

April 2, 2019

Dow Briggs, MD
Vice President and Medical Director
Blue Cross Blue Shield of Alabama
450 Riverchase Parkway East
Birmingham, Alabama 35244
dbriggs@bcbsal.org
(Submitted electronically)

RE: **Hydrogel Spacer use During Radiotherapy for Prostate Cancer**

Dear Dr. Briggs:

The American Society for Radiation Oncology (ASTRO)¹ appreciates the opportunity to provide input on Blue Cross Blue Shield of Alabama's (BCBS AL) policy on Hydrogel Spacer use During Radiotherapy for Prostate Cancer (MP-724). We are concerned by BSBS AL's decision to classify CPT code 55874, *Transperineal placement of biodegradable material, peri-prostatic*, as not medically necessary and investigational.

About the Product/Procedure:

Rectal Spacers are absorbable hydrogel spacers designed to reduce unintentional rectal toxicity in men undergoing prostate radiotherapy. Using ultrasound guidance, the hydrogel is administered as a liquid that expands in the space between Denonvilliers' fascia and the rectal wall, where it solidifies into a soft, but firm, hydrogel within 10 seconds. It is important to note that the spacer material remains intact during the course of radiation therapy (approximately 3 months), after which it liquefies and is naturally absorbed and cleared in the patient's urine within 6 months. The hydrogel is composed of water and polyethylene glycol (PEG) a compound used widely in pharmaceuticals and cosmetics due to its high level of biocompatibility, lack of toxicity, and long-term safety profile.

The leading side effects of prostate cancer radiotherapy, collectively known as "rectal toxicity" (diarrhea, rectal bleeding, urgency, pain, etc.), result from unintended radiation injury to the rectum. These complications can last for years and significantly impact patients' quality of life. Rectal spacer gels were developed to push the rectum away from the high dose region during treatment, providing protection to other 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.

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.*

Clinical Evidence:

In its policy, BCBS AL agrees that the hydrogel spacer can reduce the radiation dose to the rectum but then further alleges that there is insufficient evidence to support rectal biodegradable gel spacers as reasonable and necessary for the treatment of prostate cancer. BCBS AL concludes that additional studies are needed to corroborate these findings. However, additional studies have held a similar finding where a randomized clinical trial has shown that the biodegradable gel material reduces toxicity for patients treated with radiotherapy for prostate cancer². Specifically, this Level I clinical data demonstrates greater than 70 percent reductions in acute rectal pain and chronic rectal complications. The trial also showed improved bowel quality of life scores for patients treated with a rectal spacer versus those patients treated without a spacer. Based on published clinical outcomes data from this pivotal trial, the perirectal hydrogel spacer provides physicians with an option to help ensure patients are provided with the best clinical outcomes with the fewest adverse effects.

The benefits documented in this initial report were further confirmed with a subsequent report from the same trial, with a median follow-up period of 3 years. At 3 years, more men in the control group than in the spacer group had experienced a minimally important difference (MID) decline in bowel quality of life (41 percent versus 14 percent). Additionally, the control group were more likely to experience large declines (twice the MID) in bowel quality of life (21 percent versus 5 percent). Use of rectal spacer resulted in a sustained 75 percent reduction in any rectal toxicity persisting at 3 years, as well as significant reductions in urinary toxicity.

BCBS AL selectively cites *Hypofractionated Radiation Therapy for Localized Prostate Cancer: An ASTRO, ASCO, and AUA Evidence-Based Guideline (hereinafter "Joint Guideline")* in its decision, stating that the *Joint Guideline* provides "a strong recommendation based on high-quality evidence and 100% consensus." BCBS AL fails to note that the *Guideline* also states,

"To facilitate the meeting of rectal and bladder dose-volume constraints and achieve consistency in daily treatment, a number of strategies have been developed and use of one or more of these is suggested: protocols to ensure that the bladder is comfortably full at time of treatment, **prostate-rectal spacers to allow rectal dose sparing**, and rectal balloon devices to assist in prostate immobilization" (emphasis added).

We recommend that BCBS AL update its policy to align completely with the *Joint Guideline* and other clinical evidence.

Recent Payer Trends:

ASTRO supports federal and private payer reimbursement for the rectal spacer gel placement procedure and the material itself and urges BCBS AL to reconsider its classification of transperineal placement of biodegradable material as not medically necessary. At present, all seven Medicare Administrative Contractors (MACs) are reimbursing CPT code 55874, and many commercial carriers across the country, such as Aetna, cover CPT code 55874. Also, many veterans are receiving coverage of CPT code 55874 through the Veterans Choice Program of the Veterans Health Administration

² Mariados N, Sylvester J, Shah D, *et al.* Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy. *Int J Radiation Oncol Biol Phys*, Vol. 92, No. 5, pp. 971e977, 2015

ASTRO appreciates your consideration of our comments. Should you have any questions or require further assistance, please contact Jessica Adams, Health Policy Analyst, at 703.839.7396 or Jessica.adams@astro.org.

Respectfully submitted,

A handwritten signature in black ink that reads "Laura Thevenot". The signature is written in a cursive, flowing style.

Laura I. Thevenot
Chief Executive Officer

Enclosed:

Hypofractionated Radiation Therapy for Localized Prostate Cancer: An ASTRO, ASCO, and AUA Evidence-Based Guideline

Continued Benefit to Rectal Separation for Prostate Radiation Therapy: Final Results of a Phase III Trial

ASTRO Rectal Spacer Notice to Payers

BCBS AL Hydrogel Spacer use During Radiotherapy for Prostate Cancer