**Clinical Review Criteria**

**Benign Prostatic Hyperplasia (BPH) Treatments**
- Rezum System for the Treatment of LUTS due to BPH
- Prostatic Urethral Lift (PUL or UroLift)
- Prostate artery embolization (PAE) for benign prostatic hyperplasia (BPH)

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### Criteria for Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>None</td>
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<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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| Local Coverage Article                      | Urolift: [Local Coverage Article: Urolift (A54044)]  
Noridian retired Local Coverage Article (LCA A54044). These services still need to meet medical necessity as outlined in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCAs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on KPWA commercial criteria or literature search. |
| KPWA Medical Policy                         | Rezum: Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, "Rezum System for the Treatment of LUTS due to BPH," for medical necessity determinations. Use the Non-Medicare criteria below. |

### For Non-Medicare Members

<table>
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<th>Service</th>
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| Urolift         | Covers prostatic urethral lift (e.g., UroLift) as medically necessary for the treatment of symptomatic benign prostatic hyperplasia (BPH) when **ALL of the following** criteria are met:  
A. age 50 or above  
B. prostate volume < 80 cc on ultrasound imaging  
C. no obstructive median lobe of the prostate identified on cystoscopy  
D. failure, contraindication or intolerance to at least six months of conventional medical treatment |
Background

Benign prostatic hyperplasia (BPH), also known as prostate gland enlargement, is a common urologic condition that affects 14-30% of men 50 years of age or older. The enlarged prostate is often associated with progressive obstructive lower urinary tract symptoms (LUTS), which may impair the quality of life in older men. Common signs and symptoms of LUTS secondary to PBH include nocturia, frequent or urgent need to urinate, difficulty starting urination, weak urine stream or a stream that stops and starts, dribbling at the end of urination, and inability to completely empty the bladder. The severity of these symptoms varies among patients, but they tend to increase with age (Dixon 2016, Darson 2017, Helo 2017).

The treatment of LUTS depends on the patient’s symptoms and level of bother. Therapeutic options include:
- Watchful waiting (active surveillance) for patients with mild symptoms of LUTS secondary to BPH and for patients with moderate-to-severe symptoms who are not bothered by their symptoms and are not experiencing complications of BPH.
- Lifestyle modification is initially recommended for patients with bothersome LUTS that begin affecting their quality of life.
- Drug therapy (e.g. alpha-blockers, 5-alpha-reductase inhibitors, muscarinic receptor antagonists and phosphodiesterase 5, inhibitors) is an appropriate and effective treatment for patients with bothersome, moderate to severe LUTS secondary to BPH.
- Surgical intervention is appropriate for patients with moderate-to-severe LUTS, acute urinary retention, or other complications due BPH. Surgery is the most invasive option for BPH management and is generally performed in patients who have failed medical therapy. However, some patients may wish to pursue the most effective therapy as a primary treatment if their symptoms are particularly bothersome (American Urological Association Guideline).

Transurethral resection of the prostate (TURP) and open simple prostatectomy are currently the gold standard surgical interventions. Both are highly effective and provide durable improvement in urinary functional outcomes. However, despite the refinements made in the operative technique, these invasive procedures are associated with perioperative complications and morbidity including bleeding, erectile and ejaculatory dysfunction, urethral stricture, urinary tract infection, and urinary incontinence (Chung 2018, Christidis 2017, Magistro 2017).

Several novel minimally invasive therapies have been developed, or are at different stages of development, with the aim of improving the patients’ symptoms and avoiding the adverse outcomes of associated with the more invasive surgeries. Among these therapies are the UroLift System, intraprostatic injectables, temporary implantable nitinol device, image guided robotic waterjet ablation, transurethral microwave therapy (TUMT), convective water vapor energy (WAVE) ablation, prostatic artery embolization, and others. An ideal minimally invasive treatment would be an intervention that can be easily performed in the office or in an outpatient setting, leads to rapid and durable relief of symptoms, is associated with minimal morbidity and recovery time, and preserves the erectile and ejaculatory functions of the patient (Chung 2018, Magistro 2017).

Rezūm System; NxThera, Inc. Maple Grove, MN) is a minimally invasive transurethral therapy that uses the stored thermal energy in water vapor (steam) to treat the extra prostate tissue that is causing symptoms. Tissue ablation with Rezūm System uses the thermodynamic principle of convection energy transfer in contrast to conductive heat transfer techniques used in the transurethral microwave therapy or transurethral needle ablation. The Rezūm

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system utilizes radiofrequency (RF) to generate wet thermal energy in the form of water vapor (steam). Once the vapor (103°C) is injected, it disperses through the tissue spaces and immediately changes to liquid releasing and delivering approximately 208 cal of thermal energy in 9 seconds. The target tissue temperature reaches 70°C resulting in irreversible and near instantaneous cell death. No thermal effects occur outside the prostate or in the peripheral zone when a transition zone is targeted. In addition, as the vapor is wet thermal energy, there is no charring, desiccation, or carbonization of the treated tissue. The dead tissue will be eventually absorbed by the body through its natural healing response (Dixon 2016, Christidis 2017, Woo 2017 Magistro 2017).

The Rezūm System is composed of a generator containing a radiofrequency power supply to create water vapor from sterile water, and a single use transurethral delivery device that incorporates a standard 4 mm 30° rod lens allowing the procedure to be performed under direct cystoscopic visualization. The tip of the delivery device contains an 18-gauge polyetheretherketone needle which has 12 small emitter holes spaced around its tip at 120° intervals to allow for circumferential dispersion of water vapor into the prostate tissue. (Darson 2017, Woo 2017).

The procedure is performed in the clinic or out-patient setting, under cystoscopic guidance and oral sedation. Radiofrequency energy is applied to a few drops of water (0.5ml) to create vapor inside a hand-held device. The patient is placed in the lithotomy position and the delivery device is inserted into the urethra; the total penetrating length of the vapor needle is fixed at 10.25mm. Its tip is visually positioned and inserted approximately 1cm distal to the bladder neck. Once the delivery system is within the prostate, the needle is deployed, and a 9-second burst of water vapor is injected into the prostatic tissue. This disperses rapidly and homogeneously through the tissue spaces and immediately condenses to water releasing the energy stored in the vapor into the cell membranes causing cell death and necrosis. The needle is retracted after each treatment and repositioned in 1cm increments distal from the previous site with the objective of creating adjacent overlapping lesions running parallel to the natural slope of the urethra. Usually 1-3 injections are needed for each lateral lobe and 1-2 injections for the median lobe. The total number of injections may vary according to size of the hypertrophied prostate tissue and the length of the urethra (McVary 2016, Woo 2017, Chung 2018).

Potential procedure-related side effects include acute urinary retention, failure of the procedure requiring secondary surgery, posttreatment dysuria, hematuria, frequency & urgency, hematospermia and urinary tract infection. According to the manufacturer, most of these events resolve within 3 weeks of the procedure, but there is a possibility that some may last longer.

Medical Technology Assessment Committee (MTAC)

Convection Radiofrequency Thermal Therapy with Rezūm System (convective water vapor energy [WAVE] ablation) for the Treatment of Lower Urinary Tract Symptoms due to Benign Prostatic Hypertrophy

04/21/2018: MTAC REVIEW

Evidence Conclusion:

- There is no published evidence to determine the comparative efficacy and safety of convection radiofrequency thermal therapy with the Rezūm System and transurethral resection of the prostate (TURP), open simple prostatectomy, or other noninvasive intervention currently used in practice for relieving bothersome lower urinary tract symptoms secondary to benign prostatic hypertrophy.
- The published literature on Rezūm System consisted of one relatively small randomized sham-controlled trial with a duration of three months after which it was converted to an observational study comparing outcomes to baseline data, as well as a small pilot study and two retrospective analyses with no control groups and overall poor quality.
- The published literature only provides low quality evidence suggesting that treatment with Rezum System may improve LUTs secondary to BPH compared to sham therapy or no treatment.

Articles: The literature search for studies on the efficacy and safety of Rezūm system for the treatment LUTS secondary to BPH, identified one randomized sham-controlled trial that reported three years follow-up results in 4 publications (McVary 2015, 2016 & 2018, and Roehrborn 2017), as well as three pretest-posttest studies (one small pilot study with 2 years follow up results [Dixon 2012, and 2016] and two retrospective analyses [Darson 2017 and Mollengarden 2017]). All 4 studies were critically appraised. See Evidence Table 1.

The use of Rezūm System (convective water vapor energy [WAVE] ablation) for the Treatment of Lower Urinary Tract Symptoms due to Benign Prostatic Hypertrophy does not meet the Kaiser Permanente Medical Technology Assessment Criteria.
**Criteria | Codes | Revision History**

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**Rezum for Lower Urinary Tract Symptoms (LUTS) due to Benign Prostatic Hyperplasia (BPH)**

**03/04/2019: INTC REVIEW**

**Evidence Conclusion:** There is insufficient evidence to draw a conclusion on use of Rezum. The existing evidence is of insufficient quantity and quality.

**Articles:** The published literature on Rezūm System consisted of one relatively small randomized sham-controlled trial with a duration of three months after which it was converted to an observational study comparing outcomes to baseline data, as well as a small pilot study and two retrospective analyses with no control groups and overall poor quality. Two indirect comparisons of Rezūm versus other medical therapy trial data were also reviewed. The available published literature provided low quality evidence suggesting that treatment with Rezum System may improve LUTs secondary to BPH compared to sham therapy or no treatment.

[https://cl.kp.org/pkc/national/cpg/intc/topics/03_04_191.html](https://cl.kp.org/pkc/national/cpg/intc/topics/03_04_191.html)

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**Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH)**

**03/21/2016: MTAC REVIEW**

**Evidence Conclusion:** Conclusion from INTC review - “Urolift may be viable alternative to TURP for patients with LUTS secondary to BPH. Short-term data from low to moderate quality, industry-funded studies conclude that UroLift is effective and safe. The overall quality of the evidence is low to moderate. However, due to concerns regarding risk of bias in these studies, a definitive conclusion regarding the long-term safety and effectiveness of UroLift cannot be made from existing evidence. Additional, high quality studies with longer follow-up are needed to confirm preliminary findings”.

**Articles:** Since the search did not identify new studies, and because INTC evidence review is recent, their review can be adopted. In addition, the search did not find studies comparing PUL to medical management. See Summary of RCTs.

The use of Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH) does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

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**Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH)**

**06/28/2017: MTAC REVIEW**

**Evidence Conclusion:** One study (C Roehrborn et al., 2016) (See Evidence Table 1) assessed the long term (4 years) effectiveness and safety of PUL. PUL was compared to sham control. Characteristics of patients were similar. Patients were randomized to either PUL (N=140) or sham control (N=66) at 19 centers in North America and Australia and followed for 4 years. The authors reported that Urolift improved urinary symptoms, preserved sexual and ejaculatory function with minor adverse events. The authors indicated that durability of these effects needs to be confirmed at 5-year follow-up. The risk of bias is unclear for incomplete outcome data and the major limitation is the high attrition rate. The author of the previous study (Claus Roehrborn et al., 2017) (See Evidence Table 2) confirmed the durability of PUL effects in the 5-year follow-up study. Urinary symptoms (IPSS), BPHII, flow rate (Qmax), QoL, erectile and ejaculation functions were improved and/or preserved with minimal complications. Another abstract was reviewed (Henry Woo). Comparison was made between PUL and sham. This was a crossover study wherein 53 patients were enrolled. Patients were treated with sham, then crossover occurred, and patients were followed for 4 years. Compared to baseline, IPSS, QoL, and BPHII statistically improved at 45%, 49%, and 44% respectively (P<0.001). Flow rate (Qmax) also increased by 50% (P=0.01). Adverse events were mild. Level of evidence: In the first two studies, the risk of bias is unclear for incomplete outcome data and low in other domains of risk of bias assessment; no serious precision or directness issues were identified; findings were consistent; the quality of the study assessed by Modified Jadad Scale is high. The studies provide moderate evidence to support the use of PUL.

**Conclusion:**
- The long-term effectiveness and safety are based on three articles that compare PUL versus sham over 4 and 5 years. Compared to sham, moderate level of evidence indicates that PUL is effective and durable in patients with LUTS due to BPH on the long-term.
- The technology is also safe with minimal complications.

The use of Prostatic Urethral Lift (PUL or UroLift) for the treatment of benign prostatic hyperplasia (BPH) does meet the Kaiser Permanente Medical Technology Assessment Criteria.

Prostate artery embolization for benign prostatic hyperplasia (BPH)
10/14/2019: MTAC REVIEW

Evidence Conclusion:
- Low-quality evidence shows that prostatic artery embolization (PAE) may be less effective than TURP in terms of patient-reported and functional outcomes on the short-term.
- Low-quality evidence suggests that PAE may cause fewer complications than TURP, preserve erectile function, and decrease the duration of hospitalization. More RCTs with enough power and longer follow-up are warranted.
- There is insufficient evidence to compare PAE vs open prostatectomy.

Articles: PubMed search was conducted up to August 8, 2019 with the search terms prostate artery embolization. Other search terms included low urinary tract symptoms or LUTS, and benign prostatic hyperplasia or BPH. The search yielded 7 meta-analyses. Of these, four were retained (two meta-analyses with comparative studies and two with noncomparative studies). The other meta-analyses are included in other references because their findings are similar to that of the two meta-analyses of noncomparative studies retained. In addition, the search yielded 8 RCTs. Of the 8 RCTs, none was retained (RCTs were either included in meta-analysis or were out of scope). Regarding nonrandomized studies, search yielded 18 studies, but none was included due to their inclusion in the meta-analyses of noncomparative studies. The search was limited to English language publications and human populations. The reference lists of relevant studies were reviewed to identify additional publications. See Evidence Table.

The use of Prostate artery embolization for benign prostatic hyperplasia (BPH) does meet the Kaiser Permanente Medical Technology Assessment Criteria.

Medical Technology Assessment Committee (MTAC)

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<th>Date Created</th>
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<th>Date Last Revised</th>
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<td>12/03/2019</td>
<td>12/03/2019&lt;sup&gt;MP&lt;/sup&gt;C</td>
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<th>Revision History</th>
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<tr>
<td>12/03/2019</td>
<td>Merged all BPH criteria (Urolift, Rezum, PAE) into one document</td>
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<tr>
<td>12/03/2019</td>
<td>MPC approved non-coverage policy for Prostate artery embolization (PAE) for benign prostatic hyperplasia (BPH)</td>
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Codes

CPT
Rezum 53899
Urolift 52441, 52442, C9739, C9740
Prostate Artery Embolization (PAE) 37242, 37243