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To: NGS LCD Reconsideration-WELLPOINT (Shared Mailbox)

Subject: {EXTERNAL} FW: Rezum prostate size Date: Thursday, September 10, 2020 3:30:37 PM

Attachments: largegland.pdf

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To whom it may concern,

ope you are doing well in this crazy year. I wanted to touch base with you on the size restriction for convective water vapor thermal therapy for BPH. I have done several hundred now and am quite happy with the results. I am on the BPH Guidelines panel and thus not a consultant for any BPH companies. I have a large personal experience with Rezum here at Mayo in Rochester, MN. As I arrived in 2017, there were many men who were deemed non-operative candidates due to comorbidities but were in total urinary retention. I performed several procedures in men with prostate size > 80 grams successfully in this cohort. Conceptually, an 80 gram cut-off as a size limit for Rezum is arbitrary and simply represents the inclusion criteria in the initial BPH Rezum trials. A good rule of thumb for my practice is each steam treatment treats about 10 grams of prostate tissue – the rezum device is limited to 15 treatments. I think a reasonable size cut-off for Rezum qualification is 120 grams. This is based on the number of treatments required and our published data (PMID: 32408768 - attached). Here the mean prostate size in our large gland group was 119 grams. This group fared very well and had similar net benefit to men with proportionally smaller glands in the 30-80 range.

The abstract results:

182 patients undergoing Rezūm were identified of which 25.8% had prostate volume >80cc. Mean gland volume in this group was 119cc and 55.3% were catheter dependent. Following Rezūm, statistically significant improvement was seen in AUASS from 22 to 13.4 (p=0.04) and post-void residual from 305cc to 149cc (0.05). Statistically significant improvement was seen in peak flow rate from 7.7 mL/second to 12.7 mL/second (p=0.002). In a subset of catheter dependent patients, the postoperative catheter free rate was 83% for men with glands >80cc which was comparable to 88% in the smaller gland group. Postoperative complication rate was not significantly different between large or small glands.

Please don't hesitate to call me with further questions or concerns. I am currently also in the process of publishing data on anti-coagulated patients undergoing rezum. This shows rezum is safe on blood thinners – this study compares 68 men (on ASA or non ASA blood thinners) have similar outcomes and complications to 146 men without asa/non asa blood thinners.

All the best

Dr. Kohler

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