Oregon Urological Society, Quarterly Update
Spring 2019

AACU Update: Highlights of work on the national level

NOTE: Brian Duty MD is 1/7 AACU State Advocacy Network Committee members.

1) **AACU, Coalitions Defeat Bans on Pediatric Procedures** *(excerpt from AACU Minute)*

   Throughout the first quarter of this year, the AACU played a key role defeating legislation in several states that proposed limiting access to medical information and treatment options for children born with variations in physical sex characteristics.

   Activists representing a segment of the self-identified intersex community disseminated falsehoods and unscientific research in their quest to prohibit early surgical intervention for patients who are born with atypical genitalia - no matter the diagnosis. The proposals in California, Connecticut, Iowa, Nevada, and Texas would have had far reaching implications for the care of children affected by conditions as varied as congenital adrenal hyperplasia (CAH), hypospadias, and chordee.

   In response, wide-ranging coalitions of national urology groups, urologic sub-specialties, state urology societies, state medical associations, and surgical and pediatric organizations demonstrated the clout of committed physicians across the United States.

   AACU State Advocacy Network Chair William C. Reha, MD, MBA, who oversaw the active part played by the AACU, asserted, "The Societies for Pediatric Urology invested an incredible amount of time and resources into these efforts and we were honored to work with incredible partners like the AUA, California Urological Association, Nevada State Medical Association, Northern California Chapter of the American College of Surgeons, and districts of the American Academy of Pediatrics."

   AACU Past President and SPU Board Member Patrick H. McKenna, MD, FAAP, FACS, continued, "Each campaign demonstrated the diverse strengths of the AACU and our professional associations. These are fantastic examples of how we can succeed by working together - Individual urologists who become members of the AACU, and the AACU when we work with other organizations."

2) **Support of GME funding and Stark Law (Reform) Modernization**
   The Medicare Care Coordination Improvement Act of 2019 (S.966 / H.R.2282) would substantially improve care coordination for patients, improve health outcomes, and restrain costs by allowing physicians to participate and succeed in alternative payment models.

   MEMBER ACTION ITEM: AUA requests members to send a letter of support to their Congressional Members. Visit aacuweb.org Advocacy tab, then Action Center.

3) **Seeking solutions to drug shortages**
   The AACU joined the AUA, LUGPA and Urology Care Foundation in brining concerns about BCG shortages to the US Food and Drug Administration.

(excerpt from AACU Sentinel)

The AACU represents the interests of more than 3,000 urologists across the United States and supports the highest standards of urological clinical care through education, research and the formulation of healthcare policy. In service of that mission, the AACU is committed to working with lawmakers, regulators and the urologic community to identify immediate and enduring solutions to shortages of medically necessary drugs.

In February 2019, the AACU joined the American Urological Association, Bladder Cancer Advocacy Network, Society of Urologic Oncology, LUGPA and Urology Care Foundation to express extreme concern about the shortage of TICE BCG and its effects on the care of patients with bladder cancer. Although Merck, the sole supplier of BCG to the United States, is exploring options to increase their production of TICE BCG, they expect this global supply constraint to continue throughout 2019. Efforts to engage the U.S. Food and Drug Administration to approve additional strains and supplies of BCG are ongoing and all these organizations continue to communicate with Merck for up-to-date information on this issue.

Until the shortage has been resolved, the following strategies may help maximize the care for patients with Non-Muscle Invasive Bladder Cancer (NMIBC), subject, as always, to physician judgment in individual cases:

1. BCG should not be used for patients with low-risk disease.
2. Intravesical chemotherapy should be used as the first-line option for patients with intermediate-risk NMIBC. Patients with recurrent/multifocal low-grade Ta lesions who require intravesical therapy should receive intravesical chemotherapy such as mitomycin, gemcitabine, epirubicin or docetaxel instead of BCG.
3. If BCG would be administered as second-line therapy for patients with intermediate-risk NMIBC, an alternative intravesical chemotherapy should be used rather than BCG in the setting of this BCG shortage.
4. For patients with high-risk NMIBC, high-grade T1 and CIS patients receiving induction therapy should be prioritized for use of full-strength BCG. If not available, these patients and other high-risk patients should be given a reduced 1/2 - 1/3 dose, if feasible.
5. If supply exists for maintenance therapy for patients with NMIBC, every attempt should be made to use 1/3 dose BCG and limit dose to one year.
6. In the event of BCG supply shortage, maintenance therapy should not be given and BCG-naïve patients with high-risk disease should be prioritized for induction BCG.

7. If BCG is not available, a preferable alternative to BCG is mitomycin (induction and monthly maintenance up to one year). Other options such as gemcitabine, epirubicin, docetaxel, valrubicin or sequential gemcitabine/docetaxel or gemcitabine/mitomycin may also be considered with an induction and possible maintenance regimen.
8. Patients with high-risk features (i.e., high-grade T1 with additional risk factors such as concomitant carcinoma in situ, lymphovascular invasion, prostatic urethral involvement, or variant histology) who are not willing to take any potential oncologic risks with alternative intravesical agents should be offered initial radical cystectomy if they are surgical candidates.

Read more online at www.tinyurl.com/aacu-bcg

4) Prior Authorization Reform

While traditional Medicare generally does not require prior authorizations, Medicare Advantage plans are much freer to utilize the practice. Sources indicate that U.S. Reps. Suzan DelBene (D-Wash.) and Mike Kelly (R-Pa.) are drafting legislation that requires MA plans to file a report with regulators that details what items are subject to prior authorization, the rate of approval, and the time average time for approval. Regulation of the electronic prior auth process itself would build upon a law that was passed last October. The SUPPORT Act mandated that Medicare Part D plans accept medication prior authorizations via the NCPDP SCRIPT Standard when submitted by a prescriber. Patient and physician advocates expect Reps. DelBene and Kelly to introduce their bill this summer.

5) Senator "Wyden floats adding prescription drug comparison tool to EHRs"

https://www.healthcaredive.com/news/wyden-floats-adding-prescription-drug-comparison-tool-to-ehrs/551495