Win-win contract negotiations

Practical strategies are available to help you collaborate, not compete

Lisette Hilton / UT Correspondent

Urologists negotiating employment, payer, or other contracts often feel like they’re navigating unknown, hazardous terrain.

Thomas Stringer, MD, associate professor and associate chairman of urology at University of Florida, Gainesville, often reviews residents’ employment contracts. He recalls a recent hospital contract, where he urged the resident to seek clarification in key areas. But the resident wanted the job so much, he felt uncomfortable asking questions and potentially turning off the employer.

That’s a mistake, according to Dr. Stringer. “This [contract] is your conditions of employment. You really need to define what those are so you can feel satisfied once you sign the thing. I think physicians tend to be pretty anxious about negotiating on their own behalf,” he said.

Dr. Stringer, who for 7 years directed the course, “Physician Contract Negotiation: Employment and Ownership in the Current Economic Climate,” at AUA annual meetings, says urologists are increasingly called upon to negotiate important and binding documents, like employment contracts.

“More and more physicians, in general, are employed. In the year 2000, almost 60% of all physicians were shareholders in their practices. Currently, that’s closer to 30% of all physicians,” Dr. Stringer said. “Our data suggests that the number

Please see NEGOTIATION, on page 42

PCNL tips and tricks: Access is everything

In this interview, Thomas Chi, MD, of the University of California, San Francisco discusses how he performs PCNL, explains why he uses ultrasound instead of fluoroscopy, and offers advice to urologists looking to gain more experience with the procedure.

Q&A

Thomas Chi, MD
STONE SURGERY

For the full article, please turn to page 22
When kidneys work overtime to produce too much urine at night, think NOCTIVA

IMPORTANT SAFETY INFORMATION

WARNING: HYPONATREMIA

See full prescribing information for complete boxed warning.

- NOCTIVA™ (desmopressin acetate) Nasal Spray can cause hyponatremia. Severe hyponatremia can be life-threatening, leading to seizures, coma, respiratory arrest, or death.
- NOCTIVA is contraindicated in patients at increased risk of severe hyponatremia. See Important Safety Information below for full contraindications.
- Ensure serum sodium is normal before starting or resuming NOCTIVA. Measure serum sodium within 7 days and approximately 1 month after initiating therapy or increasing the dose, and periodically during treatment. More frequently monitor patients ≥65 years of age and those at increased risk of hyponatremia.
- If hyponatremia occurs, NOCTIVA may need to be discontinued.

INDICATIONS AND USAGE
NOCTIVA is a vasopressin analog indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

Limitation of Use: Not studied in patients <50 years of age.

CONTRAINDICATIONS
NOCTIVA is contraindicated in patients with the following conditions: hyponatremia or a history of hyponatremia, polydipsia, primary nocturnal enuresis, concomitant use with loop diuretics or systemic or inhaled glucocorticoids, estimated glomerular filtration rate <50 mL/min/1.73 m², syndrome of inappropriate antidiuretic hormone secretion (SIADH), during illnesses that can cause fluid or electrolyte imbalance, congestive heart failure (New York Heart Association Class II-IV), and uncontrolled hypertension.
WARNINGS AND PRECAUTIONS

• Fluid retention: Not recommended in patients at risk of increased intracranial pressure or history of urinary retention. Monitor volume status in patients with NYHA Class I congestive heart failure.

• Nasal conditions: Discontinue in patients with concurrent nasal conditions that may increase absorption, until resolved.

ADVERSE REACTIONS

Common adverse reactions in clinical trials (incidence >2%) included nasal discomfort, nasopharyngitis, nasal congestion, sneezing, hypertension, back pain, epistaxis, bronchitis, and dizziness.

DRUG INTERACTIONS

Monitor serum sodium more frequently when NOCTIVA is concomitantly used with drugs that may cause water retention and increase the risk for hyponatremia.

USE IN SPECIFIC POPULATIONS

• Pregnancy: Use of NOCTIVA is not recommended.
• Pediatric: Do not use NOCTIVA for primary nocturnal enuresis in children.

To report SUSPECTED ADVERSE REACTIONS, contact Avadel at 1-877-638-4579 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.


Please see Brief Summary of Full Prescribing Information on next page.
NOCTIVA™ (desmopressin acetate) Nasal Spray
The following is a brief summary. Please consult Full Prescribing Information for complete details.

WARNING: HYponATREMIA
- NOCTIVA can cause hyponatremia. Severe hyponatremia can be life-threatening, leading to seizures, coma, respiratory arrest, or death.
- NOCTIVA is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic or inhaled glucocorticoids.
- Ensure serum sodium concentrations are normal before starting or resuming NOCTIVA. Measure serum sodium within 7 days and approximately 1 month after initiating therapy or increasing the dose, and periodically during treatment. More frequently monitor serum sodium in patients 65 years of age and older and in patients at increased risk of hyponatremia.
- If hyponatremia occurs, NOCTIVA may need to be temporarily or permanently discontinued.

INDICATIONS AND USAGE
NOCTIVA is indicated for the treatment of nocturia due to nocturnal polyuria in adults who awaken at least 2 times per night to void.

Nocturnal polyuria was defined in the NOCTIVA clinical trials as nighttime urine production exceeding one-third of the 24-hour urine production.

Before starting NOCTIVA:
- Evaluate the patient for possible causes for the nocturia, including excessive fluid intake prior to bedtime, and optimize the treatment of underlying conditions that may be contributing to the nocturia.
- Confirm the diagnosis of nocturnal polyuria with a 24-hour urine collection, if one has not been obtained previously.

Limitation of Use: NOCTIVA has not been studied in patients less than 50 years of age.

CONTRAINDICATIONS
NOCTIVA is contraindicated in patients with the following conditions due to an increased risk of severe hyponatremia:
- Hyponatremia or a history of hyponatremia [see Warnings and Precautions]
- Polydipsia
- Primary nocturnal enuresis [see Use in Specific Populations]
- Concomitant use with loop diuretics [see Warnings and Precautions]
- Concomitant use with systemic or inhaled glucocorticoids [see Warnings and Precautions, Drug Interactions]
- Renal impairment with an estimated glomerular filtration rate (eGFR) below 50 mL/min/1.73 m² [see Use in Specific Populations]
- Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion
- During illnesses that can cause fluid or electrolyte imbalance, such as gastroenteritis, salt-wasting nephropathies, or systemic infection

NOCTIVA is contraindicated in patients with the following conditions because fluid retention increases the risk of worsening the underlying condition:
- Congestive heart failure (New York Heart Association Class II to IV) [see Warnings and Precautions]
- Uncontrolled hypertension

WARNINGS AND PRECAUTIONS
Risk of Hyponatremia: NOCTIVA can cause hyponatremia [see Boxed Warning and Adverse Reactions]. Severe hyponatremia can be life-threatening if it is not promptly diagnosed and treated, leading to seizures, coma, respiratory arrest, or death.

NOCTIVA is contraindicated in patients at increased risk of severe hyponatremia, such as those with excessive fluid intake, those who have illnesses that can cause fluid or electrolyte imbalances, and those using loop diuretics or systemic or inhaled glucocorticoids [see Boxed Warning, Contraindications, and Drug Interactions].

Before starting or resuming NOCTIVA, ensure that the serum sodium concentration is normal. Consider the 0.83 mcg dose as the starting dose for patients who may be at risk for hyponatremia.

When NOCTIVA is administered, fluid intake in the evening and nighttime hours should be moderated to decrease the risk of hyponatremia. Monitor the serum sodium concentration within 7 days and approximately 1 month of initiating NOCTIVA or increasing the dose, and periodically thereafter. The frequency of serum sodium monitoring should be based on the patient’s risk for hyponatremia. For example, more frequent monitoring is recommended for patients 65 years of age or older or those on concomitant medications that can increase the risk of hyponatremia, such as tricyclic antidepressants, selective serotonin reuptake inhibitors, nonsteroidal anti-inflammatory drugs (NSAIDs), chlorpromazine, carbamazepine, and thiazide diuretics [see Drug Interactions].

If hyponatremia occurs, NOCTIVA may need to be temporarily or permanently discontinued, and treatment for the hyponatremia instituted, depending on the clinical circumstances, including the duration and severity of the hyponatremia.

Fluid Retention: NOCTIVA can cause fluid retention, which can worsen underlying conditions that are susceptible to volume status. Therefore, NOCTIVA is contraindicated in patients with New York Heart Association Class II to IV congestive heart failure or uncontrolled hypertension [see Contraindications]. In addition, NOCTIVA is not recommended in patients at risk for increased intracranial pressure or those with a history of urinary retention, and should be used with caution (e.g., monitoring of volume status) in patients with New York Heart Association Class I congestive heart failure.

Concurrent Nasal Conditions: Discontinue NOCTIVA in patients with concurrent nasal conditions that may increase systemic absorption of NOCTIVA (e.g., atrophy of nasal mucosa, and acute or chronic rhinitis), because the increased absorption may increase the risk of hyponatremia. NOCTIVA can be resumed when these conditions resolve.

ADVERSE REACTIONS
The following adverse reaction is described elsewhere in the labeling:
- Hyponatremia [see Boxed Warning and Warnings and Precautions]

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Two randomized, double-blind, placebo-controlled, multicenter trials conducted in adults 50 years of age and older evaluated the efficacy and safety of NOCTIVA nasal spray compared to placebo. At baseline, 1045 patients treated with NOCTIVA 0.83 mcg or 1.66 mcg, or placebo, had nocturia due to nocturnal polyuria, awakening at least 2 times per night to urinate. Nocturnal polyuria was defined as nighttime urine production exceeding one-third of the 24-hour urine production. The mean age of the patients studied with nocturia due to nocturnal polyuria was 67 years with 42% between 50 and 64 years of age, and 58% aged 65 years and older. Fifty-seven percent were men and 43% were women. Caucasians comprised 79%, Blacks 12%, Hispanics 6%, and Asians 2% of the trial population.

During these trials, serious adverse reactions were reported in 2%, 2%, and 3% of patients with nocturia due to nocturnal polyuria treated with NOCTIVA 0.83 mcg, NOCTIVA 1.66 mcg, and placebo, respectively. There was one case of hyponatremia in the 1.66 mcg group and one case in the placebo group classified as serious adverse reactions.

Adverse Reactions Leading to Discontinuation: Among patients with nocturia due to nocturnal polyuria, the discontinuation rate due to adverse reactions was 4.0% with NOCTIVA 0.83 mcg, 4.4% with NOCTIVA 1.66 mcg, and 2.3% with placebo. Table 1 displays the most common adverse reactions leading to discontinuation in patients with nocturia due to nocturnal polyuria.

Table 1: Most Common Adverse Reactions (≥2 Incidences) Leading to Discontinuation in Patients With Nocturia Due to Nocturnal Polyuria in 2 Double-Blind, Placebo-Controlled Clinical Trials

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>NOCTIVA 1.66 mcg (n=341)</th>
<th>NOCTIVA 0.83 mcg (n=354)</th>
<th>Placebo (n=349)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Decreased</td>
<td>4 (1.2%)</td>
<td>3 (0.9%)</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>0</td>
<td>2 (0.6%)</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>Nocturia</td>
<td>2 (0.6%)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nasal Discomfort</td>
<td>0</td>
<td>2 (0.6%)</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>Dysuria</td>
<td>0 (0.3%)</td>
<td>2 (0.6%)</td>
<td>0</td>
</tr>
</tbody>
</table>

Most Common Adverse Reactions: Table 2 summarizes the most common adverse reactions reported by patients with nocturia due to nocturnal polyuria. This table shows adverse reactions reported in at least 2% of patients treated with NOCTIVA and at a higher incidence with the 1.66 mcg dose than with placebo.
No overall changes were observed in the safety profile during the open-label, uncontrolled extension trial with up to 126 weeks of follow-up.

Hyponatremia: Table 3 shows the incidence of serum sodium concentrations below the normal range reported in the 2 placebo-controlled trials.

Table 3: Hyponatremia in 2, Double-Blind, Placebo-Controlled Clinical Trials in Patients With Nocturia Due to Nocturnal Polyuria

<table>
<thead>
<tr>
<th>Serum Sodium Concentrations (mmol/L)</th>
<th>NOCTIVA 1.66 mcg (n=146)</th>
<th>NOCTIVA 0.83 mcg (n=148)</th>
<th>Placebo (n=349)</th>
</tr>
</thead>
<tbody>
<tr>
<td>130-134</td>
<td>42 (3.6%)</td>
<td>33 (3.9%)</td>
<td>18 (5.2%)</td>
</tr>
<tr>
<td>126-129</td>
<td>0 (0.0%)</td>
<td>8 (3.8%)</td>
<td>0</td>
</tr>
<tr>
<td>≤125</td>
<td>5 (1.5%)</td>
<td>0 (0.0%)</td>
<td>1 (0.3%)</td>
</tr>
</tbody>
</table>

Of the 5 patients on NOCTIVA 1.66 mcg with serum sodium ≤125 mmol/L, all were 65 years of age or older. Four were men. The onset of the hyponatremia ranged from 6 days to 12 weeks after the start of dosing. Four of these patients were taking a concomitant systemic or inhaled glucocorticoid and 3 were taking an NSAI.

See: The incidence of hyponatremia with NOCTIVA was similar in men and women.

Age: Patients 65 years of age and older treated with NOCTIVA had a higher incidence of hyponatremia compared to those younger than 65 years of age (see Table 4).

Table 4: Hyponatremia, Based on Age, in 2, Double-Blind, Placebo-Controlled Clinical Trials in Patients With Nocturia Due to Nocturnal Polyuria

<table>
<thead>
<tr>
<th>Serum Sodium Concentrations (mmol/L)</th>
<th>NOCTIVA 1.66 mcg ≥65 years (n=195)</th>
<th>NOCTIVA 0.83 mcg ≥65 years (n=148)</th>
<th>Placebo ≥65 years (n=205)</th>
</tr>
</thead>
<tbody>
<tr>
<td>130-134</td>
<td>14 (7.2%)</td>
<td>28 (14.4%)</td>
<td>15 (7.3%)</td>
</tr>
<tr>
<td>126-129</td>
<td>0 (0.0%)</td>
<td>8 (5.4%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>≤125</td>
<td>5 (2.6%)</td>
<td>0 (0.0%)</td>
<td>1 (0.5%)</td>
</tr>
</tbody>
</table>

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary: There are no data with NOCTIVA use in pregnant women to inform any drug-associated risks. No adverse developmental outcomes were observed in animal reproduction studies with administration of desmopressin during organogenesis to pregnant rats and rabbits at doses approximately <1 and 31 times, respectively, the maximum recommended human dose based on nasal surface area (see Data). NOCTIVA is not recommended for the treatment of nocturia in pregnant women. Nocturia is usually related to normal physiologic changes during pregnancy that do not require treatment with NOCTIVA.

In the U.S. general population, the estimated background rate of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data: Desmopressin acetate did not cause fetal harm in teratology studies in rats and rabbits at doses from 0.05 to 10 mcg/kg/day, which is approximately <1 times (rat) and 31 times (rabbit) the maximum recommended human dose based on nasal surface area.

Lactation: Desmopressin is present in small amounts in human milk and is poorly absorbed orally by an infant. There is no information on the effects of desmopressin on the breastfed infant or on milk production. The development and health benefits of breastfeeding should be considered along with the mother’s clinical need for NOCTIVA and any potential adverse effects on the breastfed infant from NOCTIVA or from the underlying maternal condition.

Pediatric Use: NOCTIVA is contraindicated for the treatment of primary nocturnal enuresis because of reports of hyponatremic-related seizures in pediatric patients treated with other intranasal formulations of desmopressin. Studies of NOCTIVA have not been conducted in pediatric patients [see Contraindications].

Geriatric Use: Patients 65 years and older treated with NOCTIVA had a higher incidence of hyponatremia compared to patients less than 65 years old treated with NOCTIVA [see Warnings and Precautions, and Adverse Reactions].

Renal Impairment: Desmopressin is mainly excreted in the urine. The area under the concentration-time curve (AUC) and terminal half-life of desmopressin in renally impaired patients with an eGFR below 50 mL/min/1.73 m² is 3- to 4-fold greater than in patients with an eGFR above 50 mL/min/1.73 m². Therefore, NOCTIVA is contraindicated in patients who have renal impairment with an eGFR below 50 mL/min/1.73 m² [see Contraindications].

Hepatic Impairment: The effect of hepatic impairment on the pharmacokinetics of desmopressin has not been studied.

OVERDOSAGE

Signs of overdose may include effects from hyponatremia such as seizure, altered mental status, cardiac arrhythmias, and worsening edema. Other signs of overdose may include oliguria and rapid weight gain due to fluid retention [see Warnings and Precautions]. In case of overdose, NOCTIVA should be discontinued immediately, serum sodium should be assessed, and appropriate medical treatment initiated.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide and Instructions for Use).

Hyponatremia: Inform patients that NOCTIVA can cause hyponatremia, which may be life-threatening. Inform patients to moderate fluid intake in the evening and nighttime hours, to monitor for symptoms of hyponatremia (such as headache, nausea or vomiting, restlessness, fatigue, drowsiness, dizziness, muscle cramping, or altered mental status), to undergo appropriate medical treatment initiated.

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NOCTIVA is contraindicated for the treatment of primary nocturnal enuresis [see Contraindications].

In case of overdose, NOCTIVA should be discontinued immediately, serum sodium should be assessed, and appropriate medical treatment initiated.
Rethinking race and prostate cancer outcomes

It is well established that African-American men are more likely to develop prostate cancer and experience higher mortality than other ethnic groups. Most research has focused on determining the causes of prostate cancer in this high-risk group. Numerous studies have evaluated socioeconomic issues, participation in screening, disparities in care for early disease, lifestyle issues, dietary factors, obesity, physical activity and others to identify potential causes.

However, these studies have often been conflicting and inconclusive. While genomics and other biologic analysis are a relatively new focus of these investigations, the complex interactions among all of these factors that may cause prostate cancer remain incompletely understood.

Two provocative studies reported at the 2018 ASCO annual meeting provide additional insight into prostate cancer racial disparities in a different group of patients, namely men with advanced prostate cancer who participated in a variety of clinical trials. In a large analysis of these trials by Halabi and associates, the relative risk of death was found to be 19% lower for African-American men than for Caucasian men (see page 7).

In a clinical trial of 100 men balanced by race reported by George and associates using abiraterone acetate (ZYTIGA), progression-free survival was identical in African-American men compared with Caucasians (see page 8). Surprisingly, PSA declines and the durability of this response was much greater in African-American patients. What is unique about these two studies is the investigation of racial differences in advanced prostate cancer outcomes in the era of newer therapeutic options.

These studies suggest that some African-American men with advanced disease may actually possess characteristics that make them respond better. With these two trials engaged in ongoing molecular analysis of some of their cohorts, genomic and single nucleotide polymorphism analysis should provide further insight into the optimum management and safety profiles of these advanced prostate cancer therapies.

Previous studies that have identified unique biomarkers with significant differences in expression by ethnicity suggest there may be different molecular pathways that lead to the development of prostate cancer.

These differing pathways may also be found to impact response to advanced prostate cancer therapy in different races. These two studies provide hope that when treated for advanced prostate cancer, the outcomes in African-Americans appear to be at least as good, if not better, than other ethnicities.

To read more, see African-Americans and chemo on page 7 and mCRPC Tx’s efficacy on page 8

Urology Times strives to avoid placing advertising near articles that discuss a product or service related to the advertisement. This policy may not always be enforceable because of space restrictions.

From the Board

LEONARD G. GOMELLA, MD
Dr. Gomella, a member of the Urology Times Editorial Council, is chairman of the department of urology, Sidney Kimmel Cancer Center, Thomas Jefferson University, Philadelphia.
African-American patients fare well with chemo for prostate cancer

Wayne Kuznar
UT Correspondent

CHICAGO—Median overall survival for African-American men with advanced prostate cancer who are treated with docetaxel (Taxotere) is similar to that of Caucasian men, according to an analysis of pooled data from nine randomized phase III clinical trials.

When adjusting for established risk factors, African-American men had a 19% lower risk for death than Caucasian men, Susan Halabi, PhD, reported at the American Society of Clinical Oncology annual meeting in Chicago.

“When we restrict our analysis to the three trials that were conducted by the National Clinical Trials Network in the U.S., the results were even more striking, with a median survival for African-American men of 21 months versus 20 months for Caucasian men.”

SUSAN HALABI, PhD

“This is the largest analysis comparing survival outcomes in African-American men versus Caucasian men in men with advanced and lethal prostate cancer that are treated with docetaxel and prednisone,” said Dr. Halabi, professor of biostatistics and bioinformatics at Duke University in Durham, NC. “In the first analysis, looking at the aggregate data, the survival distribution in African-American and Caucasian men appears to be the same, with a median survival duration of 21 months.

“When we zoom in and perform another type of analysis that adjusts for important variables that will affect the outcome, to our surprise what we found is that the relative risk of death was 19% lower for African-American men than for Caucasian men, and this was statistically significant.”

Despite an overall trend toward a declining incidence of prostate cancer and its associated mortality, African-American men have a higher incidence and mortality rate than Caucasian men. In addition, they are diagnosed at a later stage of prostate cancer than are Caucasian men. Access to health care has been described as unequal. Based on this information, her study group sought to test the hypothesis that African-American men who are enrolled in clinical trials on docetaxel and prednisone and who have advanced and lethal prostate cancer (metastatic castration-resistant prostate cancer) have worse survival outcomes than Caucasian men.

They identified nine phase III clinical trials of men with advanced prostate cancer with overall survival (OS) as a primary outcome. These nine trials included 8,820 men, of whom 85% were Caucasian, 6% were African-American, 5% were Asian, and 4% were other/unknown.

The National Cancer Institute/National Clinical Trials Network enrolled a higher proportion of African-American men than industry-sponsored trials (12% vs. 4%).

“It is important to know that the National Cancer Institute/National Clinical Trials Network enrolled a higher proportion of African-American men than industry-sponsored trials, whereas industry-sponsored trials were conducted globally,” said Dr. Halabi.

After adjustment for age, performance status, PSA level, site of metastases, and levels of hemoglobin and alkaline phosphatase, the hazard ratio (HR) for OS in African-American men versus Caucasian men was 0.81 (p=0.004).

“When we restrict our analysis to the three trials that were conducted by the National Clinical Trials Network in the U.S., the results were even more striking, with a median survival for African-American men of 21 months versus 20 months for Caucasian men,” Dr. Halabi said. The risk of death in the adjusted analysis was 24% lower for African-American men than for Caucasian men (HR 0.76; p<0.001).

While the percentage of African-Americans as a proportion of the U.S. population is 14%, only 6% of the men in these phase III trials were African-American, she noted.

Higher numbers needed in trials

“New methodology for enrolling higher numbers of African-American men should be actively pursued and vigorously implemented so minority groups are well represented on trials,” she said, adding that because the results were obtained from clinical trials, they cannot be generalized to the U.S. population.

Robert Dreicer, MD, associate director for clinical research and deputy director of the University of Virginia Cancer Center, Charlottesville, who was not involved in the study, commented, “I would argue that what this tells us is pretty striking... that African-American men have potentially better survival by getting conventional therapy. I think access to care is empha-
mCRPC agent’s efficacy differs depending on race

PSA response more durable in African-American vs. Caucasian patients

Cheryl Guttman Krader
UT Contributing Editor

CHICAGO—Both the efficacy and safety of abiraterone acetate (ZYTIGA) treatment for metastatic castrate-resistant prostate cancer (mCRPC) appear to differ depending on race, according to results of Abi Race, a prospective, multicenter trial presented at the American Society of Clinical Oncology annual meeting in Chicago.

The parallel group study included 50 African-American and 50 Caucasian patients with no history of chemotherapy for CRPC who were treated with abiraterone, 1,000 mg daily, plus prednisone, 5 mg twice daily. Radiographic progression-free survival (rPFS) was analyzed as the primary endpoint, and the median values did not differ significantly between the African-American and Caucasian patient groups (16.7 vs. 16.5 months).

Secondary endpoint analyses showed that PSA response rates were numerically greater in African-American men than in Caucasians whether considering a PSA decline ≥30% (82% vs. 78%), ≥50% (74% vs. 66%), or ≥90% (48% vs. 38%). In addition, Kaplan-Meier analysis showed the PSA response was more durable in the African-American versus Caucasian patient group (median PSA PFS, 16.6 vs. 11.5 months). Differences between the two study groups were also seen in rates of several adverse events of special interest that are associated with adrenal gland function, with hypertension, hyperglycemia, hypokalemia, and hypomagnesemia occurring more often in African-Americans than in Caucasians.

Senior author Daniel J. George, MD, highlighted the importance of conducting prostate cancer studies to characterize outcomes in African-American patients and shared some take-home messages from Abi Race.

“We know that black men have a 2.5-fold greater likelihood of dying from prostate cancer than white men, and so we need to have a focus on black men if we are going to identify strategies that will have a positive impact on prostate cancer-related mortality. Unfortunately, black men have been very underrepresented in phase III studies of prostate cancer treatments,” said Dr. George, professor of medicine at Duke Cancer Institute, Durham, NC.

“Further studies including more men are needed to prove that the response to abiraterone differs by race.”

ALICIA K. MORGANS, MD, MPH

“Although it was believed that accrual of black patients into prospective prostate cancer studies would be extremely difficult, Abi Race shows otherwise, and the findings pointing to potential race-related differences in efficacy and treatment-related side effects indicates the research is important.”

DANIEL J. GEORGE, MD

Although it was believed that accrual of black patients into prospective prostate cancer studies would be extremely difficult, Abi Race shows otherwise, and the findings pointing to potential race-related differences in efficacy and treatment-related side effects indicates the research is important.”

“Further studies including more men are needed to prove that the response to abiraterone differs by race,” said Dr. Morgans, associate professor of medicine, Northwestern University Feinberg School of Medicine, Chicago.

“Differences in androgen transport genes and possibly drug metabolism and other genes may be driving differences in outcomes and toxicity profiles with abiraterone treatment. We know that patient-centered care can improve outcomes, making these important issues to investigate as we try to personalize therapy for patients.”

Interest in conducting a prospective study to investigate racial differences in response to abiraterone for chemotherapy-naïve men with mCRPC arose from findings of a post-hoc analysis of data in the pivotal COUGAR-AA-302 trial that showed African-American men had a higher PSA 90% response rate and longer median rPFS compared with the overall population.

“It is noteworthy that the median PSA progression-free survival for the Caucasian men in Abi Race was very similar to the 11.1 months reported in COUGAR-AA-302 in which only 2.6% of the study population was black,” said Dr. George.

Investigating the potential race-related difference in outcomes, Dr. George and colleagues conducted a retrospective case-controlled study of men treated with abiraterone and prednisone at their center and again found higher PSA response rates among African-American men compared with Caucasians who were matched for prior chemotherapy.

Meanwhile, it was found in a study investigating abiraterone prior to prostatectomy that higher intracellular concentrations of the drug were achieved in patients with single nucleotide polymorphisms (SNPs) in certain SLCO proteins. “SLCOs are involved in cellular uptake of steroid hormones, including abiraterone and testosterone, and so these findings suggested there may be a genetic basis for differences in abiraterone efficacy and safety,” Dr. George said.

Therefore, Abi Race is also investigating germline SNPs by race. Results from analyses completed so far show differences between groups in the proportions of patients with certain SNPs in SLCOs.

Additional genetic analyses are ongoing and a follow-up study is underway. Known as PANTHER, the new prospective trial is investigating treatment with abiraterone and apalutamide (Erleada) in parallel groups of African-American and Caucasian patients with mCRPC.

Dr. George is a consultant to and receives research funding from Janssen. For full disclosures, see bit.ly/AbiRace.11

Source: Daniel J. George, MD

FIGURE / Abiraterone PSA progression-free survival by race

Source: Daniel J. George, MD
Assay/mpMRI predict grade reclassification

Combination appears to be more powerful predictor than mpMRI/PSA density

Cheryl Guttman Krader
UT Contributing Editor

SAN FRANCISCO—While both the Prostate Health Index (phi) and multiparametric magnetic resonance imaging (mpMRI) have demonstrated value for predicting grade reclassification among patients enrolled in active surveillance for prostate cancer, combining the two tools provides greater accuracy than either modality alone, according to research presented at the AUA annual meeting in San Francisco.

Furthermore, the combination appears to be a more powerful predictor of grade reclassification than the combination of mpMRI and PSA density (PSAD), which has been previously shown to be useful in the active surveillance population, Johns Hopkins researchers reported.

The improved predictive performance of combining information from the serum biomarker assay and mpMRI was identified in a retrospective study that included data from 253 men enrolled in the Johns Hopkins Active Surveillance program. The results showed that a cutoff of <25.6 for phi, which encompasses the lowest quartile of scores in the study population, combined with a PI-RADS v2 ≤3 had the highest NPV and AUC values of the three biomarkers, and it also had a higher NPV than PI-RADS v2 ≤3 used alone.

“We have been using phi and mpMRI in the follow-up of men in our active surveillance program. According to our new analysis, the combination of these tools might provide greater accuracy for reducing the number of unnecessary surveillance biopsies while minimizing the risk of missing men who may require active treatment,” said Dr. Schwen, who worked on the study with H. Ballentine Carter, MD, and colleagues.

Men were selected for inclusion in the study if they underwent mpMRI and had a phi test within 6 months of each other and subsequently had systematic biopsy with or without targeted biopsy. All men were categorized as either very-low risk or low-risk according to National Comprehensive Cancer Network Guidelines (NCCN) criteria.

The 253 men had been in active surveillance for a median of 24 months (range, 8 to 52 months). Median PSA, PSA density (PSAD), phi, and PHID values for the cohort were 6.2 ng/mL, 0.10 ng/mL2, 32.9, and 0.59, respectively. Of the 253 men, 179 (71%) had a PI-RADs v2 score ≤3.

Thirty-eight men (15%) had grade reclassification on surveillance biopsy. Compared to the group of men without grade reclassification, the men with reclassification had significantly higher median phi, PHID, and PSA density (PSAD) values. The percentages of men with PI-RADS v2 4-5 and who were NCCN low-risk were also significantly greater in the group with grade reclassification.

“Not surprisingly, median PSA did not differ significantly between men who did and did not have grade reclassification, showing the limitations of PSA use in the active surveillance population,” Dr. Schwen told Urology Times.

PI-RADS v2 score ≤3, had a 98% negative predictive value (NPV) for grade reclassification to Gleason score >6 and an area under the curve (AUC) of 0.70.

Additional calculations determined that the use of both parameters to guide biopsy decisions for men enrolled in active surveillance would avoid nearly 20% of surveillance biopsies at the cost of missing only 2.6% of cases of clinically significant disease, said first author Zeyad Schwen, MD, resident at James Buchanan Brady Urological Institute, Johns Hopkins University School of Medicine, Baltimore.

“phi appears to outperform PSAD in the active surveillance population both when used alone as well as when combined with mpMRI, which advocates for a more widespread adoption of phi in active surveillance programs.”

ZEYAD SCHWEN, MD

“I am very excited about the results of these new analyses,” Carter said.

Carter noted that in univariate analysis, PSAD, PHID, phi all predict reclassification. In multivariate analysis, only PSAD, PHID, and phi were found to be significant predictors of grade reclassification, whether the analysis was based on the primary endpoint of grade reclassification or the surrogate endpoint of biopsy.

Please see ASSAY/mpMRI, page 10

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Active surveillance use increasing in younger men

Only one-third of AS patients had undergone repeat prostate biopsy

Cheryl Guttman Krader
UT Contributing Editor

SAN FRANCISCO—The use of active surveillance for prostate cancer is increasing among younger, privately insured men, according to findings of a study presented at the AUA annual meeting in San Francisco.

The research, however, raises concern about the quality of the care provided, said first author Simon P. Kim, MD, MPH.

Using a large commercial insurance database including privately insured patients and Medicare Advantage enrollees (Optum Labs), the study identified 27,812 men ages ≥40 years diagnosed with biopsy-confirmed incident prostate cancer from January 2008 to December 2016. Regression modeling to analyze age-based time trends in the annual rate of active surveillance showed increases in men aged <70 years, with the highest gains in the subgroups of men aged 40 to 49 years and 50 to 59 years.

Data on receipt of follow-up procedures showed that nearly all men (90%) had a PSA test within 12 months after their cancer diagnosis. Only approximately one-third of patients, however, had undergone a repeat biopsy.

“Our research indicates that active surveillance is becoming an established management option for patients with low-risk prostate cancer and/or limited life expectancy. Previous studies evaluating its implementation used Medicare data, and so it is unclear how active surveillance is being used in younger men,” said Dr. Kim, associate professor of urology, Case Western Reserve University School of Medicine, Cleveland.

“Our research indicates that active surveillance is being promoted and disseminated in the younger, privately insured patient population. It seems, however, that increased attention is warranted to develop evidence-based active surveillance protocols to ensure safety for these patients. Ultimately, there is also a need for prospective studies to assess outcomes of active surveillance for younger patients.”

Lack of guidelines may account for low Bx rate

Dr. Kim suggested that the absence of standardized guidelines for surveillance strategies may be contributing to the less-than-optimal performance of follow-up biopsies.

“Existing surveillance protocol recommendations are mixed, and the inability to look to a universally accepted guideline for follow-up with PSA testing and prostate biopsy may be part of the problem,” Dr. Kim told Urology Times.

Men included in the database were identified as having received active surveillance based on absence of any primary therapy within the 6 months after they were diagnosed with localized prostate cancer.

For men ages 40 to 49 years, the rate of active surveillance approximately tripled between 2008 and 2016 from 95.24 per 1,000 patients to 312.50 per 1,000 patients. The active surveillance rate for the 50- to 59-year-old cohort rose approximately 2.5-fold between the first and last years of the study period, from 88.71 per 1,000 patients to 226.60 per 1,000 patients.

In 2008, annual rates of active surveillance in the 60- to 69-year-old subgroup (133.05 per 1,000 patients) and the ≥70-year-old subgroup (196 per 1,000 patients) were higher than in the younger cohorts. The next year, active surveillance utilization grew in the two older subgroups. Thereafter, the annual rate was stable in the oldest cohort and increased more incrementally among 60- to 69-year-old men.

The multivariable logistic regression analysis also investigated associations between other patient-related variables and receipt of active surveillance. Looking at race/ethnicity and using Caucasian men as the reference group, it found that the odds of receiving active surveillance were significantly greater among Asian-Americans and significantly lower among African-Americans. The odds of receiving active surveillance was also significantly greater among Medicare Advantage enrollees compared with men having commercial insurance. Receipt of active surveillance did not vary by geographic region, Charlson comorbidity score, or household income levels.

“The findings relating to race/ethnicity were interesting considering that access to care was not a factor in our privately insured population and that African-American men have an increased likelihood of having more aggressive disease,” Dr. Kim said.

Increased attention is warranted to develop evidence-based active surveillance protocols to ensure safety for these patients.”

Source: Simon P. Kim, MD, MPH

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Source: Simon P. Kim, MD, MPH

Cheryl Guttman Krader
UT Contributing Editor

ASSAY/msMri

continued from page 9

on a per unit increase or considered the upper limit of the 25th percentile as a cutoff.

The 25th percentile cutoff value for each of the biomarkers was then used to evaluate the performance of the biomarker alone and combined with a PI-RADS v2 score ≤3 for predicting grade reclassification. pbi ≤25.6 had the highest NPV and AUC values of the three biomarkers, and it also had a higher NPV than PI-RADS v2 ≤3 used alone.

“pbi appears to outperform PSAD in the active surveillance population both when used alone as well as when combined with mpMRI, which advocates for a more widespread adoption of pbi in active surveillance programs,” Dr. Schwen said.

Dr. Schwen noted that annual biopsies were performed routinely when the Johns Hopkins Active Surveillance program was launched.

“We have learned a lot since then and the protocol has been modified over time. Currently, we are using the findings from mpMRI, serum biomarkers, and other patient characteristics in decisions about extending the interval and minimizing the morbidities associated with surveillance biopsies,” he said.

“We also believe reducing the number of biopsies will improve active surveillance compliance.”

One of Dr. Schwen’s co-authors is a consultant/adviser for GenomeDx Biosciences and HealthTronics and conducts scientific studies/trials for Novartis.
Some MIBC patients could forgo cystectomy

Cheryl Guttman Krader
UT Contributing Editor

CHICAGO—Findings of a multi-institutional cohort study provide further evidence that favorable outcomes can be achieved by carefully selected patients with muscle-invasive bladder cancer (MIBC) who forgo radical cystectomy after achieving a clinical complete response to neoadjuvant chemotherapy (NAC).

Considering the limitations of the available research and the need to optimize methods for selecting and monitoring patients for conservative management, however, radical cystectomy after NAC should remain the standard of care, according to the authors.

The study included 148 patients treated at Columbia University Medical Center and Memorial Sloan Kettering Cancer Center, both in New York. During median follow-up of 55 months (range, 5-145 months), 71 patients (48%) experienced a recurrence in the bladder, including 16 with M1 disease and 35 with nonmuscle-invasive (NM1) disease. Eleven of the 71 patients and four others had a systemic recurrence. Twenty-seven patients underwent salvage cystectomy, which prevented cancer-specific death in 75% of those who underwent the procedure after MIBC relapse and in 93% operated on after NM1B relapse.

For the overall population, rates for 5-year disease-specific survival, overall survival, cystectomy-free survival, and recurrence-free survival were 90%, 86%, 76%, and 64%, respectively.

“To our knowledge, ours is the largest study investigating outcomes of patients with MIBC who forgo radical cystectomy after having a complete response to NAC. Its results are consistent with previous research showing high survival rates in this population and match those seen for patients in a SWOG trial who were pT0 after NAC and underwent immediate radical cystectomy, which suggests radical cystectomy may not provide benefit in the setting of a complete response to NAC,” said Patrick Mazza, clinical research coordinator in the department of urology, Columbia University Medical Center, working with James M. McKiernan, MD, and co-authors.

“While the findings are encouraging, more work is needed to understand the safety of implementing this conservative management approach,” Mazza added.

Outcome predictors identified

The study also sought to identify outcome predictors and found that survival was significantly worse among patients who relapsed with MIBC compared to those without a muscle-invasive relapse.

In addition, univariate analysis showed that hydronephrosis at diagnosis was associated with both muscle-invasive recurrence and cancer-specific death. On multivariate analysis, the presence of carcinoma in situ at diagnosis was predictive of intravesical recurrence.

“Either of these findings at diagnosis would be reasons to exclude patients from conservative management,” Mazza said.

“All patients in our study had solitary, small-to-medium-sized muscle-invasive lesions, with no nodal or distant metastases, urothelial cell carcinoma or mixed histology (no small cell), and a complete TURBT both prior to and following NAC,” he added. “These characteristics seem to be predictive of successful bladder sparing, but it should also be noted that the patients in our study were treated at two centers of urologic oncology expertise. The treatment approach they received, and in particular the extent of TURBT, may not be deliverable at the majority of centers or community hospitals.”

A prospective trial enrolling patients who have a complete clinical response to NAC and randomizing them to cystectomy or surveillance would be needed to definitively determine whether or not cystectomy provides a survival benefit or if a bladder-sparing approach can be safely implemented.

Recognizing that it may not be feasible to conduct such a trial, the investigators suggested that developments to improve patient selection and follow-up may enable bladder sparing to become an acceptable option.

“We believe there is a need to identify genomic biomarkers that are predictive of durable cT0 status and low risk of invasive relapse as well as novel imaging methods that can provide assurance that cT0 disease equals pT0 disease,” Mazza told Urology Times.

“While the findings are encouraging, more work is needed to understand the safety of implementing this conservative management approach.”

PATRICK MAZZA

Bladder Ca guideline adherence boosts survival

Cheryl Guttman Krader
UT Contributing Editor

Significant variation in receipt of guideline-based care observed, however

Across the various surgical and chemoradiation guidelines, however, there is significant variation in the receipt of guideline-based care, reported Nikhil Waingankar, MD, MSHP, assistant professor of urology at Icahn School of Medicine at The Mount Sinai Hospital, New York.

“Delivery of guideline-based care may involve several factors, including awareness of the guidelines by the provider, application of each measure in the appropriate patient, and active participation by the patient. However, the guidelines are well-vetted and the recommendations are evidence-based; we believe that our study underscores the importance of improving dissemination of the guidelines and their implementation and uptake in practice,” Dr. Waingankar told Urology Times.

The study, presented at the AUA annual meeting in San Francisco, identified patients
Ablation shows benefits in small renal tumors

Procedure provides similar outcomes as radical nephrectomy

Andrew D. Bowser / UT Correspondent

Compared to radical nephrectomy, percutaneous ablation provides similar oncologic outcomes with fewer complications in older patients with small renal tumors, results of a large, population-based comparative analysis suggest. The benefits of percutaneous ablation were less certain when compared to partial nephrectomy, though patients undergoing ablation appeared to have fewer complications, according to investigator Adam D. Talenfeld, MD, MS, assistant professor of clinical radiology at Weill Cornell Medicine and attending radiologist at NewYork-Presbyterian, New York.

This first-ever population-level study of percutaneous ablation outcomes strengthens findings of single-institution studies, and raises the level of evidence supporting its use in well-selected older patients, Dr. Talenfeld said in an interview with Urology Times.

“The real question here is, for those older patients that can’t get partial nephrectomy, are we doing the right thing by taking out their kidneys? And I think the answer is probably more often than not, no,” he said. “I think that we should consider percutaneous ablation ahead of radical nephrectomy for older patients when partial nephrectomy is considered less feasible.”

The observational cohort analysis by Dr. Talenfeld and colleagues, published in the Annals of Internal Medicine (June 26, 2018 [pub ahead of print]), was based on data from the SEER (Surveillance, Epidemiology, and End Results) cancer registry tied to Medicare claims data.

The investigators included data for a total of 4,310 individuals aged 66 years or older who underwent treatment for T1a renal cell carcinoma (RCC) between 2006 and 2011.

5-year OS similar for ablation, radical nephrectomy

The 5-year overall survival rates for percutaneous ablation versus radical nephrectomy were similar, at 74% and 75%, respectively, results of the analysis show. Likewise, RCC-specific survival rates were 96% for percutaneous ablation and 95% for radical nephrectomy. Results were similar in a sensitivity analysis excluding patients with tumors not histologically confirmed as malignant, with 5-year RCC-specific survival of 94% for both percutaneous ablation and radical nephrectomy.

By contrast, 5-year overall survival was shorter for percutaneous ablation versus partial nephrectomy, at 77% and 86%, respectively. RCC-specific survival of 94% for both percutaneous ablation and radical nephrectomy.

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GUIDELINE continued from page 11

with non-metastatic MIBC (cT2-4aN0M0) who underwent radical cystectomy (RC) or bladder preservation therapy (BPT). Searching the NCDB for the years 2004 to 2014, it identified 20,079 patients who underwent RC and 8,774 who underwent BPT.

Care measures reviewed for the surgical cohort were use of neoadjuvant chemotherapy, adjuvant chemotherapy in high-risk patients, adequate lymph node dissection (≥10 nodes), and timeliness of care (within 90 days of diagnosis), and they were received by 15%, 22%, 59%, and 79% of patients, respectively. For the BPT cohort, the measures reviewed pertained to concurrent chemotherapy, appropriate radiation dose, and timeliness of care; the receipt rates for these measures were 61%, 58%, and 79.1%, respectively. “Only the recommendation for neoadjuvant chemotherapy has a category I evidence rating, but it was the measure with the lowest level of receipt. Going forward with this treatment involves patient consent after an honest discussion of the risks and benefits of getting not only chemotherapy upfront but also having radical surgery, which may involve a range of potential complications. Adherence to the recommendation depends not only on it being presented to the patient. It also requires patient buy-in,” Dr. Waingankar said.

The impact of guideline-based care on survival was analyzed using an adjusted Cox proportional hazards regression model. In the surgical cohort, adequate lymph node dissection, receipt of perioperative chemotherapy, and timeliness of care were each associated with a significant improvement in survival. In the BPT cohort, receipt of concurrent chemotherapy and appropriate radiation dose also were associated with a significant survival benefit.

Hazard of death significantly reduced

Analysis of the survival impact from increasing the number of guideline measures met for the surgical cohort showed that the hazard of death was significantly reduced by 14% with receipt of one measure, 30% with receipt of two measures, and 41% with receipt of three measures. For the patients undergoing BPT, receipt of one guideline measure was associated with a 4% reduction in the hazard of death, which was not statistically significant. The benefit was statistically significant with receipt of additional measures and increased incrementally to 39% reduction in the hazard of death for receipt of two measures and 58% for receipt of three measures.

Although the survival analyses accounted for patient age and Charlson comorbidity index, Dr. Waingankar acknowledged that adjustment for additional factors that could impact survival was not possible because of the limited granularity of NCDB data. Nevertheless, he said he was confident in the findings that incremental adherence to guideline measures is associated with improved survival.
San Francisco—An investigational oncolytic immunotherapy based on a modified common cold adenovirus now is showing promise for treating bacillus Calmette-Guérin-unresponsive non-muscle-invasive bladder cancer (NMIBC).

New interim findings presented at the AUA annual meeting in San Francisco demonstrated that intravesical CG0070, which is a selective oncolytic adenovirus that exploits retinoblastoma pathway defects, produced an overall 30% complete response rate at 12 months for patients with high-risk BCG-unresponsive NMIBC and a 48% complete response rate for those with BCG-refractory disease.

“It is certainly innovative and a promising approach,” said study investigator Gary Steinberg, MD, professor of surgery and the director of urological oncology at the University of Chicago. CG0070 contains a cancer-specific promoter and a GM-CSF transgene. The company developing it says CG0070 is designed to work in two important and complementary ways. It replicates inside the tumor’s cells causing tumor cell lysis and immunogenic cell death. Then, the rupture of the cancer cells releases tumor-derived antigens with GM-CSF, stimulating a systemic anti-tumor immune response.

In this study, 10 patients underwent cystectomy and six of these patients had muscle-invasive disease. The adverse events (AEs) were found to be Grade 1-3 at 12 months and the immunologic AEs included influenza type illness (7%), fatigue (4%), and chills (1%). There were five deaths that were secondary to progressive urothelial carcinoma, esophageal carcinoma, lung carcinoma, and cardiac disease, according to the authors. “This is a burgeoning area and this has shown the most promise of any product for patients with BCG-unresponsive non-muscle-invasive bladder cancer,” Dr. Steinberg said in an interview with Urology Times.

“Overall CR rate of 30% seen”

For this current investigation, the authors defined CR as no disease on cystoscopy, cytology, and/or random biopsies. At interim analysis of 61 patients, the overall 12-month CR rate was 30%. The authors found that 45 patients (27%) with CIS-containing tumors had a CR at 12 months. They also found that 16 patients (38%) with pure Ta/T1 had a CR at 12 months. None of the six patients with T1/CIS or Ta/CIS had a CR at 12 months. The interim results also showed that 25 BCG-refractory patients (48%) had a CR at 12 months.

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RENAI MASS SURVEILLANCE TRENDS REVEALED

A recent analysis of contemporary trends in the management of clinical T1a renal masses shows growing use of active surveillance. Over the 4-year study period, active surveillance use increased from 1.9% to 3.1%, partial nephrectomy use increased from 53.7% to 60.1%, and radical nephrectomy use decreased from 28.7% to 21.8% (p<.001 for all temporal trends). For more, see www.urologytimes.com/renal-mass.
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Over the last 10 years, low-risk prostate cancer has garnered significant attention and the focus has been on identifying strategies to avoid overtreatment. The opposite end of the prostate cancer spectrum has received less attention. A recent report by Sandler et al aims to provide some insights into the treatment-related outcomes in our highest risk prostate cancer patients (ie, biopsy Gleason score 10) (Int J Radiat Oncol Biol Phys 2018; 101:883-8).

The authors point out that over 50% of these patients can remain free of systemic disease for 5 years after treatment with a combination of modalities.

Biopsy Gleason score 10 is uncommon and in the more recent Gleason grouping system, both Gleason scores 9 and 10 are combined into group 5. The authors combined data from 12 different centers to identify 112 patients with biopsy Gleason score 10 over the last 13 years. These patients had been treated with either radical prostatectomy (RP), external beam radiation therapy (EBRT), or external beam radiation therapy plus brachytherapy boost (EBRT-BT). In addition, androgen deprivation therapy for nearly 2 years was used in 98% of patients undergoing EBRT and in 79% undergoing EBRT-BT. In the RP group, 35% had received neoadjuvant systemic therapy and 34% received postoperative EBRT.

Due to the lack of uniformity in defining biochemical recurrence, the authors focused on the clinical outcomes following prostate cancer treatment such as overall survival (OS), prostate cancer-specific survival (PCSS), and distant metastasis-free survival (DMFS).

After a median follow-up of 4.9 years, no differences were noted among various treatment groups in terms of OS or PCSS. The 5-year OS rates in the RP, EBRT, and EBRT-BT groups were 80%, 73%, and 83%, respectively, while the 5-year PCSS rates were 87%, 75%, and 94%, respectively. The EBRT-BT group appeared to have some statistical advantage over EBRT in terms of DMFS (87% vs. 62%), but there was no difference when compared to the RP group (64%).

Nearly two-thirds can remain free of metastatic disease

These data highlight the fact that regardless of the treatment combination, nearly two-thirds of these high-risk patients can remain free of metastatic disease. This is in contradistinction to the long-held and often presented view that patients with Gleason score 10 prostate cancer may already have metastases and that primary treatment may not be necessary.

It is important to point out that the patients in this report were likely detected through a screening process and thus may have somewhat lower volume of disease compared to the historical controls, as evident from the fact that median PSA level was less than 10 ng/mL and 67% of patients had clinical stage T1 or T2. The authors correctly point out some of the weaknesses of the study, which are often unavoidable when retrospectively pulling data from different centers, such as heterogeneity and lack of central pathology review. Other information, such as quality of life following various combinations of treatment, would have been quite informative.

While these results cannot be extrapolated to men with very high PSA level or advanced clinical stage, the study provides appropriate benchmark data for our contemporary patients with high-risk clinically localized prostate cancer. Unlike the historical approach to Gleason score 10 prostate cancer management, it appears that aggressive, multimodality combination therapy can result in significantly long metastasis-free (and treatment-free) intervals.

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**Badar M. Mian, MD**

Dr. Mian is associate professor of surgery in the division of urology at Albany Medical College, Albany, NY.
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Percutaneous nephrolithotomy (PCNL) offers a potentially shorter recovery time for patients but is a challenging procedure to perform. In this interview, Thomas Chi, MD, discusses how he performs PCNL, explains why he uses ultrasound instead of fluoroscopy, and offers advice to urologists looking to gain more experience with the procedure.

**Q:** What are the indications for PCNL?

**A:** If you look at the guidelines, the indications for PCNL are any stone 2 cm to 2.5 cm or larger. We don’t have a lot of guidance for the medium-size stone (1 cm-2 cm). For those stones, I leave it up to the patient and discuss shock wave lithotripsy, ureteroscopy, and PCNL with them. I think the trade-off with PCNL is that even though it’s more invasive, patients recover a little faster and may return to work a little sooner. Some people like the idea of a nephrostomy tube for a short time versus a stent for a longer time.

**Q:** Do you think patients prefer the percutaneous approach compared to a noninvasive approach?

**A:** I think a lot of patients come in with a preconceived notion, but I spend a lot of time describing a stent and the uncertainties associated with having to wear a stent and how much it may impact their life. When they weigh having the stent versus having a nephrostomy tube in the hospital for 1 or 2 days, I think a lot of people change their mind. My experience has been that patients in the short term may prefer a small nephrostomy tube for a day or two compared to a stent for a couple of weeks, but I don’t know that a lot of data exist to guide us either way.

**Q:** Who do you think should do these procedures? Should it be any urologist versus specialized urologists? Should radiologists be involved?

**A:** It’s a complex answer. Every hospital system and practitioner has a different set-up, which makes the relationship between interventional radiology, their own training, and comfort different. PCNL certainly is a challenging procedure, but it’s probably because a lot of the approaches we have are a little bit difficult to learn. There’s a long learning curve to master fluoroscopy. That takes some level of comfort. I think that everybody should be doing PCNL if we can make the procedure easier and more facile on their hands. That way, patients will get the optimum procedure for the stone as opposed to avoiding a procedure because providers feel uncomfortable with it.

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**What are the indications for PCNL?**

**STEPHEN Y. NAKADA, MD**

If you look at the guidelines, the indications for PCNL are any stone 2 cm to 2.5 cm or larger. We don’t have a lot of guidance for the medium-size stone (1 cm-2 cm).

**Q:** Please take us through how you do a PCNL.

**A:** I trained with fluoroscopy, so I did traditional prone percutaneous nephrolithotomy using fluoroscopy guidance for the puncture and the dilatation. Over the last several years, we’ve transitioned almost entirely to ultrasound use. Ultrasound is used very widely in other countries that don’t have easy access to fluoro such as parts of Asia and Europe, and there are a lot of good things about it. Nowadays, I use ultrasound for all my access and we’ve published data that, at least in our experience, it’s easy to learn.

If you have any abdominal ultrasound that you can use in the operating room, the first skill is figuring out how to image the kidney well. After that, it’s learning how to guide the needle into the kidney. One of the reasons it’s easier in my mind is that you can distinguish between posterior and inferior calyces easier.

If providers aren’t used to using ultrasound, having a fluoro as a bail-out is a good idea. We’ll get our needle entry in the calyx of choice and then use any coaxial wire with a J-tip on it. Generally speaking, a coaxial wrapped movable cord wire with a J-tip is my wire of choice, which I put down the needle into the collecting system. When I see that it’s inside, I make the tip floppy so that we don’t injure or perforate the collecting system.

I back out the needle and then use an 8F or 10F dilator to get to the fascia, then switch that out for a safety wire introducer, and put a second safety wire in place. I pin that off at the side and then I usually use a balloon. I think the balloon is nice because it’s a single-set dilator as opposed to serial dilatation, and we’ll dilate up. My normal tract now is 24F and so I use a 24F sheath, which requires a 20F or 21F nephroscope, which is a good match for that sheath.

Then you use your lithotrite of choice. My current instrument is the UreTron, made by Med-Sonics, but the Olympus ShockPulse and CyberWand are excellent and Boston Scientific makes a great device. There are a lot of great lithotrites out there. Afterwards, I do tubed nephrostomy. I’ll leave an 8F or 10F nephrostomy tube, usually a Cope, in place. Our patients generally stay 1 or 2 nights in the hospital and most have the nephrostomy tube removed at the point they go home.
Q: The use of ultrasound for PCNL is unique to you and your practice. What is your best tip for using ultrasound?

A: My best tip is to use ultrasound on everybody, which will get you through that first learning curve—learning how to image the kidney well. When I started out, I put an ultrasound in my office and I performed ultrasound on every patient. When they came in for something unrelated to their kidneys, I would still say, “If you don’t mind, I’ll take a look at your kidneys,” and I would actually turn them prone in the office and ultrasound their kidneys. That let me do more in the operating room.

Then, in the operating room, I would just give myself 5 minutes and do whatever I could. Initially, it was just imaging, and then over time, as I got more done in that 5 minutes, I would try one pass of the needle. If you’re using an 18-gauge needle or a smaller needle for a single pass, if it doesn’t work out it’s not going to hurt anybody. If you stick to that 5-minute rule, you’ll be learning consistently but you’re not going to waste any time and nobody’s getting mad at you for trying something new.

Q: If you had a really tough anatomic case, would you still go with ultrasound or is there a point where you’d go back to fluoroscopy?

A: The ideal patient to start off with is one who is not super obese and who has moderate hydronephrosis and a pretty simple stone. I think the most challenging ones are where you have a staghorn stone, non-dilated case in a patient with a high body mass index. In our last 100 cases or so, more than 90% of the time I don’t even wear lead, so it’s pure ultrasound guidance head to toe.

The times when I have had to use fluoro to get myself out of trouble are for a really complex anatomy and non-dilated systems with big stones, so I think that having a “plan B” is a good idea. Whether your plan B is having a fluoroscopy machine in the room or having an interventional radiologist or a senior colleague there to help you out, having that plan B is what helps you to transition over.

Q: How do you get informed consent for a PCNL? What do you talk with patients?

A: I go through the risk of a bowel, lung, or visceral injury in a lot of detail, because even though the risk is relatively low, they’re very impactful for the patient. I always review the risk of bleeding. In our institution, it’s about one in 100, and I will tell patients that if that does happen, usually they’ll need a transfusion but that sometimes they’ll need an embolization or stent placed to deal with the bleeding issues. I always talk about pain. I tell them there will be a fair amount of pain for about 3 days and that they’ll have a nephrostomy tube and a Foley catheter, usually for one night.

What is your best tip for using ultrasound?

STEPHEN Y. NAKADA, MD

My best tip is to use ultrasound on everybody, which will get you through that first learning curve—learning how to image the kidney well.

THOMAS CHI, MD

Q: What would you tell someone who has a lower volume practice in PCNL? How would you advise them to gain experience and get better?

A: That can be a real challenge because even at the trainee level, the access is key. The access is everything. You only have a certain number of “at-bats,” even while you’re training, and when you get in a practice and you’re not doing a lot of them, those opportunities come up infrequently.

I’m a big advocate for getting your own access because that’s the key to making the procedure go well, but at the end of the day, patient safety is the most important thing. Whether you’re partnering up with an interventional radiologist or you’re doing it yourself, do whatever you’re most comfortable with to get good access. If you’re going to partner with your interventional radiologist, having a great relationship and being present so that you’re helping them to make a decision on where that access goes is key to making that portion of the procedure go well.

Q: What would you tell someone who is just starting in their practice? Is PCNL something they should try to retain, or is it something more for fellowship-trained urologists?

A: My experience has been that most of the people who end up leaving our program and then doing PCNL in a practice who are not fellowship-trained are people who left their residency comfortable with the procedure at that point. Patient safety always comes first, so you shouldn’t push yourself to do something you felt uncomfortable with at the time of your training. At the same time, we have had a lot of people come to learn ultrasound from us because part of what makes fluoroscopy tough is that it takes a lot of cases to get it under your belt. Having better instrumentation and having an easier access approach can help you to do it in your own practice. It is a challenging case, it is a humbling case, and the margin of error can be very high. You have to feel confident, particularly with the access portion, to do it well. If you’re not comfortable with getting access, having a good relationship with an interventional radiologist and doing the rest of the procedure yourself is a very reasonable way to go.

FDA ORDERS LABEL CHANGES FOR FLUOROQUINOLONES

The FDA is requiring safety labeling changes for fluoroquinolones to strengthen the warnings about the risks of mental health side effects and serious blood sugar disturbances, and make these warnings more consistent across the labeling for all fluoroquinolones taken by mouth or given by injection.

The safety labeling changes the FDA is requiring were based on a comprehensive review of the FDA’s adverse event reports and case reports published in medical literature.

Across the fluoroquinolone antibiotic class, a range of mental health side effects are already described in the Warnings and Precautions section of the drug labeling, but differed by individual drug. The new class-wide labeling changes will require that the mental health side effects be listed separately from other central nervous system side effects and be consistent across the labeling of the fluoroquinolone class. The mental health side effects to be included in the labeling across all the fluoroquinolones are disturbances in attention, disorientation, agitation, nervousness, memory impairment, and delirium.

Additionally, the recent FDA review found instances of hypoglycemic coma where users of fluoroquinolones experienced hypoglycemia. As a result, the Blood Glucose Disturbances subsection of the labeling for all systemic fluoroquinolones will now be required to explicitly reflect the potential risk of coma with hypoglycemia.

The FDA also published a drug safety communication about safety information regarding hypoglycemic coma and mental health side effects with fluoroquinolones.
Patients have become voracious consumers of the medical literature. Each week, a flurry of new urology studies surface in the popular media to feed public interest. Many of the high-profile articles focus on prostate disease and lifestyle factors. Popular topics include associations of prostate cancer and BPH with diet, exercise, vitamins, and supplements. Many present contradictory results; all have the potential to provoke anxiety and/or confusion among our patients.

A recurring topic is alcohol. Excessive alcohol consumption is, of course, unhealthy and should be discouraged. But what about moderate alcohol intake, such as a glass of red wine each day? Is moderate alcohol intake beneficial or harmful to the prostate, or neither?

Numerous observational studies have addressed this question with respect to prostate cancer, BPH, and lower urinary tract symptoms (LUTS). Here are some take-aways (summarized in the table).

### Prostate Cancer

For prostate cancer, the answer appears to be: neither.

A large number of studies and several meta-analyses have failed to turn up any consistent patterns of moderate alcohol consumption with prostate cancer risk. While some studies have observed dose-dependent, modestly increased risks of incident disease (BMC Cancer 2016; 16:845; Int J Cancer 2014; 134:971-8), others have not (Cancer Epidemiol Biomarkers Prev 2008; 17:1282-7). Still others have arrived at mixed results. For example, a meta-analysis of 17 observational studies (611,169 participants) concluded that, while there were no overall associations between wine intake with prostate cancer, moderate white wine consumption increased while red wine decreased incident cancer risk (Clinical Epidemiology 2018; 10:431-44).

Keeping with the theme of red wine, patients may ask about resveratrol, a polyphenolic, antioxidant compound found in red wine and grape skin. Despite some pre-clinical in vitro and animal studies suggesting antineoplastic activity, there are no conclusive clinical data to demonstrate resveratrol prevents or protects against prostate cancer.

### BPH

How does moderate alcohol intake impact BPH? Research shows it appears to be beneficial.

Individual studies and meta-analyses have observed that moderate alcohol intake appears to prevent incident BPH. Definitions of BPH in these studies included radiologic enlargement, decreased urinary flow rates, urodynamic studies consistent with bladder outlet obstruction, incidence of BPH surgery, acute urinary retention, physician-diagnosed BPH, LUTS, and histologic diagnosis. In a meta-analysis of 19 studies that incorporated 120,091 men, alcohol intake ≥36 g/day was associated with a 35% decreased likelihood of BPH (J Urol 2009; 182:1463-8).

### TABLE: ALCOHOL’S EFFECT ON THREE UROLOGIC CONDITIONS

<table>
<thead>
<tr>
<th>Effect</th>
<th>Key study(ies)</th>
<th>Study type(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate cancer</td>
<td>Dose-dependent, modestly increased risk of incident disease</td>
<td>BMC Cancer 2016; 16:845; Int J Cancer 2014; 134:971-8</td>
</tr>
<tr>
<td>Increased incident cancer risk (moderate white wine consumption) and decreased incident cancer risk (red wine)</td>
<td>Clinical Epidemiology 2018; 10:431-44</td>
<td>Meta-analysis</td>
</tr>
<tr>
<td>BPH</td>
<td>35% decreased likelihood</td>
<td>J Urol 2009; 182:1463-8</td>
</tr>
<tr>
<td>LUTS</td>
<td>Both positive and negative effects</td>
<td>J Urol 2017; 198:1010-20</td>
</tr>
<tr>
<td>Decreased LUTS risk (low to moderate intake), but dose-dependent increased risk with increased amounts</td>
<td>J Urol 2012; 187:1312-7</td>
<td>Cross sectional, population based</td>
</tr>
</tbody>
</table>

Source: Data compiled by J. Kellogg Parsons, MD, MHS
On its face, this concept would appear counterintuitive. Alcohol is a potent diuretic with the potential to provoke symptoms associated with bladder outlet obstruction. Yet moderate alcohol intake has also been associated with a decreased risk of cardiovascular disease. Because obesity, metabolic syndrome, and cardiovascular disease increase the risk of BPH, a potential explanation is that alcohol positively modulates the phenotypic expression of BPH through beneficial effects on shared metabolic perturbations linked to cardiovascular health.

LUTS
Finally, for LUTS, the answer to whether alcohol intake is beneficial or harmful appears to be: possibly beneficial.

LUTS, rather than BPH, has become the preferred term for describing urinary symptoms in male populations. The most commonly used measures are the AUA Symptom Index and the International Prostate Symptom Score.

Observational studies have demonstrated both positive and negative effects of alcohol on LUTS, with a slight preponderance of studies favoring a positive effect.

Observational studies have demonstrated both positive and negative effects of alcohol on LUTS, with a slight preponderance of studies favoring a positive effect (J Urol 2017; 198:1010-20). The relationship is complex, and perhaps the most robust way of describing it is through a so-called “J” curve, with LUTS severity (or LUTS probability) plotted on the y-axis and alcohol intake on the x-axis. In this model, low to moderate alcohol decreases LUTS risk, but increased amounts of alcohol increase LUTS in a dose-dependent manner (J Urol 2012; 187:1312-7).

Still, clinical judgment in individual cases should prevail. Reduction of alcohol intake in men with storage-predominant LUTS or primary nocturia, for example, is a simple and often efficacious approach to reducing symptoms.

Summary
Epidemiologic evidence suggests that alcohol intake is linked to prostate disease in surprising and beneficial ways, with moderate consumption associated with decreased risks of both BPH and LUTS. Alcohol appears to have no substantive effects on prostate cancer risk. Patients should be counseled, as with other lifestyle factors such as diet and exercise, to practice moderation when considering these data.

In a meta-analysis of 19 studies... alcohol intake ≥36 g/day was associated with a 35% decreased likelihood of BPH.

In a meta-analysis of 19 studies... alcohol intake ≥36 g/day was associated with a 35% decreased likelihood of BPH.
Medicare proposed rule outlines significant changes

E/M documentation, cystoscopy payment among components to watch for

RAY PAINTER, MD
Dr. Painter is the president of Physician Reimbursement Systems, Inc., in Denver, and is also publisher of Urology Coding and Reimbursement Sourcebook.

MARK PAINTER
Mr. Painter is CEO of PRS Urology SC in Denver.

Every year, Medicare is required to publish a proposed set of rule changes for the next year. If the rule changes proposed by Medicare for 2019 are passed, they may very well change the way you practice. While this rule is not final, the proposed rule set is often very close to the final rule, which will be published in early November.

In this article, we will summarize a few of the most important proposed changes. You can download the entire document at bit.ly/2019proposedrule. We encourage urologists to consider commenting on the proposed rule. (See “How to comment on proposed rule,” page 28.)

As we see the reaction and get closer to deciphering the final rule to be implemented, we will be providing more information on its impact and how to implement these changes in your practice.

Key changes to be discussed in this article include:
• documentation guidelines and changes to payment for evaluation/management (E/M) services
• add-on G codes for certain urologic E/M services
• payment for some phone calls or other non-face-to-face inpatient encounters
• cuts in payment for the –25 modifier
• changes in documentation for time-based E/M services
• changes in payment for some Part B drugs
• payment for cystoscopies.

E/M documentation guidelines and payment for E/M services

The proposed changes remind us of the old saying, “Be careful what you wish for; you just might get it.” If adopted, you will no longer have to record detailed information that is not pertinent to your office and outpatient E/M services (99201-99215), nor will you have to document physical observations and perform physical exams that are not medically necessary. Copying previous encounters should be a thing of the past. How often have you wished you did not have to spend time documenting information that was not medically necessary?

The proposed changes to documentation requirements include:
• simplified documentation for all outpatient visits
• allowing practitioners to choose medical decision-making (MDM), time, or keep using the 1995 or 1997 guidelines, as a basis to determine the appropriate level of E/M visit
• allow any E/M visit to be charged based on time
• chief complaint and history of present illness can be entered by staff or patient and reviewed by practitioner, but does not have to be reentered.

The proposed changes to payment for outpatient E/M services include:
• pay a single rate for levels 2 through 5 of office and other outpatient new and established patient E/M services
• add-on G codes for certain E/M visits, including some urologic visits.

The details of the proposals provide us with some pleasant surprises. First and foremost, the documentation requirements have been reduced even if you choose to document based on the ‘95 and ‘97 guidelines. For the purposes of payment for an office/outpatient E/M visit, practitioners would only need to meet documentation requirements currently associated with a level 2 visit for history, exam, and/or MDM. For example, to qualify for the established patient E/M visit, one would have to document only three elements on the history of present illness, no review of systems or past family social history, and document no physical exam, for a problem not requiring active treatment.

Even though the requirements have been reduced, they make it clear that their expectation is that practitioners would continue to perform and document E/M visits as medically necessary for the patient to ensure quality and continuity of care. What a novel idea: Document only what you think is medically necessary for the patient.

The CPT codes would not be changed and the current codes would still be reported as supported by the now-optional method chosen by the practice: either MDM, time, or under the current guidelines with some modification.

One proposed option for billing based on time includes a blend of the times currently required for levels 2 through 5. For an established patient, the required time would be 31 minutes. Then apply the rules established by CPT in which time documented for each code is an average rather than threshold time. The documented time required to bill the established patient code would be 16 minutes.

Prolonged E/M service add-on code reporting would be changed to require specific notation of the prolonged time as well as the typical or base time for the E/M code reported. (This will require more input and discussion.)

The single payment for all E/M services (levels...
Help Preserve Your Prostate Cancer Patients’ Quality of Life with SpaceOAR Hydrogel.

- In the pivotal trial, SpaceOAR patients did not experience any Grade 2 or greater rectal adverse events (e.g. proctitis, rectal bleeding, or fecal incontinence).1,2
- In-office transperineal injection under local anesthesia
- New Category 1 CPT code - 55874 - effective January 1, 2018

To learn how you can integrate SpaceOAR hydrogel into your urology practice, go to www.spaceoar.com/aua

1. From 3 months onward post radiotherapy (data on file)

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2-5) would be $135 for a new patient and $93 for an established patient. These are considered to be a weighted average of the four codes over the past 5 years. Tables 1 and 2 were included in the proposed rule illustrating the payment plan.

Physician Reimbursement Services projected a blended payment rate using Medicare percentages for urology and current 2018 prices reported to Medicare to approximate a blended level 2 to 5 fee for new patients and established patients. This calculation is a rough estimate by summing the product of the current fee and percentage for each category. Using this formula, the new patient fee would be $183.89 and the established patient fee would be $84.82.

To project an overall impact for urology, we used data from IntrinsiQ’s InfoDive data platform (used by PRS and a number of urology practices across the country) to estimate the number of visits for each category billed in a 12-month period.

### TABLE 1 COMPARISON OF PAYMENT RATES FOR OFFICE VISITS—NEW PATIENTS

<table>
<thead>
<tr>
<th>HCPCS code</th>
<th>CY 2018 non-facility payment rate</th>
<th>CY 2018 non-facility payment rate under proposed methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>99201</td>
<td>$45</td>
<td>$44</td>
</tr>
<tr>
<td>99202</td>
<td>$76</td>
<td>$135</td>
</tr>
<tr>
<td>99203</td>
<td>$110</td>
<td></td>
</tr>
<tr>
<td>99204</td>
<td>$167</td>
<td></td>
</tr>
<tr>
<td>99205</td>
<td>$211</td>
<td></td>
</tr>
</tbody>
</table>

Source: Federal Register, July 27, 2018

### TABLE 2 COMPARISON OF PAYMENT RATES FOR OFFICE VISITS—ESTABLISHED PATIENTS

<table>
<thead>
<tr>
<th>HCPCS code</th>
<th>Current non-facility payment rate</th>
<th>Proposed non-facility payment rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>99211</td>
<td>$22</td>
<td>$24</td>
</tr>
<tr>
<td>99212</td>
<td>$45</td>
<td>$93</td>
</tr>
<tr>
<td>99213</td>
<td>$74</td>
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<td>99214</td>
<td>$109</td>
<td></td>
</tr>
<tr>
<td>99215</td>
<td>$148</td>
<td></td>
</tr>
</tbody>
</table>

Source: Federal Register, July 27, 2018

Using this method, an average urologist would see an increase of $18,891.71 in a year under the new payment system. This projection does not take into account the lost revenue that would result from the decrease in payments for E/M codes billed with modifier –25 addressed below. Nor does the number take into account the increase that would result from using the G code for standalone E/M codes addressed below. CMS projected less than a 3% increase in overall payments to urology.

We continue to search for more data to refine our projections. Additionally, we will need some clarification on appropriate use of the G code in the final rules to provide a more accurate projection. We anticipate revising these projections in our December column.

Of course, the impact on your practice income will require analysis of your current billing patterns. Please feel free to contact PRS for assistance in calculating projections for your practice; we hope that the explanation provided here can assist you in running these projections on your own.

### New E/M ‘add-on’ G codes

The Centers for Medicare & Medicaid Services is proposing to create two new HCPCS codes that might be used by urologists:

- **GPC1X.** Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an established patient evaluation and management visit).
- **GCG0X.** Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management-centered care (Add-on code, list separately in addition to an evaluation and management visit).

GPC1X is proposed to be used only with established patient visits that include primary care services. This code is targeted to the specialties providing true primary care, such as family practice or pediatrics. CMS, however, does acknowledge that some specialties do provide primary care services to some of their patients. While urology is not specifically mentioned in the proposed rule, an argument could be made that some patients rely on urologists for their primary care while not under the care of other providers, and some urology practices have added primary care to their service mix through either urologists or advanced-practice providers employed by the practice. We will keep an eye on the final rules surrounding the use of this code.

GCG0X will be an add-on code to be charged with the appropriate standalone E/M code for visits. The code will pay about $14 in addition to the new common payment. The final rules governing when this code can be used will be very important as we look at the impact of this change.

### 50% pay cut for E/M services with –25 modifier

CMS is proposing to apply the surgical multiple payment discount rule to any E/M service provided on the same day as a procedure. Therefore, the agency has proposed cutting the payment for the lower valued code—either the E/M code or the procedure code reported—by 50%.

This is a rule change that deserves many comments by urologists explaining that an E/M service that results in performing a cystoscopy on the same day constitutes two services with minimum overlap in time and resources. CMS is required to make changes in a budget-neutral manner and has estimated that this change will save CMS 6.7 million relative value units (RVUs) per year (roughly $239 million). The RVUs/money saved by reducing the payment for encounters in which a –25 modifier is used is targeted to fund the new Evaluations and Management Specialty Add-on G code GCG0X.

### Virtual check-in code

CMS is proposing to add coverage for a virtual check-in visit patterned after current telephone codes included in CPT. This service would be
TECENTRIQ®
THE FIRST FDA-APPROVED ANTI-PDL1 CANCER IMMUNOTHERAPY

Results for first-line, cisplatin-ineligible patients1

<table>
<thead>
<tr>
<th></th>
<th>CR (%)</th>
<th>ORR (%)</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>6.7</td>
<td>23.5</td>
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</table>

(n=28/119*; 95% CI, 16.2, 32.2)

MEDIAN DoR NOT REACHED
(range: 3.7, 16.6+)

TECENTRIQ delivered durable responses (median follow-up: 14.4 months)1

- 33% ORR in patients with disease progression at least 12 months following neoadjuvant or adjuvant therapy (n=6/19*; 95% CI, 16, 55)

IMvigor210 was a pivotal Phase II, multicenter, open-label, 2-cohort trial that included a cohort of 119 patients with locally advanced or metastatic urothelial carcinoma (UC) who:

- Were not eligible for cisplatin-containing chemotherapy, or
- Had disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy.

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Important Safety Information

Serious Adverse Reactions
Please refer to the full Prescribing Information for important dose management information specific to adverse reactions.

Immune-Mediated Pneumonitis
- Immune-mediated pneumonitis or interstitial lung disease, including fatal cases, have occurred with TECENTRIQ treatment.
- Across clinical trials, 2.5% of patients developed pneumonitis, including Grade 3 (0.6%), Grade 4 (0.3%), and Grade 5 (<0.1%) events.
- Monitor patients for signs and symptoms of pneumonitis. Evaluate patients with suspected pneumonitis with radiographic imaging. Administer corticosteroids followed by a taper. Withhold TECENTRIQ for Grade 2 and permanently discontinue for Grade 3 or 4 pneumonitis.

Immune-Mediated Hepatitis
- Liver test abnormalities and immune-mediated hepatitis, including fatal cases, have occurred with TECENTRIQ treatment.
- Across clinical trials, hepatitis occurred in 9% of patients, including Grade 3 (2.3%), Grade 4 (0.6%), and Grade 5 (<0.1%) events.
- Monitor patients for signs and symptoms of hepatitis, during and after discontinuation of TECENTRIQ, including clinical chemistry monitoring. Administer corticosteroids followed by a taper for immune-mediated hepatitis. Withhold TECENTRIQ for AST or ALT elevations more than 3 and up to 8 times the upper limit of normal or total bilirubin more than 15 and up to 3 times the upper limit of normal. Permanently discontinue TECENTRIQ for AST or ALT elevations more than 8 times the upper limit of normal or total bilirubin more than 3 times the upper limit of normal.

Immune-Mediated Colitis
- Immune-mediated colitis or diarrhea have occurred with TECENTRIQ treatment.
- Across clinical trials, diarrhea or colitis occurred in 20% of patients, including Grade 3 (0.4%) events.
- Monitor patients for signs and symptoms of diarrhea or colitis. Withhold TECENTRIQ for Grade 2 or 3 and permanently discontinue for Grade 4 diarrhea or colitis.

Immune-Mediated Endocrinopathies
- TECENTRIQ can cause immune-mediated endocrinopathies, including thyroid disorders, adrenal insufficiency, and type 1 diabetes mellitus, including diabetic ketoacidosis, and hypophysitis/hypopituitarism.
- Withhold TECENTRIQ for Grade 2 to 4 endocrinopathies.

Thyroid Disorders
- Across clinical studies, hypothyroidism occurred in 4.6% of patients and hyperthyroidism occurred in 1.6% of patients.
- Monitor thyroid function prior to and during treatment with TECENTRIQ. Initiate hormone replacement therapy or medical management of hyperthyroidism as clinically indicated.

Adrenal Insufficiency
- Across clinical studies, adrenal insufficiency occurred in 0.4% of patients, including Grade 3 (<0.1%) events.
- Monitor patients for clinical signs and symptoms of adrenal insufficiency. For Grade 2 to 4 adrenal insufficiency, initiate corticosteroids and hormone replacement therapy as clinically indicated.

Type 1 Diabetes Mellitus
- Across clinical studies, type 1 diabetes mellitus occurred in <0.1% of patients.
- Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated.

Infusion-Related Reactions
- Across clinical trials, infusion-related reactions occurred in 1.3% of patients, including Grade 3 (0.2%) events.
- Monitor for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion in response involving a major organ

Other Immune-Mediated Adverse Reactions

- TECENTRIQ can cause severe and fatal immune-mediated adverse reactions. These immune-mediated reactions may involve any organ system.
- Across clinical trials, cardiac, dermatologic, gastrointestinal, general, hematologic, musculoskeletal, neurological, ophthalmologic, renal, and vascular immune-mediated adverse reactions occurred at an incidence of <0.1% in patients who received TECENTRIQ or were reported for other products in this class of therapy.
- For suspected Grade 2 immune-mediated adverse reactions, exclude other causes and initiate corticosteroids as clinically indicated. For severe (Grade 3 or 4) adverse reactions, withhold TECENTRIQ immediately and administer corticosteroids.
- Permanently discontinue TECENTRIQ for Grade 4 immune-mediated adverse reactions involving a major organ.

Immunotherapy-Related Infections
- TECENTRIQ can cause severe infections involving fatal cases.
- Across clinical trials, infections occurred in 42% of patients, including Grade 3 (8.7%), Grade 4 (4.1%), and Grade 5 (1%) events.
- Monitor patients for signs and symptoms of infection. For Grade 3 or 4 infections, withhold TECENTRIQ and resume once clinically stable.

Embryo-Fetal Toxicity
- Based on its mechanism of action, TECENTRIQ can cause fetal harm when administered to a pregnant woman. Verify pregnancy status of females of reproductive potential prior to initiating TECENTRIQ. Advise females of reproductive potential to use effective contraception during treatment with TECENTRIQ and for at least 5 months after the last dose.

TECENTRIQ® [atezolizumab]

Initial U.S. Approval: 2016

This is a brief summary of information about TECENTRIQ. Before prescribing, please see full Prescribing Information.

1 INDICATIONS AND USAGE

1.1 Locally Advanced or Metastatic Urothelial Carcinoma

TECENTRIQ (atezolizumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:

- are not eligible for cisplatin-containing chemotherapy, or
- have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy

This indication is under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit.

2 CONTRAINDICATIONS

None.

3 WARNINGS AND PRECAUTIONS

6.1 Immune-Mediated Pneumonitis

TECENTRIQ can cause immune-mediated pneumonitis or interstitial lung disease, defined as requiring use of corticosteroids, including fatale cases. Monitor patients for signs and symptoms of pneumonitis or interstitial lung disease. Administer corticosteroids, prednisone 1–2 mg/kg/day or equivalents, followed by a taper for Grade 2 or higher pneumonitis. Withhold or permanently discontinue TECENTRIQ based on the severity [see Dosage and Administration (2.2)].

In clinical studies enrolling 2616 patients with various cancers who received TECENTRIQ [see Adverse Reactions (6.1)], pneumonitis occurred in 2.5% of patients, including Grade 3 (0.6%), Grade 4 (0.1%), and Grade 5 (<0.1%) immune-mediated pneumonitis. The median time to onset of pneumonitis was 20.5 months (range: 0.4 to 205.8 months). Median duration of pneumonitis was 1.4 months (1 day to 151.5 months). Pneumonitis resolved in 67% of patients. Pneumonitis led to discontinuation of TECENTRIQ in 0.5% of the 2616 patients. Systemic corticosteroids were required in 1.5% of patients, including 0.8% who received high-dose corticosteroids (prednisone ≥40 mg per day or equivalent) for a median duration of 4 days (1 day to 45 days) followed by a corticosteroid taper.

5.6 Infections

TECENTRIQ can cause liver test abnormalities and immune-mediated hepatitis, defined as requiring use of corticosteroids. Fatal cases have been reported. Monitor patients for signs and symptoms of hepatitis, including jaundice. Inhibition of PD-L1/PD-1 pathway can lead to increased risk of infusion-related reactions. For suspected Grade 2 immune-mediated adverse reactions, exclude other causes and initiate hormone replacement therapy as clinically indicated. If indicated, interrupt TECENTRIQ based on the severity [see Adverse Reactions (6.1)].

In clinical studies enrolling 2616 patients with various cancers who received TECENTRIQ [see Adverse Reactions (6.1)], infections occurred in 42% of patients, including Grade 1 (8.7%), Grade 2 (4.5%), and Grade 5 (1%). In patients with urothelial carcinoma, the most common Grade 3 or higher infection was urinary tract infections, occurring in 6% of 2616 patients, with the most common Grade 3 or higher infection being pneumonia, occurring in 3.8% of patients.

5.7 Hypophysitis

Hypophysitis: <0.1% of patients. Insulin was required in one patient.

2.2 Infusion-Related Reactions

Infusion reactions can occur during each cycle of treatment. TECENTRIQ can cause severe or life-threatening infusion-related reactions. Monitor for signs and symptoms of infusion-related reactions. For suspected Grade 2 infusion-related reactions, interrupt, slow the rate of, or permanently discontinue TECENTRIQ based on the severity [see Adverse Reactions (6.1)]. For Grade 1 or 2 infusion-related reactions, consider using pre-medications with subsequent doses.

In clinical studies enrolling 2616 patients with various cancers who received TECENTRIQ [see Adverse Reactions (6.1)], infusion-related reactions occurred in 1% of patients, including Grade 1 in 0.7% patients and Grade 2 in 0.3% patients.

5.8 Embryo-Fetal Toxicity

Based on its mechanism of action, TECENTRIQ can cause fetal harm when administered to a pregnant woman. There are no available data on the use of TECENTRIQ in pregnant women. Animal studies have demonstrated that inhibition of the PD-L1/PD-1 pathway can lead to increased risk of immune-related adverse reactions of the developing fetus resulting in embryopathy or fetal death. Verify pregnancy status of females of reproductive potential prior to initiating TECENTRIQ. Advise females of reproductive potential to use effective contraception during treatment with TECENTRIQ and for at least 5 months following the last dose of TECENTRIQ [see Warnings and Precautions (5.3)].

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the label:

- Immune-Mediated Pneumonitis
- Immune-Mediated Hepatitis
- Immune-Mediated Colitis
- Immune-Mediated Endocrinopathies
- Hypophysitis
- Hypothyroidism
- Increased Pancreatic Hormone Secretion

7.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described in the Warnings and Precautions section reflect exposure to TECENTRIQ in 2616 patients in two randomized, active-controlled studies (POPLAR, OAK) and four open-label, single arm studies (PCD4989g, IMvigor210, BIRCH, FIR) which enrolled 524 patients with metastatic urothelial carcinoma. 1636 patients with metastatic non-small cell lung cancer (NSCLC), and 144 patients with metastatic renal cell carcinoma. TECENTRIQ was administered at a dose of 1200 mg intravenously every 3 weeks in all studies except PCD4989g. Among the 2616 patients, 36% were exposed for longer than 6 months and 20% were exposed for longer than 12 months.

The data described in this section were obtained from one open-label, single arm, multiple-cohort study [eg IMvigor210] and one randomized open-label, active-controlled study [OAK] in which TECENTRIQ was administered to 429 patients with locally advanced and metastatic urothelial carcinoma and 609 patients with metastatic NSCLC. In these trials, TECENTRIQ was administered at a dose of 1200 mg intravenously every 3 weeks.

8.1 Cisplatin-Ineligible Patients with Locally Advanced or Metastatic Urothelial Carcinoma

The safety of TECENTRIQ was evaluated in IMvigor210 (Cohort 1), a multicenter, open-label, single-arm study that included 119 patients with locally advanced or metastatic urothelial carcinoma who were ineligible for cisplatin-containing chemotherapy and were either previously untreated or had disease progression at least 12 months after neoadjuvant or adjuvant chemotherapy [see Clinical Studies (14.1)]. Patients received TECENTRIQ 1200 mg intravenously every 3 weeks until after unacceptable toxicity or disease progression. The median duration of reporting was 15 weeks (0 to 87 weeks).

The most common adverse reactions (≥20%) were fatigue (52%), decreased appetite (24%), diarrhea (24%), and nausea (22%). The most common Grade 3–4 adverse reactions (≥2%) were fatigue, urinary tract infection, anemia, diarrhea, blood creatinine increase, intestinal obstruction, ALT increase, hypomagnesemia, decreased appetite, epigastric pain, back pain, pain, renal failure, and hypothyroidism.

Five patients (4.2%) who were treated with TECENTRIQ experienced one of the following events which led to death: sepsis, cardiac arrest, myocardial infarction, respiratory failure, or respiratory distress. One additional patient (0.8%) was experiencing herpetic meningoencephalitis and disease progression at the time of death. TECENTRIQ was discontinued for adverse reactions in 4.2% of patients and severe adverse reactions in 1.7% of patients.

The adverse reactions leading to discontinuation were mainly infusion-related reactions (1.7%), fatigue (0.8%), hypereosinophilia (0.8%), and dyspnea (0.8%). Adverse reactions leading to interruption occurred in 4% of patients; the most common (1%) were intestinal obstruction, fatigue, diarrhea, urinary tract infection, infusion related reaction, cough, abdominal pain, peripheral edema, pyrexia, respiratory tract infection, upper respiratory tract infection, creatinine increase, decreased appetite, hypomagnesemia, back pain, pruritus, and venous thromboembolic events in 3% of patients.

The most frequent serious adverse reactions (≥2%) were diabetes, interstitial lung disease, acute kidney injury, and renal failure.

Table 2 summarizes the adverse reactions that occurred in ≥10% of patients and Table 3 summarizes Grade 3–4 selected laboratory abnormalities that occurred in ≥1% of patients treated with TECENTRIQ [see Adverse Reactions (6.1)].

For suspected Grade 2 immune-mediated adverse reactions, exclude other causes and initiate hormone replacement therapy as clinically indicated. For suspected Grade 3 or 4 adverse reactions, administer corticosteroids, prednisone 1 to 2 mg/kg or equivalents, followed by a taper. Interrupt or permanently discontinue TECENTRIQ, based on the severity of the reaction [see Dosage and Administration (2.2)].

If this occurs in combination with a suspected immune-mediated adverse reaction for Vogt-Koyanagi-Harada syndrome, which has been observed with other products in this class and may require treatment with systemic steroids to reduce inflammation and maintain vision loss.

The following clinically significant, immune-mediated adverse reactions occurred at an incidence of <1% in 2616 patients who received TECENTRIQ or were reported in other products in this class [see Adverse Reactions (6.1)].

- Cardiac myocardiitis
- Immune-related bulbar palsy, paresthesia, dysphagia, or myopathy
- Immune-related hemorrhagic stroke
- Ophthalmologic: uveitis, iritis.
- Acral skin syndromes, neutropenia.
- Vasculitis.
The safety of TECENTRIQ was evaluated in IMvigor210 (Cohort 2), a multicenter, open-label, single-arm trial that included 310 patients with locally advanced or metastatic urothelial carcinoma who had disease progression during or following at least one platinum-containing regimen or had demonstrated disease progression during or following at least one platinum-containing chemotherapy regimen. Patients received TECENTRIQ 1200 mg intravenously every 3 weeks weeks until unacceptable toxicity, radiographic progression, or either radiographic or clinical progression. The median duration of exposure was 12.3 weeks (0.1 to 46 weeks).

Table 4 summarizes the adverse reactions that occurred in ≥ 10% of patients. The most frequent serious adverse reactions (≥ 2%) were urinary tract infection, hematuria, acute kidney injury, intestinal obstruction, pyrexia, venous thromboembolism, urinary tract infection bacterial, cystitis, and urosepsis. The most common Grade 3−4 adverse reactions in ≥ 20% of patients treated with TECENTRIQ were fatigue (26%), pneumonia, dyspnea, pyrexia, and back pain. The most frequent serious adverse reactions occurred in 1.1% of patients. The most frequent serious adverse reactions occurred in 1.1% of patients. The most frequent serious adverse reactions (≥ 2%) were urinary tract infection, hematuria, acute kidney injury, intestinal obstruction, pyrexia, venous thromboembolism, urinary tract infection bacterial, cystitis, and urosepsis.

Table 5 summarizes selected laboratory abnormalities worsening from baseline that occurred in ≥ 20% of patients treated with TECENTRIQ. The most common laboratory abnormalities worsening from baseline were increased alkaline phosphatase (9%), increased creatinine (7%), increased AST (3%), decreased albumin (2%), and increased bilirubin (2%).
2 Each test incidence is based on the number of patients who had both baseline and at least one on-study
5 includes rash, erythematous rash, generalized rash, maculopapular rash, papular rash, pruritic rash,
4 includes musculoskeletal pain, musculoskeletal stiffness, musculoskeletal chest pain, myalgia
3 includes cough and exertional cough
1 Graded per NCI CTCAE v4.0
8.1 Pregnancy
in an assay may be influenced by several factors including assay methodology, sample handling,
The detection of antibody formation is highly dependent on the sensitivity and specificity of the
Patients who tested positive for treatment-emergent ADA also had decreased systemic atezolizumab
As with all therapeutic proteins, there is a potential for immunogenicity.
• Infertility
Based on animal studies, TECENTRIQ may impair fertility in females of reproductive potential while receiving treatment [see Nonclinical Toxicology (13.1)].
8.3 Females and Males of Reproductive Potential
Females
Based on its mechanism of action, TECENTRIQ can cause fetal harm when administered to a pregnant woman. There are no available data on the use of TECENTRIQ in pregnant women.
• Infertility
Based on the presence of atezolizumab in human milk, the effects on the breastfed infant, or the effects on milk production, the safety and efficacy of TECENTRIQ for breastfeeding women is unknown. Because of the potential for serious adverse reactions in breastfed infants from TECENTRIQ, advise women not to breastfeed during treatment and for at least 5 months after the last dose.
8.5 Geriatric Use
In Specific Populations (8.1)

Table 6: Adverse Reactions Occurring in ≥ 10% of Patients with NSCLC Receiving TECENTRIQ in OAK

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>TECENTRIQ 1200 mg every 2 weeks n=609</th>
<th>Docetaxel 75 mg/m² every three weeks n=578</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades (%)</td>
<td>Grade 3–4 (%)</td>
</tr>
<tr>
<td>Fatigue/Anorexia</td>
<td>44</td>
<td>4</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>18</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Respiratory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>26</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>22</td>
<td>2.8</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia/pain</td>
<td>20</td>
<td>1.3</td>
</tr>
<tr>
<td>Arthritis</td>
<td>12</td>
<td>0.5</td>
</tr>
<tr>
<td>Metabolism and Nutrition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>23</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>18</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Constipation</td>
<td>18</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>16</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td>12</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

1 Graded per NCI CTCAE v4.0
2 Includes fatigue and anemia
3 Includes cough and exertional cough
4 Includes musculoskeletal pain, musculoskeletal stiffness, musculoskeletal chest pain, myalgia
5 Includes rash, erythematous rash, generalized rash, maculopapular rash, papular rash, pruritic rash, pustular rash, pemphigoid

Table 7: Laboratory Abnormalities Worsening From Baseline Occurring in > 20% of NSCLC Patients Receiving TECENTRIQ in OAK

<table>
<thead>
<tr>
<th>Laboratory Abnormality</th>
<th>TECENTRIQ 1200 mg every 3 weeks</th>
<th>Docetaxel 75 mg/m² every 3 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades (%)</td>
<td>Grade 3–4 (%)</td>
</tr>
<tr>
<td>Chemistry</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyperuricemia</td>
<td>48</td>
<td>4</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>42</td>
<td>7</td>
</tr>
<tr>
<td>Increased Alkaline Phosphatase</td>
<td>39</td>
<td>2</td>
</tr>
<tr>
<td>Increased AST</td>
<td>31</td>
<td>3</td>
</tr>
<tr>
<td>Increased ALT</td>
<td>27</td>
<td>3</td>
</tr>
<tr>
<td>Hyperglycemia</td>
<td>27</td>
<td>5</td>
</tr>
<tr>
<td>Increased Creatinine</td>
<td>26</td>
<td>1</td>
</tr>
<tr>
<td>Hematological</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anemia</td>
<td>67</td>
<td>3</td>
</tr>
<tr>
<td>Lymphopenia</td>
<td>49</td>
<td>14</td>
</tr>
</tbody>
</table>

1 Graded according to NCI CTCAE version 4.0

Each test incidence is based on the number of patients who had both baseline and at least one on-study laboratory measurement available: TECENTRIQ (range: 546–585) and docetaxel (range: 532–560)

8.2 Lactation
Risk Summary
There is no information regarding the presence of atezolizumab in human milk, the effects on the breastfed infant, or the effects on milk production. The safety and efficacy of TECENTRIQ for breastfeeding women is unknown. Because of the potential for serious adverse reactions in breastfed infants from TECENTRIQ, advise women not to breastfeed during treatment and for at least 5 months after the last dose.

8.3 Females and Males of Reproductive Potential

Females
Based on its mechanism of action, TECENTRIQ can cause fetal harm when administered to a pregnant woman. There are no available data on the use of TECENTRIQ in pregnant women.

8.4 Pediatric Use

The safety and effectiveness of TECENTRIQ have not been established in pediatric patients.

8.5 Geriatric Use

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data
Animal Data
Animal reproduction studies have not been conducted with TECENTRIQ to evaluate its effect on reproduction and fetal development. A literature-based assessment of the effects of reproduction demonstrated that a central feature of the PD-L1/PD-1 pathway is to preserve pregnancy by maintaining maternal immune tolerance to a fetus. Blockage of PD-L1 signaling has been shown in murine models of pregnancy to disrupt tolerance to a fetus and to result in an increase in fetal loss; therefore, potential risks of administering TECENTRIQ during pregnancy include increased rates of abortion or stillbirth. As reported in the literature, there were no malformations related to the blockade of PD-L1/PD-1 signaling in the offspring of these animals; however, immune-mediated disorders occurred in P0-1 and P0-1 knockout mice. Fetal exposure to atezolizumab may increase the risk of developing immune-mediated disorders or altering the normal immune response.

Graded per NCI CTCAE v4.0
Includes musculoskeletal pain, musculoskeletal stiffness, musculoskeletal chest pain, myalgia
Includes rash, erythematous rash, generalized rash, maculopapular rash, papular rash, pruritic rash, pustular rash, pemphigoid
PROPOSED RULE
continued from page 28

We can see a number of applications for this code in urology. CMS is seeking comment on appropriate parameters to prevent overuse and abuse of this service.

52000 practice expense adjustment

CMS has acknowledged that essential sterilization equipment was left out of the practice expense calculation in 2017. The equipment and the associated time for the process will be added back into the practice expense value. This should provide at least a little gain in the value of code 52000 for 2019.

Wrap-up
We have only provided a high-level review of a portion of the proposed rule. We encourage you to also read Dr. Robert Dowling’s “Practice Matters” column in an upcoming edition of Urology Times for more information on the proposed rule and its impact on urology. We will continue to add information in future articles and encourage you to consider ways to support or oppose these proposals. Based on the tone of the proposed rule, it appears that CMS is listening. Last but not least, we anticipate significant resistance to the simplification from medical specialties. The demands of numerous internal medicine subspecialties for more pay for non-surgical patients is the reason we have the current complicated system. Prior to 1992, there were only three levels of outpatient visits and only medically necessary documentation was required.

The information in this column is designed to be authoritative, and every effort has been made to ensure its accuracy at the time it was written. However, readers are encouraged to check with their individual carrier or private payers for updates and to confirm that this information conforms to their specific rules.

When to police practice staff social media use
Establish ground rules with employees regarding activity outside the office

Batya Swift Yasgur, MA, LSW

Ms. Yasgur is a contributor to Urology Times sister brand Medical Economics, where this article was originally published.

Smartphones are ubiquitous. Beyond phone calls and texting, rarely does a moment go by without an urge to peek at the latest Facebook message or newest Instagram picture. While this may be fine at home, it can cause some problems in a medical practice setting if staff members use their smartphones to access social media.

Nitin S. Damle, MD, MS, MACP, board member and physician at South County Internal Medicine in Wakefield, RI, says his staff are instructed to leave their phones in their lockers and turned off during work hours.

“There is no reason anyone should be getting onto any website other than one that is related to work during working hours," he said.

Some practices allow use of staff smartphones during breaks, but within specific guidelines. For example, personal social media accounts must be clearly personal and not representative of the office, practice, or health system and no protected patient or other office-related data can appear anywhere on those personal accounts.

Dr. Damle adds that the same rules that apply to use of social media at work apply to personal phone calls as well.

“There are certainly exceptions in more acute circumstances—for example, when an employee has an ill family member—but an employee who has to be constantly accessible to an elderly parent, for example, taking multiple phone calls from the parent or caregivers during patient care hours wouldn’t bode well for work performance,” he said.

Facebook friends with patients?
A more challenging issue is personal social media relationships between staff and patients. Sometimes office staff may refer friends or relatives to the practice, which can also be tricky where social media is concerned.

In situations like these, the staff member already has a relationship with the patient, so physicians should emphasize that they should not use social media to give medical advice, information, scheduling, test results, or any other practice-related communications via their personal account.

Instead, practice-related communications should flow through normal channels, such as the secure patient portal.

Outside the office
Although it is more difficult to control staff members’ social media behavior outside the office, ground rules can still be established.

“Clearly, staff members shouldn’t talk about patients, even if they de-identify them, or about co-employees, or employers,” Dr. Damle said. Patients also should not post photographs of the work site, patients, physicians, or medical personnel.

He emphasizes that if this type of activity comes to his attention, “it is immediate grounds for dismissal.” However, if the staff member is a friend or relative of a patient, it is acceptable to post pictures that might include the patient in an out-of-office setting.

Photographs taken within the office might seem innocuous, but can also potentially compromise the privacy of other staff members. For example, perhaps one of the physicians has pictures of his family on his desk—or of patients, even after hours. These posted pictures can also give the misimpression that the photographer is speaking on behalf of the practice.

Dr. Damle concludes by stressing that patient care “is at the center of any medical practice” and anything that causes a distraction or interruption of that care, such as inappropriate use of social media, should be avoided.
CMS data breaks down industry payments to urologists

Prostate cancer, BPH, OAB represent most spending in the specialty

Dr. Dowling is the president of Dowling Medical Director Services, a private health care consulting firm specializing in quality improvement, clinical informatics, and health care policy affecting specialty care. He is the former medical director of a large, metropolitan single-specialty urology group in Ft. Worth, TX.

On June 29, 2018, the Centers for Medicare & Medicaid Services (CMS) released its 2017 Open Payments Financial Data (https://openpaymentsdata.cms.gov/). Section 6002 of the Affordable Care Act (also known as the Physician Payments Sunshine Act) requires that manufacturers of “covered drugs, devices, biologicals, and medical supplies” report payments or other transfers of value to physicians to CMS. It also requires that manufacturers and group purchasing organizations (GPOs) report to CMS ownership or investment interests that physicians (or their family members) have in their company.

Payments see increase from 2016

In 2017, $8.4 billion in payments or investment value was reported by 1,525 unique companies to physicians, teaching hospitals, and other entities; this is an increase of 2.4% over the 2016 total. The total amount of general payments to individual physician recipients was $2.82 billion, research payments totaled $4.66 billion, and other transfers of value (investments, etc.) were just over $927 million.

According to the data, 9,343 urologists received a total of $35,961,655 in general payments, or 1.27% of the total general payments (table). The largest single payment to a urologist was $3 million for royalty/license, and the average payment to a urologist in 2017 was $176.42. Fifty-four urologists received more than $100,000, representing more than 47% of all payments to urologists (figure). Most of the payments to urologists came in the form of cash, and were compensation for royalty or license, services other than consulting, consulting fees, and food and beverage.

CMS requires manufacturers to associate a payment with a drug, biologic, device, or medical supply where appropriate. General payments to urologists associated with devices comprised the largest collective payments, totaling $19,867,410, or more than half of all general payments; the majority of these payments were from six device manufacturers. Payments associated with drugs and biologics totaled almost $12 million, less than in 2016; eight drug manufacturers accounted for almost 80% of total payments in this category.

CMS reported $1,099,241 in research payments from 17 manufacturers to 64 unique urologists in 2017; this represents a tiny fraction of 2017 total research payments to physicians overall. CMS also reports on transfers of value outside of general payments and research payments. In 2017, $3.8 million in investments were transferred to urologists from nine entities, most in the form of common stock.

Bottom line: General payments from manufacturers to urologists in 2017 reported to and by CMS under the Sunshine Act represent a tiny fraction of general payments to physicians; conversely, research payments to urologists were a tiny fraction of payments to physicians. Most of these payments are from device manufacturers, and payments are concentrated in just a handful of individual companies, drugs, devices, recipients, and disease states. Prostate cancer, BPH, and overactive bladder together represent most of the collective spending in the specialty.

The vast majority of urologists appear in the data, but need not worry about the appearance of impropriety.
FROM ACCESS
TO IRRIGATION
TO DUSTING
TO EXTRACTION

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Why inexperienced investors should consider target date funds

Popular financial strategy offers ‘hands-off’ investing for retirement

JEFF WITZ, CFP
DAVID ZEMON

Mr. Witz (top) is educational program director and Mr. Zemon is a wealth manager at MEDIQUIS Asset Advisors, Inc. in Chicago. They can be reached at 800-883-8555 or witz@mediqus.com or zemon@mediqus.com.

The disadvantage of using a target date fund is that you hand off control of your retirement investing to another decision maker.

Q: I noticed there are a lot of target date funds listed in my 401(k) investment options. Can you explain how these types of funds work and whether they are worth using in my retirement account?

A: Target date funds have become quite popular, and many physicians have them as available investment options in their employer-sponsored retirement accounts such as their 401(k)s and 403(b)s. The first target date fund was introduced in 1994 in response to retirement plan participants’ relative lack of knowledge about investing and how to approach managing their retirement accounts. Fund companies wanted to provide participants with basically a ‘hands-off’ approach to investing for their retirement.

A target date fund works in a relatively simple way. They often reference the target date in retirement, so they may include ‘Target Retirement Date 2040’ or ‘Target Retirement Date 2050.’ Investors simply select the fund that correlates to the approximate year they will retire. The funds are professionally managed and start an investor off in an aggressive growth portfolio. As years go by, the fund manager incrementally reduces the risk of the fund by slowly making it more conservative.

As the investor approaches retirement age, the fund is significantly invested in a more conservative allocation designed to preserve the investment gains made during the lifetime of the fund. Depending on which fund company your retirement plan uses, once the target date is reached, the fund will either continue to invest your assets and slowly make them even more conservative, or it will transfer your assets into a separate asset preservation fund with a fixed equity-to-bond ratio.

There are advantages and disadvantages to using target date funds. These funds are particularly advantageous for someone who has little or no experience investing. It takes most of the responsibility for investing for retirement out of the individual’s hands and puts it in the hands of a professional fund manager. For individuals not comfortable choosing their investments or not knowing when it’s appropriate to change to a more conservative allocation, these funds are excellent options.

The disadvantage of using a target date fund is that you hand off control of your retirement investing to another decision maker. Whether a target date fund is appropriate for your retirement account really depends on your comfort level in managing your own retirement assets. Target date funds were created for investors with little or no knowledge of investing. It is a great option for some. More experienced investors may want to remain in greater control of their investments and utilize other options available through their retirement plans.

Q: I’ve been hearing a lot recently about tariffs. Can you explain what they are and why the markets have been reacting negatively to them?

A: A tariff is simply a tax or duty to be paid on a particular class of imports or exports. For example, President Trump recently announced a 25% tariff on roughly 1,100 Chinese imports. That significantly increases the cost of trying to sell these goods on U.S. soil. The United States has a long history of using tariffs, and the tariffs themselves are not wholly responsible for the increased stock market volatility. Mainly, the tariffs have created uncertainty. There is concern that if the U.S. implements tariffs on China or Europe that they will retaliate with tariffs on U.S. goods.

This environment could make things unpredictable, and the markets hate unpredictability. Therefore, we have seen greater swings in the market and a general retreat from previous market highs.

FINANCIAL TIPS

- Target date funds are professionally managed and start an investor off in an aggressive growth portfolio then slowly make it more conservative over time.
- For individuals not comfortable choosing their investments or knowing when it’s appropriate to change to a more conservative allocation, target date funds are excellent options.
- The uncertainty created by tariffs can lead to unpredictability, creating greater swings in the market and a retreat from previous market highs.

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*Based on a tertiary clinical literature search performed 11/2014. 89 peer-reviewed articles were accepted according to Inclusion/Exclusion criteria, of which 80% (71 articles) showed favorable outcomes in support of Hem-o-lok Clips. Data on file, Teleflex Incorporated, Report #MLIB-000588.

† Data on file (2013 internal study), Teleflex Incorporated, Report #D001591. Testing conducted on porcine carotids, sample size = 33, p≤ 0.05. Clinical performance cannot be extrapolated from the data. Testing pressures range beyond physiological pressures.

Hem-o-lok Clips are not intended for use as a fallopian contraceptive tubal occlusion device. Hem-o-lok Clips are contraindicated for use in ligating the renal artery during laparoscopic donor nephrectomy.

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How to reap the full benefits of your patient portal

These seven steps will maximize your portal and deepen patient engagement

GARY HAMILTON
Mr. Hamilton is chief executive officer of patient portal software provider InteliChart. This article originally appeared in Urology Times sister publication Medical Economics.

Alexa, find my health care records.”

Today’s tech-savvy patients expect quicker, easier access to their health records—all of them. They also want to be more involved in their own care, and when they go to the doctor or hospital, they want the same conveniences they’ve already experiencing in other industries.

In other words: It’s clear that health care consumerism is here to stay.

This can be challenging for providers who don’t offer the right tools or services to meet their patient’s needs. The implications of failing to meet these growing needs are far reaching, ranging from patients leaving the practice in search of better service to feeling the long-term financial effects of disengaged patient populations due to declining reimbursements due to value-based care models.

Many organizations are actively striving to offer more convenient services for their patients. They’re also working to quickly ensure they meet requirements under the Merit-based Incentive Payment System (MIPS) for Medicare patients. Still, a recent InteliChart survey of 800 health care professionals shows many don’t yet understand the potential impact of negative payment adjustments. As the MIPS 2017 payment difference between maximum negative and exception performance was 26%, this represents significant dollars that may be left on the table. Success is not just about avoiding penalties—it’s also about focusing on what can be gained, because reimbursements can be up to 22% higher for top performers.

A great starting point for happier health care consumers, and the heart of maximizing an organization’s reimbursement potential, begins with deeper patient engagement.

Population health management technologies are rapidly advancing to help clinicians identify which patients can benefit from intervention programs and automate the management of population health programs. These programs are creating touch points that include education, reminders, self-management, and adherence tracking to help drive better outcomes.

Increasing patient engagement can also be accomplished by taking advantage of an existing patient portal in more strategic ways. Since many patients already use their practice’s portal to access and schedule appointments or find lab results, it’s a natural place to engage them more fully and more often. Not only can the portal help make a patient’s experience easier, it can improve organizational efficiency and cost savings at the same time.

Here are seven ways practices can put their patient portal to use and reap the rewards of deeper patient engagement.

1. Access health records in one place
Perhaps most importantly, the portal can be used to share a patient’s full picture of their records, which can help them more proactively manage their health. Enabling a patient to connect to all of their clinicians and hospitals and see all of their health care data in a single portal can be accomplished using tools that collect data from multiple acute and ambulatory information sources, and standardize them into a single registry for easy viewing.

2. Monitor patient engagement activity
Obtaining outcomes requires modifying patient behavior. Enabling patients to engage in self-management and then tracking whether they are fulfilling the desired actions is a critical step to determine which interventions are most successful at an individual patient level.

3. Schedule appointments
To save time and make scheduling vastly more efficient, patients can be given the ability to schedule their own appointments online or via a mobile app. This saves time for front-office staff and allows them to be more efficient and focus on other priorities.

4. Complete electronic forms—once
Being able to fill out necessary forms online before and after visits is a big convenience for patients. Having information imported into the EHR so it only has to be completed once is even bigger, reducing friction in the patient experience while making data collection much more efficient in the process.

5. Make communication easier
Giving patients the option to choose how they receive communications, including automated emails, texts, or phone calls, can streamline communications while helping organizations comply with additional requirements. The portal can also be used to coordinate medication refill requests, pay bills, and supply visit and discharge summaries. To maximize the portal further, organizations can enable secure messaging between patients and practice staff as well.

6. Provide patient education
Providing online education materials for patients to access and review at their convenience is another key aspect of the portal. Educational tools including specific information regarding a health condition, what symptoms a patient may experience, or discussing what decisions a patient might face due to their condition help patients increase their participation in care decisions and overall management of their care.

7. Set up home device monitoring
Wireless monitoring devices that automatically transmit data and store it in the patient portal can help patients better manage their chronic conditions, while helping clinicians manage their care plans, spot trends, and improve and sustain their clinical and financial outcome goals. As a quickly growing market, today’s most popular vital signs monitoring devices include blood pressure, pulse oximeters, temperature monitoring, and blood glucose monitoring devices. Practices looking to include home monitoring data within their patient portal should check with their vendor to check the availability of interfaces and application programming interfaces that can enable integration of this information into their practice.
Improving QOL in Prostate Radiotherapy

What every urologist needs to know

Study data has shown that SpaceOAR® hydrogel significantly improves quality of life for patients with prostate cancer who have undergone radiotherapy. But what does it take to implement this procedure into routine practice, and what can urologists expect regarding reimbursement?

In this supplement, practicing urologists will share perspectives on this procedure, addressing topics that include reimbursements, learning curves, clinical implementations, and equipment needs.

read more at urologytimes.com/spaceoar
Leaving daily practice: Advice from physicians who have made the leap

A career transition can alleviate burnout and restore work-life balance

It will shorten the transition time dramatically and save doctors a lot of heartache by having someone to help guide and mentor them through the process,” said Dr. Moskowitz, executive director of the Center for Professional and Personal Renewal and emeritus clinical professor of radiology at Stanford University School of Medicine, Stanford, CA.

Pressure from colleagues as well as family, not to mention internal guilt, doubt, and fear may lead doctors to simply stay the course, even if that means an unsatisfying career. But there are other paths, some in medicine and some not, that allow physicians to transfer their hard-earned skills as they pursue their passions. Four doctors who forged ahead and made a career transition share the lessons they’ve learned.

Giving burnout the boot

After 17 years in a busy hospital-based private clinical radiology practice, Dr. Moskowitz experienced significant professional burnout. The effects were devastating and impacted his marriage, his children, and even his health. “It forced me to confront the fact that my work life was killing me and my family,” he said. Dr. Moskowitz, then a managing practice partner, took time away to gain perspective. As he focused on getting healthy and adopting a better work-life balance, he began to see more clearly just how much he disliked his job.

Dr. Moskowitz knew his long-term happiness rested on making a career change but didn’t know what he might do as an alternative, a situation that created a lot of anxiety for him. Having never heard of career coaches or similar support systems, Dr. Moskowitz struggled along on his own. Through his reading on career options and managing career transitions—along with recovering from burnout and dealing with competing pressures of stress, family dynamics, and job satisfaction—Dr. Moskowitz discovered he was drawn to those issues far more than radiology.

He volunteered at his son’s boarding school, where he acted as a facilitator for parent-student discussion groups. Dr. Moskowitz enjoyed sharing his experiences with other struggling parents. It was an illuminating moment. He realized his skills and background perfectly aligned with his growing desire to provide coaching support for other doctors coping with the same stress, burnout, and career and family difficulties he faced. Dr. Moskowitz completed a coaching certification training program in 1998 and opened a physician coaching practice the same year. Today, he is retired from clinical radiology and estimates he spends about half his time doing one-on-one coaching.

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Determining how—and when—physicians should explore a career shift can be difficult.

It’s not easy, says Michelle Mudge-Riley, DO, MHA, RDN, founder and CEO of Physicians Helping Physicians and Docibiz in San Antonio. “The fact is, it’s messy. That’s just the reality,” Dr. Mudge-Riley said of her own career shift and the transition process other doctors encounter as they move away from clinical practice. But in the rush to find something other than clinical work, physicians sometimes overlook figuring out what they want and need. Dr. Mudge-Riley acknowledges it can be a long and arduous process, but unless doctors have a clear idea of their larger goals, that longed-for job satisfaction may continue to elude them.

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career and life coaching for physicians throughout the United States and Europe. He claims he spends the rest of his time playing, but his professional productivity is as high as ever. Dr. Moskowitz’s second book on physician career management was published in 2017, and he continues to participate in keynote lectures and workshops. It’s evident Dr. Moskowitz loves lecturing, teaching workshops, writing, and coaching.

New plan, new career satisfaction

For Dr. Mudge-Riley, a longstanding unhappiness ultimately led her to shift her career path away from practicing clinical medicine. She had already come to grips with the fact that she didn’t enjoy direct patient care, a realization that drove an initial move into pathology. There, she found the culture to be so negative and the environment so toxic that she knew she couldn’t stay. “I wasn’t willing to spend the next 40 years being one of the angry and burned-out doctors I saw all around me,” she said.

Feeling stifled and dreading the future, Dr. Mudge-Riley took a year off from clinical practice and worked for a medical device firm. One year turned into several years, during which she got a business degree while continuing to explore her options.

“I felt alone, like I was a huge failure,” she recalled. “It was pretty awful.” Despite the support from friends and family, Dr. Mudge-Riley felt very alone in her pursuit to find a career outside clinical practice. She was surprised when her speaking and outreach efforts started prompting other doctors to approach her with tales of their own job dissatisfaction. Learning that others in the clinical profession harbored similar longings for something that didn’t involve practicing medicine, Dr. Mudge-Riley began sharing her story more widely. As she helped other physicians forge new careers, her own coaching business grew organically.

Her planned return to clinical practice never happened. Instead, Dr. Mudge-Riley estimates she focuses 80% of her time coaching and mentoring other physicians in some capacity. She conducts workshops, spends one-on-one time supporting doctors who are in need of their own career adjustment, and travels to different organizations to help address work force issues from the inside. Never wanting to find herself in a situation where she’s unsure what she’ll do next, Dr. Mudge-Riley maintains other areas of interest, too. She consults on wellness for Fortune 500 companies and teaches a course for undergrads at a university.

Doing it all

Sometimes things happen in life that make clinical practice a less attractive, even impractical, full-time career. Dr. Pewitt Kinder was just out of residency when she and her husband had their first child. Ella was born with an extra chromosome (Down syndrome), so Dr. Pewitt Kinder wanted to ensure she could devote time to maximizing Ella’s developmental potential. Knowing there would be a lot involved in raising her, Dr. Pewitt Kinder’s first goal was adding flexibility to her career schedule. She was frustrated by the lack of information available at the time about childhood issues she expected she’d face, such as teaching Ella to crawl, walk, and potty train. As she navigated those waters, Dr. Pewitt Kinder sought to tweak her career further so she could speak with and consult other parents who had many of the same questions she did.

A few years later, Dr. Pewitt Kinder had twins. One was born with multiple medical problems, making a career of clinical medicine even more difficult. But Dr. Pewitt Kinder still wanted a career, still wanted to be a mom, still wanted to do it all. Quitting work to be a stay-at-home mom wasn’t going to cut it, but neither could she continue clinical practice full time and still give her family the attention they needed. She asked herself what she needed to do to make it happen.

Dr. Pewitt Kinder, like many physicians who have transitioned away from daily clinical practice, now enjoys a portfolio career—where multiple part-time jobs replace the traditional single revenue stream—that combines several different occupations in order to meet her many goals.

“I discovered there wasn’t one job that checked all the boxes for me,” she explained. The process took more than a decade of trying different things, adding a job here and cutting back on clinical practice there before eventually finding a way to fit everything into the puzzle.

Today, Dr. Pewitt Kinder has two consulting businesses: one working with new parents who have children with Down syndrome and the other helping doctors navigate the career transition process. She also works for a hospice company and a major health plan. All of her jobs are done from her home in Tennessee, but Dr. Pewitt Kinder’s arrangement still offers occasional travel. She also has opportunities to speak at conferences and workshops. Altogether, she says she makes good money. It isn’t the traditional path most doctors envision at the outset of their careers, but Dr. Pewitt Kinder says it’s a path that has worked for her.

A transition toward what matters most

Dr. Fork enjoyed her dermatology residency and immediately purchased a private practice in Austin, TX, but she was questioning her career path after 4 or 5 years. She found gratification talking with her patients during longer procedures, but shorter visits left her with little opportunity to get to know people. She made some changes to enjoy her work more. Nine years later, things had improved, but Dr. Fork still felt there was something else she was meant to do. She just didn’t know what that was.

Seeking space to find out what came next, Dr. Fork took what sound like drastic steps. “I left medicine, sold my house and everything in it, and I lived in an 800-square-foot cabin out near Willie Nelson in the Texas hill country,” she says. It isn’t something everyone can do, but it worked wonders for Dr. Fork. She had the time and space to do some volunteer work and ruminante on things she enjoyed without the pressure to make any of them a bona fide career path.

When she was ready to think about what was next, it took Dr. Fork only 2 weeks to settle on a course. Dr. Fork says it was obvious to her that she should coach and help others figure out their career paths. She launched her physician career coaching firm nearly 9 years ago.

Dr. Fork continues to support other doctors as they find their own answers about what they want from their jobs and develop a strategy to get them where they ultimately want to be. And in helping others, Dr. Fork found a way to help herself lead the life she always wanted—just not in the way she initially imagined.

IMPROVE BILLING: START WITH PATIENT EXPERIENCE

Billing is not something most physicians learn about in medical school, according to Matt Buder Shapiro, co-founder and chief marketing officer of MedPilot, a company that offers a digital tool to help patients understand and resolve medical expenses.

“But billing is what keeps the lights on for all these practices, so you need to develop a strategy to provide a better experience for your patients,” he said.

Shapiro recommends that an improved experience should begin the moment patients come to the front desk. It helps to pair requests for payment information with “helpful resources.” These resources can take the form of “clarity on costs from the insurance side, clarity on procedure information, cost estimation,” and so on.

To read the rest of this article, which was originally published by Urology Times sister brand Medical Economics, go to bit.ly/improvebilling.
of employed urologists is going up, and that’s according to AUA Census data. Fifty-one percent of urologists were employed in 2015; now it’s 56%. But there’s an age differential. According to the AUA Census, among urologists under age 45, 72% are employed.

In fact, urologists can be employed by hospitals, health systems, academic institutions, independent practices, and the government. “You even need an employment contract if you’re self-employed,” Dr. Stringer said.

Every entity has its own interests in mind when employing physicians. Sometimes, the interest is largely profit-driven. For example, private equity firms are a relatively new physician employer. Private equity firms have been buying physician group practices, including, in 2016, the purchase of Chesapeake Urology by Audax Private Equity.

“The goal of the private equity purchase is to scale up the business, build a portfolio, and sell it again in an average of 3 to 5 years,” Dr. Stringer said.

Urologists need to represent themselves to ensure employers meet their employment goals and interests. It’s critical especially for female physicians to negotiate well for themselves, according to Michele G. Cyr, MD, MACP, senior associate dean for academic affairs in biology and medicine and professor of medicine and medical science at Brown University, Providence, RI.

In 2017, the national gender gap for physicians increased compared to 2016 as female doctors earned 27.7% less ($105,000) than male doctors, according to Doximity’s second annual Physician Compensation Report, released March 14, 2018. There’s no medical specialty in which female doctors earn more than male doctors, and women earn less than men in all of the top 50 metro areas, according to Doximity.

Negotiation fundamentals
Contract negotiations aren’t about standing up, beating your chest, and making threats. They’re about, not just your job,” Bonds said.

“Beware of any restrictive covenants. They have to be reasonable as to scope and time.”

Christopher L. Nuland, JD

“Under both the Stark law and the Anti-Kickback Statute, it is absolutely imperative that urologists be either shareholders or employees of the practice,” said health care attorney Christopher L. Nuland, JD. “Many physicians have an independent streak and want to be independent contractors, but being an independent contractor limits the ways in which you can be reimbursed and limits some of the things that you can actually do in a urology office.”

“In any contract, the physician needs to understand who the parties are. It may sound simple. But are you contracting on your own behalf or on behalf of the entire practice?” Nuland said. “This is especially true in managed care contracts. When it comes to managed care contracts, can somebody cover for you? Are you contracting with the managed care company’s PPO? Or are you contracting with their HMO, EPO [exclusive provider organization], and every one of their products?”

“In any contract, be very careful to look at the amendment section. You never want to sign a contract that gives the other party the ability to amend the contract unilaterally,” Nuland said. “Again, this is very important in managed care contracts, but it’s also very important in employment contracts.”

“Beware of any restrictive covenants. They have to be reasonable as to scope and time,” Nuland said. “The general rule is 2 years and 20 miles will always be upheld. But if you’re working in a hospital, you should endeavor to negotiate a contract that restricts your ability to work for another hospital, not one that would restrict you from entering private practice.”

Urologists should beware of physician recruitment agreements with hospitals, which offer income guarantees, according to urologist Thomas Stringer, MD, associate professor and associate chairman of urology at University of Florida, Gainesville. “I tell urologists to be really careful of that because that is essentially a loan, based on performance and completion of the contract,” Dr. Stringer said.

“If you don’t complete the contract, you may owe your entire salary back to the hospital. When it says income guarantee, it’s a little different than a salary guarantee. It’s a loan.”

Physician consultant Roger G. Bonds, MBA, FMSD, CMSR, has seen his share of what he calls abusive contracts, where someone who is anti-physician and anti-employee crafts the employment contract. Abusive contracts might exert too much control over what the physician does, can’t do, and is reimbursed for. Oftentimes, physicians encounter those contracts in desirable metropolitan areas, where supply outpaces demand.

The goal should be to achieve at least what’s normal as far as compensation, responsibilities, reimbursement, and more, according to Bonds. For contracts that start too far off the mark, urologists should consider walking away. “This is your life we’re talking about, not just your job,” Bonds said.

“I always also advise physicians going into negotiations to utilize colleagues, both inside and outside the organizations.”

Michele G. Cyr, MD, MACP

Danger zones: Easily missed aspects of contracts

Urologists can easily miss or disregard these important aspects of contracts, which could come back to haunt them.

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priorities?” Bonds said. “Realize that typically you are not in the strong position to negotiate everything that you want. For the most part, you’re going to be subservient to the organization that is writing the checks. Therefore, you have to make sure that the defenses don’t come up. You need to work with the employer, so that you’re asking good questions instead of demanding.”

Do your homework
The key to effective negotiation is preparation, according to Brown University’s Dr. Cyr. Urologists negotiating employment contracts, for example, need to get as much information as possible about benchmarks for compensation and productivity.

“The good news is, there is a wealth of information on the Internet,” she said.

Among the reliable resources: the Medical Group Management Association (www.mgma.com) and Association of American Medical Colleges (www.aamc.org).

Urologists should also tap professional organizations, like the AUA.

“I always also advise physicians going into negotiations to utilize colleagues, both inside and outside the organizations,” Dr. Cyr said. “Find out what their contracts look like, the terms of their employment, what things they felt were important to negotiate.”

A urologist’s compensation depends on many factors, according to Bonds. These include location, practice type, and more. It also depends on variables that go beyond base pay, including benefits—even continuing education reimbursement or relocation assistance.

“There are many factors that can be very positive for the individual physician but also very positive for the practice. That’s where you’re looking for the proverbial win-win,” Bonds said. (Also see, “Danger zones: Easily missed aspects of contracts,” page 42.)

Need a lawyer?
Urologists should consider having legal representation, according to Dr. Stringer.

“No one is more motivated than you are to make the employment contract fit. But we often don’t have the expertise,” Dr. Stringer said. Christopher L. Nuland, JD, a Jacksonville, FL-based health care attorney, suggests urologists have experienced lawyers review their contracts, but not necessarily hire those lawyers to do the actual negotiations.

“Lawyers, as a breed, tend to be contentious, adversarial, and expensive,” Nuland said.

Lawyers can review the contracts and provide urologists with a written review of what they think should be changed. The urologist can then go into the negotiations, mentioning that they had their attorney review the contract and the attorney had some good points. The strategy, according to Nuland, is to let the employer know that the urologist would rather work things out without further involvement from an attorney.

“The urologist gets brownie points for not involving an attorney but also told the powers-to-be that he or she has an attorney if it comes to that,” Nuland said.
Olaparib/abiraterone combination improves rPFS in mCRPC patients

AstraZeneca and Merck and Co., Inc., recently presented data that showed clinical improvement in median radiologic progression-free survival (rPFS) with olaparib (Lynparza) in combination with abiraterone (ZYTIGA) compared to abiraterone monotherapy in metastatic castration-resistant prostate cancer (mCRPC). Olaparib is being jointly developed and commercialized by AstraZeneca and Merck. The results of Study 08, a randomized, double-blinded, multicenter phase II trial, comparing olaparib in combination with abiraterone (n=71) to abiraterone monotherapy (n=71) in patients with previously treated mCRPC, regardless of homologous recombination repair mutation status, were presented at the American Society of Clinical Oncology annual meeting in Chicago and published in *Lancet Oncology* (2018; 19:975-86). The primary endpoint was rPFS. Secondary endpoints included time to second progression or death, overall survival, and health-related quality of life. Median rPFS was 13.8 months with olaparib and abiraterone compared to 8.2 months with abiraterone alone (HR: 0.65; 95% CI: 0.44-0.97; p=0.034). Median time to second progression or death was 23.3 months versus 18.5 months (HR: 0.79; 95% CI: 0.51-1.21). Median overall survival was 22.7 months with combination treatment versus 20.9 months with abiraterone alone (HR: 0.91; 95% CI: 0.60-1.38).

Durable responses seen with metastatic urothelial cancer agent

Recently presented phase II data indicate that treatment with Janssen Pharmaceutical’s erdafitinib, a once-daily oral pan-fibroblast growth factor receptor (FGFR) inhibitor, resulted in durable responses in patients with metastatic or surgically unresectable urothelial cancer and FGFR alterations, a population with high unmet need based on poor outcomes when treated with available therapies. BLC2001 (NCT02365597) is a multicenter, open-label study evaluating the efficacy and safety of erdafitinib in the treatment of adult patients with locally advanced or metastatic urothelial cancer, whose tumors have certain FGFR alterations. Ninety-nine patients were treated with an optimized dosing schedule using pharmacodynamically guided dose up-titration: a starting dose of erdafitinib at 8 mg daily, with the possibility to increase the dose to 9 mg daily based on serum phosphate levels. There was a 40% confirmed overall response rate (RECIST 1.1; 3% complete response, 37% partial response), a median progression-free survival of 5.5 months, and median overall survival of 13.8 months, according to Janssen. The data were presented at the American Society of Clinical Oncology annual meeting in Chicago.

Genomic assay data presented for bladder, kidney cancers

New data generated from Foundation Medicine, Inc.’s comprehensive genomic profiling (CGP) assays were presented at the American Society of Clinical Oncology annual meeting in Chicago. One study outlined new data from PURE-01, a phase II study evaluating neoadjuvant pembrolizumab (Keytruda) in urothelial bladder cancer. The findings demonstrate the ability of CGP to detect genomic biomarkers (RB1, PBRM1, and tumor mutational burden) when combined with T-cell inflammation signatures to potentially predict response to immunotherapy, according to Foundation Medicine. In another study, CGP was performed on more than 140,000 solid tumors and hematologic malignancies and found that PBRM1 alterations were highly enriched in clear cell renal cell carcinoma (45%) compared with other tumor types (2.6%).

Randomized study initiated for oxalate-reducing enzyme

Captozyme, Inc. is initiating a prospective, double-blind, randomized, placebo-controlled, crossover study with Nephure, an oxalate-reducing enzyme, to determine the extent to which Nephure versus placebo reduces urinary oxalate excretion (mg/24 hour) in healthy subjects who are provided a controlled diet. The key ingredient in Nephure was developed as a food ingredient to reduce both soluble and insoluble oxalate from a variety of foods and beverages. Nephure has the ability to degrade oxalate in food over a wide pH range, including the acidic pH of the stomach, according to Captozyme. About 80% of patients who develop kidney stones form calcium stones, mostly from calcium oxalate.

Phase II data: Clear cell RCC treatment combo well tolerated

X4 Pharmaceuticals announced positive clinical results from the phase II expansion of an ongoing phase I/II study of X4P-001-IO in combination with axitinib (Inlyta) in patients with clear cell renal cell carcinoma (ccRCC). The results were the first from the phase II portion of the study and demonstrated that the combination was well tolerated with a manageable safety profile and had encouraging response in heavily pretreated patients. In patients with ccRCC, the combination treatment of X4P-001-IO, a CXCR4 antagonist, and axitinib, a VEGFR kinase inhibitor, showed an objective response rate of 23%, including one patient with a confirmed complete response, X4 Pharmaceuticals reported. Nearly 75% of patients received at least two prior lines of therapy prior to entering the study. The data were presented at the American Society of Clinical Oncology annual meeting in Chicago.

Agreement will help launch prostate cancer biomarker test

MDxHealth SA has announced a worldwide licensing agreement with Koninklijke Philips NV. For the rights to manufacture and market Philips’ recently validated prognostic biomarker for prostate cancer, phosphodiesterase-4D7 (PDE4D7), as a prognostic test. The agreement enables MDxHealth to prepare the launch of its InformMDx test for prostate cancer, a tissue-based test utilizing PDE4D7 that can stratify patients according to their risk of disease progression and the development of secondary tumors. MDxHealth said it anticipates that InformMDx will provide actionable information to help clinicians guide post-biopsy treatment decisions at the time of diagnosis, as well as post-surgical treatment decisions following prostatectomy.

Phase IV trial of testosterone nasal gel recruiting participants

A phase IV trial (NCT03201681) that will evaluate the impact of testosterone nasal gel (Natesto) use on sperm count is currently recruiting at the University of Miami department of urology. Researchers aim to enroll 40 men with confirmed hypogonadism (T <350 ng/dL on two samples). Each participant will take 11 grams of testosterone nasal gel three times per day for 24 weeks. FSH, LH, estradiol, testosterone, and semen analysis will be assessed after 12 and 24 weeks of treatment. The subjects will also be given Sexual Health Inventory for Men and quality of life questionnaires, which will be repeated after 25 weeks of treatment.

Positive 6-month data reported for SUI technology platform

Viveve reported positive and sustained 6-month data from an ongoing single-arm feasibility study using its cryogen-cooled, monopolar radiofrequency (CMRF) technology platform for the treatment of mild-to-moderate stress urinary incontinence (SUI) in women. This single-arm feasibility study included 36 subjects with mild to moderate SUI (based on the 1-hour pad weight test) who underwent treatment with Viveve’s CMRF technology under a proprietary treatment protocol. Currently, 29 subjects have successfully completed the 6-month follow-up. One-hour pad weight changed from 6.2 grams at baseline to 1.7 grams at 6 months, while daily incontinence episode frequency went from 2.0 at baseline to 1.0 at 6 months.
**New Products & Services**

**Laser line offers dusting, fragmentation, ablation capabilities**

Olympus has launched its EMPOWER laser portfolio line, which offers a range of capabilities in Ho:YAG lithotripsy, including dusting, fragmentation, and soft tissue ablation. The EMPOWER system offers physicians and hospitals several choices in mode, power, and frequency. Its Stabilization mode reduces retropulsion effect, meaning that it produces a vapor tunnel bubble path to the stone to stabilize the stone and limit retropulsion. Olympus says the high-power platform offers greater efficiency and higher hertz than competitive systems with similar power offerings and also features customizable user settings.

For more information, visit [www.medical.olympusamerica.com](http://www.medical.olympusamerica.com).

**Intermittent catheter line expands with affordable additions**

CompactCath has expanded its intermittent urinary catheter product line with the addition of CompactCath Coudé and OneCath. Available in both a straight and coudé tip in pediatric and adult sizes, OneCath is a high-quality catheter at an affordable price point, CompactCath says. CompactCath Coudé (shown) combines the compact design of CompactCath, providing a smaller, easy-to-use, and discreet catheterization experience. The company says it is the only pocket-sized 16-inch long catheter with a coudé tip that fits in the palm of the hand and features a 100% non-touch system, fire-polished eyelets, silicone oil lubrication, and drainage control.

For more information, visit [www.compactcath.com](http://www.compactcath.com).

**Mobile app helps men navigate fertility challenges**

Ferring Pharmaceuticals has teamed up with fertility experts to launch FertiSTRONG, a fertility mobile application designed specifically for men. The app is designed to better help men navigate fertility challenges and address the current lack of available resources. FertiSTRONG provides more than 500 custom coping options for over 50 specific situations that have the potential to cause distress for men throughout the family-building journey and serves as a helpful resource for the exact moment that a man may feel stressed, whenever and wherever they are, by providing them with techniques and strategies for common scenarios they may face, according to Ferring.

For more information, visit [www.fertistrong.com](http://www.fertistrong.com).

**Test guides treatment for cystitis, complicated UTI, prostatitis**

GenomeDx Biosciences and Pathnostics have launched the next generation Guidance diagnostic testing for patients suffering from simple cystitis; recurrent, persistent, or complicated urinary tract infections; prostatitis; and interstitial cystitis. The Guidance test is performed by Pathnostics and distributed by GenomeDx to urologists. The molecular test helps personalize treatment options through swift identification of 42 pathogens followed by antibiotic sensitivity for the collection of identified pathogens, and this next generation of Guidance adds the evaluation of the presence of antibiotic-resistant genes, according to the companies. This dual, patent-pending approach to antibiotic sensitivity is believed to provide more reliable information than traditional urine culture regarding the evaluation of treatment options for patients with polymicrobial infections and/or infections with slow-growing pathogens.

For more information, visit [www.genomedx.com/guidance](http://www.genomedx.com/guidance) or [www.pathnostics.com](http://www.pathnostics.com).

**Ultrasound maker, GPO partner on prostate biopsy solution**

Exact Imaging, a leader in high resolution micro-ultrasound systems enabling real-time imaging and prostate biopsy guidance, has become a UroGPO Imaging Partner. UroGPO is a urology-specific group purchasing and service organization. As an Imaging Partner, Exact Imaging’s ExactVu micro-ultrasound platform for targeted prostate biopsies will be available to UroGPO’s 550-plus member urology practices as part of the UroGPO suite of offerings to U.S. urology practices. As part of the partnership, Exact Imaging will provide UroGPO members with preferential pricing for the ExactVu platform, as well as a collection of value-added services including enhanced instructor-led training, extended support, and a patient-focused marketing toolkit.

For more information, visit [www.exactimaging.com](http://www.exactimaging.com).

**Radiofrequency treatment improves local vaginal circulation**

TempSure Vitalia from Hologic’s Cynosure division is a new FDA-cleared advanced radiofrequency treatment that delivers therapeutic heat to internal and external vaginal tissue to improve local circulation. The treatment, administered using a probe specifically designed for women’s genitalia, delivers precise heating for smaller, hard-to-reach areas such as vaginal and labial tissue, without hormones or the need for invasive procedures. Treatments can last between 15 and 30 minutes, and there’s no downtime once the procedure is complete. TempSure Vitalia features Therapeutic Logic Control, a time and temperature monitoring system that ensures treatment timing will begin only when the target tissue is at therapeutic temperature. The device also has a unique dose counter that monitors and delivers the recommended dose of radiofrequency energy to the target area.

For more information, visit [www.hologic.com](http://www.hologic.com).

**‘Smart’ lithotripter uses real-world shock wave lithotripsy data**

Dornier MedTech has introduced Dornier Delta III SmartLitho, which the company says is the first lithotripter system that uses big data in urology. Delta@ III SmartLitho™ can utilize Dornier’s proprietary analytic algorithm, which is able to provide real-world data from extracorporeal shockwave lithotripsy (ESWL) treatments of urologic stones by validating against a broad set of data points collected globally. The novel algorithm enables urologists to make personalized, evidence-based decisions by assessing historical success rates of treatment modalities as well as identify and balance costs.

For more information, visit [www.dornier.com](http://www.dornier.com).

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For more information, visit [www.exactimaging.com](http://www.exactimaging.com).
What do you like/dislike about practicing in your state?

Honestly, what I like best about practicing in North Carolina is living in North Carolina. It’s an excellent way to live, particularly in Charlotte. We have a wonderful city and access to a lot of activities. I’m mainly here for family. I prefer to be close to my family, which is in this area.

As far as actually practicing medicine, it is excellent here.

We do have issues in my specialty, but that’s true most everywhere you would choose to practice. I’m in pediatrics and Medicaid is a big part of our payer base. I practiced for a long time in Tennessee, and dealing with the managed care of Medicaid is probably our biggest constraint.

What I like least is Medicaid. There’s always pressure on our practice to provide circumcisions because North Carolina Medicaid doesn’t cover that. That’s not what I became a pediatric urologist to do. It’s not covered by Medicaid, and it becomes a real frustrating point.

I practiced as a hospital-employee physician with residency programs in Memphis at the University of Tennessee, and now in Charlotte at Atrium Health. My bias is toward the hospital-employed model in a teaching practice. In that context, it’s really been the same between Memphis and here.”

Mark Williams, MD / Charlotte, NC

Florida, specifically South Florida, is a very tough place to practice. There’s a fairly prominent infiltration of Medicare HMOs with a lot of obstruction to doing anything for the patient that’s necessary. It’s very obstructive in the sense that everything needs a referral or precertification, and patients get upset very easily because basically we’re not able to do anything on our own. It’s like trying to practice medicine with our hands tied behind our back.

I’m here because of my family. That’s the only reason.

It’s a beautiful place to live, don’t get me wrong. But problems came about because of the infiltration of Medicare HMOs. Our population is a little bit older where I practice. Many patients sell their Medicare to HMOs and think they’re getting a great deal. But then HMOs take over and limit what you can do, how you can do it, and when you can do it. It’s just a shame.

Unfortunately, you have to jump through hoops. Significantly fewer people have just Medicare, because they cannot afford it because they’re liable for 20%.

My wife, kids, my parents, and other family were already established here. Other than family, I do enjoy the patients in Florida. They’re super sweet, super nice, and for the most part the majority appreciates what you do. Also, the hospital systems, for the most part, are excellent. It’s just frustrating dealing with the insurance companies.”

Boris Klopukh, MD / Miami/North Miami Beach, FL

The culture and leadership of our department are great and very supportive. There’s an opportunity for me to do reconstructive urology here in a beautiful area that has a lot to do outside of work. Oregon is a really beautiful place—the year-round climate is pretty moderate. You have mountains, the ocean, rivers. There’s skiing nearby, lots of hiking. The food is great. Portland is kind of a small city but has a lot of things you like in a city—museums, performing arts, and fabulous restaurants—without big-city hassles. There’s a big creative culture, as opposed to a corporate vibe you get with Microsoft and Amazon in Seattle. It’s a quirky place for sure. One of the things that attracted me to Oregon in the first place was the liberal and progressive political climate.

Medically, I basically do 100% transgender surgery, and it’s supported by medical insurance of Oregon. There are a growing number of states where insurance coverage for transgender surgery is mandated, but Oregon was one of the first. We now have one of the largest academic programs for transgender genital surgery in the country, and the supportive environment for the transgender community and for medical resources make that possible. That’s a big deal for my practice. It’s not why I came here, but my surgery grew into that.

The biggest drawback to practicing in Oregon is that Portland is the medical center, but the state has a lot of rural areas and people have to come from a long way away. That makes follow-up difficult to do with people who have to travel long distances.”

Daniel Dugi, III, MD / Portland, OR

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Antitrust case may impact referrals
AMA warns of interference with medical judgments

The U.S. Supreme Court has issued a ruling in an antitrust case that has the potential to affect patient care and the extent to which physicians can refer patients to out-of-network specialists.

The case, decided June 25 in a 5-4 decision, actually dealt with whether American Express could impose anti-steering provisions in its contracts with retailers. The court ruled that the plaintiffs, which included Ohio and 10 other states, had “not carried out their burden to show anticompetitive effects” of American Express’ prohibitions against merchants encouraging customers to use other credit cards with lower transaction fees.

While the case involves the credit card industry, the American Medical Association (AMA) believes it can have a direct impact on physicians and their patients.

A threat to physician autonomy
Thus, the AMA filed an amicus brief with the Ohio State Medical Association warning that supporting American Express’ position would mean dominant health insurers or dominant hospital systems could create contracts that include anti-referral rules prohibiting physicians from referring patients to out-of-network specialists for innovative or medically necessary tests that would provide the patient with the best care.

“Material interference with physicians’ medical judgments threatens physician autonomy, damages the doctor-patient relationship, decreases medical innovation, and lowers the overall quality of patient care,” the AMA’s brief states. “The antitrust laws have historically played an instrumental role in preventing such outcomes. This court should ensure that antitrust law’s vital role in health care continues.”

The AMA said that “dominant health insurance networks (or their agent benefit managers) have imposed and could further impose rules or effectively erect barriers that prohibit physicians from referring patients to certain specialists, particularly out-of-network specialists.”

That could happen, the AMA said, despite the fact that such restraints interfere with physician judgment and harm patient care.

The high court upheld a decision by the 2nd U.S. Circuit Court of Appeals, under which the AMA said it would be extremely difficult for a patient or physician to prove to a court that antitrust laws were being violated.

“I have a big problem with dominant systems that are out there trying to devour physicians’ independence. It has negative implications for the consumer.”

NEAL D. SHORE, MD
LUGPA PRESIDENT

Dr. Shore said patients should be able to select the physician of their choice and that physicians should have the ability to refer patients to other physicians with special skills and expertise who can best serve patients’ needs.

“Urologists want to do what’s in the best interest of our patients, not what’s in the best interest of payers or hospital systems,” said Dr. Shore. “Any payer will want to corral patients and limit choice, but that sacrifices what is in the best interest of the patient. If I am a patient and I believe I should be sent to a provider who is not in my plan, I should be able to do so.”

Dr. Shore said the high court’s ruling is contrary and limiting “to the important concept of choice” in the physician-patient relationship.

The Supreme Court’s decision did not directly address the concerns expressed in the AMA’s amicus brief. It noted that the case was brought against American Express claiming that its anti-steering provisions violate the Sherman Antitrust Act and that the appeals court found that those provisions did not violate the antitrust law. It upheld that ruling.

The high court said the plaintiffs failed to prove that Amex’s anti-steering provisions increased the cost of credit card transactions above a competitive level, reduced the number of transactions, or otherwise stifled competition.

Alliance comments on drug price initiatives
Meanwhile, the AUA, as part of the Alliance of Specialty Medicine, has sent detailed comments to the Department of Health and Human Services regarding efforts to reduce drug prices and out-of-pocket costs for consumers. Their comments, which can be read in full at bit.ly/Alliancecomments, covered the following topics:

MOVING DRUGS FROM PART B TO PART D. The Alliance opposes moving products from Part B into Part D in its current form.

PART B COMPETITIVE ACQUISITION PROGRAM (CAP). Should the Centers for Medicare & Medicaid Services (CMS) move forward with CAP, the Alliance urges the agency to allow physicians to remain in the current direct buy-and-bill system should they choose to do so, ensure a minimum of three vendor choices per physician, allow physicians to easily switch among vendors or move back to direct buy-and-bill, should they be dissatisfied with vendor performance, and prohibit CAP vendors and carriers from engaging in any utilization management or medical review work.

SITE NEUTRALITY. Any change in payment policy must carefully consider patient access. As such, this may be a good topic to fine-tune through a demonstration project.

COPAY DISCOUNT CARDS. Any policy limiting use of copay discount cards must have an exception for products without a generic or biosimilar alternative.

PHARMACY BENEFIT MANAGERS (PBMS) AND LIST PRICES. The Alliance supports a prohibition on rebates but oppose leveraging the protected classes to bring down list prices. Additionally, it supports creating a fiduciary duty for PBMs to hold them accountable to patients.

BIOSIMILARS. The Alliance says it is eager to assist the FDA in further education efforts for prescribers on biosimilars, their interchangeability, and the role states should play in pharmacy substitution practices and clinician education.  

Urology Times
August 2018
Wrong antibiotic leads to $250K lawsuit

Infection results in testicle removal, prostate damage

The defendants contended that the patient had a venous bleed caused by the administration of heparin and that the patient died as a result of a recognized risk of the procedure. All defendants maintained that they met the appropriate standard of care, and that the patient’s symptoms were appropriately and timely diagnosed and treated.

After 3 hours of deliberation, an Ohio jury returned a defense verdict.

LEGAL PERSPECTIVE: In an Ohio medical malpractice claim, the plaintiff must prove by a preponderance of the evidence the existence of a standard of care within the medical community, a breach of that standard of care by the defendants, and proximate cause between the medical negligence and the injury sustained. The Ohio Supreme Court has determined that proof of the recognized standards of care, and breach of the standard of care, must be established by expert testimony to a reasonable degree of medical probability. In defense, a defendant physician can offer expert testimony supporting his care and treatment. Thus, a medical malpractice trial often produces a battle of the experts.

Consider the above cases, which were each presented to an Ohio jury. While both involved treatment for kidney stones, one resulted in loss of a testicle and the other resulted in a bleed out and death. The reader may find it surprising that the testicle loss resulted in an award to the plaintiff, while the death resulted in a defense verdict.

In the first case, the plaintiff’s counsel reported that the defendant’s infectious disease expert conceded that tetracycline was ineffective against *Pseudomonas aeruginosa*. In addition, the defendant’s urology expert testified that he himself did not use tetracycline to treat *Pseudomonas aeruginosa*. Although the defense maintained that treatment was appropriate and not a breach of the standard of care, this testimony likely tipped the scales in the plaintiff’s favor.

Conversely, in the second case, the defense experts testified that the patient had a venous bleed caused by the administration of heparin, and that the patient died as a result of a recognized risk of the procedure. This known complication and recognized risk likely moved the jury to find for the defendants.

A 58-year-old male steel worker sought treatment from his urologist for kidney stones. A culture revealed that he suffered from a *Pseudomonas aeruginosa* urinary tract infection. The urologist prescribed tetracycline.

However, the patient continued to experience symptoms for 2 months. He then presented to his primary care physician, who changed the antibiotic treatment. By that time, however, the infection had spread and caused systemic damage. As a result, the patient underwent surgical removal of his left testicle and a damaged portion of his prostate via a transurethral resection.

The patient then brought a malpractice action against his urologist, claiming medical negligence. The plaintiff claimed his urologist was negligent in prescribing tetracycline, which the plaintiff said was the wrong antibiotic to treat the infection indicated by the culture. According to the plaintiff, tetracycline was known to be ineffective against *Pseudomonas aeruginosa*. The plaintiff claimed that his urologist should have followed the culture sensitivities and prescribed one of four appropriate antibiotics to treat the infection.

Because of the urologist’s failure to do so, treatment was delayed, the infection spread, and ultimately resulted in the loss of plaintiff’s left testicle and a part of his prostate, the plaintiff said. The plaintiff claimed approximately $90,000 in past medical specials and $25,000 in past wage loss.

The defendant urologist maintained that he did not breach the standard of care and that his treatment was appropriate.

After a 4-hour deliberation, an Ohio jury returned a $250,000 verdict for the plaintiff.

Complications following kidney stone removal

A 60-year-old married retired male underwent kidney stone removal and placement of an arterial stent. Following the stent placement, the patient was prescribed heparin to prevent clotting at the site of the stent. The patient continued to suffer hemorrhaging at the stent.

Shortly after the procedure, the patient developed a clot and died of a pulmonary embolism.

The patient’s estate brought a medical malpractice claim against the defendant urologist, pulmonologist, and cardiologist, who all treated the patient shortly before death. According to the plaintiff, the defendants breached the standard of care by failing to timely diagnose and treat the arterial bleed, failing to recognize the signs and symptoms of the bleed, failing to order appropriate testing, and failing to take steps necessary to stop the bleed.

The plaintiff claimed his urologist was negligent in prescribing tetracycline, which the patient said was the wrong antibiotic to treat the infection indicated by the culture. According to the plaintiff, tetracycline was known to be ineffective against *Pseudomonas aeruginosa*. The plaintiff claimed that his urologist should have followed the culture sensitivities and prescribed one of four appropriate antibiotics to treat the infection.

Because of the urologist’s failure to do so, treatment was delayed, the infection spread, and ultimately resulted in the loss of plaintiff’s left testicle and a part of his prostate, the plaintiff said. The plaintiff claimed approximately $90,000 in past medical specials and $25,000 in past wage loss.

The defendant urologist maintained that he did not breach the standard of care and that his treatment was appropriate.

After a 4-hour deliberation, an Ohio jury returned a $250,000 verdict for the plaintiff.

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Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence. Most symptoms were mild to moderate in severity and resolved within two to four weeks after the procedure.
Management of Large Proximal Ureteral Stones

Keng-Siang Png, MD

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