

March 27, 2020

Virginia Muir  
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LCD Comments  
National Government Services, Inc.  
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RE: **Proposed Local Coverage Determination (LCD): Prostate Rectal Spacers (DL37485)**

Dear Ms. Muir:

The American Society for Radiation Oncology (ASTRO)<sup>1</sup> appreciates the opportunity to provide input on National Government Services, Inc.'s (NGS) Proposed Local Coverage Determination (LCD): Prostate Rectal Spacers (DL37485). We appreciate the addition of coverage associated with moderate hypofractionated radiation therapy, but we are concerned that some of the language describing the ideal constraints and comorbidities will restrict coverage for patients in the NGS jurisdiction. ASTRO recommends NGS edit the Proposed LCD to address the following considerations.

#### **Prostate Rectal Spacers Selection Criteria**

The proposed LCD states that rectal spacers should not be used in patients who have active inflammatory or infectious disease in the perineum or injection area. However, rectal spacer gels are proven to have the greatest benefit to patients with these complications and comorbidities. By pushing the rectum away from the high dose region during treatment, the gels protect vital organs that might otherwise require treatment due to side effects. As protracted rectal toxicity is expensive to manage, rectal spacer gels ultimately reduce the overall cost of care for patients receiving radiotherapy for prostate cancer. **ASTRO recommends NGS refine the LCD selection criteria to exclude only the patients for whom the procedure may cause problems with tumor control (patients with obvious rectal invasion and/or T3 posterior extra-prostatic extension).**

The selection criteria also requires knowledge of rectal constraints in advance of the placement of the rectal spacer (1D). To meet this criteria, patients undergo a computed tomography scan, which causes additional radiation exposure. If the patient does not meet the necessary criteria, they undergo a second procedure for interstitial placement of the rectal spacer, followed by a second computed tomography scan, as the treatment plan changes with the placement of the spacer. **ASTRO urges NGS to remove these requirements from the proposed LCD and limit unnecessary procedures for patients.**

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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.*

### **Brachytherapy**

Although the updated LCD allows coverage for moderate hypofractionation, no mention is made of brachytherapy. There are multiple studies showing the efficacy of rectal spacers for prostate brachytherapy patients. A study of hydrogel rectal spacers in 200 patients treated with high-dose-rate brachytherapy and intensity modulated radiation therapy (IMRT) showed significant rectal sparing using this technique<sup>2</sup>. Another randomized trial compared patients undergoing dose-escalated radiation therapy for intermediate and high-risk prostate cancer patients. This study found that patients receiving IMRT with brachytherapy boost had superior outcomes with prostate cancer control and disease free survival, but also had a higher risk of grade three rectal complications.<sup>3</sup> **ASTRO recommends NGS add brachytherapy to the LCD coverage indications.**

### **National Comprehensive Cancer Network Guidelines**

The National Comprehensive Cancer Network (NCCN) published new prostate cancer guidelines on March 16, 2020. The *Principles of Radiation Oncology* state,

“Biocompatible and biodegradable perirectal spacer materials may be implanted between the prostate and rectum in patients undergoing external radiotherapy with organ-confined prostate cancer in order to displace the rectum from high radiation dose regions. A randomized phase III trial demonstrated reduced rectal bleeding in patients undergoing the procedure compared to controls. Retrospective data also supports its use in similar patients undergoing brachytherapy. Patients with obvious rectal invasion or visible T3 and posterior extension should not undergo perirectal spacer implantation.<sup>4</sup>”

**ASTRO recommends that NGS revise Proposed LCD: Prostate Rectal Spacers (DL37485) to comply with NCCN Guidelines.**

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](mailto:Jessica.adams@astro.org).

Sincerely,



Laura I. Thevenot  
Chief Executive Officer

Enclosed:

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<sup>2</sup> Strom et al, A dosimetric study of polyethylene glycol hydrogel in 200 prostate cancer patients treated with high-dose rate brachytherapy ± intensity modulated radiation therapy. *Radiotherapy and Oncology* 2014; Apr;111(1):126-31.

<sup>3</sup> Rodda S, et al. ASCENDE-RT: An Analysis of Treatment-Related Morbidity for a Randomized Trial Comparing a Low-Dose-Rate Brachytherapy Boost with a Dose-Escalated External Beam Boost for High- and Intermediate-Risk Prostate Cancer. *Int J Radiat Oncol Biol Phys.* 2017 Jun 1;98(2):286-295.

<sup>4</sup> NCCN Guidelines Version 1.2020 – Prostate Cancer, p 36.