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49 Magnifying ACA's administrative headaches
New

NOW for frequent heartburn
Take OTC acid control to the Nexium Level

Give patients stronger, longer acid control vs. omeprazole 20 mg (equivalent to Prilosec OTC®*)†

Register for coupons and resources at GoNexium24HR.com

*Prilosec OTC contains the active ingredient omeprazole magnesium 20.6 mg, equivalent to omeprazole 20 mg, used in this study.
†Acid control (pH >4) does not imply symptom relief. The correlation of pH data to clinical outcome has not been directly established.
TIME IS MONEY

4 ways to better manage productivity and organize your staff
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MEDICAL ECONOMICS
SMARTER BUSINESS. BETTER PATIENT CARE.

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A substantial number of patients at the highest risk receiving therapy are unable to achieve LDL-C goal.

~70% of patients at the highest risk who are receiving therapy do not achieve an optional LDL-C goal of <70 mg/dL (1.8 mmol/L).1

* Data are from a 2006–2007 multinational survey, of which 2,334 patients were considered very high risk (defined as CHD plus two or more major risk factors). National Cholesterol Education Program (NCEP) Adult Treatment Panel III U.S. optional goal is <70 mg/dL (1.8 mmol/L). Countries in this analysis included the United States, Canada, Spain, the Netherlands, France, Taiwan, Korea, Brazil, and Mexico.

WIKIPEDIA MEDICAL INFORMATION OFTEN WRONG

Healthcare professionals should be wary of using Wikipedia to research patients’ illnesses, according to a recent study. The study’s authors compared information found on the popular website regarding the 10 most expensive diseases—including cancer, heart disease, and diabetes—to data from peer-reviewed articles, and found that Wikipedia had incorrect information on all 10 ailments. Learn more at MedicalEconomics.com/Wikipedia

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More than 80% of people obtaining insurance through exchanges are current on payments. MedicalEconomics.com/premums

#2 SAFETY-NET HOSPITAL EDs SEEING FEWER PATIENTS
Drop in numbers of uninsured patients credited for trend. Details at MedicalEconomics.com/safetynet

#3 MEASLES CASES AT 20-YEAR HIGH
International travel, growing numbers of unvaccinated fuel worrying trend. Find out more at MedicalEconomics.com/measles

Wikipedia medical information often wrong

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Medical Economics is a part of the ModernMedicine Network, a Web-based portal for health professionals offering best-in-class content and tools in a rewarding and easy-to-use environment for knowledge-sharing among members of our community.
Most practices are built to create current income for the owner. Creating equity value requires strategy.

—Keith Borglum, CHBC

CONSULTANTS

Mary Ann Bauman, MD
Internal Medicine
Oklahoma City, OK

John L. Bender, MD
Family Medicine
Ft. Collins, CO

Maria Y. Chandler, MD, MBA
Business of Medicine, Pediatrics
Irvine, CA

George G. Ellis Jr., MD
Internal Medicine
Youngstown, OH

David C. Judge, MD
Internal Medicine
Cambridge, MA

Jeffrey M. Kagan, MD
Internal Medicine
Newington, CT

Elizabeth A. Pector, MD
Family Medicine
Naperville, IL

Patricia J. Roy, DO
Family Medicine
Muskegon, MI

Joseph E. Scherger, MD
Family Medicine
La Quinta, CA

Salvatore S. Volpe, MD
Internal Medicine-Pediatrics
Staten Island, NY

Craig M. Wax, DO
Family Medicine
Mullica Hill, NJ

Mary Ann Bauman, MD
Internal Medicine
Oklahoma City, OK

John L. Bender, MD
Family Medicine
Ft. Collins, CO

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Naperville, IL

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Family Medicine
Muskegon, MI

Joseph E. Scherger, MD
Family Medicine
La Quinta, CA

Salvatore S. Volpe, MD
Internal Medicine-Pediatrics
Staten Island, NY

Craig M. Wax, DO
Family Medicine
Mullica Hill, NJ
Within the first year of opening our office we realized that it made no sense for anybody other than our patients to decide how much our services were worth. We therefore decided not to participate in any insurance arrangements at all...and requested full payment from all our patients at the time of service.

Neil Berkowitz, MD, SAN DIEGO, CALIFORNIA

**Patients will respond to caring physicians**

I sympathize with the sentiments expressed by William M. Gilkison, MD in his letter (“Changes in Medicine Lead to Retirement Decision,” May 10, 2014) in which he mentions many of the encumbrances and frustrations which caused him to retire from practice.

However, I would like to offer an alternative practice model which I have been implementing successfully for the past 29 years in my private family practice in San Diego, California, which even in this crazy age still allows me to love practicing as a family physician.

My wife and I received our medical training in South Africa, and emigrated to the U.S. in 1981. We did some additional training in the U.S. to obtain the required licensure and in 1985 opened our practice in San Diego together.

Within the first year of opening our office we realized that it made no sense for anybody other than our patients to decide how much our services were worth. We therefore decided to not participate in any insurance arrangements at all (including preferred provider organizations, Medicare and everything else,) and requested full payment from all our patients at the time of service.

When our patients left our office having paid the bill in full, they had a very simple question they needed to answer. “Did I get value for the price I paid, or not?”

If they felt they did, they would return again. If not, they would not return and we would have been out of business many years ago. They have been returning for 29 years.

All our patients have insurance, but our fees are significantly higher than any insurance allowables, and the superbill which we give patients to submit themselves permits the patient to receive whatever their insurance may decide to pay. We do not get involved in this decision.

We do not intend to EVER use electronic health records, and we are not board certified, so the concepts of “recertification,” "meaningful use,” “medical home,” “Obamacare,” etc. have no place nor meaning in our lives or practice.

We are not a concierge practice in that we don’t ask for any retainer, nor do we limit the number of patients we are prepared to accept. We will see anybody, any time.

Since all of our patients have insurance, they all have many other doctors they could choose to see and pay them much less than they pay us.

So why do they choose us? To quote Dr. Gilkison, “All they care about is having a physician who cares about them, responds to their needs, answers their questions, and gets them well (when possible).”

The tragedy is that such simple, time-
NEW ACP KIDNEY DISEASE GUIDELINES NOT NEEDED
The new American College of Physicians guidelines against screening for chronic renal disease (“Recommendations on the screening, monitoring, and treatment of early-stage chronic kidney disease,” April 10, 2014) are really a moot point since every chemistry panel has three numerical indices for this very disease.

For the last five or six years, every laboratory in the U.S. includes: BUN (blood urea nitrogen), creatinine, and eGFR (Glomular Filtration Rate). The estimated GFR is even broken down for African-American patients and non-African-Americans. Therefore, when a patient receives a printout of his/her blood chemistry, implied is the actual stage of renal function and/or diseases.

“...false positives, unnecessary treatment and added healthcare costs” are now built into the system. I myself had three different chemistry panels done last summer at three different labs and my eGFR differed by 13 points!

Of course, those with long-standing hypertension, diabetes, obesity and other single- or multiple-risk factors can often be motivated into treatment and lifestyle modifications by these numbers. Others become quite concerned and I often have to perform a renal ultrasound to make sure the patient has two functioning kidneys. Some, with eGFR in the 50 point range do in fact have only one functioning kidney. Others are reassured that they have normal anatomy. Either way, often a follow-up evaluation is necessary to the data found on a routine chemistry panel.

Arnold Chanin, MD
EL SEGUNDO, CALIFORNIA

MOC BOARDS ARE NOT VOLUNTARY
Raj Patel, MD, in his letter of March 25 (“MOC has little value”) resents, and aptly so, one of the most contemptible issues in the maintenance of certification issue, namely that MOC, despite what its proponents say, is mandatory.

Although officials of the American Board of Medical Specialties proclaim that the boards are voluntary, they are being dishonest or confused because the boards are being used as credentialing requirements by insurers and hospital staffs.

When the boards were created almost 100 years ago, they were voluntary. If they were mandatory physicians would not have supported them and the boards would not exist today.

Edward Volpintesta, MD
BETHEL, CONNECTICUT

Although officials at the American Board of Medical Specialties proclaim that the boards are voluntary, they are being dishonest or confused because the boards are being used as credentialing requirements by insurers and hospital staffs.

Edward Volpintesta, MD, BETHEL, CONNECTICUT
NEW HBV TEST GUIDELINES

The U.S. Preventive Services Task Force (USPSTF) is trying to reduce the incidence of hepatitis B (HBV) by recommending screening for individuals who are at high risk of infection.

“This is very important especially since HBV can be prevented,” says James M. Wooten, PharmD, associate professor, department of medicine, section of clinical pharmacology at the University of Missouri-Kansas City. “Unfortunately, it can also be spread easily, so screening is important.”

High risk is defined as individuals who are born in foreign countries with a high rate of HBV infection, household contacts of those with the infection, injection drug users, patients with HIV/AIDS, and men who have sex with men, according to the USPSTF.

Between 700,000 and 2.2 million Americans have chronic HBV infection. This recommendation applies to asymptomatic, nonpregnant adolescents and adults who have not been vaccinated and other persons at high risk for HBV infection (including those at high risk who were vaccinated before being screened for HBV).

SALARY REPORT SHOWS MORE RECRUITMENT EFFORTS

A recent Medical Group Management Association (MGMA) report found that primary care physicians (PCPs) at hospital-owned practices earned a median, first-year guaranteed compensation of $192,554, while those at physician-owned practices earned $185,000.

Among all job placements, 72% of employers paid the provider’s relocation expenses, 18.2% offered loan forgiveness, and 60.3% gave a signing bonus.

MGMA credits the additional physician recruitment benefits to the predicted increase in patient volume from the Affordable Care Act health insurance exchanges.

The survey also showed that PCPs still make significantly less than specialists. Specialists at hospital-owned practices reported a median, first-year guaranteed compensation of $300,000, and specialists at private practices earned $275,000.

TO ATTRACT PCPS:

- 72% of employers pay relocation expenses
- 60.3% give signing bonuses
- 18.2% offer loan assistance
Covered for more than 80% of commercially insured patients without prior authorization

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- History of a serious hypersensitivity reaction to INVOKANA®.
- Severe renal impairment (eGFR < 30 mL/min/1.73 m²), end stage renal disease, or patients on dialysis.

WARNINGS and PRECAUTIONS

- Hypotension: INVOKANA® causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA®, particularly in patients with impaired renal function (eGFR < 60 mL/min/1.73 m²), elderly patients, and patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system (eg, angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA® in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.

The recommended starting dose of INVOKANA® (canagliflozin) is 100 mg once daily. INVOKANA® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. INVOKANA® is not recommended in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.
EXPERIENCE THE DIFFERENCE

INVOKANA® 300 mg vs Januvia® 100 mg
at 52 weeks, each in combination with metformin + a sulfonylurea (SU)²

**Greater reductions in A1C²**

Adjusted Mean Change in A1C From Baseline (%)

<table>
<thead>
<tr>
<th></th>
<th>Mean baseline:</th>
<th>8.13%</th>
<th>8.12%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Januvia® 100 mg + metformin and an SU (n=378)</td>
<td>–0.66</td>
<td></td>
<td></td>
</tr>
<tr>
<td>INVOKANA® 300 mg + metformin and an SU (n=377)</td>
<td>–1.03</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Difference from Januvia® (sitagliptin): –0.37% (95% CI: –0.50, –0.25); P<0.05**

**INVOKANA® (canagliflozin) starting dose**: 100 mg once daily. In patients tolerating the starting dose who have an eGFR ≥60 mL/min/1.73 m² and require additional glycemic control, the dose can be increased to 300 mg once daily.²

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**IMPORTANT SAFETY INFORMATION (cont’d)**

- **Impairment in Renal Function**: INVOKANA® increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating INVOKANA®. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m².

- **Hyperkalemia**: INVOKANA® can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia. Monitor serum potassium levels periodically after initiating INVOKANA® in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.
**Greater reductions in body weight**

Difference from Januvia® 100 mg: −2.8%, *P* < 0.001

**Greater reductions in systolic blood pressure**

Difference from Januvia® 100 mg: −5.9 mm Hg, *P* < 0.001

INVOKANA® is not indicated for weight loss or as antihypertensive treatment.

*Adjusted mean.

†Prespecified secondary endpoint.

**Incidence of hypoglycemia**

INVOKANA® 300 mg: 43.2%; Januvia® 100 mg: 40.7%

The incidence of hypoglycemia increases when used in combination with insulin or an insulin secretagogue.

**Adverse reactions (ARs)**

Incidences of ARs were similar between groups except for:

- **Male/female genital mycotic infection:**
  - INVOKANA® 300 mg: 9.2%/15.3%
  - Januvia® 100 mg: 0.5%/4.3%
- **Increased urine frequency/volume:**
  - INVOKANA® 300 mg: 1.6%/0.8%
  - Januvia® 100 mg: 1.3%/0%

Learn more and register for updates at INVOKANAHcp.com

A randomized, double-blind, active-controlled, 52-week study of patients with type 2 diabetes inadequately controlled on maximum doses of metformin (≥2000 mg/day, or ≥1500 mg/day if higher dose not tolerated) and near-maximally or maximally effective doses of an SU.

**Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues:** Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA® can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA®.

**Genital Mycotic Infections:** INVOKANA® increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections. Monitor and treat appropriately.

**Hypersensitivity Reactions:** Hypersensitivity reactions (eg, generalized urticaria), some serious, were reported with INVOKANA® treatment; these reactions generally occurred within hours to days after initiating INVOKANA®. If hypersensitivity reactions occur, discontinue use of INVOKANA®; treat per standard of care and monitor until signs and symptoms resolve.

Please see additional important safety information and brief summary of full prescribing information on the following pages.
DRUG INTERACTIONS

» UGT Enzyme Inducers: Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including UGT1A9, UGT2B4, decreased canagliflozin area under the curve (AUC) by 51%. This decrease in exposure to canagliflozin may decrease efficacy. If an inducer of these UGTs (eg, rifampin, phenytoin, phenobarbital, ritonavir) must be co-administered with INVOKANA® (canagliflozin), consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA® 100 mg once daily, have an eGFR greater than 60 mL/min/1.73 m², and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m² receiving concurrent therapy with a UGT inducer and requiring additional glycemic control.

» Digoxin: There was an increase in the area AUC and mean peak drug concentration (Cmax) of digoxin (20% and 36%, respectively) when co-administered with INVOKANA® 300 mg. Patients taking INVOKANA® with concomitant digoxin should be monitored appropriately.

USE IN SPECIFIC POPULATIONS

» Pregnancy Category C: There are no adequate and well-controlled studies of INVOKANA® in pregnant women. Based on results from rat studies, canagliflozin may affect renal development and maturation. In a juvenile rat study, increased kidney weights and renal pelvic and tubular dilatation were evident at ≥0.5 times clinical exposure from a 300-mg dose. These outcomes occurred with drug exposure during periods of animal development that correspond to the late second and third trimester of human development. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. INVOKANA® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

» Nursing Mothers: It is not known if INVOKANA® is excreted in human milk. INVOKANA® is secreted in the milk of lactating rats, reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA® showed risk to the developing kidney (renal pelvic and tubular dilatations) during maturation. Since human kidney maturation occurs in utero and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from INVOKANA®, a decision should be made whether to discontinue nursing or to discontinue INVOKANA®, taking into account the importance of the drug to the mother.

Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA® or any other antidiabetic drug.

IMPORTANT SAFETY INFORMATION (cont’d)

» Increases in Low-Density Lipoprotein (LDL-C): Dose-related increases in LDL-C occur with INVOKANA® (canagliflozin). Monitor LDL-C and treat per standard of care after initiating INVOKANA®.

» Renal Impairment: The efficacy and safety of INVOKANA® were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to <60 mL/min/1.73 m²). These patients had less overall glycemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR ≥60 mL/min/1.73 m²); patients treated with INVOKANA® 300 mg were more likely to experience increases in potassium. The efficacy and safety of INVOKANA® have not been established in patients with severe renal impairment (eGFR <30 mL/min/1.73 m²), with end-stage renal disease (ESRD), or receiving dialysis. INVOKANA® is not expected to be effective in these patient populations.

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June 2014
01346-140404
Hepatic Impairment: No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. The use of INVOKANA® has not been studied in patients with severe hepatic impairment and it is therefore not recommended.

OVERDOSAGE
- There were no reports of overdose during the clinical development program of INVOKANA® (canagliflozin).

In the event of an overdose, contact the Poison Control Center. It is also reasonable to employ the usual supportive measures, eg, remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as dictated by the patient's clinical status. Canagliflozin was negligibly removed during a 4-hour hemodialysis session. Canagliflozin is not expected to be dialyzable by peritoneal dialysis.

ADVERSE REACTIONS
- The most common (≥25%) adverse reactions were female genital mycotic infections, urinary tract infections, and increased urination. Adverse reactions in ≥22% of patients were male genital mycotic infections, vulvovaginal pruritus, thirst, nausea, and constipation.

Please see brief summary of full Prescribing Information on the following pages.


INVOKANA™
(canagliflozin) tablets, for oral use

Brief Summary of Prescribing Information.

INDICATIONS AND USAGE
INVOKANA™ (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus [see Clinical Studies (14) in full Prescribing Information].

Limitation of Use: INVOKANA is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

CONTRAINDICATIONS
- History of a serious hypersensitivity reaction to INVOKANA [see Warnings and Precautions].
- Severe renal impairment (eGFR less than 30 mL/min/1.73 m²), end stage renal disease or patients on dialysis [see Warnings and Precautions and Use in Specific Populations].

WARNINGS AND PRECAUTIONS

Hypotension: INVOKANA causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA [see Adverse Reactions] particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m²), elderly patients, patients on diuretics or other medications that interfere with the renin-angiotensin-aldosterone system (e.g., angiotensin-converting enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.

Impairment in Renal Function: INVOKANA increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating INVOKANA [see Adverse Reactions]. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m².

Hyperkalemia: INVOKANA can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia [see Adverse Reactions]. Monitor serum potassium levels periodically after initiating INVOKANA in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions. Hyperkalemia with Concomitant Use with Insulin and Insulin Secretagogues: Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue [see Adverse Reactions]. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA.

Genital Mycotic Infections: INVOKANA increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections [see Adverse Reactions]. Monitor and treat appropriately.

Hypersensitivity Reactions: Hypersensitivity reactions (eg, generalized urticaria), some serious, were reported with INVOKANA treatment; these reactions generally occurred within hours to days after initiating INVOKANA. In 26-week placebo-controlled trials, increases in lipids and low-density lipoprotein (LDL) were observed with INVOKANA treatment. In three trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Clinical Studies 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 the rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. Use of INVOKANA as an add-on to another antidiabetic drug or treatment in the clinical studies (14) in full Prescribing Information). These data reflect exposure of 1667 patients to INVOKANA and a mean duration of exposure to

ES506217_ME062514_E8_FP.pgs 06.03.2014 02:31 ADV
INVOKANA™ (canagliflozin) tablets

INVOKANA of 24 weeks. Patients received INVOKANA 100 mg (N=833), INVOKANA 300 mg (N=834) or placebo (N=646) once daily. The mean age of the patients was 56 years and 2% were older than 75 years of age. Fifty percent (50%) of the population was male and 72% were Caucasian, 12% were Asian, and 5% were Black or African American. At baseline the population had diabetes for an average of 7.3 years, had a mean HbA1C of 8.0% and 20% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 88 mL/min/1.73 m²).

Table 1 shows common adverse reactions associated with the use of INVOKANA. These adverse reactions were not present at baseline, occurred more commonly on INVOKANA than on placebo, and occurred in at least 2% of patients treated with either INVOKANA 100 mg or INVOKANA 300 mg.

Table 2: Proportion of Patients With at Least One Volume Depletion-Related Adverse Reaction (Pooled Results from 8 Clinical Trials)

<table>
<thead>
<tr>
<th>Baseline Characteristic</th>
<th>Comparator Group*</th>
<th>INVOKANA 100 mg</th>
<th>INVOKANA 300 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall population</td>
<td>1.5%</td>
<td>2.3%</td>
<td>3.4%</td>
</tr>
<tr>
<td>75 years of age and older</td>
<td>2.6%</td>
<td>4.9%</td>
<td>8.7%</td>
</tr>
<tr>
<td>eGFR less than 60 mL/min/1.73 m²</td>
<td>2.5%</td>
<td>4.7%</td>
<td>8.1%</td>
</tr>
</tbody>
</table>
| Volume depletion-related adverse reactions (e.g., hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration). An increased incidence was observed in patients on the 300 mg dose. The three factors associated with the largest increase in volume depletion-related adverse reactions were the use of loop diuretics, moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²), and age 75 years and older (Table 2) [see Dosage and Administration (2.2) in Full Prescription Information, Warnings and Precautions, and Use in Specific Populations].

Table 2: Changes in Serum Creatinine and eGFR Associated with INVOKANA in the Pool of Four Placebo-Controlled Trials and Moderate Renal Impairment Trial

<table>
<thead>
<tr>
<th>Pool of Four Placebo-Controlled Trials</th>
<th>Baseline</th>
<th>Week 6 Change</th>
<th>End of Treatment Change*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>Creatinine (mg/dL)</td>
<td>0.84</td>
<td>0.62</td>
</tr>
<tr>
<td></td>
<td>eGFR (mL/min/1.73 m²)</td>
<td>87.0</td>
<td>88.3</td>
</tr>
<tr>
<td>INVOKANA 100 mg</td>
<td>Creatinine (mg/dL)</td>
<td>0.01</td>
<td>0.03</td>
</tr>
<tr>
<td></td>
<td>eGFR (mL/min/1.73 m²)</td>
<td>-1.6</td>
<td>-3.8</td>
</tr>
<tr>
<td>INVOKANA 300 mg</td>
<td>Creatinine (mg/dL)</td>
<td>0.01</td>
<td>0.02</td>
</tr>
<tr>
<td></td>
<td>eGFR (mL/min/1.73 m²)</td>
<td>-1.6</td>
<td>-2.3</td>
</tr>
</tbody>
</table>

* Includes placebo and active-comparator groups

Patients could have more than 1 of the listed risk factors

Impairment in Renal Function: INVOKANA is associated with a dose-dependent increase in the incidence of volume depletion-related adverse reactions (e.g., hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration). An increased incidence was observed in patients on the 300 mg dose. The three factors associated with the largest increase in volume depletion-related adverse reactions were the use of loop diuretics, moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m²), and age 75 years and older (Table 2) [see Dosage and Administration (2.2) in Full Prescription Information, Warnings and Precautions, and Use in Specific Populations].

Table 3: Changes in Serum Creatinine and eGFR Associated with INVOKANA in the Pool of Four Placebo-Controlled Trials and Moderate Renal Impairment Trial

<table>
<thead>
<tr>
<th>Pool of Four Placebo-Controlled Trials</th>
<th>Baseline</th>
<th>Week 3 Change</th>
<th>End of Treatment Change*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>Creatinine (mg/dL)</td>
<td>1.81</td>
<td>1.62</td>
</tr>
<tr>
<td></td>
<td>eGFR (mL/min/1.73 m²)</td>
<td>40.1</td>
<td>39.7</td>
</tr>
<tr>
<td>INVOKANA 100 mg</td>
<td>Creatinine (mg/dL)</td>
<td>0.03</td>
<td>0.18</td>
</tr>
<tr>
<td></td>
<td>eGFR (mL/min/1.73 m²)</td>
<td>-0.7</td>
<td>-4.6</td>
</tr>
<tr>
<td>INVOKANA 300 mg</td>
<td>Creatinine (mg/dL)</td>
<td>0.07</td>
<td>0.16</td>
</tr>
<tr>
<td></td>
<td>eGFR (mL/min/1.73 m²)</td>
<td>-1.5</td>
<td>-3.6</td>
</tr>
</tbody>
</table>

* Week 26 in mITT LDFC population

In the pool of four placebo-controlled trials where patients had normal or mildly impaired baseline renal function, the proportion of patients who experienced at least one event of significant renal function decline, defined as a 30% decrease in eGFR below 80 mL/min/1.73 m² and 30% lower than baseline, was 2.1% with placebo, 2.0% with INVOKANA 100 mg, and 4.1% with INVOKANA 300 mg. At the end of treatment, 0.5% with placebo, 0.7% with INVOKANA 100 mg, and 1.4% with INVOKANA 300 mg had a significant renal function decline.
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In a trial carried out in patients with moderate renal impairment with a baseline eGFR of 30 to less than 60 mL/min/1.73 m² (mean baseline eGFR 30 mL/min/1.73 m²) (see Clinical Studies (14.3) in full Prescribing Information), the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR 30% lower than baseline, was 6.5% with placebo, 18% with INVOKANA 100 mg, and 22.5% with INVOKANA 300 mg. At the end of treatment, 4.6% with placebo, 3.4% with INVOKANA 100 mg, and 3.4% with INVOKANA 300 mg had a significant renal function decline.

In a pooled population of patients with moderate renal impairment (N=1085) with baseline eGFR of 30 to less than 60 mL/min/1.73 m² (mean baseline eGFR 48 mL/min/1.73 m²), the overall incidence of these events was lower than in the dedicated trial but a dose-dependent increase in incident episodes of significant renal function decline compared to placebo was still observed.

Use of INVOKANA was associated with an increased incidence of renal-related adverse reactions (e.g., increased blood creatinine, decreased glomerular filtration rate, acute renal failure), particularly in patients with moderate renal impairment.

In the pooled analysis of patients with moderate renal impairment, the incidence of renal-related adverse reactions was 3.7% with placebo, 8.9% with INVOKANA 100 mg, and 8.3% with INVOKANA 300 mg. Discontinuations due to renal-related adverse events occurred in 1.0% with placebo, 1.2% with INVOKANA 100 mg, and 1.6% with INVOKANA 300 mg (see Warnings and Precautions).

Genital Mycotic Infections: In the pool of four placebo-controlled clinical trials, female genital mycotic infections (e.g., vulvovaginal mycotic infection, vulvovaginal candidiasis, and vulvovaginitis) occurred in 3.2%, 10.4%, and 11.4% of females treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. In patients with a history of genital mycotic infections, and in those with female genital mycotic infections on INVOKANA, patients who developed genital mycotic infections on INVOKANA were more likely to develop genital mycotic infections on INVOKANA. Female patients who developed genital mycotic infections on INVOKANA were more likely to experience recurrent infections (22% on INVOKANA versus none on placebo), and require treatment with oral or topical antifungal agents and anti-microbial agents (see Warnings and Precautions).

In the pool of four placebo-controlled clinical trials, male genital mycotic infections (e.g., candidal balanitis, balanoposthitis) occurred in 0.6%, 4.2%, and 3.7% of males treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Male genital mycotic infections occurred more commonly in uncircumcised males and in males with a prior history of hospitalization or other procedures who developed genital mycotic infections on INVOKANA were more likely to experience recurrent infections (22% on INVOKANA versus none on placebo), and require treatment with oral or topical antifungal agents and anti-microbial agents than patients on comparators. In the pooled analysis of 8 controlled trials, phimosis was reported in 0.3% of uncircumcised male patients treated with INVOKANA and 0.2% required circumcision to treat the phimosis (see Warnings and Precautions).

Hypoglycemia: In all clinical trials, hypoglycemia was defined as any event regardless of symptoms, where biochemical hypoglycemia was documented (any glucose value below or equal to 70 mg/dL). Severe hypoglycemia was defined as an event consistent with hypoglycemia where the patient required the assistance of another person to recover, lost consciousness, or experienced a seizure (regardless of whether biochemical documentation of a low glucose value was obtained).

Laboratory Tests: Increases in Serum Potassium: Dose-related, transient mean increases in serum potassium were observed early after initiation of INVOKANA (i.e., within 3 weeks) in a trial of patients with moderate renal impairment (see Clinical Studies (14.3) in full Prescribing Information). In this trial, increases in serum potassium of greater than 5.4 mEq/L and 15% above baseline occurred in 16.1%, 12.4%, and 27.0% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. More severe elevations (i.e., equal or greater than 6.5 mEq/L) occurred in 1.1%, 1.5%, and 2.2% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. In patients with moderate renal impairment, increases in potassium were more commonly seen in those with elevated potassium at baseline and in those using medications that reduce potassium excretion, such as potassium-sparing diuretics, angiotensin-converting enzyme inhibitors, and angiotensin-receptor blockers (see Warnings and Precautions).

Increases in Serum Magnesium: Dose-related increases in serum magnesium were observed early after initiation of INVOKANA (within 8 weeks) and remained elevated throughout treatment. In the pool of four placebo-controlled trials, the mean change in serum magnesium levels was 8.1% and 9.3% with INVOKANA 100 mg and INVOKANA 300 mg, respectively, compared to -0.6% with placebo. In a trial of patients with moderate renal impairment (see Clinical Studies (14.3) in full Prescribing Information), serum magnesium levels increased by 0.2%, 9.2%, and 14.8% with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively, compared to 1.5% with placebo. In a trial of patients with moderate renal impairment (see Clinical Studies (14.3) in full Prescribing Information), the mean serum phosphate levels increased by 1.2%, 5.0%, and 9.3% with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively, compared to 3.4% with placebo.

Increases in Serum Phosphate: Dose-related increases in serum phosphate levels were observed with INVOKANA. In the pool of four placebo controlled trials, dose-related increases in serum phosphate levels were observed in LDL-C with INVOKANA were observed. Mean changes (percent changes) from baseline in LDL-C relative to placebo were 4.4 mg/dL (4.5%) and 8.2 mg/dL (8.0%) with INVOKANA 100 mg and INVOKANA 300 mg, respectively. The mean baseline LDL-C levels were 104 to 110 mg/dL across treatment groups (see Warnings and Precautions).

Dose-related increases in non-HDL-C with INVOKANA were observed. Mean changes (percent changes) from baseline in non-HDL-C relative to placebo were 2.1 mg/dL (1.9%) and 5.1 mg/dL (6.3%) with INVOKANA 100 mg and 300 mg, respectively. The mean baseline non-HDL-C levels were 140 to 147 mg/dL across treatment groups.

Increases in Hemoglobin: In the pool of four placebo-controlled trials, mean changes (percent changes) from baseline in hemoglobin were -0.18 g/dL (-1.1%) with placebo, 0.47 g/dL (0.5%) with INVOKANA 100 mg, and 0.51 g/dL (3.8%) with INVOKANA 300 mg. The mean baseline hemoglobin value was approximately 14.1 g/dL across treatment groups. At the end of treatment, 0.8%, 4.0%, and 2.7% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively, had hemoglobin above the upper limit of normal.

Drug Interactions: UGT Enzyme Inducers: Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including
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OVERDOSAGE

There were no reports of overdose during the clinical development program of INVOKANA (canagliflozin).

In the event of an overdose, contact the Poison Control Center. It is also reasonable to employ the usual supportive measures, e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as dictated by the patient's clinical status. Canagliflozin was negligibly removed during a 4-hour hemodialysis session. Canagliflozin is not expected to be dialyzable by peritoneal dialysis.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

Instructions: Instruct patients to read the Medication Guide before starting INVOKANA (canagliflozin) therapy and to reread it each time the prescription is renewed.

Inform patients of the potential risks and benefits of INVOKANA and of alternative modes of therapy. Also inform patients about the importance of adherence to dietary instructions, regular physical activity, periodic blood glucose monitoring and HbA1C testing, recognition and management of hypoglycemia and hyperglycemia, and assessment for diabetes complications. Advise patients to seek medical advice promptly during periods of stress such as fever, trauma, infection, or surgery, as medication requirements may change.

Instruct patients to take INVOKANA only as prescribed. If a dose is missed, advise patients to take it as soon as it is remembered unless it is almost time for the next dose, in which case patients should skip the missed dose and take the medicine at the next regularly scheduled time. Advise patients not to take two doses of INVOKANA at the same time.

Inform patients that the most common adverse reactions associated with INVOKANA are genital mycotic infection, urinary tract infection, and increased urination.

Inform female patients of child bearing age that the use of INVOKANA during pregnancy has not been studied in humans, and that INVOKANA should only be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Instruct patients to report pregnancies to their physicians as soon as possible.

Inform nursing mothers to discontinue INVOKANA or nursing, taking into account the importance of drug to the mother.

Laboratory Tests: Due to its mechanism of action, patients taking INVOKANA will test positive for glucose in their urine.

Hypotension: Inform patients that symptomatic hypotension may occur with INVOKANA and advise them to contact their doctor if they experience such symptoms [see Warnings and Precautions]. Inform patients that dehydration may increase the risk for hypotension, and to have adequate fluid intake.

Genital Mycotic Infections in Males (e.g., Vulvovaginitis): Inform male patients that yeast infection of penis (e.g., balanitis or balanoposthitis) should occur, especially in uncircumcised males and patients with prior history. Provide them with information on the signs and symptoms of vaginal yeast infection. Advise them of treatment options and when to seek medical advice [see Warnings and Precautions].

Genital Mycotic Infections in Females (e.g., Vulvovaginitis): Inform female patients of child bearing age that the use of INVOKANA during pregnancy has not been studied in humans, and that INVOKANA should only be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Inform patients to seek medical advice promptly during periods of stress such as fever, trauma, infection, or surgery, as medication requirements may change.

Active ingredient made in Belgium

Manufactured for: Janssen Pharmaceuticals, Inc.

Tiusville, NJ 08050

Finished product manufactured by: Janssen Ortho, LLC

Gurabo, PR 007425

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UGT1A9, UGT2B4, decreased canagliflozin area under the curve (AUC) by 51%. This decrease in exposure to canagliflozin may decrease efficacy. If an inducer of these UGTs (e.g., rifampin, phenytoin, phenobarbital) must be co-administered with INVOKANA (canagliflozin), consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA 100 mg once daily, have an eGFR greater than 60 mL/min/1.73 m², and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m² receiving concurrent therapy with a UGT inducer and require aggressive glycemic control [see Dosage and Administration (2.2) and Clinical Pharmacology (12.3) in full Prescribing Information].

DIAGNOSIS: There was an increase in the AUC and mean peak drug concentration (Cmax) of digoxin (20% and 36%, respectively) with co-administered with INVOKANA 300 mg [see Clinical Pharmacology (12.3) in full Prescribing Information]. Patients taking INVOKANA with concomitant digoxin should be monitored appropriately.

USE IN SPECIFIC POPULATIONS

Pregnancy: Teratogenic Effects: Pregnancy Category C: There are no adequate and well-controlled studies of INVOKANA in pregnant women. Based on results from rat studies, canagliflozin may affect renal development and maturation. In a juvenile rat study, increased kidney weights and renal pelvic and tubular dilatation were evident at greater than or equal to 0.5 times clinical exposure from a 300 mg dose [see Nonclinical Toxicology (13.2) in full Prescribing Information].

These outcomes occurred with drug exposure during periods of animal development that correspond to the late second and third trimester of human development. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. INVOKANA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known if INVOKANA is excreted in human milk. INVOKANA is secreted in the milk of lactating rats reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA showed risk to the developing kidney (renal pelvic and tubular dilatations) during maturation. Since human kidney maturation occurs in utero and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from INVOKANA, a decision should be made whether to discontinue nursing or to discontinue INVOKANA, taking into account the importance of the drug to the mother [see Nonclinical Toxicology (13.2) in full Prescribing Information].

Geriatric Use: Use: Safety and effectiveness of INVOKANA in pediatric patients under 18 years of age have not been established.

Geriatric Use: Use: Safety and effectiveness of INVOKANA in patients 65 years and older, and 945 patients 75 years and older were exposed to INVOKANA in nine clinical studies of INVOKANA [see Clinical Studies (14.3) in full Prescribing Information].

Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300 mg daily dose, compared to younger patients. The most common incidence was seen in patients who were 75 years and older [see Dosage and Administration (2.1) in full Prescribing Information and Adverse Reactions]. Smaller reductions in HbA1C with INVOKANA relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA 100 mg and -0.74% with INVOKANA 300 mg relative to placebo) compared to younger patients (0.72% with INVOKANA 100 mg and -0.87% with INVOKANA 300 mg relative to placebo).

Renal Impairment: The efficacy and safety of INVOKANA were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to less than 50 mL/min/1.73 m²) [see Clinical Studies (14.3) in full Prescribing Information]. These patients had less overall glycemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR greater than or equal to 60 mL/min/1.73 m²); patients treated with INVOKANA 300 mg were more likely to experience increases in potassium (see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Adverse Reactions).

The efficacy and safety of INVOKANA have not been established in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m²), with ESRD, or receiving dialysis. INVOKANA is not expected to be effective in these patient populations [see Contraindications and Clinical Pharmacology (12.3) in full Prescribing Information].

Hepatic Impairment: No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. The use of INVOKANA has not been studied in patients with severe hepatic impairment and is therefore not recommended [see Clinical Pharmacology (12.3) in full Prescribing Information].
More veterans could seek healthcare from private practices, hospitals

Physicians in private practices and hospitals could be treating more veterans in the near future, as the U.S. Department of Veterans Affairs (VA) works to alleviate its overburdened healthcare system amid reports of mismanagement leading to backlogs in treatment of veterans.

The VA aims to "accelerate care" and enhance clinic capacity across the country by making more medical services available through its VA system of clinics, according to a statement released May 24. The VA will also allow more veterans to seek care at non-VA facilities in areas where clinics can’t handle more patients.

The rush to increase healthcare options for veterans comes as the VA faces reports that more than 40 veterans may have died awaiting treatment at a clinic in Phoenix, Arizona. Currently, 26 of the more than 1,700 VA hospitals and clinics are under investigation for mismanagement that is thought to have resulted in longer wait times for doctor visits, and possible cover-ups of additional deaths.

"In response to these allegations at the Phoenix VA Medical Center and a number of other facilities, the VA Office of Inspector General [IG] is conducting a comprehensive, independent review," Veterans Affairs Secretary Eric K. Shinseki said prior to resigning his position. "In addition to the IG’s independent review, I ordered the Veterans Health Administration (VHA) to conduct a nationwide audit of all other major VA healthcare facilities to ensure understanding of, and compliance with, our appointment policy. That audit is being conducted now by more than two hundred senior VHA staff. All teams are independent of the facilities they are visiting."

The U.S. House of Representatives passed a bill on May 22 that aims to add more accountability to the VA healthcare system and its 300,000 employees. "VAs well-documented reluctance to ensure its leaders are held accountable for negligence and mismanagement is tarnishing the reputation of the organization and may actually be encouraging more veteran suffering instead of preventing it. With all the problems VA hospitals and regional offices have recently had and new issues continually arising, we need to give the VA Secretary the authority he needs to fix things," said U.S. Representative Jeff Miller, chairman of the House Committee on Veterans' Affairs.

In 2013, Veterans Affairs spent $4.8 billion on care at non-VA clinics.
Improving patient care with the latest medical guidelines

EUROPEAN ASSOCIATION OF UROLOGY

EAU updates evidence-based guidelines on male sexual dysfunction

by CHERYL GUTTMAN KRADER Contributing author

Current guidelines on male sexual dysfunction issued by the European Association of Urology (EAU) provide an evidence-based update on the evaluation and management of erectile dysfunction (ED) and premature ejaculation (PE). Sections on ED were revised in March, 2013, based on critical review of literature published through January, 2013. Minor changes to recommendations regarding PE were incorporated in 2014. The latest version of the guidelines can be accessed at www.uroweb.org.

The 54-page document includes discussions pertaining to epidemiology, risk factors, evaluation and management of these common male sexual dysfunction disorders. However, key information, including treatment algorithms and evidence level/recommendation grade ratings, is summarized in simple tabular and algorithmic formats.

Recommendations on treatment of ED are adapted from the Princeton Consensus conferences on sexual dysfunction and cardiac risk. They emphasize the importance of appropriate lifestyle changes, risk factor modification, and early use of pro-erectile treatments in men who have undergone radical prostatectomy. Curable causes of ED (testosterone deficiency, post-traumatic arteriogenic ED) should be treated first and psychological dysfunction may be addressed with counselling when initiating therapy.

An oral phosphodiesterase-5 inhibitor (PDE5I) is recommended as first-line therapy for ED, although the guidelines only review sildenafil, tadalafil, and vardenafil, which are the three PDE5Is approved by the European Medicines Agency for the treatment of ED. The guidelines recommended that patients be encouraged to try all three agents to determine which has the greatest efficacy, while taking into account time to onset, duration of action, and adverse effects.

Intracavernous injection is recommended as second-line therapy for ED along with intraurethral alprostadil, which is less invasive but also less effective. Penile implant is recommended as third-line therapy for men who do not respond to pharmacotherapy or who desire a permanent solution.

The guidelines also emphasize the importance of warning patients seeking treatment for ED that sexual intercourse is a vigorous physical activity and of assessing cardiac fitness prior to prescribing treatment.

Diagnosis of PE is based on medical and sexual history and should include self-estimated intravaginal ejaculatory latency time along with physical examination to identify underlying medical conditions that may be associated with PE or other sexual dysfunction. Lab or neurophysiological tests are not recommended for routine evaluation of PE.

Recommendations on treatment of PE identify the need to first address ED, other sexual dysfunction, or genitourinary infection. Pharmacotherapy is considered the basis of treatment in lifelong PE. Psychological/behavioral therapy for PE may be attempted, but there are no clinical data demonstrating it provides prolonged effect. Recommended pharmacotherapy includes dapoxetine on-demand (a short-acting SSRI approved for treatment of PE in some European countries), off-label daily use of other SSRIs or clomipramine antidepressant, or a topical anesthetic agent. The guidelines note that recurrence of PE is likely with treatment cessation.

Guidelines for the diagnostic evaluation of ED recommend:

- A validated ED-related questionnaire,
- Physical examination to identify underlying medical conditions associated with ED, and
- Routine laboratory tests to identify and address reversible lifestyle and other risk factors.

Diagnosis of ED is based on medical and sexual history and should include self-estimated intravaginal latency time along with physical examination to identify underlying medical conditions associated with ED, and routine laboratory tests to identify and address reversible lifestyle and other risk factors.
I'm a physician, not a financial expert.

How do doctors’ lives differ from other professions? We start our careers nearly 10 years later. Many of us leave med school with more than $150K in debt. There is simply less time to save for the kids’ tuition and our retirement. Disability? Life insurance? Financial planning? I need someone to do the legwork for me; help me calculate what I need to build a safety net, so that my family can maintain their lifestyle. I want a resource that gets it—a doctor’s financial life is different.

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TIME IS MONEY
Solutions to managing productivity, organizing your practice for greater efficiency

by PAMELA LEWIS DOLAN Contributing author

Time is the physician’s most important resource. Although healthcare is moving toward fee-for-outcome-based payment models, most physician income still depends largely on effective time use based on the number and intensity of services provided. Because reimbursements do not seem to be keeping pace with escalating costs, physicians need to focus on efficiency.

HARNESSING TIME by creating workflows and processes can boost physician and staff productivity, increase revenue and improve patient care. But physicians face regulatory and administrative burdens on a daily basis that threaten their ability to use time most effectively. There are strategies doctors can embrace to improve productivity, and reduce these daily hassles.

It starts with putting detailed processes in place that physicians and employees can turn to when navigating challenges, allowing each practice member to do the work they are trained to do, and freeing up the physician to do what he or she does best: treat patients.

“This is about taking decision-making out of a doctor’s hands, and placing it in the hands of a protocol,” says Frederick Turton, MD, MBA, MACP, medical director of gen-
Most practice managers and administrators are virtually clueless as to how each of the processes work, which steps are involved and the data that surround those steps. The process map details each step. It helps to identify steps that are not necessary, that don’t benefit the practice or the patient.”

—FRANK COHEN, MPA, MEDICAL CONSULTANT, THE FRANK COHEN GROUP

Physician practices looking to start mapping processes should focus on three key areas that can provide the most benefit, says Frank Cohen, MPA, a practice management consultant in Clearwater, Florida and Medical Economics editorial consultant.

The key areas to map include:

- the patient visit (from check-in to check-out),
- the billing cycle (from patient check-out, through the reimbursement process, to payment posting), and
- the clinical event

Each of these process areas can be broken down into more distinct processes. For example, in the clinical event area, the practice could analyze the turn-around time for imaging or lab results, charting every step along the way from the patient encounter when the test was ordered, through the referral or performance of the test, and ending with patient notification of the test results and next steps.

For each workflow mapping project, every employee who touches that process must be identified and involved, says Peggy Evans, PhD, CPHIT, consulting director with Qualis Health in Seattle. Employees then meet and, literally, draw a map using a large white board or paper easels that shows each step of a process.

Writing out the process in incremental steps is vital, Cohen says. “Most practice managers and administrators are virtually clueless as to how each of the processes work, which steps are involved and the data that surround those steps,” he says. “The process map details each step. It helps to identify steps that are not necessary, that don’t benefit the practice or the patient.”

The key to making sure the new process works is by mapping the old, or existing, process. To do that, practices must collect baseline data to define the baseline for whatever problem it is attacking and set goals for improvements. One of the first steps after identifying the process to be mapped is to figure out how to collect data to measure that, Cohen says.
Hertz says the practice should look at each step and ask, “Why are we doing this?” The steps most hazardous to a practice’s health are those for which the answer is, “because this is the way we’ve always done it.” There must be a value associated with each step. If that step does not provide some type of value, it should be considered waste.

The next step is defining the desired improvements and re-designing the workflow to achieve that outcome. Once a new process is put in place, the data should be run again a month later and compared to the baseline data to see if the changes are working, says Evans. If things are not improving, the workflow may need more tweaking. This is why the baseline data are important, and why workflow redesign can often take a year or more to complete.

Hummel says efficiencies can be realized with a workflow that includes daily morning huddles. He explains that in most settings, the day starts with the medical assistant (MA) preparing the exam room and the doctor seeing the first patient.

But if the MA spends a few minutes with the doctor at the start of the day going over the patient list, it will help the MA know what to prep for each patient. If the MA knows the patient at 11:15 is coming in to go over a report, she can have that report ready. If the MA knows the 1:30 appointment is getting a PAP test, she can have the set-up ready to go.

The front desk can also help make the examinations go more smoothly by giving the patients their medication lists to review in the waiting room, crossing off old medications and adding new ones. Because the patient is already thinking about the medications before he or she enters the exam room, time will be saved, Hummel says.

Workflows can also be crucial for dealing with staff turnover and training new employees, because new employees will have defined steps and procedures to follow and refer to, Cohen says. He says training a new front-desk receptionist will go much more smoothly if that person has a map on the wall that details every step in the patient check-in process, including how to address difficult issues such as collecting payment in advance, declined insurance, or complicated changes in patient classification.

### The Five Cs of Process Mapping

1. **Classification**
   Focus on educating team members on the concepts and steps of process mapping. Begin with a SWOT (strengths, weaknesses, opportunities, and threats) analysis and include both training and execution of process mapping and creating a workflow for the process being examined for the change, such as wait times.

2. **Correlation**
   Review the current-state map created in the first phase. Focus on measuring the process steps through data collection and analysis, perhaps the most time-consuming phase in the process. Create a prioritization of projects.

3. **Causation**
   Get to the root cause of the issues that are discovered during creation of the process map. Looking for the real reasons behind waste in the form of bottlenecks, constraints, replication, duplication, and confounding events. For example, just because you see a decrease in revenue associated with a change in payer mix doesn’t mean that the change in payer mix caused the revenue decline. If you can’t figure out the root cause of a problem, you won’t find the solution.

4. **Collaboration**
   Begin collecting possible solutions and testing those that can be tested. For example, having identified the intake form as one cause of extended wait-time for new patients, you can create a couple of different modifications to the form and see which, if any, may be a viable solution. Collect a manageable list of possible solutions, test them, and create a plan.

5. **Culmination**
   Finally, implement the recommendations and measure the impact. Re-evaluate goals and the process to figure out what, if anything, went wrong. It is also important to determine what went right and to set up for the next project.
data.
"It will shorten the training process, and more important, everyone is on the same page resolving challenges the same way," Cohen says.

2/ Working at the top of your license
Kenneth Hertz, CMPE, principal with the MGMA Health Care Consulting Group, once worked with a physician who liked to give patients brochures and handouts. He had an original copy of each one and every time he wanted to give one to a patient, he left the exam room to make a trip to the copier.

"It was a nice gesture, recalls Hertz, but there were plenty of people in that practice qualified to make copies besides the highest-credentialed member of the staff.

Physicians are often the busiest people in a practice because they feel they can do everything better than anyone else, Turton says. And while that may be true, there's no reason for physicians to perform work that can be performed by a lower-salaried worker. Turton says it's about "allowing the least trained—but still qualified—person do the work."

If physicians focused on the things only they were qualified to do while delegating the remaining tasks to others, they will gain more time in a day. When this concept trickles down to every member of the staff, no employee will be performing work they are overqualified to do and tasks will be assigned appropriately.

But delegating must be a standardized process based on protocols, says Turton. The way to do this is to create protocols for various functions, from scheduling patients to conducting wellness exams.

For example, Turton says practices should create a prescription refill protocol that allows refill inquiries to be routed to a certified staff member so that most refills can be authorized without the physician. The times when a refill needs to be brought to the physician's attention should be outlined in the protocol.

Many practices are turning to non-physician providers (NPPs) such as nurse practitioners and physician assistants to help improve practice productivity. While they aren't able to provide all of the same services as a physician, NPPs can perform a large number of services such as routine well visits or diagnosing and treating minor acute problems. According to the MGMA, practices that employ NPPs perform better financially.

Effective delegation to NPPs can also improve outcomes. Turton says that his practice improved adherence to diabetes markers by creating a protocol that called for having medical assistants conduct the basic interview with patients and perform A1c tests and foot exams, based on protocols designed by the physician.

A practice must decide exactly how the NPP will fit into the workflow. The NPP's job description should include work that he or she is credentialed to perform and for which the doctor is over-qualified. A practice can achieve ultimate efficiencies when it continues this exercise for each staff member: if there is work an NPP is doing that an RN is qualified to do, or work an RN is doing that a medical assistant (MA) is qualified to do, changes to the practice's workflow may be required.

3/ Patient portal
For James Morrow, MD, installing a patient portal presented an opportunity to improve communication with his patients without the use of other employees' time.

From anywhere, at any time, patients can send a message. Patients can also access their lab results, request prescription refills, or schedule an appointment without the time-draining routine of calling, leaving a message with the front desk staff, waiting for the message to be relayed to the appropriate person, then waiting for that person to respond.

Because he is able to message the patient back directly whenever he has a free moment, the patient gets a much quicker and satisfactory response, says Morrow, chief executive officer of Morrow Family Medicine, a primary care practice in Cumming, Georgia. "It just makes everything about the communication better, in my opinion," he says.

Few comprehensive studies have looked at both the financial and administrative benefits of patient portals, according to a May 2011 literature review conducted by the California HealthCare Foundation. But numerous studies have shown the potential for patient portals to lower costs and im-
Boosting productivity

Physician Productivity: By the Numbers

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
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<tbody>
<tr>
<td>Median weekly hours worked by internists in 2012</td>
<td>52 hours</td>
</tr>
<tr>
<td>Median weekly hours worked by family practice physicians in 2012</td>
<td>50 hours</td>
</tr>
<tr>
<td>Number of patients internists reported seeing per week in 2012</td>
<td>93</td>
</tr>
<tr>
<td>Number of patients family practice physicians reported seeing per week in 2012</td>
<td>99</td>
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Productivity Tip: Improve Time Management by Avoiding ‘Batching’

Physicians have fallen into some bad time management habits that are only going to exacerbate problems until changes are made to their practices, according to Frederick Turton, MD, MBA, MACP, medical director of general internal medicine at Emory University Hospital Midtown in Atlanta.

Many physicians feel so pressed for time, they are either skipping some tasks altogether or working late into the night to get everything done, says Turton.

One common mistake he sees is “batching,” defined as all of the tasks that need to be accomplished that get stacked and put off until later, such as unfinished charting, unanswered messages, lab values, imaging results, and more.

“When you stack something, you reduce quality and increase the costs,” Turton says.

For example, instead of a physician doing document contemporaneously, he or she does it all at once at the end of the day. When things are missed, billing isn’t as accurate as it could be. And physicians are wasting time by essentially charting twice; they take notes during the exam then enter them in the computer later, Turton says.

Avoiding batching will better enable physicians to complete tasks efficiently and in a time-effective manner.

Physician Productivity: By the Numbers

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Physicians have fallen into some bad time management habits that are only going to exacerbate problems until changes are made to their practices, according to Frederick Turton, MD, MBA, MACP, medical director of general internal medicine at Emory University Hospital Midtown in Atlanta.

“Everyone is trying to do more with less and trying to save where they can, and [secure messaging] is a tremendous place where you can save. It’s remarkable the monetary savings that can come from that,” says Morrow.

While no practice will ever have 100% participation in its portal, it’s possible to get close to 90%, Morrow says.

The best way to do that is to tell patients that this is the way you are doing it now, instead of saying, “Well, if you’d like to, you can get online,” explains Morrow. By explaining the benefits to patients, most will be eager to sign up, even the older patients, he says.

Creating a process for staff members to inform patients about the availability and features of the portal is key. One option is to have staff members assist patients with registering on the portal while in the office. Overcoming the registration barrier will introduce more patients to the portal.

A 2011 case study by the Office of the National Coordinator for Health Information Technology illustrated how medical practices can best im-
AAOS, ACR, and OARSI have released updated guidelines on OA therapy, as recently as this year, based on the latest efficacy and safety data. Below is an overview of what's new in the guidelines.

**Key takeaways from current OA guidelines**

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<tbody>
<tr>
<td>NSAIDs</td>
<td>Strongly recommended</td>
<td>Now included among first-line options for knee and hip OA; with chronic NSAID use, add PPIs to reduce GI toxicity</td>
<td>Appropriate only for patients without comorbidities</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>Recommendation inconclusive</td>
<td>Recommended as a first-line option for knee and hip OA; stronger recommendations to avoid concomitant use with other acetaminophen products</td>
<td>Appropriate in patients without comorbidities; rating lowered to uncertain for patients with comorbidities</td>
</tr>
</tbody>
</table>

*See below for descriptions of AAOS recommendations.

**AAOS: Strong recommendation for NSAIDs in knee OA**

2013 updates: AAOS has given its “strong recommendation” for the use of NSAIDs in patients with symptomatic OA of the knee, based on 202 favorable results from 19 studies. In contrast, its 2008 “moderate recommendation” of acetaminophen was downgraded to an “inconclusive recommendation.” The 2013 review examined acetaminophen separately and found only one relevant study that tested it against placebo. The study found no statistically significant benefit vs placebo. In addition, the recommendation was downgraded because it was based on the maximum daily usage of 4000 mg, which the FDA has now recommended be reduced to 3000 mg.1

**ACR elevates NSAIDs to a first-line option**

2012 updates: Recommendations for knee and hip OA now include NSAIDs as first-line pharmacologic options, with the consideration of adding PPIs to reduce potential GI toxicity in cases of chronic NSAID use. Tramadol and intra-articular corticosteroid injections have also been upgraded to initial OA treatment, while previous guidelines listed only acetaminophen as first line. ACR continues to caution against exceeding a daily 4-g dose of acetaminophen.2,3

Also new in the 2012 update, ACR strongly recommends non-selective NSAIDs, excluding ibuprofen and COX-2 inhibitors, in patients who take concomitant aspirin. The new recommendation is based on the FDA warning that ibuprofen can interfere with the anti-platelet effect of low-dose aspirin, potentially decreasing aspirin’s effectiveness in cardioprotection and stroke prevention.2

**OARSI: Acetaminophen rating lowered from “appropriate” to “uncertain” in patients with comorbidities**

2014 updates: OARSI guidelines now distinguish between knee and multi-joint OA, with further classification of patients with and without comorbidities. The 2008 recommendation deemed acetaminophen “appropriate” for all patients. The 2014 update now specifies a rating of “uncertain” for patients with comorbidities.4,5

The lower rating for acetaminophen is attributed to an increased risk of adverse events, particularly GI side effects and multi-organ failure. Consistent with the previous OARSI guidelines, NSAIDs are not recommended for patients with comorbidities, including cardiovascular risk factors.4,5

However, in patients without comorbidities, both NSAIDs and acetaminophen were considered appropriate treatments for both knee and multi-joint OA.4

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*AAOS recommendation levels*1

- **Strong:** Benefits of the recommended approach clearly exceed the potential harm and/or the quality of the supporting evidence is high. **Moderate:** Benefits exceed the potential harm (or the potential harm clearly exceeds the benefits in the case of a negative recommendation), but the quality/applicability of the supporting evidence is not as strong. **Inconclusive:** There is a lack of compelling evidence that has resulted in an unclear balance between benefits and potential harm.
2014 OARSI Guidelines: Recommended Analgesic Treatments

**Appropriate for the following OA types**

### Multi-joint OA without comorbidities

**Pharmacologic:**
- Oral non-selective NSAIDs (7.5)
- Acetaminophen (7)
- Oral COX-2 inhibitors (7)
- Intra-articular corticosteroids (7)
- Duloxetine (7)

**Non-pharmacologic:**
- Biomechanical interventions (7)

### Knee-only OA without comorbidities

**Pharmacologic:**
- Topical NSAIDs (8)
- Oral non-selective NSAIDs (7)
- Oral COX-2 inhibitors (7)
- Acetaminophen (7)
- Intra-articular corticosteroids (7)
- Duloxetine (7)
- Capsaicin (7)

**Non-pharmacologic:**
- Biomechanical interventions (7)
- Walking cane (7)

### Multi-joint OA with comorbidities

**Pharmacologic:**
- Intra-articular corticosteroids (7)
- Oral COX-2 inhibitors (7)
- Duloxetine (7)

**Non-pharmacologic:**
- Balneotherapy (7)
- Biomechanical interventions (7)

### Knee-only OA with comorbidities

**Pharmacologic:**
- Intra-articular corticosteroids (7)
- Oral COX-2 inhibitors (7)
- Duloxetine (7)
- PPIs (7)

**Non-pharmacologic:**
- Biomechanical interventions (7)
- Walking cane (7)

*Treatment options not listed in this table were given an “uncertain” or “not appropriate” recommendation.

†COX-2 inhibitors are deemed “appropriate” for patients with moderate comorbidity risk, which includes the following comorbidities: diabetes, advanced age, hypertension, CV disease, renal failure, GI complications, depression, or physical impairment limiting activity (including obesity). COX-2 inhibitors are considered “not appropriate” for patients with high comorbidity risk, which includes comorbidities such as history of GI bleeding, myocardial infarction, and chronic renal failure.

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These guideline updates from AAOS, ACR, and OARSI reflect the safety and efficacy concerns emerging from the latest analgesic OA research. These guidelines may impact your future treatment decisions and are therefore important to consider in your recommendations.

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Bayer HealthCare

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OARSI = Osteoarthritis Research Society International; NSAIDs = non-steroidal anti-inflammatory drugs; PPIs = proton pump inhibitors; GI = gastrointestinal; COX = cyclooxygenase; CV = cardiovascular.
Implement patient portals and reap their benefits. The Primary Health Medical Group, an Idaho-based independent practice with 11 clinics, uses a coordinated strategy to inform patients about its portal that includes distributing fliers and posting materials at the clinics, and providing talking points for staff to encourage patient registration.

The practice developed a flow for patient messages, including a determination of whether messages should go directly to the physician or to another provider. They built templates for common messages such as delivery of lab results. The messages were monitored and reviewed to ensure they were succinct and patient-friendly.

The result? Secure messaging to provide patients with lab results resulted in five to 10 fewer phone calls to the practice each day. In addition, patients responded to portal messages at a much higher rate than to phone calls. The portal helped financially, too, cutting down on the practice’s expenses by reducing the amount of overtime staff members had to work.

Motivating employees
No initiative will be successful without buy-in from employees. Employees must be willing to accept that they might not be as efficient in their jobs as they could be, and they must be open to change. How to get them in this mindset can sometimes be tricky.

Building a motivated team starts with hiring, Hertz says. In the interview process, practice leaders need to share their vision and culture and determine whether that candidate shares the same commitments.

But employees still like to be recognized for a job well done. While financial incentives may seem like the most effective form of motivation, it is possible to motivate employees without the promise of a hefty bonus at the end of the year, something that most physicians cannot afford to offer.

The staffing and human resources consulting firm Adecco has a set of recommendations for rewarding and recognizing employees. Among them is to involve employees when developing a recognition program. The reward doesn’t have to cost a lot of money; it can simply be a token of appreciation. When employees help to decide what that token will be, it becomes more meaningful and motivating to them to work harder to obtain the reward.

Adecco also recommends giving a reward to all who meet the set goals instead of holding contests. If the entire staff accomplished the task given to them but only one person receives recognition, there will likely be one person feeling appreciated and a handful of others who feel resentful.

Many of Adecco’s recommendations come down to building an appreciative culture inside the practice: saying ‘thank you’ often, nurturing self-esteem and recognizing behaviors, not just outcomes.

Little gestures also can go a long way. Hertz says a great example he once saw was a physician who sent a handwritten note to three employees each month, recognizing something special they did. Another possibility is to hold fundraisers for community causes and allow employees to take turns deciding which causes will be supported.

Practice leaders who treat employees as respected members of their team instead of subordinates will find a higher level of motivation. Employees must feel respected and valued, says Hertz.

“None of that costs any money,” he says. “Give them good direction and good training. Treat them like human beings with respect and let them know how they fit in.”

Valuing the opinion of employees can do more than just make them feel good. It can also help empower them to drive positive changes in the practice. They know their jobs better than anyone else, so when the practices is looking for ways to improve efficiencies, those employees will likely have the best ideas.

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Lean Six Sigma: How process maps can improve practice productivity
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ACOs: Multi-year transition requires an overhaul to healthcare delivery

Success hinges on forging new alliances with partners and payers

by SUSAN KREIMER Contributing author

HIGHLIGHTS
01 Prospering as an ACO often hinges on being physician-driven and focused on care transformation.
02 Having access to Medicare data and analytics on healthcare utilization is helpful for physicians wondering how they stack up against their counterparts.

To join or not to join? It’s a question many physicians ask themselves about accountable care organizations (ACOs). Even after coming on board, they may harbor doubts about their decision.

ACOs are a relatively new phenomenon, and data for a complete evaluation of their effectiveness are not yet available. In July 2013, nearly one-third of ACOs in the Pioneer Program—created by the Centers for Medicare & Medicaid Services (CMS)—announced that they were dropping out or recalibrating because providers had accepted too much financial risk.

Several of them transitioned to an ACO under the Medicare Shared Savings Program. Others revamped to focus on commercial ACO products, while some completely re-evaluated their readiness for shared risk models. Medical Economics decided to explore why the ACO model has failed in some cases and succeeded in others.

PURPOSE AND EVALUATION
Designed with the Affordable Care Act (ACA) in mind, the ACO model stresses quality and a continuum of services leading to a healthier population while curbing costs. ACOs create incentives for physicians’ offices, hospitals and long-term care facilities to collaborate in treating a patient across the entire spectrum of settings.

“The Medicare Shared Savings Program will reward ACOs that lower their growth in healthcare costs while meeting performance standards on quality of care and putting patients first,” says Alper Ozinal, a spokesman for CMS.

At the end of each calendar year, CMS assesses the ACO’s quality and financial performance based on a population’s use of services. The results determine whether an ACO should be rewarded for improving care and reducing growth in expenditures compared to a benchmark population.

“This gives the ACO an incentive to improve the quality of care for all patients seen by its participating providers and suppliers,” Ozinal says.

“Studies have shown that better care often costs less, because coordinated care helps to ensure that the patient receives the right care at the right time, with the goal of avoiding unnecessary duplication of services and preventing medical errors.”

Medicare beneficiaries don’t have to
select an ACO for their care; they maintain the right to select any physician, hospital or other provider participating in Medicare. ACO beneficiaries also retain the same right as regular Medicare beneficiaries. However, Medicare Advantage patients relinquish that right and are managed similarly to HMO plan members, who must stay in the network to avoid high fees, prior authorizations or both.

Provider participation in an ACO is voluntary. Some ACOs are led by physicians, others are directed by hospitals, and many more ACOs are hybrids.

“Our physicians were very interested in us developing ACOs,” says Anthony D. Slonim, MD, DrPH, executive vice president and chief medical officer of Barnabas Health in West Orange, New Jersey. “We took the lead of our physicians and responded to their interest. Several were concerned about new payment models and what healthcare reform meant after the ACA was passed,” he adds. “Getting into the game early and learning how to do this work was very important to them. They wanted to make sure that we were advancing those kinds of conversations and relationships.”

In response to this demand, the system launched two ACOs—Barnabas Health ACO-North in July 2012 and Central Jersey ACO in January 2013. Barnabas Health ACO-North, which operates in northern New Jersey, consists of 341 physicians and three hospitals. Central Jersey ACO includes 278 physicians and three of the system’s hospitals in Southern New Jersey, as well as an external hospital partner.

Preliminary results are positive, with Barnabas Health ACO-North demonstrating improvement in 21 out of 23 quality measures set by CMS. Whether or not these changes will lead to cost savings remains to be seen. “We don’t have any concrete financial savings data yet,” says Slonim, who is also chairman of the board of directors at CMR Institute, a Roanoke, Virginia-based provider of non-branded education for pharmaceutical, biotech and medical device industries.

“The ACO movement has created new opportunities for providers and industry” to collaborate in managing patient populations, he says. “Industry brings some really important skills to the conversation. Pharma, for example, knows how to run drug trials over large populations. Device manufacturers are starting to look at their outcomes from both a clinical and econometric perspective.”

ACO CHALLENGES

Acclimating to an ACO model poses major challenges. Provider groups that already were operating efficiently won’t see as much financial benefit as their less-efficient counterparts, says Margaret O’Kane, president of the National Committee for Quality Assurance (NCQA), a Washington-based not-for-profit organization.

“The ability to save money seems to be somewhat related to how much money was
SUCCESSFUL ACOs ARE ENGAGING PATIENTS IN NEW AND INNOVATIVE WAYS WELL BEYOND PHYSICIAN VISITS. IF YOU JUST FOCUS ON ONE DIMENSION AS AN ACO, IT’S VERY HARD TO SUCCEED.”

—JASON DINGER, PHD, CHIEF EXECUTIVE OFFICER, MISSIONPOINT HEALTH PARTNERS, NASHVILLE

being wasted in the first place,” she says. “Ironically, some of the dropouts from the ACO programs are some of the organizations that have the longest track records of success in delivering high-quality care, so it’s kind of disappointing.”

While hesitating to over-generalize, O’Kane describes the care model shift as “a harder journey for a hospital-based ACO than it is for a provider group-based ACO.” Learning to function “180 degrees differently” will require a lot of innovation in a leaner environment, she says.

“The business incentive for a hospital usually is to have heads in beds, and if you’re an ACO, you’re trying to keep people out of the hospital and healthy,” she says. “It could take down the whole organization if your hospital beds are empty, so it’s a complicated transition for a hospital.”

This multi-year transition to an ACO model requires significant overhauls to healthcare delivery, technology systems, operations and governance. Forging alliances with new partners and payers is also critical. Participants in the Medicare Shared Savings Program also are accepting greater responsibility and risk in the effectiveness and quality of care, according to the Brookings Institution, a Washington-based public policy organization.

First-year interim results, released by CMS in late January, were “mixed.” Of the 114 ACOs in the program, 54 saved money but only 29 saved enough to collect bonus payments, according to the Brookings Institution. The savings generated by the 54 ACOs amounted to $126 million, with Medicare reaping $128 million in total trust fund savings.

Although most ACOs manage Medicare patients, MissionPoint Health Partners in Nashville launched an ACO for its own employees of Saint Thomas Health. While insuring 12,000 people, the ACO decreased overall costs of care by more than 12% from 2012 to 2013.

“All parts of the system are incentivized to help a patient get better,” says Jason Dinger, PhD, chief executive officer of MissionPoint. “It takes the whole system to do that.”

MissionPoint also reduced its avoidable admissions rate for Saint Thomas Health’s employee population from 4.5% to 2.23% and its emergency department revisits at Saint Thomas Health facilities within three days from 1.85% to 0.0%.

At the heart of this ACO’s success is a
clinically integrated network of more than 1,600 physicians, seven hospitals and 100 outpatient facilities—from imaging centers to physical therapy offices and nursing homes in central Tennessee.

Addressing unique nonclinical factors also makes a big difference. For instance, schedulers inquire about patients’ access to transportation for office appointments, while nurses conducting home visits monitor chronic diseases and oversee care transitions after hospital discharge, such as confirming the installation of grab bars in the shower as a safety measure.

“Our initial experience has shown that a lot of our savings come from working on real-life needs that patients have,” Dinger says. Results for the Medicare population will be released later this summer. “Successful ACOs are engaging patients in new and innovative ways well beyond physician visits,” he adds. “If you just focus on one dimension as an ACO, it’s very hard to succeed.”

BUILDING A SUCCESSFUL ACO

Prospering as an ACO often hinges on being physician-driven and focused on care transformation.

“It takes a lot of change management and change leadership,” says Aric Sharp, vice president of accountable care at UnityPoint Health Partners in West Des Moines, Iowa. “This change has to happen in the clinical space.”

UnityPoint—an ACO since January 2012 and now providing services in Iowa, Illinois and Wisconsin—relies extensively on physician engagement through committees and boards that conceive various initiatives.

“Among the protocols in development is the management of low back pain,” says David M. Williams, MD, CPE, medical director of the ACO. Costly imaging doesn’t necessarily improve care. “There’s a lot of medical evidence that we have vast overutilization of imaging like MRIs for patients with uncomplicated low-back pain.”

The transformation of care and payment models is a delicate balancing act that needs to occur at a sustainable pace, says Rob Lazerow, practice manager at The Advisory Board Company, a Washington-based global research, technology and consulting firm specializing in healthcare and higher education.

Accountability shouldn’t take precedence over devising a care model that works. If that happens, it’s time to recalibrate. “We’ve seen some organizations that have gone too far too fast with care redesign; others that have gotten in over their heads with financial accountability,” he says.

Incentives are more clear-cut for physicians than hospitals. Rewards are structured as shared savings, capitation or a combination of the two. Providers may be rewarded for reducing avoidable care—for example, preventing hospital admission or readmission for patients with diabetes or heart failure, Lazerow says. But they could also receive incentives for treating patients who need unavoidable care—such as hip and knee replacements—with effective coordination, high quality and efficiency.

Another successful ACO strategy entails classifying patients into risk-based segments and employing different clinical interventions for each group, he says. For high-risk patients, a complex care manager would coordinate services. And for rising-risk patients with chronic conditions, the ACO would engage them through a medical home model to prevent deterioration. In the low-risk category, an online portal would facilitate communication with providers in a less costly and less intrusive way.

In a fee-for-service system that is often “focused on volume over value,” change is welcome, says Timothy Peterson, MD, MBA, executive medical director of the east division at Physician Organization of Michigan ACO and medical director of the Population Health Office at the University of Michigan Health System.

“The ACO model is a nice transition away from that,” he says. “But if we do our job well, it will eventually become impossible to cut costs out of the healthcare delivery system without risking compromising the quality of care provided. I do not think shared savings models are the final step in the evolution of payment reform in the U.S.”

However, having access to Medicare data and analytics on healthcare utilization is helpful for physicians wondering how they stack up against their counterparts. “It’s hard if you only have your own medical records to look at,” Peterson says. “Medicare sharing that complete patient experience of data with us has really been eye-opening.”
As a result of increased competition within the healthcare industry, many providers are considering, or have pursued, marketing activities to bolster their practices. The most common question posed by healthcare providers when contemplating marketing is ensuring compliance with the Health Insurance Portability and Accountability Act (HIPAA).

**HEALTHCARE providers** must ensure that they are not violating HIPAA through the impermissible use or disclosure of a patient’s protected health information (PHI). In addition, healthcare providers need to be aware of other federal and state laws when developing their marketing strategies. HIPAA defines marketing as any oral or written communication about a product or service that encourages the recipient of the communication to purchase or use the product or service. With limited exceptions, the HIPAA Privacy Rule requires that a healthcare provider, as a covered entity, obtain the written authorization of the patient prior to any use or disclosure of the patient’s PHI for marketing purposes.

**HIPAA exceptions**
The two stated exceptions to the HIPAA Privacy Rule are:
- face-to-face communication between the personnel of the healthcare provider and the patient, and
- promotional gifts to the patient of nominal value (e.g., pens, toothbrushes, key chains, coffee mugs with the healthcare provider’s name on it).

Absent an exception, the healthcare provider would need to obtain the written authorization of the patient. What information must be included in the written authorization? The HIPAA Privacy Rule details a list of core elements and required statements that need to be included in the written authorization for it to be effective.

**Paying patients for marketing**
There is a key additional requirement in connection with marketing practices. If the marketing involves financial remuneration (i.e., direct or indirect payment from or on behalf of a third party whose product or service is being described) to the healthcare provider from a third party, the authorization must state that such remuneration is involved.

**Other laws, regulations**
Obtaining a HIPAA-compliant authorization is merely the first step. The healthcare provider must also ensure that any marketing activities are in accordance with all federal and state statutes and regulations.

**Patient testimonials**
Because there has been an exponential increase in the utilization of patient testimonials as a marketing tool, it is worth spending a moment to discuss the Federal Trade Commission Act (FTCA).

The FTCA aims to prevent unfair competition methods and unfair or deceptive acts that may affect business commerce.

In 2009, the Federal Trade Commission (FTC) released “Guides Concerning the Use of Testimonials and Endorsements” to provide direction to advertisers, including healthcare providers, on how to ensure that testimonial and endorsement advertisements are in accordance with the FTCA. The 2009 release of the Guides was the first re-interpretation of the testimonial and endorsement regulations in nearly 30 years, as the FTC had not updated the guide since 1980.

The guidelines define an endorsement (which
HIPAA PATIENT AUTHORIZATIONS

10 items you must include

Generally, HIPAA authorizations must include the following:

1. A specific description of the information to be used or disclosed
2. The name of the individual or organization who is authorized to make the requested use or disclosure of protected health information.
3. The name of the individual or organization to whom the PHI may be disclosed
4. A description of each purpose of the requested use or disclosure
5. An expiration date or expiration event that relates to the individual or the purpose of the use or disclosure
6. The signature of the individual or his or her authorized representative (if an authorized representative he or she must disclose his or her authority to act on behalf of the individual)
7. The date the authorization was signed
8. A statement that the individual who signed the authorization has the right to revoke it in writing and either: (a) the exceptions to the right to revoke and description of how the individual may revoke the authorization, or (b) a reference to the healthcare provider’s notice of privacy practices, to the extent that the right to revoke the authorization is provided for in same
9. A statement concerning the ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the authorization
10. A statement that once disclosed to others, the information may be re-disclosed to individuals or organizations not subject to HIPAA and may no longer be protected by HIPAA.

Conclusions

The use of marketing by healthcare providers will continue to grow and evolve.

It is essential that providers develop and implement a marketing strategy that is compliant with HIPAA, the FTC, and all other federal and state laws.

Matthew Colongeli, JD, is an associate at Garfunkel Wild, PC, in Great Neck, New York. Send your legal questions to medec@advanstar.com.

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3 OPPORTUNITIES TO GROW YOUR PRACTICE

by PHIL DALTON Contributing author

The introduction of the Affordable Care Act coupled with a host of assorted marketplace dynamics is causing physicians to think anew regarding how to build a practice that is not only sustainable in the near term but will maximize its growth potential over time.

PHYSICIANS NEED to position themselves in a population health management marketplace where strategic affiliations, the ability to differentiate, and a value-driven (rather than volume-driven) philosophy comprise a winning formula. The reality is that healthcare dollars are going to keep diminishing. Only through a smart growth strategy and careful planning can physicians succeed in a marketplace that is increasingly challenging, complex, and confusing. Here are three opportunities for growth physicians can’t overlook.

1. Get bigger

One look at the medical marketplace makes it clear that unmistakable trends are occurring relative to size. Independent Physicians Associations (IPAs) are acquiring other IPAs, and large groups are getting larger and stronger. But beyond simply banding together, there are new dynamics taking place relative to physician-hospital relationships.

First, many physicians are joining hospital-owned practices. Physicians find such arrangements attractive because they can provide stability, guaranteed income, and a more balanced lifestyle.

Second, physician networks are partnering with local hospitals and attempting to control the healthcare dollar by limiting or eliminating the insurance company and taking on the risk of managing the care of a defined population.

Physicians participating in such an arrangement are willing to put their compensation at risk in a true pay-for-performance model based on quality, customer satisfaction, and other measurable metrics. Physicians need to consider if they are ready for the benefits or potential drawbacks that such bold arrangements might bring.

2. Embrace technology

The smart use of technology increases productivity, improves cash flow, and provides office efficiencies that can enhance a practice’s growth potential.

Concerns regarding cost, complexity, and customization still stand in the way. They shouldn’t. Affordable systems are available even to the solo practice that take the hassle out of automation. It is time for physicians to embrace electronic health records, welcome clinical messaging, use a web-based clearinghouse, and interact online with patients.

3. Begin marketing

While there are many tools in a marketing tool box, two are particularly worth noting.

The first is traditional public relations, which combines high credibility with a relatively low cost. Resources put into public relations—such as using the local media to tell your story, speaking at appropriate community events, or leveraging hospital relationships—can help build your brand, raise your visibility, and position your practice favorably.

Developing an online strategy that allows you to push messages directly to your patients through a website, social media, and other platforms, is the second. It’s about inviting two-way communication that allows patients to communicate with you through whichever medium they feel most comfortable. It’s all about the patient experience, which means interactions before, during and after an office visit.

Phil Dalton is president and chief executive officer of MDS Consulting, in Torrance and Costa Mesa, California. Send your practice management questions to medec@advanstar.com.
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ICD-10-CM READINESS
An overview of the steps for documenting hernia cases

by LORI BECKS, RHIA, AHIMA certified ICD-10-CM/PCS trainer

Editor’s note
In a unique collaboration, Contexo Media and Medical Economics have teamed up to deliver this 10-part series on one of the most important management challenges facing physician practices in the coming years.

For more information about Contexo’s ICD-10 training materials go to: www.contexomedia.com.

Reporting hernias in ICD-10-CM has many similarities to ICD-9-CM coding and thus will be familiar to coders and physicians when using the new system.

There are, however, a few differences in the way the codes are organized within the new classification system. This article provides a brief overview and explanation of how the hernia codes are structured in the International Classification of Diseases-10th Revision-Clinical Management (ICD-10-CM).

CODING SIMILARITIES
In both ICD-10-CM and ICD-9-CM, the subsections in the digestive system chapters that contain hernia codes include both acquired and congenital forms, with the exception of diaphragmatic or hiatal congenital hernias. These types of congenital hernias are reported with codes from the chapter for conditions originating in the perinatal period.

In ICD-10-CM, these codes include Q40.1 Congenital hiatus hernia and Q79.0 Congenital diaphragmatic hernia.

All other hernia codes for the digestive system are found in the K40-K46 subsection, which includes a note stating that hernias presenting with both gangrene and obstruction are classified as hernia with gangrene, as is the same for reporting inguinal and other hernias of the abdominal cavity in ICD-9-CM.

Another similarity is the axis of coding for hernias, which are reported by type (e.g., inguinal, femoral, ventral, etc.), presentation (e.g., with or without gangrene and/or obstruction), laterality (unilateral or bilateral), and status (recurrent or not specified as recurrent).

CODING DIFFERENCES
The organization of hernia codes following these specific axes for coding is somewhat different in ICD-10-CM.

The ICD-9-CM system reports each different type of hernia, with the exception of inguinal, all together under three categories that are first defined as other hernia of the abdominal cavity, either ‘with gangrene’ (category 551), or ‘with obstruction, but without...
mention of gangrene’ (category 552), and ‘without mention of obstruction or gangrene’ (category 553). The type of hernia, whether femoral, umbilical, ventral, or diaphragmatic, is then listed as a subcategory under these three categories, which are further subdivided by the other axes of laterality or recurrent status as appropriate.

Only inguinal hernias are organized first by type under category 550, then subclassified by presentation with or without gangrene or obstruction. Fifth digits are assigned for the other axes of laterality or recurrent status.

In ICD-10-CM, all hernia codes are organized first into categories by type:

K40: Inguinal hernia
K41: Femoral hernia
K42: Umbilical hernia
K43: Ventral hernia
K44: Diaphragmatic hernia
K45: Other abdominal hernia
K46: Unspecified abdominal hernia

The category for the type of hernia is then further subdivided based on laterality and/or presentation.

Below are some examples for inguinal hernia subcategories:

- K40.0 Bilateral inguinal hernia, with obstruction, without gangrene
- K40.1 Bilateral inguinal hernia, with gangrene
- K40.2 Bilateral inguinal hernia, without obstruction or gangrene
- K40.3 Unilateral inguinal hernia, with obstruction, without gangrene
- K40.4 Unilateral inguinal hernia, with gangrene
- K40.9 Unilateral inguinal hernia, without obstruction or gangrene

Both the inguinal and femoral hernia categories (K40 and K41) are subdivided in this manner to the next level by laterality and presentation.

For these two types of hernia, a further

ICD-9-CM | ICD-10-CM
--- | ---
550.00: Inguinal hernia, with gangrene, unilateral or unspecified, not specified as recurrent | K40.40: Unilateral inguinal hernia, with gangrene, not specified as recurrent
550.01: Inguinal hernia, with gangrene, unilateral or unspecified, recurrent | K40.41: Unilateral inguinal hernia, with gangrene, recurrent
550.02: Inguinal hernia, with gangrene, bilateral, not specified as recurrent | K40.10: Bilateral inguinal hernia, with gangrene, not specified as recurrent
550.03: Inguinal hernia, with gangrene, bilateral, recurrent | K40.11: Bilateral inguinal hernia, with gangrene, recurrent
550.10: Inguinal hernia, with obstruction, without mention of gangrene, unilateral or unspecified, not specified as recurrent | K40.30: Unilateral inguinal hernia, with obstruction, without gangrene, not specified as recurrent
550.11: Inguinal hernia, with obstruction, without mention of gangrene, unilateral or unspecified, recurrent | K40.31: Unilateral inguinal hernia, with obstruction, without gangrene, recurrent
550.12: Inguinal hernia, with obstruction, without mention of gangrene, bilateral, not specified as recurrent | K40.00: Bilateral inguinal hernia, with obstruction, without gangrene, not specified as recurrent
550.13: Inguinal hernia, with obstruction, without mention of gangrene, bilateral, recurrent | K40.01: Bilateral inguinal hernia, with obstruction, without gangrene, recurrent
550.90: Inguinal hernia, without mention of obstruction or gangrene, unilateral or unspecified, not specified as recurrent | K40.90: Unilateral inguinal hernia, without obstruction or gangrene, not specified as recurrent
550.91: Inguinal hernia, without mention of obstruction or gangrene, unilateral or unspecified, recurrent | K40.91: Unilateral inguinal hernia, without obstruction or gangrene, recurrent
550.92: Inguinal hernia, without mention of obstruction or gangrene, bilateral, not specified as recurrent | K40.20: Bilateral inguinal hernia, without obstruction or gangrene, not specified as recurrent
550.93: Inguinal hernia, without mention of obstruction or gangrene, bilateral, recurrent | K40.21: Bilateral inguinal hernia, without obstruction or gangrene, recurrent

Source: Contexo Media
ICD-10-CM documentation and coding requirements

Hernias

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**STEP 1** Identify inguinal hernia as unilateral/bilateral

**STEP 2** Identify presence/absence of complications
- Gangrene (with obstruction)
- Obstruction
- Without mention of obstruction or gangrene

**STEP 3** Identify as recurrent or not recurrent

---

Subclassification then provides the status as recurrent or not specified as recurrent:

- K40.30 Unilateral inguinal hernia, with obstruction, without gangrene, not specified as recurrent
- K40.31 Unilateral inguinal hernia, with obstruction, without gangrene, recurrent

All other types of hernias—umbilical, ventral, diaphragmatic, other, and unspecified abdominal hernias—are subdivided to the next level based on their presentation alone. No laterality is necessary. These are specified as with obstruction but without gangrene; with gangrene; or without obstruction or gangrene.

In the case of ventral hernias, the subcategories specify the particular type of ventral hernia as incisional, parastomal, or other and unspecified ventral hernia with the identified presentation.

For example:

- K43.0 Incisional hernia with obstruction, without gangrene
- K43.5 Parastomal hernia without obstruction or gangrene
- K43.6 Other and unspecified ventral hernia with gangrene

Epigastric, hypogastric, midline, spigelian, and subxiphoid hernias are all included under other and unspecified ventral hernias.

Acquired hiatal, esophageal, sliding, and paraesophageal hernias are included under diaphragmatic hernia, category K44, remembering that congenital diaphragmatic hernias are reported with Q79.0 and congenital hiatal hernias are coded to Q40.1 in the chapter for conditions arising in the perinatal period.

**NO ADDITIONAL CODES NEEDED**

As a last point for discussing coding hernias in ICD-10-CM, it is important to note that there are no additional digits to be added to hernia codes in ICD-10-CM in order to complete the code description. All possible code combinations are provided in a complete code description for each code.

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MORE ONLINE

Ischemic heart disease:
ICD-10-CM documentation steps
http://bit.ly/1sAjt7F

ICD-10 training:
Detailing patient encounters
http://bit.ly/1rhwAJP

ICD-10 delay will cost practices more money
The meaningful use 2 challenge

Recent changes allowing more flexibility for physicians to attest highlight the difficulty of the stage 2 requirements

by ANDREA DOWNING PECK Contributing author

Is meaningful use Stage 2 (MU2) obtainable for most small-practice physicians? Perhaps not, as evidenced by the government’s decision to delay implementing MU2 and allow providers to attest using 2011-certified software. As 2014 moves beyond the halfway point, the answer may hinge on what your practice does to prepare for attestation and the relationship you have with your electronic health record (EHR) vendor.

FOR ELIGIBLE PROVIDERS who have participated in the Medicaid or Medicare EHR Incentive program since 2011 or 2012, Stage 2 ups the ante by focusing on using the EHR for advanced clinical measures including health information exchange (HIE), additional requirements for e-prescribing and incorporating lab results, electronic transmission of patient care summaries and increased patient engagement.

“Many of these changes are going to raise the bar a bit higher,” says Greg Chittim, senior director of Boston-based Arcardia Healthcare Solutions, because Stage 2 requires providers to begin using EHRs “in a way that actually affects patient care and the cost of delivering care.”

While Stage 1 prompted a transition from paper charts to EHRs, Stage 2 begins to take advantage of EHRs’ promise of improved patient care by increasing HIE between providers and promoting patient engagement.

HIGHLIGHTS

01 Physicians now can use either 2011- or 2014-certified EHR software to attest in 2014, depending on if they are in stage 1 or stage 2.

02 Achieving stage 2 attestation requires staff cooperation and help from your EHR vendor.
Meaningful use 2

by giving patients secure online access to their health information.

“In stage 1, everything was really in the hands of providers and in the hands of the technology,” Chittim says. “Stage 2 is about not only using the technology correctly, but also leveraging that technology effectively and using it to drive better outcomes.”

MU2 CHALLENGES VENDORS, PROVIDERS

Although the Centers for Medicare and Medicaid Services (CMS) delayed the start of MU2 attestation for a year, 2014 is proving to be a challenging deadline for many EHR vendors and their clients.

Medicare-eligible providers attesting for MU2 now must report on a total of 20 objectives—17 core objectives and three of six menu-set objectives—as well as nine of 64 approved clinical quality measures (CQMs), during a fixed quarter of the calendar year.

Early results show that MU2 attestation is off to a tepid start. As of May 1, CMS reported that only 50 eligible professionals and four hospitals had attested for Stage 2 in the 2014 reporting year.

Michael Zaroukian, MD, PhD, FACP, vice president and chief medical information officer for Sparrow Health System, says some practices are struggling due to their vendors’ inability to provide a certified product in a timely manner, while other physicians may not have anticipated the impact that Stage 2 would have on workflow.

While there were no “big surprises” in Stage 2, Zaroukian says, “perhaps some of the vendor challenges in getting their software ready to meet the requirements and the increased emphasis on information exchange is more than practices or vendors were expecting.”

Zaroukian, who works in two practices that use different EHR vendors, says his own experience has been mixed, with one practice experiencing a “comparatively smooth path” toward attestation while the other is being challenged by a vendor slow to upgrade its EHR.

Until earlier this month, all practices were required to use a 2014-edition certified EHR to qualify for incentive payments no matter if they are in MU1 or MU2, but that vendor certification was a roadblock for many practices. As of May, about 115 vendors representing 220 products had received full 2014 ambulatory certification. That contrasts with the 1,932 complete products certified for 2011.

If a vendor promises to be certified by a specific date, Rosemarie Nelson, a medical practice consultant with MGMA Healthcare Consulting Group, recommends asking for a “letter of agreement” from the vendor to cover a practice’s loss of incentive money or penalty in a subsequent year because of an inability to attest in 2014.

Mark Anderson, chief executive officer of AC Group consultants in Montgomery, Texas, points out that CQM selection can derail providers because few EHRs are certified for all 64 CQMs.

“You need to look at the CQMs and say, ‘These are the ones that make sense to me,’ and then see if your software vendor can actually report on those,” he says. “Most vendors only do 10 or 15 of them.”
Establishing a point person in the practice to monitor vendor progress in providing functionality is essential.

“You have to be proactive and diligent and never assume the vendor is going to take care of it for you even when they say they will,” Nelson says. “If you are waiting on somebody else to do something, then you need to monitor that more than you would a fever of 102 with your child.”

The federal government did throw providers a lifeline earlier this year when it created a hardship exception to avoid the upcoming Medicare payment adjustment for the 2013 reporting year. The exception, however, is not automatic. (Payment adjustments for the program will begin on January 1, 2015, for eligible professionals.)

Mary Giskewicz, MS, FHIMSS, senior director of health information systems for the Healthcare Information and Management Systems Society, recommends filing your application early if you have a “documented reason” from your vendor showing you are unable to successfully demonstrate MU due to circumstances beyond your control.

Ultimately, the rocky EHR landscape may mean some doctors will have no alternative but to switch vendors because the product they installed cannot keep pace with the MU timeline and requirements.

“It’s a difficult choice to make, but you have to look at the dollars and cents,” says Rachelle Blake, PA, MHA, founder and chief executive officer of Omni Micro and Omni Med Solutions in San Francisco. "Does it make sense to change a more expensive, more comprehensive EMR, or should you continue throwing money into a vendor you’re having to pay for each little change or where you have to go through 10 interfaces to meaningfully use the system?"

Not all vendors have struggled equally to provide doctors with a 2014 certified product. Todd Rothenhaus, MD, chief medical officer for athenahealth, which was able to obtain 2014 certification for its cloud-based athenaClinicals EHR last year, says successful attestation requires a “we do-you do” relationship between vendor and client.

Rothenhaus says two MU2 core measures—having patients view, download and transmit their health information and use secure electronic messaging to communicate clinically with the practice—are among the biggest difficulties for providers in the early going. In response, the company recently added functionalities to athenaCommunicator, its patient communication service, that encourage patients to “view, download and transmit” their personal health information as well as to respond to secure post-visit email messages from their provider.

Rothenhaus is proud of athenahealth’s MU track record of 95.4% of participating physicians attesting successfully in 2013, but he acknowledges that Stage 2’s more challenging measures mean the "we-do" is not done.

“We’ve got a lot more work to do this year than we thought,” he says.

MU2 SUCCESS STRATEGIES
Carol Choi, DO, physician consultant, NextGen Healthcare, suggests providers follow these best practices:

- Start as early as possible preparing for Stage 2
- Educate yourself on all Stage 2 requirements
- Make sure you have all the necessary interfaces and infrastructure installed to meet Stage 2 measures such as patient engagement, clinical information exchange and immunization registry reporting.
- Early on identify necessary clinical and administrative workflow changes
- Run reports regularly to monitor performance.

“You need your entire staff to collaborate and cooperate in terms of achieving MU Stage 2 requirements,” Choi says. "It’s not simply a provider meeting some measures and reporting on it. It does have to be somewhat of a group effort.”

When workflow or other EHR issues crop up, MGMA’s Nelson says the vendor should be the first place a practice calls.

“The vendor knows where you have erred. They know where the opportunities are,” Nelson says. "Most vendors want to retain their clients. They are going to find ways to try to help.”

Establishing a solid staff-training program, a must at the onset of EHR implementation, remains a baseline for success during Stage 2. Supplemental training can take many forms, from vendor-supplied white papers, checklists and online modules to in-person assistance from vendors or consultants.

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—ROSEMARIE NELSON, MEDICAL PRACTICE CONSULTANT, MGMA HEALTHCARE CONSULTING GROUP

relatively new to EHRs,” Chittim says. “If you implemented an EHR with Stage 1 MU, there may be pieces of functionality you have never used before.”

Griskewicz also recommends participating in vendor user groups and connecting with other practices using the same EHR, steps that can alert providers to issues they may encounter.

Griskewicz maintains that doctors who experience the fewest difficulties understand that participating in MU means not simply mastering a new technology but “re-engineering their practice” with the goal of improving quality outcomes for patients.

Chittim goes one step further, arguing providers who “connect their objectives for MU” to a bigger goal, such as becoming a patient-centered medical home or participating in a pay-for-performance payment model, are the biggest winners.

“Physicians are in this business because they want to do good,” Chittim says. “Using MU as a stepping stone to doing something great is really effective.”

Jennifer Brull, MD, a family medicine physician in Plainville, Kansas, is confident her practice will successfully attest for Stage 2, mostly because her staff began preparing for the new standards months before her EHR vendor released its certified Stage 2 software. While a practice cannot dictate its vendor’s certification timeline, Brull says it can “make a plan for everything within their control.”

A solo practitioner who collaborates with nine other providers using eMDs’ EHR, Brull established a project team that planned for Stage 2 implementation and educated staff about the new requirements and higher thresholds for objectives such as patients’ online access to their health information.

“you may not know the exact workflow that is going to be different but you know—it’s clearly published—what the goals and objectives are,” she explains. “you can pull your staff in as part of a team and make sure they understand the changes. If you are barely meeting a threshold now, then chances are that is an area that needs work” in order to meet Stage 2 requirements.

Brull, who plans to attest in the third quarter, says her practice’s biggest challenge has been persuading patients to use the portal.

“You mean you don’t want to interact that way,” she says. “I don’t understand it. I love the portal. [As of March] when I ran my reports, I am at 38%, and I need 50%. That’s the one piece I’m worried about.”

Peter Basch, MD, medical director for Medstar Health’s ambulatory EHR and health IT policy, believes doctors can entice patients to use portals and secure online communication by educating them on the technology’s benefits, as they did when meeting the Stage 1 goal for e-prescribing.

Basch’s approach is to “make lemonade out of lemons” by developing strategies that make Stage 2 requirements a win-win for both doctor and patients. For example, doctors can boost their numbers for clinically relevant messaging by emailing pre-visit screening questionnaires and risk assessments to patients, who then submit their answers electronically.

“Think of it as a two-for, an experience where you are leveraging the MU requirement to shift the unpleasant work of a visit to what you should be doing, which is have the patient, where possible, enter his or her clinical information,” he says.

ROCKY ROAD AHEAD
Despite his optimism that MU is moving medicine in the right direction, Basch is not optimistic regarding Stage 2 attestations. He cites the medication reconciliation requirement, in which doctors must declare visits a “transition of care” to be counted, and the patient-specific-educational-materials measure, which uses a denominator based on a fixed percentage of patients, as potential problems for providers.

“I think there is going to be a higher failure rate for Stage 2 because there are more opportunities to trip up,” he says. “People will fail because they did in their minds what they thought was the right thing, but they didn’t understand how their vendor was mapping something.”

Providers also need to be prepared for MU audits, which can occur for up to six years after attestation. “Once you are audited, you potentially can be audited again because it’s truly random,” Griskewicz says. “Do not throw out your documentation even if you are audited once.”

Blake, meanwhile, says doctors need to make their voices heard as Stage 3 approaches. “Providers and practices need to speak up about where they’re having challenges and meeting roadblocks,” she says.
EHR DOCUMENTATION: AVOID NOTE CLONING AND UP-CODING

We are using an electronic health record (EHR) system for our clinical documentation. Are we putting our providers at risk because there are so many ways to misuse it?

A: If you’ve ever been involved in the sales pitch or training for an electronic health record (EHR), you know that they focus on ways the system can cut down on the time a practitioner needs to document the patient record.

These include short cuts such as templates and sets of information that can be inserted at the touch of a button, copying information verbatim from your own note or another provider’s note, and pulling an entire note into your patient visit. While these are great time-savers, they might cost you in the long run if they are misused.

According to the Centers for Medicare and Medicaid Services (CMS), the cost of healthcare fraud is estimated to be between $75 billion and $250 billion. Additionally, experts in health information technology caution that EHR technology can make it easier to commit fraud. The Office of Inspector General has listened to these experts and made EHR cloning and over-documentation a top priority in 2014.

Here’s more detail regarding these two areas:

Copy-and-paste

Copy-and-pasting, also known as cloning, allows a user to select information from one source and paste it to another location. When clinical staff members (i.e., physicians, non-physician practitioners, nurses and other clinicians) clone information but fail to update it or ensure its accuracy, inaccurate information may be placed in the patient’s medical record and inappropriate charges may be billed to payers and/or patients.

Also, inappropriate cloning could facilitate attempts to increase the information and create fraudulent claims.

Up-coding

This is the practice of inserting false or irrelevant documentation to create the appearance of supporting a higher level of service. Some EHRs auto-populate fields when using templates built into the system. Other systems generate extensive documentation on the basis of a single click of a checkbox, that, if not appropriately edited by the physician, may be inaccurate.

This can produce information suggesting that the practitioner performed more comprehensive services than were actually billed.

Use caution

While it is easy to get caught up in using these shortcut features, be careful when doing so.

If you use them, be sure to review and update the information to reflect the any changes in the patient’s history or condition—and your work—specific to that day’s visit. EHRs have an audit trail that shows what and when you and your clinical staff have touched the patient record.

Avoiding EHR note ‘cloning’ while maintaining efficiency

Use your EHR system to boost practice revenue

The answer to the reader’s question was provided by Renee Dowling, a billing and coding consultant with VSI Consulting Services in Indianapolis, Indiana. Send your coding and billing questions to medec@advanstar.com.
5 tips to improve your practice’s financial management

From insurance eligibility checks to sound collection strategies, medical practices must build processes for dealing with patients’ financial issues.

Growing financial pressure on patients in the post-healthcare reform world means physicians need to be prepared to deal with payment issues to protect the financial health of their practices.

The keys: Be up front and pro-active.

The fastest-growing type of health insurance is the high-deductible health plan. According to America’s Health Insurance Plans, enrollment in these plans grew by roughly 15% from 2011 to 2012, and again from 2012 to 2013, so that nearly 15.5 million Americans were covered by this type of plan as of January, 2013.

In addition, millions of Americans have entered the insurance market for the first time under the Affordable Care Act (ACA), and many of the new health plans come with high out-of-pocket costs. According to Laura Palmer, senior industry analyst with the Medical Group Medical Association (MGMA), the growth of high-deductible health plans, combined with the economic downturn has made collecting fees from patients a growing challenge for medical practices.

“We’re seeing universally increased out-of-pocket expenses from the patient side. Deductibles are definitely going up, copays and premiums are going up, so there is a lot more awareness [by patients] of what things cost and the patient responsibility,” says Palmer. The medical community is being proactive in engaging patients on these financial matters. Health insurance eligibility checks should be conducted before every appointment.
Financial management

As high-deductible health plans have been rising over the past few years, practices need to really do a good job collecting up-front when they can.”

—Margo Williams, Senior Associate, American College of Physicians Center for Practice Support.

A recent Robert Wood Johnson Foundation analysis of health plans sold in the ACA exchanges, the average annual deductible for a silver-level health plan is $2,267.

Out-of-pocket medical costs are even higher for those who purchased ACA-compliant insurance policies directly from insurers or through brokers. For example, eHealth, one of the largest private health insurance exchanges, found that individuals buying coverage from October, 2013 through March 2014 had an average annual deductible of $4,164. For family plans the average deductible was $7,771.

As patients face higher out-of-pocket costs, physician practices see an impact on their cash flow. An MGMA survey found that multispecialty practices saw their bad debt go up by 14% between 2008 and 2012.

As costs rise, physicians need to adjust or refine their approach to billing strategies.

“As high deductible health plans have been rising over the past few years, practices need to really do a good job collecting up-front when they can,” says Margo Williams, senior associate with the American College of Physicians’ Center for Practice Support.

Here are some steps to help increase fee collections from patients:

1/ Set clear financial policies

Setting clear policies that everyone in your practice understands and knows how to enforce is critical, experts say.

That starts with checking a patient’s insurance eligibility before every appointment. “A lot of offices had a policy to check once a quarter or once a year but that’s long gone,” Palmer says. “Just because someone has a card doesn’t mean they have the benefits. You have to be a lot more conscious and do this on the front end.”

In addition, Williams says, patients should be reminded at the time they schedule appointments to bring a form of payment with them, and that they will be expected to pay their portion of the visit when they come for their appointment.

“We keep tabs on patients and try to collect copays before they are seen because they manage to sneak out at the end of the visit,” says Rebecca Jaffe, MD, FAAFP, a family physician in Wilmington, Delaware and a board member of the American Academy of Family Physicians.

Make sure that all of your policies are communicated clearly and in advance so that patients aren’t caught off guard. That includes making sure any forms patients sign contain notices about extra costs applied if accounts must be sent to collections, or if interest on outstanding balances will be charged.

2/ Educate your patients

Patients tend to have a poor understanding of their insurance policies, which can lead to surprise charges they’re sometimes unable to pay.

“A lot of patients don’t know their policy or what’s required of them and sometimes the practice has to educate them,” Williams says. “It behooves the practices to figure out what the rules are and help the patients understand.”

3/ Make it easy to pay

Offer as many payment options as possible. Equip your practice so that fees can be accepted by any method the patient has access to—credit or debit card, cash, or check. “Make it as easy as possible,” Williams says.

Maria K. Todd, PhD, chief executive

MedicalEconomics.com
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Johnny’s mom struggles with overall MDD symptoms...in the emptiness of her depression.

Symptoms were evaluated based on MADRS or HAM-D$_{24}$ total scores at 6 or 8 weeks.
INDICATION

BRINTELLIX is indicated for the treatment of major depressive disorder (MDD) in adults.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a trend toward reduced risk with antidepressant use in patients aged 65 and older.

In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.

BRINTELLIX has not been evaluated for use in pediatric patients.

CONTRAINDICATIONS

Hypersensitivity: Hypersensitivity to vortioxetine or any components of the BRINTELLIX formulation. Angioedema has been reported in patients treated with BRINTELLIX.

Monoamine Oxidase Inhibitors (MAOIs): Due to an increased risk of serotonin syndrome, do not use MAOIs intended to treat psychiatric disorders with BRINTELLIX or within 21 days of stopping treatment with BRINTELLIX. Do not use BRINTELLIX within 14 days of stopping an MAOI intended to treat psychiatric disorders. Do not start BRINTELLIX in a patient who is being treated with linezolid or intravenous methylene blue.

WARNINGS AND PRECAUTIONS

Clinical Worsening and Suicide Risk: All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality (anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia, hypomania, and mania), especially if these symptoms are severe, abrupt in onset, or were not part of the patient’s presenting symptoms. Families and caregivers of patients being treated with antidepressants for MDD or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients daily.

Serotonin Syndrome: The development of a potentially life-threatening serotonin syndrome has been reported with serotonergic antidepressants (SNRIs, SSRIs, and others), including BRINTELLIX, when used alone but more often when used concomitantly with

Efficacy Demonstrated in Multiple Clinical Studies

SHORT-TERM EFFICACY

- Six 6- to 8-week randomized, double-blind, placebo-controlled studies in MDD patients aged 18 to 88 years (including 1 study in the elderly)
- Improvement in overall depressive symptoms determined by mean change from baseline to endpoint of 6 or 8 weeks of MADRS or HAM-D$_{24}$ total scores

LONG-TERM EFFECTIVENESS

- Time to recurrence of depressive episodes evaluated in 1 long-term (24- to 64-week) placebo-controlled maintenance study in patients in remission following treatment with open-label BRINTELLIX (5 mg or 10 mg) for 12 weeks

BRINTELLIX was evaluated for safety in more than 4,700 MDD patients.

In clinical studies, the most common adverse reactions (incidence ≥5% and at least twice the rate of placebo in 6- to 8-week trials) were nausea, constipation, and vomiting.

INDICATION

BRINTELLIX is indicated for the treatment of major depressive disorder (MDD) in adults.

Efficacy Demonstrated in Multiple Clinical Studies

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INDICATION

BRINTELLIX is indicated for the treatment of major depressive disorder (MDD) in adults.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a trend toward reduced risk with antidepressant use in patients aged 65 and older.

In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber.

BRINTELLIX has not been evaluated for use in pediatric patients.

CONTRAINDICATIONS

Hypersensitivity: Hypersensitivity to vortioxetine or any components of the BRINTELLIX formulation. Angioedema has been reported in patients treated with BRINTELLIX.

Monoamine Oxidase Inhibitors (MAOIs): Due to an increased risk of serotonin syndrome, do not use MAOIs intended to treat psychiatric disorders with BRINTELLIX or within 21 days of stopping treatment with BRINTELLIX. Do not use BRINTELLIX within 14 days of stopping an MAOI intended to treat psychiatric disorders. Do not start BRINTELLIX in a patient who is being treated with linezolid or intravenous methylene blue.

WARNINGS AND PRECAUTIONS

Clinical Worsening and Suicide Risk: All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases. Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is persistently worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality (anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia, hypomania, and mania), especially if these symptoms are severe, abrupt in onset, or were not part of the patient’s presenting symptoms. Families and caregivers of patients being treated with antidepressants for MDD or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients daily.

Serotonin Syndrome: The development of a potentially life-threatening serotonin syndrome has been reported with serotonergic antidepressants (SNRIs, SSRIs, and others), including BRINTELLIX, when used alone but more often when used concomitantly with
BRINTELLIX Multiple Pharmacologic Activities

MECHANISM OF ACTION

The mechanism of the antidepressant effect of vortioxetine is not fully understood, but is thought to be related to its enhancement of serotonergic activity in the CNS through inhibition of the reuptake of serotonin (5-HT). It also has several other activities including 5-HT₁₅ receptor antagonism and 5-HT₁₆ receptor agonism. The contribution of these activities to vortioxetine’s antidepressant effect has not been established.

PHARMACODYNAMICS

In vitro studies also indicate that vortioxetine is a 5-HT₁₀ and 5-HT₃ receptor antagonist, and a 5-HT₁₅ receptor partial agonist. The clinical relevance of this is unknown.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John’s Wort), and with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue). Serotonin syndrome symptoms may include mental status changes (eg, agitation, hallucinations, delirium, and coma), autonomic instability (eg, tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (eg, tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and/or gastrointestinal symptoms (eg, nausea, vomiting, diarrhea). If such symptoms occur, discontinue BRINTELLIX and any concomitant serotonergic agents, and initiate supportive symptomatic treatment. If concomitant use of BRINTELLIX is clinically warranted, patients should be made aware of and monitored for potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases.

Abnormal Bleeding: Treatment with serotonergic antidepressants (SSRIs, SNRIs, and others) may increase the risk of abnormal bleeding. Patients should be cautioned about the increased risk of bleeding when BRINTELLIX is coadministered with NSAIDs, aspirin, or other drugs that affect coagulation.

Activation of Mania/Hypomania: Activation of mania/hypomania can occur with antidepressant treatment. Prior to initiating treatment with an antidepressant, screen patients for bipolar disorder. As with all antidepressants, use BRINTELLIX cautiously in patients with a history or family history of bipolar disorder, mania, or hypomania.

Hyponatremia: Hyponatremia has occurred as a result of serotonergic drugs and in many cases, appears to be the result of the syndrome of inappropriate antidiuretic hormone secretion (SIADH). Elderly patients and patients taking diuretics or who are otherwise volume-depleted can be at greater risk. More severe or acute cases have included hallucination, syncope, seizure, coma, respiratory arrest, and death. Discontinue BRINTELLIX in patients with symptomatic hyponatremia and initiate appropriate medical intervention.

Adverse Reactions: The most commonly observed adverse reactions for BRINTELLIX in 6- to 8-week placebo-controlled studies (incidence ≥5% and at least twice the rate of placebo) were by dose (5 mg, 10 mg, 15 mg, 20 mg) vs placebo: nausea (21%, 26%, 32%, 32% vs 9%), constipation (3%, 5%, 6%, 6% vs 3%), and vomiting (3%, 5%, 6%, 6% vs 1%).

Drug Interactions: Concomitant administration of BRINTELLIX and strong CYP2D6 inhibitors or strong CYP inducers may require a dose adjustment of BRINTELLIX.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.
BRINTELLIX (vortioxetine)
for the Treatment of Overall MDD Symptoms¹

- Efficacy established on overall MDD symptoms as measured by mean change from baseline to endpoint of 6 or 8 weeks on MADRS or HAM-D₂₄ total score
- More than 2,700 MDD patients aged 18 to 88 years were evaluated in 7 randomized, double-blind, placebo-controlled studies (5 to 20 mg/day)
  - The most common adverse reactions (incidence ≥5% and at least twice the rate of placebo in 6- to 8-week studies) were nausea, constipation, and vomiting

BRINTELLIX DOSING AND ADMINISTRATION¹

- Recommended starting dose is 10 mg once daily without regard to meals
- BRINTELLIX should then be increased to 20 mg once daily as tolerated; higher doses demonstrated better treatment effects in US trials
- For patients unable to tolerate higher doses, 5 mg/day may be considered
- BRINTELLIX can be discontinued abruptly; however, it is recommended that doses of 15 mg/day or 20 mg/day be reduced to 10 mg/day for one week prior to full discontinuation if possible
- In known CYP2D6 poor metabolizers, the maximum recommended dose is 10 mg/day

For additional dosage and administration information please see full Prescribing Information.

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS
See full Prescribing Information for full Boxed Warning.
- Increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants.
- Monitor for worsening and emergence of suicidal thoughts and behaviors.
- BRINTELLIX has not been evaluated for use in pediatric patients.

- Contraindicated in patients with hypersensitivity to vortioxetine or to any components of the BRINTELLIX formulation.
- Do not use BRINTELLIX concomitantly with an MAOI or within 14 days of stopping an MAOI. Do not use an MAOI within 21 days of stopping BRINTELLIX. Do not start BRINTELLIX in a patient who is being treated with linezolid or intravenous methylene blue.

Please see additional Important Safety Information including full Boxed Warning on previous pages. See Brief Summary of full Prescribing Information on the following pages.


Learn more at BRINTELLIXHCP.com
BRINTELLIX is indicated for the treatment of major depressive disorder (MDD). The efficacy of BRINTELLIX was established in six 8 to 16 week studies (including four in the elderly) and one maintenance study in adults.

**CONTRAINDICATIONS**

- Hypersensitivity to vortioxetine or any components of the formulation. Angioedema has been reported in patients treated with BRINTELLIX.
- The use of MAOIs intended to treat psychiatric disorders with BRINTELLIX or within 14 days of stopping treatment with BRINTELLIX is contraindicated because of an increased risk of serotonin syndrome. The use of BRINTELLIX within 14 days of stopping an MAOI may increase the risk of bleeding events. This risk may persist until 21 days after the last MAOI treatment. Use of BRINTELLIX within 14 days of stopping an MAOI may increase the risk of serotonin syndrome.

**WARNINGS AND PRECAUTIONS**

Clinical Worsening and Suicide Risk

Patients with major depressive disorder (MDD), both adult and pediatric, may experience worsening of their depression and/or the emergence of suicidal ideation and behavior (suicidality) or unusual changes in behavior, whether or not they are taking antidepressive medications, and this risk may persist until significant remission occurs. Suicide is a known risk of depression and certain other psychiatric disorders, and these disorders themselves are the strongest predictors of suicide. There has been a long-standing concern, however, that antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients during the early phases of treatment.

The pooled analyses of short-term placebo-controlled studies of antidepressant drugs (selective serotonin reuptake inhibitors [SSRIs] and others) showed that these drugs increase the risk of suicidal thinking and behavior in children, adolescents, and young adults (ages 18 to 24) with MDD and other psychiatric disorders. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a trend toward reduction with antidepressant use compared to placebo in adults aged 65 and older.

The pooled analyses of placebo-controlled studies in children and adolescents with MDD, obsessive compulsive disorder (OCD), or other psychiatric disorders included a total of 24 short-term studies of nine antidepressant drugs in over 4,400 patients. The pooled analyses of placebo-controlled studies in adults with MDD or other psychiatric disorders included a total of 258 short-term studies (median duration of two months) of 11 antidepressant drugs in over 77,000 patients. There was considerable variation in risk of suicidality among drugs, but a tendency toward an increase in the younger patients for almost all drugs studied. There were differences in absolute risk of suicidality across the different indications, with the highest incidence in MDD. The risk of suicidality (drug vs. placebo), however, was relatively stable within age strata and across indications. These risk differences (drug-placebo difference in the number of cases of suicidality per 1000 patients treated) are provided in Table 1.

The risk differences (drug-placebo difference in the number of cases of suicidality per 1000 patients treated) are provided in Table 1 of the BRINTELLIX Full Prescribing Information, which states: 14 additional cases in patients under the age of 18, 5 additional cases in patients between 18 and 24 years of age. There was 1 fewer case in patients between 25 and 64 years of age and 6 fewer cases in patients 65 years of age and over.

No suicides occurred in any of the pediatric studies. There were suicides in the placebo-controlled studies, but the number was not sufficient to reach any conclusion about drug effect on suicide.

It is unknown whether the suicidality risk extends to longer-term use, i.e., beyond several months. However, there is substantial evidence from placebo-controlled maintenance studies in adults with depression that the use of antidepressants can delay the recurrence of depression.

All patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, and unusual changes in behavior, especially during the initial few months of a course of drug therapy, or at times of dose changes, either increases or decreases.

The following symptomatic anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia (psychomotor restlessness), hypomania, and mania have been reported in adult and pediatric patients being treated with antidepressants for MDD as well as for other indications, both psychiatric and nonpsychiatric. Although a causal link between the emergence of such symptoms and either the worsening of depression and/or the emergence of suicidal impulses has not been established, there is concern that such symptoms may represent precursors to emerging suicidality.

Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients whose depression is presenting worse, or who are experiencing emergent suicidality or symptoms that might be precursors to worsening depression or suicidality, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

Families and caregivers of patients being treated with antidepressants for MDD or other indications, both psychiatric and nonpsychiatric, should be alerted about the need to monitor patients for the emergence of agitation, irritability, unusual changes in behavior, and the other symptoms described above, as well as the emergence of suicidality, and to report such symptoms immediately to healthcare providers. Such monitoring should include daily observation by families and caregivers.

Serotonin Syndrome

The development of a potentially life-threatening serotonin syndrome has been reported with serotoninergic antidepressants including BRINTELLIX, when used alone or in combination with other serotonergic drugs (including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John’s Wort), and with drugs that impair metabolism of serotonin (in particular, MAOIs, both those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue).

Serotonin syndrome symptoms may include mental status changes (e.g., agitation, hallucinations, delirium, and coma), autonomic instability (e.g., tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g., tremor, rigidity, myoclonus, hyperreflexia, incoordination), and gastrointestinal symptoms (e.g., nausea, vomiting, diarrhea). Patients should be monitored for the emergence of serotonin syndrome.

The concomitant use of BRINTELLIX with MAOIs intended to treat psychiatric disorders is contraindicated. BRINTELLIX should also not be started in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue. All reports with methylene blue that provided information on the route of administration involved intravenous administration in the dose range of 1 mg/kg to 8 mg/kg. No reports involved the administration of methylene blue by other routes (such as oral tablets or local tissue injection) or at lower doses. There may be circumstances when it is necessary to initiate treatment with a MAOI such as linezolid or intravenous methylene blue in a patient taking BRINTELLIX. BRINTELLIX should be discontinued before initiating treatment with the MAOI [see Contraindications].

If concomitant use of BRINTELLIX with other serotonergic drugs, including triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, and St. John’s Wort is clinically warranted, patients should be made aware of a potential increased risk for serotonin syndrome, particularly during treatment initiation and dose increases.

Treatment with BRINTELLIX and any concomitant serotonergic agents should be discontinued immediately if the above events occur and supportive symptomatic treatment should be initiated.

Abnormal Bleeding

The use of drugs that interfere with serotonin reuptake inhibition, including BRINTELLIX, may increase the risk of bleeding events. Concomitant use of aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin, and other anticoagulants may add to this risk. Case reports and epidemiological studies indicate that both children and adults with symptoms described above represent use of drugs that interfere with serotonin reuptake and the occurrence of gastrointestinal bleeding. Bleeding events related to drugs that inhibit serotonin reuptake have ranged from ecchymosis, hematoma, epistaxis, and petechiae to life-threatening hemorrhages.
Patients should be cautioned about the increased risk of bleeding when BRINTELLIX is coadministered with NSAIDs, aspirin, or other drugs that affect coagulation or bleeding [see Drug Interactions].

**Activation of Mania/Hypomania**

Symptoms of mania/hypomania were reported in ∼0.1% of patients treated with BRINTELLIX in pre-marketing clinical studies. Activation of mania/ hypomania appeared to be a treatment-emergent manifestation of psychiatric disorders, but they may also be consequences of pharmacologic treatment. In the MDD 6 to 8 week controlled trials of BRINTELLIX, voluntarily reported adverse reactions related to sexual dysfunction were captured as individual event terms. These event terms have been aggregated and the overall incidence was as follows. In male patients the overall incidence was 3%, 4%, 4%, 5% in BRINTELLIX 5 mg/day, 10 mg/day, 15 mg/day, 20 mg/day, respectively, compared to 2% in placebo. In female patients, the overall incidence was <1%, 1%, <1%, 2% in BRINTELLIX 5 mg/day, 10 mg/day, 15 mg/day, 20 mg/day, respectively, compared to <1% in placebo.

Because voluntarily reported adverse sexual reactions are known to be underreported, in part because patients and physicians may be reluctant to discuss them, the Arizona Sexual Experiences Scale (ASEX), a validated measure designed to identify sexual side effects, was used prospectively in seven placebo-controlled trials. The ASEX scale includes five questions that pertain to the following aspects of sexual function: 1) sex drive, 2) ease of arousal, 3) ability to achieve erection (men) or lubrication (women), 4) ease of reaching orgasm, and 5) orgasm satisfaction.

The presence or absence of sexual dysfunction among patients entering clinical studies was based on their ASEX scores. For patients without sexual dysfunction at baseline (approximately 1/3 of the population across all treatment groups in each study), Table 3 shows the incidence of patients that developed treatment-emergent sexual dysfunction when treated with BRINTELLIX or placebo in any fixed dose group. Physicians should routinely inquire about possible sexual side effects.

**Clinical Worsening and Suicide Risk**

The presence or absence of sexual dysfunction among patients entering clinical studies was based on their ASEX scores. For patients without sexual dysfunction at baseline (approximately 1/3 of the population across all treatment groups in each study), the following values from Table 3 of the BRINTELLIX Full Prescribing Information show the ASEX incidence of patients who developed treatment-emergent sexual dysfunction when treated with BRINTELLIX or placebo in any fixed dose group. The incidence in female patients treated with BRINTELLIX 5 mg (N=65), 10 mg (N=94), 15 mg (N=57), 20 mg (N=67) or placebo (N=135), respectively was 22%, 23%, 33%, 34% vs. 20%. For male patients, the incidence of treatment-emergent sexual dysfunction when treated with BRINTELLIX 5 mg (N=67), 10 mg (N=86), 15 mg (N=67), 20 mg (N=59) or placebo (N=162), respectively was 16%, 20%, 19%, 29% vs. 14%. Incidence was based on the number of subjects with sexual dysfunction during the study / number of subjects without sexual dysfunction at baseline. Sexual dysfunction was defined as a subject scoring any of the following on the ASEX scale at two consecutive visits during the study: 1) total score ≥19; 2) any single item ≥3; 3) three or more items each with a score ≥4. The sample size for each dose group was the number of patients without sexual dysfunction at baseline. Physicians should routinely inquire about possible sexual side effects.

**Adverse Reactions Following Abrupt Discontinuation of BRINTELLIX**

Discontinuation symptoms have been prospectively evaluated in patients taking BRINTELLIX 10 mg/day, 15 mg/day, and 20 mg/day using the Discontinuation-Emergent Signs and Symptoms (DESS) scale in clinical trials. Some patients experienced discontinuation symptoms such as headache, muscle tension, mood swings, sudden outbursts of anger, dizziness, and runny nose in the first week of abrupt discontinuation of BRINTELLIX 15 mg/day and 20 mg/day.

**Laboratory Tests**

BRINTELLIX has not been associated with any clinically important changes in laboratory test parameters in serum chemistry (except sodium), hematology and urinalysis as measured in the 6 to 8 week placebo-controlled studies. Hyponatremia has been reported with the treatment of BRINTELLIX [see Warnings and Precautions]. In the 6-month, double-blind, placebo-controlled phase of a long-term study in patients who had responded to BRINTELLIX during the initial 12-week, open-label phase, there were no clinically important changes in lab test parameters between BRINTELLIX and placebo-treated patients.

**Weight**

BRINTELLIX had no significant effect on body weight as measured by the mean change from baseline in the 6 to 8 week placebo-controlled studies. In the 6-month, double-blind, placebo-controlled phase of a long-term study in patients who had responded to BRINTELLIX during the initial 12-week, open-label phase, there was no significant effect on body weight between BRINTELLIX and placebo-treated patients.

**Vital Signs**

BRINTELLIX has not been associated with any clinically significant effects on vital signs, including systolic and diastolic blood pressure and heart rate, as measured in placebo-controlled studies.**
Other Adverse Reactions Observed in Clinical Studies

The following listing does not include reactions: 1) already listed in previous tables or elsewhere in labeling, 2) for which a drug cause was remote, 3) which were so general as to be uninformative, 4) which were not considered to have significant clinical implications, or 5) which occurred at a rate equal to or less than placebo.

Ear and labyrinth disorders — vertigo
Gastrointestinal disorders — dyspepsia
Nervous system disorders — dysgeusia
Vascular disorders — flushing

DRUG INTERACTIONS

CNS Active Agents

Monamine Oxidase Inhibitors

Adverse reactions, some of which are serious or fatal, can develop in patients who use MAOIs or who have recently been discontinued from an MAOI and started on a serotonergic antidepressant(s) or who have recently had SSRIs or SNRIs therapy discontinued prior to initiation of an MAOI [see Contraindications and Warnings and Precautions].

Serotonergic Drugs

Based on the mechanism of action of BRINTELLIX and the potential for serotonin toxicity, serotonin syndrome may occur when BRINTELLIX is coadministered with other drugs that may affect the serotonergic neurotransmitter systems (e.g., SSRIs, SNRIs, triptans, buspirone, tramadol, and tryptophan products etc.). Closely monitor symptoms of serotonin syndrome if BRINTELLIX is co-administered with other serotonergic drugs. Treatment with BRINTELLIX and any concomitant serotonergic agents should be discontinued immediately if serotonin syndrome occurs [see Warnings and Precautions].

Serotonin Reuptake Inhibitors

Serotonin release by platelets plays an important role in hemostasis. Epidemiological studies of case-control and cohort design have demonstrated an association between use of psychotropic drugs that interfere with serotonin reuptake and the occurrence of upper gastrointestinal bleeding. These studies have also shown that concurrent use of an NSAID or aspirin may potentiate this risk of bleeding. Altered anticoagulant effects, including increased bleeding, have been reported when SSRIs and SNRIs are coadministered with warfarin.

Following coadministration of stable doses of warfarin (1 to 10 mg/day) with multiple daily doses of BRINTELLIX, no significant effects were observed in INR, prothrombin values or total warfarin (protein bound plus free drug) pharmacokinetics for both R- and S-warfarin [see Drug Interactions]. Coadministration of aspirin 150 mg/day with multiple daily doses of BRINTELLIX had no significant inhibitory effect on platelet aggregation [see Drug Interactions]. Patients receiving other drugs that interfere with hemostasis should be carefully monitored when BRINTELLIX is initiated or discontinued [see Warnings and Precautions].

Potential for Other Drugs to Affect BRINTELLIX

Reduce BRINTELLIX dose by half when a strong CYP inducer (e.g., rifampicin, carbamazepine, phenytoin) is coadministered. Consider increasing the BRINTELLIX dose when a strong CYP inhibitor (e.g., bupropion, fluoxetine, paroxetine, quinidine) is coadministered. The maximum dose is not recommended to exceed three times the original dose (Figure 1).

Figure 1. Impact of Other Drugs on Vortioxetine PK

Potential for BRINTELLIX to Affect Other Drugs

No dose adjustment for the comedication is needed when BRINTELLIX is coadministered with a substrate of CYP1A2 (e.g., duloxetine), CYP2A6, CYP2B6 (e.g., bupropion), CYP2C8 (e.g., repaglinide), CYP2C9 (e.g., S-warfarin), CYP2C19 (e.g., diazepam), CYP2D6 (e.g., venlafaxine), CYP2D6/4/5 (e.g., budesonide), and P-gp (e.g., digoxin). In addition, no dose adjustment for lithium, aspirin, and warfarin is necessary.

Vortioxetine and its metabolites are unlikely to inhibit the following CYP enzymes and transporter based on in vitro data: CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, CYP3A4/5, and P-gp. As such, no clinically relevant interactions with drugs metabolized by these CYP enzymes would be expected.

In addition, vortioxetine did not induce CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, and CYP3A4/5 in an in vitro study in cultured human hepatocytes. Chronic administration of BRINTELLIX is unlikely to induce the metabolism of drugs metabolized by these CYP isozymes. Furthermore, in a series of clinical drug interaction studies, coadministration of BRINTELLIX with substrates for CYP2B6 (e.g., bupropion), CYP2C9 (e.g., warfarin), and CYP2C19 (e.g., diazepam), had no clinical meaningful effect on the pharmacokinetics of these substrates (Figure 2).

Because vortioxetine is highly bound to plasma protein, coadministration of BRINTELLIX with another drug that is highly protein bound may increase free concentrations of the other drug. However, in a clinical study with coadministration of BRINTELLIX (10 mg/day) and warfarin (1 mg/day to 10 mg/day), a highly protein-bound drug, no significant change in INR was observed [see Drug Interactions].

Figure 2. Impact of Vortioxetine on PK of Other Drugs

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C

Risk Summary

There are no adequate and well-controlled studies of BRINTELLIX in pregnant women. Vortioxetine caused developmental delays when administered during pregnancy to rats and rabbits at doses 15 and 10 times the maximum recommended human dose (MRHD) of 20 mg, respectively. Developmental delays were also seen after birth in rats at doses 20 times the MRHD of vortioxetine given during pregnancy and through lactation. There were no teratogenic effects in rats or rabbits at doses up to 77 and 58 times, the MRHD of vortioxetine, respectively, given during organogenesis. The incidence of malformations in human pregnancies has not been established for BRINTELLIX. All human pregnancies, regardless of drug exposure, have a background rate of 2 to 4% for major malformations, and 15 to 20% for pregnancy loss. BRINTELLIX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Clinical Considerations

Neonates exposed to SSRIs or SNRIs, late in the third trimester have developed complications requiring prolonged hospitalization, respiratory support and tube feeding. Such complications can arise immediately upon delivery. Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, heart rate and rhythm abnormalities, hypocalcemia, poor feeding. Such complications can arise immediately upon delivery. Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, heart rate and rhythm abnormalities, hypocalcemia, poor feeding. Such complications can arise immediately upon delivery. Reported clinical findings have included respiratory distress, cyanosis, apnea, seizures, temperature instability, feeding difficulty, vomiting, hypoglycemia, hypotonia, heart rate and rhythm abnormalities, hypocalcemia, poor feeding.

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Figure 1. Impact of Other Drugs on Vortioxetine PK

Figure 2. Impact of Vortioxetine on PK of Other Drugs
Neoates exposed to SSRIs in pregnancy may have an increased risk for persistent pulmonary hypertension of the newborn (PPHN). PPHN occurs in one to two per 1,000 live births in the general population and is associated with substantial neonatal morbidity and mortality. Several recent epidemiologic studies suggest a positive statistical association between SSR1 use in pregnancy and PPHN. Other studies do not show a significant statistical association.

A prospective longitudinal study was conducted of 201 pregnant women with a history of major depression, who were either on antidepressants or had received antidepressants less than 12 weeks prior to their last menstrual period, and were in remission. Women who discontinued antidepressant medication during pregnancy showed a significant increase in relapse of their major depression compared to those women who remained on antidepressant medication throughout pregnancy. When treating a pregnant woman with BRINTELLIX, the physician should carefully consider both the potential risks of taking a serotonergic antidepressant, along with the established benefits of treating depression with an antidepressant.

Animal Data
In pregnant rats and rabbits, no teratogenic effects were seen when vortioxetine was given during the period of organogenesis at oral doses up to 160 and 60 mg/kg/day, respectively. These doses are 77 and 58 times, in rats and rabbits, respectively, the maximum recommended human dose (MRHD) of 20 mg on a mg/m² basis. Developmental delay, seen at 120 mg/kg and development (specifically eye opening) was slightly delayed at 40 and 120 mg/kg. Additionally, pup weights were decreased at birth to weaning at 120 mg/kg and development (specifically eye opening) was slightly delayed at 40 and 120 mg/kg. These effects were not seen at 10 mg/kg (5 times the MRHD).

Nursing Mothers
It is not known whether vortioxetine is present in human milk. Vortioxetine is present in the milk of lactating rats. Because many drugs are present in human milk and because of the potential for serious adverse reactions in nursing infants from BRINTELLIX, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use
Clinical studies on the use of BRINTELLIX in pediatric patients have not been conducted; therefore, the safety and effectiveness of BRINTELLIX in the pediatric population have not been established.

Geriatric Use
No dose adjustment is recommended on the basis of age (Figure 3). Results from a single-dose pharmacokinetic study in elderly (>65 years old) subjects demonstrated that the pharmacokinetics were generally similar between the two age groups.

Of the 2616 subjects in clinical studies of BRINTELLIX, 11% (286) were 65 years of age or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Serotonergic antidepressants have been associated with cases of clinically significant hyponatremia in elderly patients, who may be at greater risk for this adverse event [see Warnings and Precautions].

Use in Other Patient Populations
No dose adjustment of BRINTELLIX on the basis of race, gender, ethnicity, or renal function (from mild renal impairment to end-stage renal disease) is necessary. In addition, the same dose can be administered in patients with mild to moderate hepatic impairment (Figure 3). BRINTELLIX has not been studied in patients with severe hepatic impairment. Therefore, BRINTELLIX is not recommended in patients with severe hepatic impairment.

Figure 3. Impact of Intrinsic Factors on Vortioxetine PK

<table>
<thead>
<tr>
<th>Population Description</th>
<th>PK</th>
<th>Fold Change and 90% CI</th>
<th>Recommendation</th>
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<tbody>
<tr>
<td>Age:</td>
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<tr>
<td>65-85/18-45</td>
<td>AUC</td>
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<td>Gender:</td>
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<tr>
<td>Females/Males</td>
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<td>Cmax</td>
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<td>Race:</td>
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<tr>
<td>Black/White</td>
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<tr>
<td>Renal Impairment:</td>
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<tr>
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<td>No dose adjustment</td>
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<td>Cmax</td>
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<td>Hepatic Impairment:</td>
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<td>Cmax</td>
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Change relative to reference: 0.50 0.75 1.00 1.25 1.50 1.75

DRUG ABUSE AND DEPENDENCE
BRINTELLIX is not a controlled substance.

OVERDOSAGE

Human Experience
There is limited clinical trial experience regarding human overdose with BRINTELLIX. In pre-marketing clinical studies, cases of overdose were limited to patients who accidentally or intentionally consumed up to a maximum dose of 40 mg of BRINTELLIX. The maximum single dose tested was 75 mg in men. Ingestion of BRINTELLIX in the dose range of 40 to 75 mg was associated with increased rates of nausea, dizziness, diarrhea, abdominal discomfort, generalized pruritus, somnolence, and flushing.

Management of Overdose
If specific antidotes for BRINTELLIX are known. In managing overdosage, consider the possibility of multiple drug involvement. In case of overdose, call Poison Control Center at 1-800-222-1222 for latest recommendations.

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Financial Strategies

GROW YOUR PRACTICE’S EQUITY VALUE

by KEITH BORGLUM, CHBC Contributing author

A large number of physicians are facing retirement soon, yet few have a plan in place to transition out and maximize the value of their practice.

While many practice owners wonder how much their practice is worth, and some would like to maximize the financial value of the practice in order to sell it for the most money possible at exit. Most practices are built to create current income and lifestyle for the owner, and not to create “equity value” at sale. Equity is created by value above-and-beyond labor. Creating equity value requires specific strategies.

Buyers have multiple professional opportunities. They can take employment somewhere, start a practice, or buy a practice. Taking employment involves no risk to the buyer’s savings or equity position, because they merely work and receive pay. Starting a practice involves investing some cash or taking on the responsibility of a loan. When buying a practice, buyers want to get not only some return on investment (ROI), but also a return of the original capital. If there is no ROI above what employment pays, and no return of the original capital, there is no reason to invest. A prudent buyer would merely take employment and invest elsewhere.

Most physicians are compensated based on productivity (and with quality incentives and bonuses for some). The harder and faster you work, the more you get paid. But it is still only compensation for labor. Working 80 hours a week doesn’t create any more equity than working 40 hours a week. It merely increases labor and proportionate compensation.

To create equity value (and especially financial “goodwill” value), you need to create income that is not directly dependent on your personal labor and reimbursement. The technical term for this is dividends.

Dividends in medical practices are most commonly created by leveraging labor or ancillary services. You can leverage labor by employing other physicians, non-physician-providers (NPP), and billable support personnel, and profiting from their labor by paying them less than the cost of their labor plus related overhead.

Instead of working 80 hours per week yourself, if you can employ an NPP at $100,000 per year for 40 of those hours, instead of another physician at $200,000 per year, and get the same work-output from them, you have probably $70,000-plus dividends (after other expenses) from employing the NPP rather than the physician. Employ three NPPs, and you have generated more income without seeing the patients yourself. That’s leverage.

A potential buyer of your practice can see that owning your practice—with or without working in your stead—earns them $210,000 more than merely taking employment elsewhere. That $210,000 creates income and value. How much value is determined by appraisal or sale.

Other common sources of dividends are: in-house lab, imaging, pharmacy, product sales, facility fees, technical-components, and ambulatory surgery centers. Those leveraged components can create millions of dollars of value to a prospective buyer.

Keith Borglum, CHBC is a practice management consultant, appraiser, and broker in Santa Rosa, California. Send your financial questions to medec@advanstar.com.

MedicalEconomics.com
Giant EHR-based network will compare treatments

The National Patient-Centered Clinical Research Institute’s program may allow physicians to compare how treatments work.

A new, voluntary government program will use electronic health records (EHR) data to compare different treatments for particular conditions, using the largest clinical database ever assembled. This program has the potential to advance medical research and improve care in physician practices.

**HIGHLIGHTS**

- Physicians who participate in PCORnet will help advance medical research, and be able to apply the results of the studies directly to their own practices.

- A major challenge to the project is that EHR data can’t be used in research unless it’s structured.

**BY SEPTEMBER** 2015 the program, known as the National Patient-Centered Clinical Research Network (PCORnet) is expected to give investigators access to data on 20 million to 30 million patients from 29 research networks across the country.

These include 11 clinical data research networks (CDRNs) based in healthcare systems and 18 patient-powered research networks (PPRNs) that are operated and governed by patients with particular conditions and their caregivers. The EHR data will remain within the local networks and will be made available to researchers via data mining applications.

The physicians who participate in PCORnet will not only help advance medical research, but may also be able to apply the results of the studies directly in their own practices. The Patient-Centered Outcomes Research Institute (PCORI), which is funding the networks and tying them together through PCORnet, envisions that some networks will provide the participating doctors with study results to help them improve the quality of care.

“We haven’t made it a requirement, but what we’re funding has the capacity to generate those kinds of reports that can be fed back to doctors,” Joe V. Selby, MD, MPH, executive director of PCORI, told *Medical Economics*.

The CDRN based at New York’s Weill Cornell Medical College intends to do just that, says Rainu Kaushal, MD, MPH, chair of the college’s department of Healthcare

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**IN DEPTH**

**THE LAST WORD** Physicians are facing a slew of administrative challenges resulting from the Affordable Care Act.
PCORnet: Where does the data come from?

PCORnet will be a large, representative, national network for conducting clinical outcomes research. The network integrates data from 11 Clinical Data Research Networks and 18 Patient-Powered Research Networks.

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<td>American BRCA Outcomes and Utilization of Testing Patient-Powered Research Network (ABOUT Network)</td>
<td>University of South Florida</td>
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Source: Patient-Centered Outcomes Research Institute

Policy and Research. “We plan to develop a rigorous dissemination plan which will enable all participating health systems, including both clinicians and patients, to readily benefit in a timely manner from the research happening in our network,” she explained.

From the viewpoint of research, PCORnet’s major advantage is its potential to increase greatly the speed and efficiency of comparative effectiveness research (CER).

“PCORnet has significant potential to improve the efficiency of conducting comparative effectiveness research, not only due to the depth and breadth of the data network, but also by streamlining the contracting and regulatory approval processes,” Kaushal says.

The ability of PCORnet to answer research questions quickly, using a large and rich database, looks promising to some observers.

“What’s powerful about EHR research is that it’s quick and inexpensive to acquire a large amount of data that’s important for certain questions,” says Steven Ornstein,
Data completeness is a big problem, and it’s one reason why we say there has to be a business case in this for physicians. They’ve got to step up their game. It will be much better when data entry into EHRs is more systematic.”

The size of the cohorts used in PCORnet studies, he says, will enable researchers to gather very precise data about the impact of therapies on subgroups of patients. He concedes, however, that those studies can’t necessarily establish whether one treatment is more effective than any other. To get closer to that answer, he says, well-designed observational studies must compare control and study groups of similar patients who are being treated in different ways.

In addition, researchers can use PCORnet “to launch randomized trials more efficiently and more quickly,” he says. “EHRs allow you to identify the patients who would be eligible. You approach the patients with the help or the consent of their health systems. Then the EHR and possibly patient-reported data help you follow these patients over time after you’ve randomized the treatment choices.”

Kaushal says that the Weill-Cornell network plans to do both observational and “prospective interventional” trials, using EHR data as well as patient-reported and patient-generated data, including genomic information. The network participants have all had extensive clinical trial experience, she adds.

Among the 22 organizations involved, Kaushal says, are several healthcare systems; their clinical and translational science award centers; patient engagement organizations; a practice-based research network; a genome center; a central institutional review board (IRB); regional health information organizations; and the New York state health department.

**TRANSLATING RESEARCH INTO PRACTICE**

The results of pragmatic studies are more likely to change how doctors practice than are the results of traditional clinical trials, say advocates of PCORI’s approach.

“If the study is done in a real-world delivery system and not in a highly selective population in a research clinic, other physicians and other delivery systems are going to be more likely to adopt the findings into practice,” Selby says, adding that it’s easier to generalize the results of pragmatic studies than those of traditional clinical trials.

Kaushal agrees that the outcomes of PCORnet studies will be “far more generalizable than research that might occur in
Zwelling is skeptical, but doesn’t rule out the possibility that observational studies based on EHR data could influence practice. “A lot of that depends on what you found out, the statistical power of what you found out, and your clear articulation of the question being asked and of the answer you received,” he says.

**EHR LIMITATIONS**

From a technical standpoint, PCORnet faces several significant challenges.

First, the data networks will have to find ways to combine data from multiple EHRs in a standardized format that can be analyzed. Second, much EHR data is unstructured, and the information of interest to researchers isn’t always entered in structured fields or entered correctly.

Some of the PCORnet funding of the data networks is earmarked for data standardization, Selby notes. Networks are expected to put the data they gather into a standard data model to participate in PCORnet. That allows the researchers to do “distributed data analysis” without having to roll up the data into a central database.

The larger challenge, he says, is that the EHR data can’t be used in research unless it’s structured. “Data completeness is a big problem, and it’s one reason why we say there has to be a business case in this for physicians. They’ve got to step up their game. It will be much better when data entry into EHRs is more systematic.”

The “business case” he refers to is the feedback of study results to practices. Ornstein’s PPRNet has been doing that for many years in its translational research, and participating physicians have been able to use PPRNet reports to intervene with patients who have care gaps.

Here’s how it works: the doctors send de-identified data extracts from their EHRs to Ornstein and his colleagues at MUSC. After the data has been analyzed, it’s sent back to the physicians, and they can use a specialized software tool to re-identify the data on a spreadsheet.

**PATIENT CONSENT**

Zwelling, who formerly administered clinical trials at M.D. Anderson Cancer Center, says that PCORI would have to figure out how to obtain patient consent for its networks’ EHR studies.

Patients can’t give blanket permission for use of their clinical data in a non-specific fashion, he points out. Physicians either have to ask every patient for permission for each study, or they need to request a waiver of consent from an IRB, even if the data is de-identified.

Selby says that PCORI would deal with this issue in different ways for different studies. In very large observational studies, involving 1 million people or more, it would be impossible to contact and obtain consent from all the participants, he says. So in those cases, participating data networks would seek IRB waivers.

In other studies that require doctors to change how patients are treated, individuals will be asked for their consent—a given in the patient-powered data networks.

**DOCTORS’ SUPPORT IS ESSENTIAL**

By all accounts, PCORnet offers unparalleled opportunities for comparative effectiveness research, but its success depends on the support of physicians.

Whether doctors will ever see a “business case” for this research is open to question, since they won’t be paid for it. But the physicians that participate, either on their own or through their institutions, can make a significant contribution to medical research. Moreover, the researchers’ analysis of their EHR data, if it’s made available to the doctors, could help them provide better care to their patients, say proponents of PCORnet.

Adam Stracher, MD, a faculty member at Weill-Cornell and a practicing internist, says of his institution’s clinical data network, “The benefit to us, as it is to all physicians, is to get a rich depository of good clinical data to be able to use for outcomes research, for developing clinical guidelines, and to figure out the best ways to take care of patients with multiple diseases.”

Stracher also looks forward to getting feedback on his own patients’ outcomes from the Weill Cornell-led network.

By seeing how his patients fare compared with other doctors’ patients with similar diseases and demographics, he says, “You can get a sense of whether you’re providing the best, most valuable care you can be giving, and learning how others are taking care of patients with similar diseases.”
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<td>AMA Insurance Agency, Inc.</td>
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<td>Bayer AG</td>
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<td>Janssen Pharmaceuticals, Inc.</td>
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<td>Pfizer Inc</td>
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<td>Takeda Pharmaceuticals</td>
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* Indicates a demographic advertisement.

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*June 25, 2014*
ACA EXCHANGES CREATING NEW ADMINISTRATIVE HEADACHES FOR PRACTICES

by JEFFREY BENDIX, MA  Senior Editor

Seven months after the startup of the Affordable Care Act’s (ACA) health insurance exchanges, medical practices have yet to see a major influx of new patients, but are still facing a new set of administrative challenges, ranging from verifying coverage to coping with narrow networks.

THOSE ARE among the conclusions to emerge from a recent survey of medical practices conducted by the Medical Group Management Association (MGMA) on the effects of the exchange implementation. The survey included about 700 medical groups across the county with more than 40,000 practicing physicians.

“Physician group practices are expressing dissatisfaction with the complexity and lack of information associated with insurance products sold on ACA exchanges,” Susan Turney, MD, MS, FACP, FACMPE, MGMA president and chief executive officer said in a written statement. “Even though there hasn’t been a huge influx of patients into physician offices as many predicted, simple tasks such as obtaining patient insurance coverage information or finding specialists for in-network referrals have proven to be significant challenges.”

To-date about eight million people have obtained coverage through the ACA exchanges. Approximately three million more enrolled in Medicaid or the Children’s Health Insurance Program between October, 2013 and April, 2014 according to the Centers for Medicare and Medicaid Services.

What the survey says:

75% of respondents said it was “very” or “extremely” likely that, on average, patients with ACA exchange coverage would have high deductibles compared with patients with traditional commercial insurance coverage.

56% of practices had seen no change in the size of their patient population through the end of April, with another 24%.

41% have seen patients to whom they could not provide covered services because their practice was not included in the exchange product’s network.

23.5% are not accepting insurance plans sold through an ACA exchange. The most common reasons cited were concerns about assuming financial liability for patients during the 90-day grace period for ACA enrollees an the practice not being asked to participate by payers.

80% of respondents said that payments rates offered by ACA exchange insurers are equal to or less than average payment rates from all traditional commercial insurance contracts, and from traditional commercial products offered by the same payer(s).

50% are finding it more difficult to verify patient eligibility, obtain information on cost-sharing and about other in-network providers from exchange plans.
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See resource centers related to our Business of Health series as well as topics such as Patient-Centered Medical Homes, accountable care organizations, and our EHR Best Practices Study at the above link.