “Delivery of up to 21 fractions (inclusive of a boost to the tumor bed)” is medically necessary.” **ASTRO recommends this be changed to 23 fractions (inclusive of a boost to the tumor bed) to align with ASTRO’s Evidence-Based Guideline, *Radiation Therapy for the Whole Breast* (hereafter, “The Guideline”), which allows 16 fractions with a boost to the tumor bed.**

The policy also states that “When providing external beam radiation therapy for breast cancer, delivery of greater than 33 fractions (inclusive of a boost to the tumor bed) is not medically necessary,” However, the Guideline, explains,

“Certain rare histologies that arise in the breast are commonly treated with conventional fractionation when they arise in other parts of the body. These include, but are not limited to, histologies such as metaplastic carcinoma, squamous cell carcinoma, sarcoma, and adenoid cystic carcinoma” (enclosed, Statement KQ1H, page 14).

ASTRO urges UHC to edit the policy to allow rare histologies to be treated using a standard fractionation regimen, as a hypofractionated regimen can lead to a higher local recurrence rate for this patient population.

Finally, when outlining coverage for locally advanced non-small cell lung cancer (NSCLC), UHC requires that, “When providing external beam radiation therapy, with or without chemotherapy, for locally advanced non-small cell lung cancer, delivery of greater than 30 fractions is not medically necessary.” However, the most recent National Comprehensive Cancer Network (NCCN) NSCLC Guidelines state, “The most commonly prescribed doses for definitive RT are 60 to 70 Gy in 2 Gy fractions. Doses of at least 60 Gy should be given. Dose escalation is associated with better survival in non-randomized comparisons in RT alone, sequential chemo/RT, or concurrent chemo/RT. While optimal RT dose intensification remains a valid question, a high dose of 74 Gy is not currently recommended for

routine use”². **ASTRO urges UHC to increase the number of allowed fractions from 30 to 35, to better align with NCCN guidelines.**

Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery

ASTRO recognizes that UHC’s updated SBRT and SRS commercial policy includes positive coverage changes for disease sites, such as prostate and adrenal cancers. However, we are concerned that functional disorders, such as medically refractory epilepsy, Parkinson’s disease, and essential tremor are not included as indications as coverage for SRS. **We recommend UHC edit the policy to include these indications to further enhance the treatment options for UHC patients who suffer from these conditions.** Additionally, UHC states that brain metastases patients qualify for SRS if they do *not* have a diagnosis of small cell carcinoma. **ASTRO urges UHC to allow these patients to receive SRS when they have tumor recurrence after previous whole brain irradiation or when enrolled in either an IRB-approved clinical trial or in a multi-institutional patient registry adhering to Medicare requirements for clinical evidence development, as recent study outcomes suggest that SRS alone is a viable option for some small cell carcinoma patients**³.

Thank you for your consideration of our comments. Should you have any questions or wish to discuss our recommendations further, please contact Jessica Adams, Health Policy Analyst (703) 839-7396 or via email at Jessica.adams@astro.org.

Sincerely,



Laura I. Thevenot
Chief Executive Officer

Enclosed:

Radiation Therapy for the Whole Breast: An American Society for Radiation Oncology (ASTRO) Evidence-Based Guideline

² https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf, p 63.

³ Rusthoven CG, Yamamoto M, Bernhardt D, et al. Evaluation of First-line Radiosurgery vs Whole-Brain Radiotherapy for Small Cell Lung Cancer Brain Metastases: The FIRE-SCLC Cohort Study. *JAMA Oncol.* 2020;6(7):1028–1037. doi:10.1001/jamaoncol.2020.1271.