



PROCEPT BioRobotics' AquaBeam® Robotic System Receives CMS Approval for Transitional Pass-Through Payment Status

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Incremental Reimbursement in Outpatient Setting Will Expand Availability of Transformative Next-Generation Benign Prostatic Hyperplasia (BPH) Treatment

REDWOOD SHORES, Calif. – November 06, 2019 —[PROCEPT BioRobotics Corporation](#), a Silicon Valley surgical robotics company developing intelligent solutions to transform the field of urology, today announced that the Centers for Medicare and Medicaid Services (CMS) granted approval for a transitional pass-through (TPT) payment for [Aquablation Therapy](#) performed by the AquaBeam® Robotic System as part of the 2020 Outpatient Prospective Payment System (OPPS) ruling on Nov. 1, 2019. The TPT payment provides incremental payment for devices used in the outpatient setting. The AquaBeam Robotic System is the first FDA granted surgical robot providing autonomous removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH), or enlarged prostate.

TPT status is intended to encourage the use of newly FDA-approved medical devices, drugs, and biologics across all fields of medicine and to boost Medicare patients' access to these innovative therapies by temporarily paying more than established facility fees. The TPT is only available to new technologies meeting a number of criteria, including demonstrating substantial clinical improvement over existing surgical techniques. The TPT payment will be effective Jan. 1, 2020 and will continue for three years through Dec. 31, 2022.

"This represents a significant step forward in the surgical treatment of LUTS due to BPH by expanding patient access to Aquablation therapy," said Steven Kaplan, MD, Director of the Men's Wellness Program, [Mount Sinai Health System in New York City](#) and Professor of Urology at [Icahn School of Medicine at Mount Sinai](#). "Urologists continually strive to find minimally invasive solutions in an outpatient setting to ensure favorable outcomes for patients in an economically responsible fashion. TPT status for Aquablation therapy now enables urologists to accomplish this goal."

In its final ruling, CMS concluded:

- The additional scientific data provided demonstrated Aquablation therapy's superiority to other techniques, specifically reducing operative time and complications in general, especially for larger prostates.
- The results of the WATER clinical study were statistically significant and showed Aquablation therapy was superior to TURP in safety as evidenced by a lower proportion of persistent adverse events (incontinence, ejaculatory dysfunction and erectile dysfunction) at three months.
- Additionally, results from the WATER II clinical study for patients with large prostates demonstrated better outcomes from Aquablation therapy over open prostatectomy, regarding shorter operative time, shorter length of stay, and decreased rates of severe hemorrhage and transfusions. The minimally invasive nature of Aquablation therapy offers men with large prostates (>80mL) an outpatient option.

"We are thrilled that CMS determined that the AquaBeam Robotic System meets the criteria for approval for TPT in the 2020 OPPS," said Nikolai Aljuri, Ph.D., PROCEPT BioRobotics co-founder, president and CEO. "In combination with the new technology add-on payment (NTAP), which was granted in 2018, CMS now provides hospitals with an incremental payment for our robotic surgical treatment in both the outpatient and inpatient setting. This further validates the efficacy of Aquablation therapy as a substantial clinical improvement compared to other surgical techniques for BPH and allows more patients to benefit from this transformative solution for prostate disease."

About PROCEPT BioRobotics Corporation

Based in Silicon Valley, PROCEPT BioRobotics is a privately held surgical robotics company enabling better patient care by developing transformative solutions in urology. With an initial focus on BPH, the company's first offering, the AquaBeam Robotic System delivering Aquablation therapy, is the first FDA granted surgical robot providing autonomous tissue removal for the treatment of BPH. Aquablation therapy combines the clarity of real-time, multi-dimensional imaging, autonomous robotics and heat-free waterjet ablation for targeted, controlled, and immediate removal of prostate tissue for the treatment of lower urinary tract symptoms caused by BPH. Aquablation therapy offers predictable and reproducible outcomes, independent of prostate anatomy, prostate size or surgeon experience. For more information visit <https://www.procept-biorobotics.com>.

Important Safety Information

All surgical treatments have inherent and associated side effects. The most common side effects are mild and transient, and may include mild pain or difficulty when urinating, discomfort in the pelvis, blood in the urine, inability to empty the bladder or a frequent and/or urgent need to urinate, and bladder or urinary tract infection. Other risks include ejaculatory dysfunction and a low risk of injury to the urethra or rectum where the devices gain access to the body for treatment. For more information about potential side effects and risks associated with Aquablation therapy, speak with your urologist or surgeon. No claim is made that the AquaBeam Robotic System will cure any medical condition, or entirely eliminate the diseased entity. Repeated treatment or alternative therapies may sometimes be required.