

IMPLICATIONS TO IN-OFFICE PROCEDURES FOR BENIGN PROSTATIC HYPERPLASIA

The Economic Viability of Benign Prostatic Hyperplasia In-Office Treatment Options: Considerations for Value-based Care and Health Plans with Capitated Payment

Executive Summary

Value-based care and capitation have increasingly been recognized as a fundamental cost savings model in health care and have become a major pillar in commercial insurance reimbursement strategies for both facilities and individual physician providers. The current fee-for-service system is designed to reimburse healthcare providers based principally on the volume of services provided rather than outcomes and cost, which is notably gaining attention in the world of treating benign prostatic hyperplasia (BPH). Nevertheless, significant pros and cons apply among the various models of payment in the healthcare system, all of which have their own advantages and disadvantages depending on variables such as operational feasibility, including the cost of capital equipment, overhead, practice types, and geographical location. For providers to make an informed decision on providing minimally invasive treatment modalities for BPH, both costs of capital equipment and quality measures are taken into consideration. Physicians and healthcare organizations as a whole need to examine the circumstances of their present systems and decide based on finances and accessibility to care which models are most efficient to all stakeholders for BPH procedures that can be performed in a non-facility setting.

How the Capitation Model Impacts In-Office Minimally Invasive Treatments for BPH

Rezūm™ Water Vapor Therapy is an in-office BPH therapy with proven prostate volume reduction and long-term durability out to 5 years.¹

- The American Urological Association Guidelines recommend Rezūm Therapy as a treatment modality for patients with BPH.²
- Clinical studies support that Rezūm Water Vapor Therapy is a safe, effective and durable treatment option for patients with moderate-to-severe symptoms of BPH without the need for general anesthesia.³
- Majority of surgical treatments for BPH have been performed in the facility setting (**figure 1**).
- With capitation payments, it is not financially viable for the physicians to perform Rezūm Therapy, potentially resulting in limited patient access.

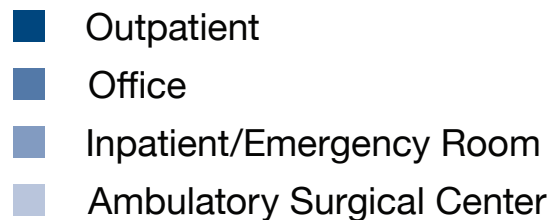
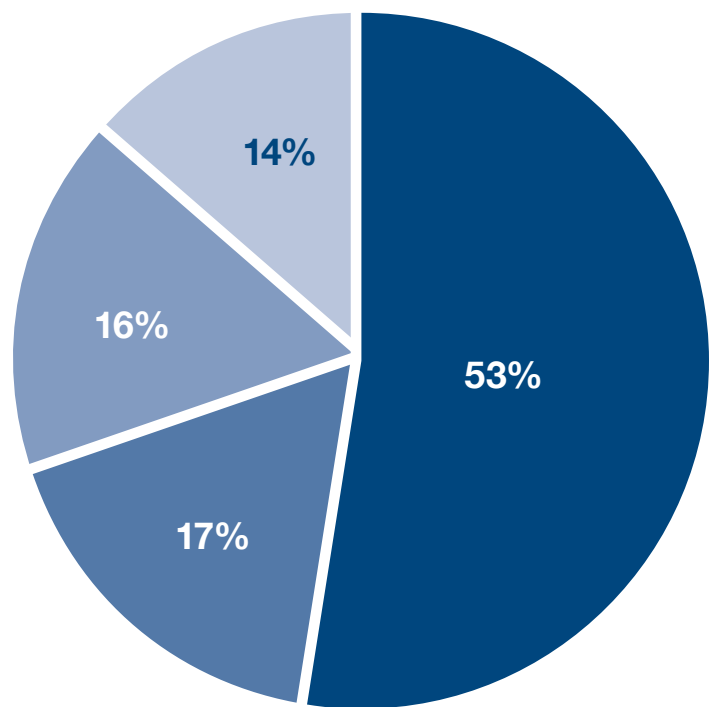


Figure 1. The volume of BPH procedures by site of service in 2018 obtained from the IBM® MarketScan® Commercial Claims and Encounters Database (Total volume=5,025)⁴

What are Capitation Payments?

Capitation payments are pre-arranged payment methods of prospective reimbursement whereby a health plan, Health Management Organization (HMO), or independent practice association (IPA) has accepted financial risk and delivers medical services on a per member per month basis (PMPM) for all members of the plan who are assigned to that provider. For health plans, capitation payments ensure predictability of healthcare costs, by requiring acceptance of a payment in advance of the need of service(s) in return giving providers the ability to champion quality care, cost efficiency, and help the slow rising of healthcare costs.

Disease Burden of BPH

BPH is the most common chronic condition for men aged at least 50.⁵ While the prevalence of BPH increases with age, the condition is substantial among younger men. Approximately 50% of men aged 51-60 years old had presence of histological BPH, and at least one-fourth of the men experienced moderate-to-severe lower urinary tract symptoms (LUTS).⁶ These patients should be presented with available treatment options to treat their symptoms.^{7,8} The goals of BPH treatment are to improve bothersome LUTS and prevent disease progression that would result in invasive surgical procedures.⁷ Untreated BPH may result in serious complications, such as acute urinary retention (AUR).⁹ A study using the California Office of Statewide Health Planning and Development Database reported that BPH-associated AUR was 5.23 per 1,000 ER visits in 2010.¹⁰ Therefore, providing patients with appropriate BPH treatments could reduce the preventable healthcare utilizations and costs.

Rezūm Therapy Delivers Clinical Benefits to Men with Moderate-to-Severe BPH

Clinical studies support that Rezūm Water Vapor Therapy is an effective and safe minimally invasive treatment option for moderate-to-severe LUTS due to BPH. Rezūm Therapy delivers targeted, controlled doses of stored thermal energy in water vapor directly to the region of the prostate gland with the obstructive tissue causing the LUTS secondary to BPH. The Rezūm System is intended to relieve symptoms, obstructions, and reduce prostate tissue associated with BPH and is indicated for men ≥ 50 years of age with a prostate volume $30\text{cm}^3 \leq 80\text{cm}^3$.

- **Safety** – In the Rezūm II randomized controlled trial (RCT), non-serious adverse events included anticipated events that may develop after rigid cystoscopy; they were infrequent and mild to moderate in severity.³ The most common included dysuria (16.9%), hematuria (11.8%), frequency and urgency (5.9%), acute urinary retention (3.7%) and urinary tract infection suspected (3.7%); all were treated routinely or resolved without treatment within 3 weeks.³
- **Efficiency** – Rezūm Therapy can be performed in an office setting. Based on the Rezūm II RCT, the average procedure time was 5.3 ± 3.5 minutes.⁴
- **Effectiveness** – Rezūm Therapy is associated with a long-term sustained reduction of International Prostate Symptom Score (IPSS). At 5 years, surgical retreatment rate was only 4.4%.¹ According to a systematic review and meta-analysis synthesizing four Rezūm Therapy clinical studies, Rezūm Therapy significantly improved IPSS, IPSS-QOL, BPHII, and Qmax. The changes from baseline were statistically significant and clinically important at all follow-up intervals (**figure 2**).¹¹

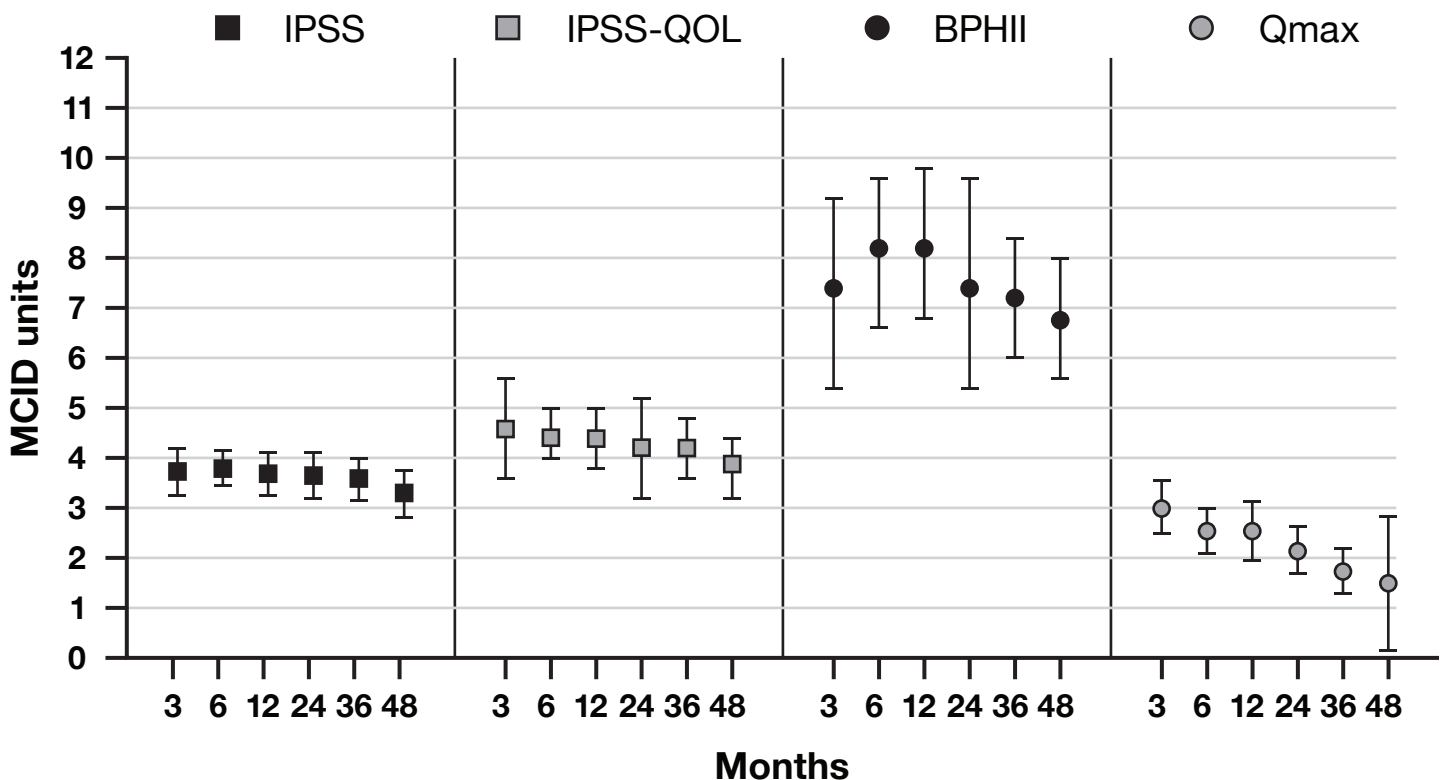


Figure 2. Standardized minimal clinically important difference (MCID) units with 95% CI from baseline post-Rezūm Therapy¹¹

Rezūm Therapy Provides Health Economic Benefits to U.S. Payers

Rezūm Therapy is an effective and financially viable treatment option in an office setting for LUTS due to BPH. The 2020 Medicare allowable national average reimbursement rate for Rezūm Therapy to be performed in the office setting is \$1,847 compared to \$2,161 for the same procedure to be performed in a hospital outpatient setting.^{12,13} Capitated health plans should consider reimbursing Rezūm Therapy separately in the in-office space, which could potentially improve patient accessibility in the office setting and reduce costs to the payers.

In addition, Rezūm Therapy could potentially provide cost-saving to capitated health plans long-term compared to other BPH treatment options, such as transurethral resection of the prostate (TURP). On average, the total cost of Rezūm Therapy to Medicare is \$2,257 at 4 years post-treatment.¹⁴ The amount accounted for procedural, adverse event treatment, and retreatment costs. The total cost of Rezūm Therapy is lower than the 2019 average Medicare reimbursement rate for a TURP procedure performed in an outpatient setting which is \$4,781.⁴

If you have further questions, please reach out to Julie Baxter (Group Senior Manager, Field Health Economics and Market Access; Julie.baxter@bsci.com) for capitated payment discussions or Sirikan (Siri) Rojanasarot (Principal Health Economist; Sirikan.rojanasarot@bsci.com) for questions about publications of Rezūm Water Vapor Therapy cited in the material.

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Conclusions

With an aging population, the incidence of BPH is rising. Thus, concerted efforts to determine the best economic value in BPH treatments, with improved and enduring outcomes, will help advance a sustainable healthcare ecosystem. To that end, evidence-based studies to analyze cost of care for procedural BPH therapies (including retreatment) should be closely considered. Rezūm Therapy has clinical evidence out to 5 years demonstrating it to be an effective in-office treatment modality for BPH patients. For physicians to deploy Rezūm Therapy as a preferred treatment option, payers that employ a capitated model should take into consideration cost of and access to capital equipment as a necessary component of the ultimate cost savings generated.

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