Transurethral Waterjet Ablation of Prostate Clinical Coverage Criteria

Overview

Transurethral waterjet ablation is a surgical treatment for benign prostatic hypertrophy.

Policy

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus
☒ MassHealth ACO
☒ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care (Commercial/Exchange)

Fallon Health requires prior authorization for transurethral waterjet ablation of prostate.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to Community Care members only.

Fallon Health considers transurethral waterjet ablation medically necessary for the treatment of symptomatic benign prostatic hyperplasia when all of the following criteria are met:

1. Prostate volume 30-150 cc.
2. Persistent moderate to severe symptoms despite maximal medical management including all of the following:
   a. International Prostate Symptom Score (IPSS) ≥12
   b. Maximum urinary flow rate (Qmax) of ≤15 mL/s
   c. Failure, contraindication or intolerance to at least three months of conventional medical therapy for LUTS/BPH (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride)
3. Transurethral waterjet ablation is performed using an FDA-approved/cleared device (e.g., Aquabeam Robotic System).

Medicare Variation

Medicare statutes and regulations do not have coverage criteria for transurethral waterjet ablation of prostate. Medicare does not have an NCD for transurethral waterjet ablation of prostate. National Government Services, Inc., the Part A/B Medicare Administrative Contractor (MAC) with jurisdiction in the Plan's service area has an LCD (L38367) for transurethral waterjet ablation of the prostate. The National Government Services, Inc. LCD is titled Fluid Jet System Treatment for LUTS/BPH. Fluid jet system for prostate tissue removal is the name FDA regulation 21 CFR 876.4350 (Medicare Coverage Database search 11/24/2025). Coverage criteria for use of fluid jet system treatment of lower urinary tract symptoms attributable to benign prostatic hyperplasia (LUTS/BPH) are fully established by Medicare in LCD L38367, therefore the Plan's coverage criteria are not applicable.

Link: LCD Fluid Jet System Treatment for LUTS/BPH (L38367)

MassHealth Variation

MassHealth does not have Medical Necessity Guidelines for transurethral waterjet ablation of the prostate (MassHealth website search 11/24/2025).

The CPT code for transurethral waterjet ablation of the prostate is 0241T. CPT 0241T is nonpayable per MassHealth, therefore, transurethral waterjet ablation of the prostate is not covered for MassHealth ACO members (MassHealth Physician Manual, PHY-173 Subchapter 6, effective 07/01/2025; MassHealth Acute Outpatient Hospital Manual, AOH-61 Subchapter 6, effective 07/01/2025).

Exclusions

- Transurethral waterjet ablation is experimental/investigational and not medically necessary when any of the following conditions are present:
  - Body mass index ≥ 42kg/m2
  - Known or suspected prostate cancer (based on NCCN Prostate Cancer Early Detection guidelines) or a prostate specific antigen (PSA) >10 ng/mL unless the patient has had a negative prostate biopsy within the last 6 months.
  - Bladder cancer, neurogenic bladder, bladder calculus or clinically significant bladder diverticulum
  - Active urinary tract or systemic infection
  - Treatment for chronic prostatitis
  - Diagnosis of urethral stricture, meatal stenosis, or bladder neck contracture
  - Damaged external urinary sphincter
  - Known allergy to device materials
  - Inability to safely stop anticoagulants or antiplatelet agents preoperatively.

Summary of Evidence

Benign prostatic hyperplasia (BPH) is nearly ubiquitous in the aging male with increases in prevalence starting at age 40-45 years, reaching 60% by age 60, and 80% by age 80. BPH can lead to benign prostatic enlargement (BPE), which can cause obstruction at the level of the bladder neck, termed benign prostatic obstruction (BPO). Parallel to the development of BPH, lower urinary tract symptoms (LUTS) increase in frequency and severity with age and are divided into those associated with storage of urine, and/or voiding/emptying. Male LUTS may be caused by a variety of conditions, including BPE and BPO. BPH and LUTS in the aging male can be progressive, as seen in the Olmsted County Study (Sarma et al., 2003). The prevalence of moderate-to-severe LUTS rose to nearly 50% by age 80, with the development of acute urinary retention (AUR) increasing from an incidence of 6.8 episodes per 1,000 patient years of follow-up in the overall population, to a high of 34.7 episodes in men aged 70 and older (Lerner et al., 2021a).

The most important motivations for men seeking treatment are severity and degree of bother associated with symptoms (McVary, 2006). While LUTS/BPH is rarely life-threatening, the impact on quality of life is significant and should not be underestimated. The most prevalent and generally first line approach is behavioral and lifestyle modifications followed by medical therapy, including alpha-adrenergic antagonists (alpha blockers), 5-alpha reductase inhibitors (5ARIs), phosphodiesterase 5 selective inhibitors (PDE5s), anticholinergics, and beta-3 agonists - which may be utilized alone, or in combination to take advantage of their different mechanisms of action. Although effective treatments for LUTS/BPH are available, this condition often occurs in the context of common, age-related comorbidities such as cardiovascular disease, hypertension, and erectile dysfunction. When selecting an appropriate course of therapy, these side effects and any impact they may have on existing comorbid conditions must be considered (Lerner et al., 2021a).

When treatment with medications is not successful, surgical options may be considered. Simple prostatectomy and transurethral resection of the prostate (TURP) are the gold standard surgical treatments for LUTS attributed to BPH and are highly effective and provide improved outcomes in urinary functions. However, neither simple prostatectomy nor TURP are without perioperative complications and morbidity (Chung and Woo, 2018).

Recently, new minimally invasive surgeries have emerged as alternatives to prostatectomy and TURP for the management of LUTS in some men with BPH. These minimally invasive surgeries include but are not limited to:

- Transurethral waterjet ablation, (also referred to as robotic waterjet ablation or Aquablation)
- Prostatic Urethral Lift (PUL)
- Water Vapor Thermal Therapy
- Holmium laser enucleation of the prostate (HoLEP)

Promising short-term, results for minimally invasive alternatives have resulted in conditional or in some cases, moderate recommendations from the American Urological Association (AUA). By and large, factors that need to be taken into consideration when choosing a surgical option come down to experience of the urologist, size of the prostate and desire to preserve sexual function (Lerner et al., 2021b).

Food and Drug Administration (FDA)

Transurethral waterjet ablation, (also referred to as robotic waterjet ablation or Aquablation) uses high-pressure waterjet technology combined with real-time, imaging and robotics to resect and remove prostatic tissue. The Aquabeam® Robotic System is approved by the FDA for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia. The Aquabeam® Robotic System (Procept BioRobotics Corp., Redwood Shores, CA) was initially granted marketing authorization pursuant to a de novo classification (DEN170024 April 17, 2017) and has subsequently been granted 510(k) clearance on March 11, 2011 (K202961), October 6, 2021 (K212835),and August 30, 2024 (K231024). On August 20, 2024, HYDROS™ Robotic System, HYDROS™ Handpiece, and HYDROS™ TRUS Probe (PROCEPT BioRobotics Corporation, Redwood City, CA) was granted 510(k) clearance (K240200). The HYDROS™ Robotic System has the same indications as AquaBeam Robotic System and is the next-generation, AI-powered platform for Aquablation therapy.

Randomized Controlled Trials

The WATER trial (Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue (WATER); ClinicalTrials.gov number, NCT02505919) was a multicenter randomized blinded study comparing Aquablation of the prostate with the AQUABEAM System (n=117) and TURP (n=67) for the treatment of Lower Urinary Tract Symptoms (LUTS). The study was sponsored by the device manufacturer (PROCEPT BioRobotics, Redwood City, CA, USA). The primary endpoints for safety and effectiveness were measured at 3 and 6 months, respectively, and subjects were followed out to 5 years to collect long-term clinical data. The WATER trial utilized standard inclusion/exclusion criteria limiting participants to men ages 45–80 years with a prostate size between 30–80 cc (measured by transrectal ultrasound), moderate-to severe LUTS as indicated by an International Prostate Symptom Score (IPSS) ≥12 and a maximum urinary flow rate (Qmax) <15 ml/s. Men were excluded if they had a history of prostate or bladder cancer, neurogenic bladder, bladder calculus or clinically significant bladder diverticulum, active infection, treatment for chronic prostatitis, diagnosis of urethral stricture, meatal stenosis or bladder neck contracture, damaged external urinary sphincter, stress urinary incontinence, post-void residual >300 ml or urinary retention, use of self-catheterization or prior prostate surgery. Men taking anticoagulants or on bladder anticholinergics or with severe cardiovascular disease were also excluded. The control group, TURP using electrocautery, represents the gold standard for the surgical treatment of moderate-to-severe BPH for patients within this volume range.

Multiple publications have reported results of the WATER trial at various time points (Gilling et al., 2018, Gilling et al., 2019, Plante et al., 2019, Gilling et al., 2020, Gilling et al., 2022). The primary efficacy end point was the reduction in International Prostate Symptom Score at 6 months. Noninferiority was declared if the lower 95% two-sided confidence limit of the difference in score change at 6 months exceeded -4.7 points. The primary safety end point was the development of Clavien-Dindo persistent grade 1, or 2 or higher operative complications. At month 6 patients treated with Aquablation and TURP experienced large IPSS improvements, the mean IPSS decreased by 16.9 points (SD 6.6) for Aquablation versus and 15.1 points (SD 7.9) for TURP; the

mean difference in change score at 6 months was 1.8 points larger for Aquablation (p<0001 for non-inferiority and p=.1346 for superiority). The prespecified study noninferiority hypothesis was satisfied (p <0.0001). Of the patients who underwent Aquablation and transurethral prostate resection 26% and 42%, respectively, experienced a primary safety end point, which met the study primary noninferiority safety hypothesis and subsequently demonstrated superiority (p = 0.0149). In this study, patients who had Aquablation were more likely to preserve their existing sexual function compared with patients who had TURP. Among sexually active men the rate of anejaculation was lower in those treated with Aquablation (10% vs 36%, p = 0.0003). The procedure times, defined as first instrument introduction to insertion of catheter, were similar at 40 minutes for Aquablation and 36 minutes for TURP. Mean resection time was lower in the Aquablation group (4 vs 27 minutes, p<0.0001). One Aquablation subject and zero TURP subjects required a blood transfusion. There were no late bleeding events in either group. Mean hospital length of stay was 1.4 days in both groups (Gilling et al., 2018).

Five-year outcomes from WATER demonstrate BPH symptom reduction and urinary flow rate improvement similar to TURP in men with prostate sizes between 30 and 80 cc. At 5 years, the mean (SD) IPSS reduction was 15.1 (6.6) points in the Aquablation group and 13.2 (8.2) points in the TURP group (p=.2764). At 5 years, the median IPSS score was 5.5 for Aquablation and 6 for TURP. For men with larger prostates (≥ 50 ml), IPSS reduction was 3.5 points greater across all follow-up points compared to the TURP group (p=.0123). There was no difference in IPSS changes when analyzing the other pre-specified subgroups of age (<65 vs ≥ 65) and LUTS severity as measured by IPSS (<20 vs ≥20). The IPSS quality of life (QoL) score can range from 0 to 6. The average baseline IPSS QoL score was 4.8 and did not differ between groups. At 5 years, the OPSS QoL score was 1.6 for both groups (p=.8009). In both groups, 5-year peak urinary flow rates (Qmax) increased markedly within 1 month after surgery and were maintained at 5 years. Mean (SD) 5-year improvements in Qmax were 8.7 (9.1) mL/sec or 125% improvement for the Aquablation group versus 6.3 (7.5) mL/sec or 89% improvement for TURP. The mean 5-year reduction in post-void residual was 62 (86) and 82 (94) mL (p=.3960). PSA was reduced at 5 years compared to baseline by 1.0 and 0.5 ng/dL in the Aquablation and TURP groups, respectively (p=.4650). At 5-year follow-up, 6.0% of the intent-to-treat population in the Aquablation arm (7/116) needed an additional BPH therapy (started BPH medication anew and continued to study exit or intervention) due to recurrent LUTS compared to 12.3% in the TURP arm (8/65), however, only 58/116 and 32/65 patients were available for follow-up after month 36. The authors note that the 4 and 5-year follow-up windows occurred during the pandemic caused by COVID-19 (Gilling et al., 2022).

Cohort Studies

There is significant patient overlap between several of these studies.

WATER II (NCT03123250) is single arm safety and effectiveness study of the waterjet ablation procedure for treatment with men (n=101) with symptomatic BPH and large volume 80-150 cc prostates. The study was sponsored by the device manufacturer (PROCEPT BioRobotics, Redwood City, CA, USA). Three-month procedural outcomes for WATER II are reported by Desai et al., 2019. One and two-year results of WATER II are published by Bhojani et al., 2019 and Desai et al., 2020, respectively. Three-year and 5-year are published by Zorn et al., 2021 and Bhojani et al., 2023. Adult men aged 45-80 years were included if they had a prostate volume between 80 and 150 mL by transrectal ultrasound, baseline International Prostate Symptom Score (IPSS) 12, a maximum urinary flow rate (Qmax) < 15 mL/s, a serum creatinine < 2 mg/dL, a history of inadequate or failed response to medical therapy, and the mental capability and willingness to participate in the study. The primary efficacy endpoint was the change in total IPSS score from baseline to 3 months. The primary safety endpoint was the proportion of patients with adverse events rated as possibly, probably, or definitely related to the study procedure classified as Clavien-Dindo (CD) Grade 2 or higher or any Grade 1 event resulting in persistent disability (e.g., ejaculatory disorder, erectile dysfunction, or permanent incontinence) evidenced through 3 months post-treatment. Although TURP is typically used to treat prostates less 80 mL, the performance goals were chosen to prove Aquablation could demonstrate reproducible results as seen in the WATER study but in larger prostates. Prior studies have demonstrated that IPSS

scores are reduced by approximately 16 points after Aquablation, values similar to those observed after TURP.

Mean (SD) baseline IPSS score was 23.2 (6.3). IPSS ranges from 0 to 35. A higher score indicates a worse outcome. Baseline mean prostate volume was 107 cc (range 80-150). A median lobe was present in 83% of cases with an average intravesical prostatic protrusion distance of 1.8 cm (0.7-6.8). Study procedures were performed under general anesthesia in 18% and spinal anesthesia in 82% of cases. Mean operative time was 37 minutes (15-97 minutes) and mean Aquablation resection time was 7.8 minutes (2.5-17 minutes). Adequate adenoma resection was achieved with a single pass in 34 patients and with additional passes in 67 patients (mean 1.8 treatment passes), all in a single operating session. Hemostasis was achieved using either a Foley balloon catheter placed in the bladder under traction (n = 98, mean duration 18 h) or direct tamponade using a balloon inflated in the prostate fossa (n = 3, mean duration 15 h). No patient required electrocautery for hemostasis at the time of the primary procedure. The average length of hospital stay following the procedure was 1.6 days. At 3 months post-treatment, the change in total IPSS score as compared to baseline was an improvement of 16.5 (14.4-18.1) points. The incidence of Clavien-Dindo Adverse Events (percentage of participants) = 45.5% The change in total IPSS score at 3 months as compared to baseline was -16.5 (-18.1 to -14.8) (n= 95) (Desai et al., 2019).

In an Editorial Comment, Jeffrey Cadeddu, MD noted that the “impressive advantage” of this technology is the short resection time (mean 7.8 minutes, range 2.5-17 minutes), however, since the water jet is not hemostatic, the challenge has been optimal post-resection hemostasis. In WATER II, a novel Foley balloon catheter traction device was introduced and deployed in almost all patient for a prolonged period (average 18 hours). The catheter was subsequently removed at an average of 4 days after treatment. Bleeding complications were noted in 10% of patients, with 6% requiring transfusion. Dr. Cadeddu notes that the outcomes are comparable to simple prostatectomy and holmium laser enucleation of the prostate with the clear advantage of technical ease. Hemostatic challenges require further research and solutions before widespread adoption (Cadeddu J, 2019).

At 12 months, mean IPSS improved from 23.2 at baseline to 6.2 (P <.0001). Mean International Prostate Symptom Score quality of life improved from 4.6 at baseline to 1.3 at 12-month follow-up (P <.0001). Significant improvements were seen in Qmax (12-month improvement of 12.5 cc/sec) and postvoid residual (drop of 171 cc in those with postvoid residual >100 at baseline). Antegrade ejaculation was maintained in 81% of sexually active men. No patient underwent a repeat procedure for BPH symptoms. There was a 2% de novo incontinence rate at 12 months, and 10 patients did require a transfusion postoperatively while 5 required take back fulgurations. At 12 months, prostate-specific antigen reduced from 7.1 ± 5.9 ng/mL at baseline to 4.4 ± 4.3 ng/mL (Bhojani et al., 2019).

For the WATER II patients who completed the 5-year visit (n=62), symptoms showed an improvement from a mean (SD) IPSS score of 22.6 (6.4) at baseline to 6.8 (4.6) at 5 years, resulting in a change of 15.9 (7.7, P < .001). The IPSS scores were independent of both baseline IPSS and prostate size. IPSS QoL decreased from 4.6 (SD 1.0) at baseline to 1.3 (1.3) at 5 years, resulting in a change of 3.3 (1.6, P < .001). Subjects observed an immediate improvement postoperatively with the maximum benefit seen at approximately 90 days postoperatively and sustained thereafter. Uroflowmetry measurements also showed a significant improvement where the mean Qmax increased from 8.6 (SD 3.4) to 17.1 (9.8) mL/s at 5 years, resulting in an improvement of 9.2 (11.1) mL/s at 5 years (P < .001). PVR urinary volume decreased from 141 (SD 140) mL at baseline to 64 (64) mL at 5 years (P < .001). During the 5-year follow-up, 6% of patients were placed on BPH medications (3 on 5-alpha reductase inhibitor, 2 on alpha-blocker, and 1 on combination therapy 5-alpha reductase inhibitor/alpha-blocker) occurring on average 34 months after the initial procedure. An additional 3% required surgical retreatment for lower urinary tract symptoms occurring on average 25 months after their initial Aquablation procedure. A Kaplan-Meier analysis showed 96.3% of patients were free from a secondary BPH intervention at 5 years. There were no surgical retreatments occurring in year 4 or 5 (Bhojani et al., 2023).

Nguyen et al. 2020 is a post hoc analysis comparing 12 month outcomes in 116 WATER (NCT02505919) patients and 101 WATER II (NCT03123250) patients and found an increase in complications and statistically significant but clinically unimportant differences in mean operative (33 minutes vs 37 minutes) and resection times (3.9 minutes vs 8 minutes). The mean change in the International Prostate Symptom Score was substantial averaging (at 12 months) 15.1 in WATER and 17.1 in WATER II (P = 0.605). Maintenance of antegrade ejaculation was 90% vs 81% between WATER and WATER II cohorts respectively.

Helfand et al., 2021 is a post hoc analysis comparing surgical times and clinical outcomes of men with very large prostates (> 150 mL) were compared to data from men with average PV ≤ 80 mL (WATER study) and large PV 80 mL-150 mL (WATER II study). The average PV of men who underwent Aquablation with very large prostates was 209 mL ± 56 (n = 34, range 151-362 mL), large PV 107 mL ± 20 (n = 101, range 80-150 mL) and average PV 54 mL ± 16 (n = 116, range 30-80 mL). For men with PV > 150 mL, baseline IPSS was 19 ± 6. With a mean follow up of 7 ± 9 months, the IPSS improved to 7 ± 5 (p < 0.001). Peak urinary flow rate, Qmax, improved from 7 ± 4 mL/s to 19 ± 5 mL/s (p<0.001). Compared to the two other PV groups, there were no differences in terms of improvements in IPSS, quality of life, or uroflowmetry. There were no reports of transfusions (0%) in the cohort of men with very large prostates.

Te et al., 2023 is a post hoc analysis of subjects from the WATER and WATER II trials who have failed to improve with medical therapy. Only patients with reported BPH medical therapy such as alpha-blockers (AB) and 5-alpha reductase inhibitors (r-ARIs) were included. Functional outcomes including post-void residual volume (PVR), peak urinary flow rate (Qmax), IPSS and QoL scores were analyzed. A total of 185 men had an AB or 5-ARI prior to undergoing Aquablation or TURP. Median prostate volume was 75 cc. There was significant improvement of parameters such as IPSS, QoL, Qmax and PVR from baseline to follow-up at 36 months. When compared with men who were not on any AB or 5-ARI, prior to surgery (n=97), there was no significant difference in any of the urinary parameters. In patients who underwent Aquablation, erectile dysfunction and ejaculation dysfunction rates were higher in the patients who were not on BHP medications at baseline however this was not significantly different in both WATER and WATER II trials. Comparing subgroups (medically refractory vs patients not on BPH medical therapy) showed no differences. Patients who were on BPH medication at baseline were more likely to return to medication or undergo another BPH intervention at 3 years follow-up in both the Aquablation and TURP groups however this difference was not significant. Men with larger prostates (> 80 g) who were medication naive were more likely to be on BPH medication at 3 years however this did not reach significance (p=0.22). TURP retreatment rate in WATER was 1.5%. The patient underwent another TURP. Retreatment rates for Aquablation in WATER and WATER II were 4.3% and 3% respectively. The majority of retreatment procedures was TURP. In the Aquablation group, Calvien-Dindo grade 2 or higher complications were higher in men on BPH medications at baseline compared to men who were not on any BPH medications at 6 months follow-up, however this did not reach clinical significance in either the WATER or WATER II trials (p=0.14 and p=0.52, respectively). Conversely, men on BPH medication at baseline in the TURP group had lower rates of Calvien-Dindo grade 2 complications compared to those not on BPH medications at baseline, however this did not reach significance (p=0.2).

Gloger et al., 2021 is a retrospective, single center nonrandomised comparative study including 167 men who had waterjet ablation with subsequent selective bipolar cauterization and 215 men who had HoLEP. The primary aim of the study was to assess the risk of perioperative bleeding complications. Transfusions were not necessary in the Aquablation group, while one man who underwent HoLEP had to receive a transfusion. Revision surgery due to bleeding was necessary during the early postoperative course in 13.2% of Aquablations and in 9.8% of HoLEPs (statistically not significant; p = 0.329). The perioperative hemoglobin loss was comparable in both entire collectives (Aquablation 1.37 +/- 1.13 mg/dL, HoLEP 1.22 +/- 1.03 mg/dL; statistically not significant; p = 0.353). For subgroup analysis the groups Aquablation and HoLEP were into three subgroups respectively according to sonographically determined preoperative prostate volume ('small' < 40 mL, 'medium' 41-80 mL, 'large' > 80 mL). The small subgroup contained primarily Aquablations, and the large subgroup contained primarily HoLEPs. There were no

significant differences between the subgroups regarding need for transfusions and hematuria-related complications. The mean length of hospital stay (SD) was significantly longer for the Aquablation group 3.9 (2.0) days compared to 3.4 (1.6) days in the HoLEP group (p=0.001). The mean catheter time in days (SD) was also significantly longer for the Aquablation group 4.2 (4.8) days compared to 3.0 (2.5) days for the HoLEP group.

Misrai et al., 2019, published results from the French Aquablation Clinical Investigation Using Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue (FRANCAIS WATER) (NCT03191734) study. The study was sponsored by the device manufacturer (PROCEPT BioRobotics, Redwood City, CA, USA). This is a single arm, multi-center prospective clinical trial to determine the safety and effectiveness of the AQUABEAM System in the treatment of benign prostatic hyperplasia (BPH) in men 45 to 80 years of age. The primary endpoint was the change in total International Prostate Symptom Score (IPSS) score at 6 and 12 mo. Functional outcomes were assessed at 1, 3, 6, and 12 months with IPSS, International Index of Erectile Function (IIEF)-15, Sexual Health Inventory for Men, and Male Sexual Health Questionnaire questionnaires and uroflowmetry. Thirty patients were enrolled in the study. The median operative time and resection time were 30.5 (24–35) and 4 (3.1–4.9) min, respectively. The median catheterization time was 43 (23–49) hours. The median hospitalization stay was 2 (2–4) days. The IPSS score improved to 3 (1–6) at the 6 months, with a mean change of 15.6 points (95% confidence interval 13–18.2). IPSS improvements persisted at month 12. The maximum urinary flow rate improved to 20.4 (17–26) ml/s at 12 mo. The 6-mo rates of Clavien-Dindo grade 2 and 3 events were 13.3%. There were no reports of incontinence or de novo erectile dysfunction. Postoperative de novo ejaculatory dysfunction was observed in 26.7% of patients.

Bach et al,, 2020 published results from the Global Post-Market Registry Using Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue (OPEN WATER) (NCT02974751). The study was sponsored by the device manufacturer (PROCEPT BioRobotics, Redwood City, CA, USA). OPEN WATER is a prospective, multicenter, single-arm, open-label, international clinical trial of the Aquablation procedure for the treatment of lower urinary tract symptoms (LUTS) due to BPH. To be included, men had to have a diagnosis of LUTS due to BPH and a prostate size between 20 and 150 cc. Men were excluded if they were unable to stop anticoagulants and antiplatelet agents perioperatively or had a bleeding disorder, had a history of gross hematuria, were using systemic immune suppressants, had a contraindication to both general and spinal anesthesia, were unwilling to accept transfusion if required, or had any severe illness that could prevent complete follow-up. Patients with prior BPH surgery were not excluded. A total of 178 men were enrolled at five centers (one each in the United Kingdom, Germany, Australia, New Zealand, and Lebanon) between September 2017 and December 2018. All patients were eligible for the study, except for one subject, who had a coagulopathy that was undiagnosed at the time of the procedure. Of the 178 subjects who enrolled and underwent the study procedure, by month 12, 30 subjects were lost to follow-up, three voluntarily withdrew and one died of non-urologic cause. Loss to follow-up at one site was high due to political instability. The study's primary efficacy endpoint was the change in total IPSS score from baseline to 3 months. The mean operative duration (handpiece placement to urinary catheter placement) was 24 min (range 8–70 min). The mean total anesthesia duration was 50 min (range 22–115 min). Post-procedure hemostasis was achieved utilizing a urinary catheter with the surgeon's preference of bladder neck traction. In 19 (10.7%) cases, hemostasis was augmented with focal cautery. The median catheterization time following surgery was 1.9 days. Hospital length of stay averaged 2.2 days (range 0–12). Five patients (2.7%) underwent transfusion in the first week after the procedure; of these, one was for delayed (day 6) bleeding. Fourteen (7.9%) patients were taken back to the operating room for post-procedure bleeding; hemostasis was achieved with cautery at the bladder neck or prostatic fossa. One patient returned twice to the operating room (OR) for clot evacuation. Mean (SD) IPSS improved from 21.7 (7.1) at the baseline to 7.1 (5.8) at the 3-month follow-up (a 14.5-point improvement, $p < 0.0001$), and 6.4 (4.8) at the 12-month follow-up (a 15.3-point improvement, $p < 0.0001$). Mean (SD) IPSS QOL scores improved from 4.7 (1.1) at the baseline to 1.5 (1.4) at the 3-month follow-up, a 3.1-point improvement ($p < 0.0001$), and 1.4 (1.4) at the 12-month follow-up (a 3.3-point improvement, $p < 0.0001$). The 3-month and 12-month IPSS scores were independent of baseline IPSS. Maximum urinary flow rate increased from 9.9 (5.3)

cc/sec at baseline to 20.3 (11.4) cc/sec at month 3 and 20.8 (11.2) cc/s at month 12 (both increases $p < 0.0001$ vs. the baseline). Post-void residual improved from 108 (108) to 47 (77) cc at three months and 61 (74) cc at 12 months (both $p < 0.0001$ vs. the baseline). Amongst 92 men who were sexually active at both the baseline and the 12-month follow-up study visit, MSHQ-EjD score changed by −1 point at 3 months ($p = 0.0994$) and by −1.1 points at 12 months ($p = 0.0884$). MSHQ bother changed by −0.3 and −0.7 points at 3 and 12 months ($p = 0.0962$ and 0.0025). Eighty-two patients (46%) were taking medications for BPH preoperatively. By month 3, all but eight had stopped these medications. Five patients began alpha blockers during the follow-up. Nineteen were taking 5-alpha reductase inhibitors at the baseline; of these, all but one stopped and one started ARIs during follow-up.

Elterman et al, 2020 was a post hoc analysis to determine the transfusion rate in patients (n=801) treated with Aquablation therapy from 2014 to 2019. These patients participated in four studies including (WATER; NCT02505919), WATER II (NCT03123250), Français-WATER (NCT03191734), and OPEN WATER (NCT02974751). The mean (SD, range) prostate volume was 67 (33, 20–280) mL and 31 (3.9%) transfusions were reported. The largest contributing factor to transfusion risk was prostate size and method of traction. There was an increasing risk of transfusions in larger prostates when robust traction using a catheter-tensioning device without cautery was used, ranging from 0.8% to 7.8% in prostates ranging from 20 to 280 mL. However, when standard traction (taping the catheter to the leg, gauze knot synched up to the meatus, or no traction at all) was used and where the surgeon performed bladder neck cautery only when necessary, the risk of transfusion was 1.4–2.5% in prostates ranging from 20 to 280 mL. Most transfusions occurred before hospital discharge and none of the transfusions occurred beyond 30 days. While the transfusion rate is similar in small prostates, the transfusion rate increased 2–5-fold with robust traction over medium and large volumes. In all, 35% of the standard traction method procedures utilized focal bladder neck cautery. Hemoglobin changes followed a similar pattern, with statistically significantly larger predicted perioperative drops in patients with larger prostates, and a lesser change when cautery was used (all $P < 0.001$). Intraoperative hemostasis management is a critical part of any prostate resective surgery to minimize bleeding events. TURP, photoselective vaporization, endoscopic enucleation of the prostate, and open simple prostatectomy all rely on intraoperative cautery by a monopolar device or laser technology for hemostasis management, which have had varying degrees of success in minimizing postoperative transfusions based on prostate size.

Elterman et al., 2021 is a post hoc analysis to determine if focal bladder neck cautery is effective in reducing bleeding following prostate tissue resection for benign h=prostatic hyperplasia using Aquablation. Between late 2019 and January 2021, 2,089 men with prostate size ranging from 20 to 363 ml, had non-resective focal cautery at the bladder neck after water-jet ablation. An inherent limitation of the athermal Aquablation procedure is the absence of a direct method to achieve post-resection hemostasis. In WATER II, a balloon tamponade without electrocautery was associated with a 9.9% rate of transfusion. In the analysis combining results from 4 trials, Elterman et al., 2020, reported a transfusion rate of 3.9%. In 2019, surgeons noted that the use of non-resective focal bladder neck cautery (FBNC) following Aquablation was associated with lower transfusion rates. Between late 2019 and January 2021, 2,089 Aquablation procedures were performed using FBNC. The mean (SD) prostate size was 87 cc ± 44 cc (range 20-363 cc). The average time spent after removing the handpiece to inserting the urinary catheter was 19.9 minutes ± 10.9 minutes. This segment of the procedure includes flushing, transitioning to the rectoscope, cauterizing at the bladder neck and final flushing. Postoperative bleeding requiring transfusion occurred in 17 cases (0.8%). This result compares favorably (p<.0001) to the previously published hemostasis aggregate transfusion rate of 3.9% (31/801). In the 17 transfusions reported, none occurred beyond 3 days post-Aquablation and the average number of units given was 2. Four (24%) of the transfusions occurred in patients who were on anticoagulant or antiplatelet therapy. Eighty-eight percent (88%) of transfusions occurred before a surgeon's sixth Aquablation procedure.

There was also a report from the FDA MAUDE database (Kaplan-Marans et al., 2021). Kaplan-Marans et al. is a comparison of device-related adverse events in the FDA MAUDE database

associated with 3 procedures used to treat BPH (water-jet ablation, prostatic urethral lift and transurethral water vapor therapy). A total of 391 adverse events were described between 2015 and 2020. The MAUDE database includes mandatory reports from manufacturers and device importers when a device may have caused injury to a patient, and voluntary reports from other sources, including healthcare professionals and patients. Limitations of the database include under-reporting, duplicate reporting, incomplete reports and uncertainty if the device caused the complication being described. The true denominator for these events is not captured and the database is not designed to calculate or compare complication rates.

Systematic Reviews

Chen et al., 2023 performed a systematic review and meta-analysis to evaluate the improvements in lower urinary tract symptoms in men with benign prostatic hyperplasia (BPH) treated with prostatic Aquablation. The literature search included clinical trials published up to August 2021. Seven studies were included in this review (n = 551 patients), one randomized controlled trial and 6 cohort studies. A significant improvement in LUTS was observed in the pooled analysis of the IPSS reported by 7 included studies. There was an estimated improvement of −16.47 (95% CI, −17.69 to −15.26) on the IPSS scale at the 3-month follow-ups. At 12 months, the pooled summary of IPSS change reported by 4 of the 7 studies was similar to the 3-month follow-up outcomes. Although not directly comparable, these results seem superior compared with medical therapies and minimally invasive surgical interventions options, which both reported improved IPSS at 12 months by 3.5–7.5 and 7.2–8.7 points, respectively. The IPSS improvements are in line with other invasive enucleative approaches, such as TURP and photoselective vaporization of the prostate, which demonstrated significant improvements in IPSS of up to 15.5 points at 3 months. However, substantial heterogeneity was observed in all of the pooled IPSS estimates. In addition to patient-reported outcomes, the objective functional benefits of Aquablation were also observed in the pooled estimate. Specifically, improvements in Qmax were observed in the pooled estimates by a magnitude of 10.95 mL/s at the 3-month follow-ups ($p < 0.001$). Similar to the IPSS, the changes demonstrated in Qmax were maintained at the 12-month follow-ups. It should be noted, however, that there was substantial heterogeneity in the preoperative Qmax score, but only some heterogeneity for all other pooled estimates. Maximal urinary flow rate improvements noted in the current meta-analysis, as demonstrated by Aquablation, seem superior to medical and minimally invasive therapies. Aquablation functional improvements produced were comparable with those of TURP and photoselective vaporization of the prostate, which are associated with improved Qmax values of 10–13 mL/s at 12-month follow-ups. Regarding sexual function, the current meta-analysis included 4 cohorts that reported MSHQ in patients undergoing Aquablation. The association between sexual dysfunction and LUTS remains complex. LUTS are an independent risk factor for sexual dysfunction suggesting that medical or surgical interventions may impact sexual outcomes. Sexual function after medical treatment has inconsistent effects on libido, sometimes resulting in erectile and ejaculatory dysfunction. It should be noted that heterogeneity in the sexual outcomes measured existed. As the included studies reported International Index of Erectile Function, MSHQ-Bother, and MSHQ (total) scores variably, meta-analysis was only performed on studies reporting MSHQ (total) because of data availability. The pooled estimates of the overall sexual function scores suggested nonsignificant declines at the 3-month follow-ups. It should be noted that the magnitude of the decline was quantified at −0.55 (95% CI, −1.621 to 0.531). This decline is of a lower magnitude than expected compared with TURP, which is estimated at −2.5 based on the placebo arm of the WATER trial. Accordingly, it may be considered that there is currently no evidence that Aquablation drastically affecting sexual function postoperatively. While it should be noted that there was moderate statistical heterogeneity in the 3-month estimate, these results seem favorable. While still requiring the patient to undergo general anesthesia along with its associated risks, the mean procedural time and mean Aquablation sequence time ranged between 24 and 59 minutes and 3.2 and 8 minutes, respectively. Such a reduction in operative time is favorable when compared with TURP, which ranges from 35 to 81 minutes in operative time. Three articles reported hematuria postoperatively, with bleeding rates of 2.12% and 19.8%. Three articles reported reoperation secondary to hematuria, with return-to-theater rates of bleeding between 2.12% and 10%. Comparatively, the return to theater rate for hematuria in TURP is approximately

2.7%. The authors conclude that Aquablation seems to improve lower urinary tract symptoms in men with BPH while providing relatively preserved sexual function. Further research is required to confirm these preliminary results. Meta-analyses of some outcomes showed evidence of publication bias.

NICE (National Institute for Health and Care Excellence)

In 2018, NICE issued the following guidance on transurethral water jet ablation for LUTS caused by BPH. "The evidence on transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia raises no major safety concerns. The evidence on efficacy is limited in quantity. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research (NICE, 2018)." Special arrangements means that there are uncertainties about whether a procedure is safe or effective. NICE may also recommend special arrangements if risks of serious harm are known. These will need to be carefully explained to a patient before they make a decision. A special arrangements recommendation places emphasis on the need for informed consent.

In 2023, NICE issued updated guidance "Transurethral water-jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia may be used if standard arrangements are in place for clinical governance, consent and audit." NICE made this recommendation because "There is a lot of good quality evidence that the procedure improves lower urinary tract symptoms caused by BPH and is safe enough to use with standard arrangements (NICE, 2023)." Standard arrangements is the most positive recommendation and means there is enough evidence for doctors to consider this procedure as an option.

American Urological Association (AUA) Guideline Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia

The American Urological Association's guidelines on the Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia (Lerner et al., 2021b) are based on the best available evidence of literature and scientific data that identify characteristics and components of quality of care.

The American Urological Association includes robotic waterjet treatment (RWT) in its surgical practice guidelines as a treatment option for patients with LUTS/BPH provided prostate volume 30-80cc. (Conditional Recommendation; Evidence Level: Grade C).

- Conditional Recommendations are non-directive statements used when the evidence indicates that there is no apparent net benefit or harm or when the balance between benefits and risks/burdens is unclear.
- Evidence Level: Grade C means that the balance between benefits and risks/burdens is unclear. Alternative strategies may be equally reasonable. Better evidence is likely to change confidence.

According to the American Urological Association, the technique is not in the MIST (Minimally Invasive Surgical Technique) category as patients must undergo general anesthesia.

Five publications from a low risk of bias RCT (Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue (WATER); ClinicalTrials.gov number, NCT02505919) assessing RWT were evaluated by the Panel (Gilling et al., 2019, Gilling et al., 2020, Gilling et al., 2018, Plante et al., 2019, Gilling et al., 2022). Other publications evaluating RWT were excluded from analysis because of their cohort (not comparative) study design.

The Water trial was an industry-sponsored (PROCEPT BioRobotics) prospective multicenter randomized blinded study comparing Aquablation of the prostate with the AQUABEAM System (n=117) and TURP (n=67) for the treatment of Lower Urinary Tract Symptoms (LUTS). The primary endpoints for safety and effectiveness were measured at 3 and 6 months, respectively, and subjects were followed out to 5 years to collect long-term clinical data. The WATER trial utilized standard inclusion/exclusion criteria limiting participants to prostate sizes between 30-80g, and ages from 45 to 80 years.

The primary effectiveness endpoint is the International Prostate Symptom Score (IPSS) change score from baseline to 6 months. IPSS ranges from 0 to 35. A higher score indicates a worse outcome. At 6 months, the IPSS score for RWT and TURP were similar, -16.9 (6.6) versus -15.1 (7.9), respectively. Long-term effectiveness was measured by IPSS score at 60 months as compared to baseline. Score range is from 0 to 35, with a low score associated with more favorable outcomes. Change score is calculated from two time points as the value at the 60 months point minus the value at the baseline. Mean improvement in LUTS based on the IPSS through 12, 24, 36, and 60 months was similar for RWT and TURP (quality of evidence was rated moderate for IPSS mean-change from baseline for RWT compared to TURP). Mean improvement in QoL based on the IPSS-QoL through 12, 24, 36, and 60 months was similar for RWT and TURP (quality of evidence was rated moderate for long-term mean improvement in QoL based on the IPSS-QoL for RWT compared to TURP). At 12 months follow-up, maximum flow rate increased similarly in the RWT group compared to TURP, 10.3 versus 10.6 mL/s (P=.86), respectively. At 24 months, maximum flow rate for RWT and TURP was 11.2 mL/s and 8.6 mL/s respectively (P=.19), at 36 months and this was maintained at 60 months.

The primary safety endpoint is the proportion of subjects with adverse events rated as probably or definitely related to the study procedure classified as Clavien-Dindo Grade 2 or higher or any Grade 1 event resulting in persistent disability (e.g. ejaculatory disorder or erectile dysfunction) evidenced through 3 months post treatment. At 3 months, RWT resulted in fewer harms classified as Clavien-Dindo grade ≥2 compared to TURP, 26% versus 42%, P=.015. Also at 3 months, reduction in prostate volume was significantly less with RWT (31%) compared to TURP (44%) (P=.007). Additionally, rates of RE were higher (P=.002) with TURP (23%) compared to RWT (6%). At three years, post-operative anejaculation was noted less frequently in the RWT group (11%) compared to the TURP group (29%), P<.05. Other harms classified as Clavien-Dindo grades 1-4 occurred at similar rates in both groups, including bladder spasms, bleeding, dysuria, pain, and urethral damage. No deaths were reported. The authors reported the need for additional therapy at 60 months follow-up in 6% of participants after RWT and 12% of participants after TURP; however the need for additional surgical therapy was 5% of participants after RWT compared to 2% after TURP.

AUA Guideline Amendment 2023

A 2023 AUA Guideline Amendment was published by Sandhu et al., 2024. In 2023, an update review assessing abstracts from new studies published since the initial release of the 2019 Guideline was completed utilizing the same search strategies employed in the original guideline with search dates updated through October 2022. Relevant literature was graded and incorporated into existing text to produce the 2023 amendment. The Amendment resulted in changes to statements/supporting text on combination therapy, photoselective vaporization of the prostate (PVP), water vapor thermal therapy (WVTT), laser enucleation, and prostate artery embolization (PAE). A new statement on temporary implanted prostatic devices (TIPD) was added. In addition, statements on transurethral needle ablation (TUNA) and transurethral microwave thermotherapy (TUMT) were removed and information regarding these legacy technologies was added to the background section. References and the accompanying treatment algorithms were updated to align with the updated text. The Amendment did not result in changes to the previous recommendation for robotic waterjet treatment (RWT).

Analysis of Evidence (Rationale for Determination)

Promising short- and mid-term results for waterjet ablation (WATER) resulted in a conditional recommendation from the American Urological Association (AUA) (Lerner et al., 2021b). The conditional recommendation with Grade C evidence level translates to “Balance between benefits & risks/burdens unclear; Alternative strategies may be equally reasonable; Better evidence likely to change confidence.”

The safety and efficacy of Aquablation were established in the WATER (NCT02505919) and WATER II (NCT03123250) clinical trials. Both of these studies are sponsored by PROCEPT BioRobotics, the device manufacturer. In the pivotal WATER trial, Aquablation demonstrated superior safety and non-inferior efficacy compared with TURP in patients with prostates ranging

from 30 mL to 80 mL. The primary safety end point for the study was met at 3-month follow-up, with Aquablation demonstrating a lower event rate (Clavien-Dindo persistent Grade 1 or Grade 2 or higher operative complications) vs TURP (26% vs 42%; P =.0149 for superiority). WATER I trial included 181 patients across clinical trial sites in the US, UK, Australia, and New Zealand. The study's primary efficacy end point of a reduction in International Prostate Symptom Score (IPSS) was achieved at 6 months, with a mean IPSS decrease of 16.9 points from baseline for Aquablation compared with 15.1 points for TURP. (P < 0.0001 for non-inferiority; P = .1346 for superiority). At the study's final follow-up at 5 years, patients in the Aquablation arm had experienced an average IPSS improvement of 15.1 points, vs 13.2 points in the TURP arm (P = 0.2764).

WATER II was a prospective, single-arm trial that evaluated the safety and efficacy of Aquablation in patients with prostates ranging from 80 mL to 150 mL. In total, the trial enrolled 101 patients across 16 clinical trial sites in the US and Canada. The study met its primary safety and efficacy end points at 3 months, which were the incidence of Clavien-Dindo adverse events and the change in total IPSS from baseline, respectively. At 5 years, the average IPSS improved from 22.6 at baseline to 6.8 ($P < .001$). The average maximum urinary flow rate also improved from 8.6 mL/s at baseline to 17.1 mL/s at 5 years ($P < .001$). Further, 96.3% of patients were free from a secondary BPH procedure at 5 years, per Kaplan-Meier estimates.

A recent systematic review and meta-analysis of seven studies (one randomized controlled trial and 6 cohort studies) concluded that Aquablation seems to improve lower urinary tract symptoms in men with BPH while providing relatively preserved sexual function. Further research is required to confirm these preliminary results. Additionally, meta-analyses of some outcomes showed evidence of publication bias. The majority of studies are industry-sponsored.

Aquablation demonstrates improvements in lower urinary tract symptoms due to benign prostatic hyperplasia lasting at least 5 years, with a safety profile comparable to that of TURP. Initial issues with hemostasis have been successfully overcome with the use of bladder neck cautery after the procedure, allowing for early catheter removal. Although long-term studies are needed, the results are promising and challenge the current surgical and laser techniques used to reduce the size of the prostate gland.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

HCPCS C2596 is specific to the probe used in image-guided, robotic, waterjet ablation. C2596 has pass-through status effective 1/1/2020 through 12/31/2022 (reimbursed at "reasonable cost"). Pass-through status for C2596 applies to OPPS and ASC settings. Beginning 1/1/2023, pass-through status is expired and C2596 will not reimbursed separately under OPPS or ASC reimbursement methodology.

Code	Description
0421T	Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)
C2596	Probe, image-guided, robotic, waterjet ablation

ICD-10-CM	Description
N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms

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Policy history

Origination date:	06/01/2022
Review/Approval(s):	Technology Assessment Committee: 05/24/2022 (policy origination), 09/24/2024 (annual review, added coverage criteria for Community Care members, added Summary of Evidence and Analysis of Evidence, updated References), 11/25/2025 (annual review, revised clinical coverage criteria by removing the voided volume requirement and by eliminating the requirement to determine prostate volume by transrectal ultrasound, added new sections for Medicare and MassHealth Variation). Utilization Management Committee: 10/15/2024 (annual review, approved coverage criteria for Community Care members), 12/16/2025 (annual review, approved removal of voided volume requirement and elimination of requirement to determine prostate volume by transrectal ultrasound).

Instructions for Use

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Fallon Health generally follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

For plan members enrolled in NaviCare, Fallon Health first follows CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.