MSSNY COMMITTEE ON INTERSPECIALTY

Thursday, OCTOBER 24, 2019

Approval of the Minutes of the February 28, 2019 Committee meeting

Dr. Steven S. Schwalbe, Chair, called the meeting for October 24, 2019 to order. The first order of business was to approve the minutes from the last meeting held on February 28, 2019. The minutes were accepted and approved as written.

Medicare CAC Local Coverage Determinations (LCDs) for consideration –

Ms. Katherine Dunphy of National Governmental Services (NGS) – Medicare advised the Committee members that Dr. Lawrence Clarke, Medical Director, is no longer affiliated with NGS. Therefore, she would provide an update from the Medicare Carrier Advisory Committee (CAC) call from a layman's perspective.

Fluid Jet System in the Treatment of Benign Prostatic Hyperplasia (BPH)

The fluid jet system in the treatment of Benign Prosthetic Hyperplasia is pretty much a non-covered service at this point. The LCD does go through the recommendations and they want to move forward and post it as an LCD.

After contacting the AUA, they provided the attached information for use of the Fluid Jet System. This material has been shared with NGS Medicare.

Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea

There is an update on Hypoglossal Nurse Stimulation for the Treatment of Obstructive Sleep Apnea. Under Provider Qualifications, the policy states: "Insertion of an FDA-approved hypoglossal nerve stimulation device addressed in this LCD must be performed by a qualified physician (MD or DO) who is a board certified **otolaryngologist** having completed the appropriate AMA or AOA certified residency and/or fellowship program and maintains ongoing certification in otolaryngology."

MSSNY takes exception to this specific policy point. MDs and DOs are licensed to practice the art of their chosen profession in the State of New York. Graduating from venerable institutions does not require Board Certification. Becoming Board Certified is a wholly **voluntary act** on behalf of the professional. It is only strongly suggested, if said professional chooses to continue a career in teaching at ACGME-institution. There are no laws which state that a graduating physician cannot practice and be paid for their outstanding work and service to their patients.

This has been shared with NGS Medicare.

Multimarker Serum Tests Related to Ovarian Cancer Testing

There was also the Ovarian testing non covered policy. Everyone wants genetic testing for Ovarian Cancer; but, there are no new studies.

Salvage High-intensity Focused Ultrasound (HIFU) Treatment in Prostate Cancer (PCa)

Kathy advised that her understanding on the HIFU is that Medicare will cover the service in a reoccurrence tumor in a patient that is not a candidate for a prostatectomy.

After contacting the AUA, they provided the following information:
Whole gland HIFU is considered medically necessary as a local treatment for recurrent PCa following radiation therapy (RT) when ALL of the following criteria are met (1, 2):
1. Biochemical recurrence (BCR) according to the Phoenix definition (PSA nadir + 2 ng/mL)
2. Positive post-RT transrectal ultrasound guided (TRUS) biopsy
3. Candidate for local curative therapy as evidenced by favorable clinical and pathologic factors (**BOTH of the following)**
    a. Original (pre-RT) - clinical stage T1-T2, NX or N0
    b. Current **(ALL are required)**
        *PSA < 10 ng/mL
        * absence of distant metastases per National Comprehensive Cancer Network (NCCN) imaging guidelines
        * no lymph node involvement
        * interval to biochemical failure > 18 months
        * International Society of Urological Pathology (ISUP) grade < 4
        * local recurrence amenable to entire destruction
4. Multi-disciplinary consensus (surgeon, oncologist, radiologist)
5. Hi comorbidity (i.e., not a candidate for radical prostatectomy (RP)) (3)

Exclusion Criteria (NONE of the below are allowed)
1. Life expectancy < 10 years (1,2)
2. PCa subtype other than adenocarcinoma (4)
3. Post-RT ADT (5,6)
4. Post-RT anal/rectal stenosis or rectal wall thickness >6 mm by TRUS or MRI (6)

This material has been shared with NGS Medicare.

Select Minimally Invasive GERD Procedures
Moving on to GERD procedures, Medicare is looking for more documentation and background regarding the quality demonstrating the effects of the tests and procedures. If anyone is involved with that, it would also be appreciated to hear some feedback. This is a reconsideration. During the CAC meeting, there was discussion about some of these procedures. The Gastroenterologist representative gave testimony adamantly opposed to these techniques.

Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT)
Another topic that was proposed was stereotactic radiation therapy and RSR procedures opening up to a specific Melanoma treatment and comments on whether that was accurate or not. Medicare does not think that the NCC guidelines have been established for that. We have asked repeatedly for any clinical updated trial responses to further substantiate coverage. However, since there is a lack of additional information, Medicare cannot substantiate coverage.

Other CAC Information – Medicare CAC

The Medicare CAC process has dramatically changed. NGS Medicare will no longer have the informative and educational meetings where the carrier explained all the proposed LCDs, LCD changes and laid out all the new Medicare updates on claims processing, enrollment, etc. Now, if you want to know what's going on with Medicare, you need to go to websites which makes things a little more difficult.

NGS Medicare heard back from some of the CAC members that there is now a disconnect from the process that they had. To alleviate the matter, Kathy Dunphy will be providing separate call updates. Medicare is pleased to keep an ongoing active communication.

New Medicare Beneficiary Identifiers

At the end of the calendar year all MEDICARE claims must carry the new MEDICARE patient identification numbers

Effective 1/1/2020 • All Medicare claims must contain the new Medicare number

April 2018 through 12/31/2019 • Live test transition period

Ways to Obtain the MBI up to 12/31/2019

• Ask your Medicare patients

– If they don't have their card with them at the time of service, remind them they can use www.MyMedicare.gov to get their new Medicare number

– Offer patients who do not have their card the Centers for Medicare & Medicaid Services (CMS) approved flyer Get Your New Medicare Card

• Use the NGSConnex secure MBI look-up tool

– Go to NGSConnex to register for a free account

• Check the remittance advice

– Medicare returns the MBI on every remittance advice when you submit claims with valid/active Health Insurance Claim Numbers (HICNs)

Any specialty specific issues:

Dr. Mary Fowkes brought up the issue of Medicare's change in benefit consideration for autopsies. The Committee members were apprised of the fact that this specific topic will be addressed at the AMA's Interim House of Delegates meeting in November 2019. AMA's Resolution 812 I-19 addresses Autopsy Standards as a Condition of Participation. The resolution urges the American Medical Association to call upon the Centers for Medicare and Medicaid Services to reinstate the Autopsy Standard as a Medicare Condition of Participation.

Legislative Update –

Mr. Morris (Moe) Auster provided updates to the Committee. The NYS legislature has been out of session since late June and will return in January. Some of the highlights include public issues expansion of the Gag clause rule. Public health issues have had a very positive year. For the appeal of the religious vaccine exemption, MSSNY, along with other health care partners - especially county health officials and the Pediatric, Family and Internal Medicine specialties were instrumental in having this exemption removed for school children. Now, the only reason

to not be vaccinated when entering or returning to school would be for medical contraindications in New York State. Another success was raising the tobacco purchase age from 18 to 21.

A number of bills that MSSNY strongly supported passed both houses; however, we are waiting for the Governor to sign them. They are:

- prohibiting midyear formulary changes to increase the cost of medications; we worked very closely with the pharmacy groups to regulate PBMS;
- on the opioid front, we support a physician, in consultation with the patient and pharmacy, to write a partial fill prescription for an opioid. It was authorized by the federal government not effective in New York till legislation passed and they did pass legislation however that bill has not been delivered to the Governor, etc.

MSSNY did a lot of work opposing adult use recreational marijuana. MSSNY supported increasing the decimalization for folks who are found to have small amounts of marijuana. MSSNY supports civil penalties, rather than criminal penalties. But MSSNY does not support legalization. The state may be looking at it again however with a tax revenue.

There is a potentially 3 million dollar hole in the Medicaid budget. No one is quite sure how they are going to fill it. It will be a series of concepts next year but we will have to see how they will try and balance that budget. This will be the major fight over the first half of the legislative session next year.

MSSNY has a litany of scope of practice bills that we will need to oppose. We will have to work closely with our specialty societies on those as well. In addition, we have bills that will expand liabilities against physicians on the state level.

On the federal level, some of you may have been following the debate taking place in Washington regarding the issue of Surprise Medical Bills. We have been working very closely with the AMA, State Medical Societies, the National Specialty Societies, Neurosurgical Society, the Anesthesiology Society and the National Specialty Societies to raise concerns before Congress that will create default rates for out of network for emergency or Surprise Bill instances. MSSNY has been advocating very strongly that congress should pass a law that was similar to the one NY passed in 2014. That law we know hit a few bumps along the way. However, for the most part, it seems that most physicians feel it is a fair way to address the issues of surprise hospital, medical, emergency room and out of network bills. Most states across the country have not passed laws that are not as favorable towards physicians.

New Business –

Dr. Schwalbe announced a piece of new business. He advised the members that this will be his last meeting with the Interspecialty Committee. The NYS Society of Anesthesiologists, Inc. will be appointing or selecting a new delegate to MSSNY on December 16. Today, will be my last time with the Committee and my last time as Chair. Dr. Schwalbe thanked members of the Committee for their participation and their tremendous support. Dr. Schwalbe thanked Ms. Dunphy, Mr. Auster for all of their help and their support over the last 12 years. Dr. Schwalbe especially thanked Regina McNally who has actually done a lot of work "for me and kept me from stepping in to many holes along the way. Thank you all and I very much appreciate this chance to observe and I want to wish you good luck going forward."

Dr. Gary Rudolph is the Vice Chair of the Committee. He steps in as Chair once Dr. Schwalbe steps down. "Thank you all. This committee is really made up of its members and I am indebted to you all."

Dr. Schwalbe will also be resigning his office as anesthesia representative to the Medicare CAC, as well. However, Dr. Schwalbe is the MSSNY representative to the CAC and has not resigned that position. Dr. Schwalbe stated that the new anesthesia rep for the CAC and a new delegate to the Interspecialty Committee will be announced once official decisions are made by the specialty society.

Dr. Schwalbe agreed to keep in touch.

There being no additional business for today's meeting, the call was concluded at 12:00 noon. Dr. Schwalbe thanked the attendees for their participation and the call ended.

Respectfully submitted,

Steven S. Schwalbe, MD,
Chairman

American
Urological
Association

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October, 2019

Medicare Administrative Contractor Medical Director

SUBJECT: Coverage of Fluid Jet System for Benign Prostatic Hyperplasia

The American Urological Association with more than 15,000 members in the United States and represents the world's largest collection of expertise and insight into the treatment of urologic disease and provides invaluable support to the urologic community by fostering the highest standards of urologic care through education, research and the formulation of health policy.

The AUA would like to make you aware of our current stance about the *Fluid Jet System (*also referred to as Transurethral Waterjet Ablation of prostate*) in the Treatment of Benign Prostatic Hyperplasia*, currently reported with Category III tracking code *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). The AUA* and our support of coverage, as we believe that the technology is medically reasonable and necessary.

Millions of men in the United States suffer from BPH. Treatment options for men with symptomatic BPH include behavioral changes, medical therapy, and procedural therapy. The "gold standard" for procedural therapy is CPT Code 52601 *Transurethral Resection of the Prostate* (TURP) in men with typical enlargement (< 80 grams), and open simple prostatectomy in men with large glands (> 80-150 grams). Both procedures are effective but have a risk of significant potential side effects. In recent years, there have been a number of new technologies aimed at improving patient outcomes or improving patients with fewer potential side effects.

One new technology is the FDA approved Aquabeam System (Aquablation, PROCEPT BioRobotics), also known as the *Fluid Jet System* or *Waterjet Ablation for treatment of BPH.* In this procedure, prostate resection is achieved from a high-powered water jet from a transurethrally placed robotic handpiece. Intra-operative transrectal ultrasound is used to map out the specific region of the prostate to be treated during and to monitor tissue resection in real time. After resection, electro-cautery via a standard cystoscope/resectoscope or traction from a 3 way catheter balloon is used to obtain hemostasis. The technique is not in the minimally invasive surgical treatment category, as patients must undergo general anesthesia, so it is more similar to a TURP. Theoretical advantages to Aquablation over TURP include achieving a potentially more complete resection (as the capsule is mapped out for the

resection, rather than viewed by the surgeon), potentially reduced damage to the bladder neck with subsequent reduction in retrograde ejaculation and bladder neck contracture, potentially reduced risk of erectile dysfunction (as conductive heat with the potential damage of erectile nerves is not used to remove prostate tissue), and the ability to treat any size prostate gland including patients with glands larger than recommended for TURP, yet less being a less invasive option than open simple prostatectomy. In clinical studies, Aquablation has been used safely on men with lager prostates (up to 150 grams) with excellent outcomes. In response to the published results, the AUA added Aquablation to our guidelines *Benign Prostatic Hyperplasia: Surgical Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms (2018, amended 2019)*[1] as an option for patients with symptomatic BPH, stating that *"Aquablation may be offered to patients with LUTS attributed to BPH provided prostate volume >30/<80g, however, patients should be informed that long term evidence of efficacy and retreatement rates, remains limited. (Conditional Recommendation; Evidence level: Grade C)"*[1].

We believe that it is important to explain the importance yet limitations of the AUA Guidelines. We write guidelines based upon the available literature at the time of the writing, as reviewed by out experts in the specific field, and look for article with low risk of bias. The guidelines are not continuously updated, so new information may come out between updates. The AUA even adds a disclaimer at the end of every guideline, which reads:

> *As medical knowledge expands and technology advances, the guidelines will change. Today these evidence-based guidelines statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases. Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ('off label') that are not approved by the Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines and best practice statements are not in tended to provide legal advice about use and misuse of these substances. Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices. For this reason, the AUA does not regard technologies or management which*

1. American Urological Association Guideline: Benign Prostatic Hyperplasia: Surgical Management of Benign Prostatic Hyperplasia/Lower Urinary Tract Symptoms. Available from https://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(bph)-guideline . 2018-reviewed-and-validity-confirmed-2019).

are too new to be addressed by this guideline as necessarily experimental or investigational.[1]

Specific to our updated BPH guidelines, the literature that was available to us to review at the time of the writing was 6-month outcome and 1-year outcomes, and the outcomes in large glands [2,3,4], and as stated "*There was one low-risk of bias randomized controlled trial that was evaluable by our panel, and it was for men with prostate size of 30-80 grams.*" [1] *The* results showed that *"through 12 months, there were similar outcomes for Aquablation and TURP in terms of symptom improvement, quality of life, blood transfusion, and flow rate. At 3 months, Aquablation resulted in fewer harms classified as Clavien-Dindo grade ≥2 compared to TURP (26% versus 42%, P=.015). Additionally, rates of retrograde ejaculation were higher (P=.002) with TURP (23%) compared to Aquablation (6%). Other harms occurring at similar rates in both groups, and classified as Clavien-Dindo grades 1-4, included bladder spasms, bleeding, dysuria, pain, and urethral damage. No deaths were reported."*[1]

However, since that time, further literature has been published, including 2-year outcome data [5] and 1-year data in men with large prostate size (80-150 grams) [6]. At 2 years, there was significant and sustained improvement in patient symptom scores and equivalent to that of TURP, whereas Aquablation had a more improved maximum flow rate than TURP. Sexual function was stable in the Aquablation group and decreased slightly in the TURP group.

Surgical retreatment rates after 12 months for Aquablation were 1.7% and 0% for TURP. Over 2 years, surgical BPH retreatment rates were 4.3% and 1.5% ($p = 0.4219$), respectively. However, one has to remember that these were the initial Aquablation procedures performed in the United States, and it was being compared to the outcomes of TURP by very experienced providers [5]. In large glands (mean volume 107cc, range 80-150cc), the mean IPSS improvement was 17 points, with the quality of life subset improving from a pre-op level of 4.6 down to 1.3 points at 12 months. Significant improvements were seen in the maximum

2. Gilling P, Barber N, Bidair M et al: WATER: A double-blind, randomized, controlled trial of Aquablation vs transurethral resection of the prostate in benign prostatic hyperplasia. J Urol 2018; 199: 1252-1261.
3. Gilling P, Barber N, Bidair M et al: Randomized controlled trial of Aquablation vs. transurethral resection of the prostate in benign prostatic hyperplasia: one-year outcomes. Urology. 2019 Mar; 125:169-173.
4. Plante M, Gilling, P, Barber N et al: Symptom relief and anejaculation after Aquablation or transurethral resection of the prostate: subgroup analysis from a blinded randomized trial. BJU Int. 2019 Apr; 123(4):651-660.
5. Gilling P, Barber N, Bidair M, et al. Two-Year Outcomes After Aquablation Compared to TURP: Efficacy and Ejaculatory Improvements Sustained. *Adv Ther.* 2019; 36(6):1326-1336.
6. Bhojani N, Bidair M, Zorn KC, et al. Aquablation for Benign Prostatic Hyperplasia in Large Prostates (80-150 cc): 1-Year Results. Urology. 2019 Jul; 129: 1-7.

flow rate (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.[6]"

In summary, the AUA believes that Aquablation is medically necessary due to its comparable outcomes to TURP with an edge to reduce side effects and complications, and can be used in larger prostates up to 150 gram as an alternative to open simple prostatectomy. At 2 years, symptomatic improvement and flow rate improvement remained comparable to TURP, but there was less anejaculation in Aquablation compared to TURP. In large glands, the outcomes were even better and complication rate was low.

We appreciate in advance your consideration for coverage of Aquablation.

Sincerely,

Jonathan Rubenstein M.D.
Chair, Coding and Reimbursement Committee
American Urological Association