We offer access to the latest treatment options and cutting-edge clinical trials.

Our multidisciplinary team is internationally recognized.

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Riley Children’s Health provides the expertise and resources to care for unborn babies, infants and children with congenital or acquired heart diseases, as well as adults with congenital heart disease.

For diagnosis and treatment of heart disease all through life.

Ranked 5th in the nation (STS National Report 2020, STAT 5).

U.S. News & World Report Designated as the Midwest's best hospital.

Home to the Riley Heart Center—a top heart center—through our partnership with Indiana University School of Medicine.

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ACCESSIBLE.

COLLABORATIVE.

EXPERIENCED.

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Collaborate with the Midwest’s best hospital for children’s heart care.

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Indiana University Health

To refer a patient, visit: rileychildrens.org/cv or scan the QR code.
We offer access to the latest treatment options and cutting-edge clinical trials.

The Riley Heart Center is one of the nation's most respected sites for diagnosis and treatment of heart disease all through life.

- **The Riley Heart Center is one of the nation’s most respected sites** for diagnosis and treatment of heart disease.
- **Our multidisciplinary team is internationally recognized** for procedures that repair undersized pulmonary arteries, remove cardiac tumors and rebuild complex heart anatomies.
- **Riley is a national leader in superior outcomes**, with mortality rates consistently below the national average, including a 0% mortality rate for the most complex cases (STS National Report 2020, STAT 5).
- **We offer access to the latest treatment options and cutting-edge clinical trials** through our partnership with Indiana University School of Medicine.

Riley Children’s Health provides the expertise and resources to care for unborn babies, infants and children with congenital or acquired heart diseases, as well as adults with congenital heart disease.

To refer a patient, visit rileychildrens.org/cv
Hiring Staff During the Great Resignation

Collaborative.

Our multidisciplinary team works directly with physicians like you to design a comprehensive, individualized treatment plan for every patient, whether the condition they face is common or complex.

At every step we keep you informed, sharing clinical notes after each outpatient visit, at hospital discharge and intermittently during prolonged hospitalization.

Accessible.

We understand how important it is to provide care that is close to home for patients, no matter where they live. That's why we offer outpatient care in Indianapolis and 12 communities across Indiana.

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Team up with a national leader in pediatric heart care.

When a patient of yours has a congenital heart defect or other cardiovascular needs, Riley Children’s Health is a trusted partner in providing the highest level of care.

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Indiana University Health

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HIRING STAFF
During the Great Resignation

Strategies practices can use to attract skilled workers to their open positions

Plus

Legal
Negotiating payer contracts

Tech
5 ways digital health is reshaping patient care

Physician Bootcamp
Recaps of our spring 2022 event

Chronic Conditions
Spotlight on lupus management

Deep Dive: Tammie Chang, M.D.
How women physicians can take care of each other
Indication
SHINGRIX is a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older. SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

Important Safety Information
• SHINGRIX is contraindicated in anyone with a history of a severe allergic reaction (eg, anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX

• Review immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX

• In a postmarketing observational study, an increased risk of Guillain-Barré syndrome was observed during the 42 days following vaccination with SHINGRIX

• Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope
ARE YOU OVERLOOKING PATIENTS LIKE JENNIFER, AGE 52?

PATIENT STORY:

Who’s in Jennifer’s Life?
• Her husband and two kids in high school
• The employees in her flower shop
• Her running buddies

Lifestyle:
She eats healthy, walks every day, and runs a few times a week

Medical History:
No current medical issues

Interaction with HCP:
Diligent about annual physicals and is proactive in discussing lifestyle changes to ensure she stays healthy

Recommendation Opportunity:
When discussing prevention during her annual exam

Recommend SHINGRIX Because:
She is always proactive about her healthcare

NO MATTER HOW HEALTHY SHE MAY FEEL, JENNIFER’S AT RISK FOR SHINGLES

She’s 52 years old and never felt healthier. But she’s still a candidate for SHINGRIX, a vaccine indicated for prevention of herpes zoster (shingles) in adults aged 50 years and older. Consider the patients in your office:

Are you overlooking patients like Jennifer?

Important Safety Information (cont’d)

• Solicited local adverse reactions reported in individuals aged 50 years and older were pain (78%), redness (38%), and swelling (26%)
• Solicited general adverse reactions reported in individuals aged 50 years and older were myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%)
• The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women
• It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion
• Vaccination with SHINGRIX may not result in protection of all vaccine recipients

Please see Brief Summary of Prescribing Information for SHINGRIX on the following pages.


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SGXJRNA210077 September 2021
Produced in USA.
BRIEF SUMMARY

SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

The following is a brief summary only; see full prescribing information for complete product information.

1 INDICATIONS AND USAGE

SHINGRIX is a vaccine indicated for prevention of herpes zoster (HZ) (shingles) in adults aged 50 years and older.

Limitations of Use:
+ SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

2 DOSAGE AND ADMINISTRATION

2.2 Administration Instructions

For intramuscular injection only.

After reconstitution, administer SHINGRIX immediately or store refrigerated between 2° and 8°C (36° and 46°F) and use within 6 hours. Discard reconstituted vaccine if not used within 6 hours.

2.3 Dose and Schedule

Two doses (0.5 mL each) administered intramuscularly according to the following schedule:

• A first dose at Month 0 followed by a second dose administered 2 to 6 months later.

4 CONTRAINDICATIONS

Do not administer SHINGRIX to anyone with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or after a previous dose of SHINGRIX [see Description (11) of full prescribing information].

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions. Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of SHINGRIX.

5.2 Guillain-Barré Syndrome (GBS)

In a postmarketing observational study, an increased risk of GBS was observed during the 42 days following vaccination with SHINGRIX [see Adverse Reactions (6.2)].

5.3 Syncope

Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX. Syncope can be accompanied by transient neurological signs such as visual disturbance, paresthesia, and tonic-clonic limb movements. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice. There is the possibility that broad use of SHINGRIX could reveal adverse reactions not observed in clinical trials.

Adults Aged 50 Years and Older

Overall, 17,041 adults aged 50 years and older received at least 1 dose of SHINGRIX in 17 clinical studies.

The safety of SHINGRIX was evaluated by pooling data from 2 placebo-controlled clinical studies (Studies 1 and 2) involving 29,305 subjects aged 50 years and older who received at least 1 dose of SHINGRIX (n = 14,660) or saline placebo (n = 14,660) administered according to a 0- and 2-month schedule. At the time of vaccination, the mean age of the population was 69 years; 7,286 (25%) subjects were aged 50 to 59 years, 4,488 (15%) subjects were aged 60 to 69 years, and 17,531 (60%) subjects were aged 70 years and older. Both studies were conducted in North America, Latin America, Europe, Asia, and Australia. In the overall population, the majority of subjects were White (74%), followed by Asian (18%), Black (1.4%), and other racial/ethnic groups (6%); 58% were female.

Solicited Adverse Reactions: In Studies 1 and 2, data on solicited local and general adverse reactions were collected using standardized diary cards for 7 days following each vaccine dose or placebo (i.e., day of vaccination and the next 6 days) in a subset of subjects (n = 4,886) receiving SHINGRIX, n = 4,881 receiving placebo with at least 1 documented dose). Across both studies, the percentages of subjects aged 50 years and older reporting each solicited local and general adverse reaction following administration of SHINGRIX (both doses combined) were pain (78%, redness (88%), and swelling (92%); and myalgia (45%), fatigue (45%), headache (38%), shivering (27%), fever (21%), and gastrointestinal symptoms (17%).

The reported frequencies of specific solicited local adverse reactions and general adverse reactions (overall per subject), by age group, from the 2 studies are presented in Table 1.

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Aged 50-59 Years</th>
<th>Aged 60-69 Years</th>
<th>Aged ≥70 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>88%</td>
<td>83%</td>
<td>69%</td>
</tr>
<tr>
<td>Pain, Grade 3</td>
<td>10%</td>
<td>7%</td>
<td>4%</td>
</tr>
<tr>
<td>Redness</td>
<td>30%</td>
<td>38%</td>
<td>38%</td>
</tr>
<tr>
<td>Redness, &gt;100 mm</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Swelling</td>
<td>31%</td>
<td>27%</td>
<td>23%</td>
</tr>
<tr>
<td>General Adverse Reactions</td>
<td>n=1,315</td>
<td>n=1,310</td>
<td>n=2,258</td>
</tr>
<tr>
<td>Myalgia</td>
<td>9%</td>
<td>9%</td>
<td>9%</td>
</tr>
<tr>
<td>Myalgia, Grade 3</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>28%</td>
<td>24%</td>
<td>37%</td>
</tr>
<tr>
<td>Fatigue, Grade 3</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Headache</td>
<td>2%</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>Headache, Grade 3</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Shivering</td>
<td>36%</td>
<td>30%</td>
<td>20%</td>
</tr>
<tr>
<td>Shivering, Grade 3</td>
<td>7%</td>
<td>5%</td>
<td>2%</td>
</tr>
<tr>
<td>Fever</td>
<td>28%</td>
<td>24%</td>
<td>14%</td>
</tr>
<tr>
<td>Fever, Grade 3</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>GI</td>
<td>2%</td>
<td>1%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Total vaccinated cohort for safety included all subjects with at least 1 documented dose (n).

a 7 days included day of vaccination and the subsequent 6 days.

b Data for subjects aged 50 to 59 years and 60 to 69 years are based on Study 1. Data for subjects 70 years and older are based on pooled data from Study 1: NCT01165177 and Study 2: NCT01165229.

c Placebo was a saline solution.

d Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.

e Grade 3 myalgia, fatigue, headache, shivering, and GI: Defined as preventing normal activity.

f Fever defined as ≥37.5°C/99.5°F for oral, axillary, or tympanic route, or ≥38°C/100.4°F for rectal route; Grade 3 fever defined as ≥39.0°C/102.2°F.

G1 = Gastrointestinal symptoms including nausea, vomiting, diarrhea, and/or abdominal pain.

The incidence of solicited local and general reactions was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

The local and general adverse reactions seen with SHINGRIX had a median duration of 2 to 3 days.

(continued on next page)
There were no differences in the proportions of subjects reporting any or Grade 3 solicited local reactions between Dose 1 and Dose 2. Headache and shivering were reported more frequently by subjects after Dose 2 (2.3%, 3%, and 4%, respectively) compared with Dose 1 (24% and 14%, respectively). Grade 3 solicited general adverse reactions (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3%, 4%, and 4%, respectively) compared with Dose 1 (1.4%, 1.4%, 2.3%, and 2.4%, respectively).

**Unsolicited Adverse Events:** Unsolicited adverse events that occurred within 30 days following each vaccination (Day 0 to 29) were recorded on a diary card by all subjects. In the studies, unsolicited adverse events occurring within 30 days of vaccination were reported in 51% and 32% of subjects who received SHINGRIX (n = 14,645) or placebo (n = 14,660), respectively (Total Vaccinated Cohort). Unsolicited adverse events that occurred in ≥1% of recipients of SHINGRIX and at a rate at least 1.5-fold higher than placebo included chills (4% versus 0.2%), injection site pruritus (2.2% versus 2%), malaise (1.7% versus 0.3%), arthralgia (1.7% versus 1.2%), nausea (1.4% versus 0.5%), and dizziness (1.2% versus 0.8%).

Gout (including gouty arthritis) was reported by 0.18% (n = 27) versus 0.05% (n = 8) of subjects who received SHINGRIX or placebo, respectively, within 30 days of vaccination; available information is insufficient to determine a causal relationship with SHINGRIX.

**Serious Adverse Events (SAEs):** In the 2 studies, SAEs were reported at similar rates in subjects who received SHINGRIX (2.3% of placebo (2.2%) from the first administered dose up to 30 days post-last vaccination. SAEs were reported for 10.1% of subjects who received SHINGRIX and for 10.4% of subjects who received placebo from the first administered dose up to 1 year post-last vaccination. One subject (0.01%) reported lymphadenitis and 1 subject (<0.01%) reported fever greater than 39°C; there was a basis for a causal relationship with SHINGRIX.

Optic ischemic neuropathy was reported in 3 subjects (0.02%) who received SHINGRIX (all within 50 days after vaccination) and 0 subjects who received placebo; available information is insufficient to determine a causal relationship with SHINGRIX.

**Deaths:** From the first administered dose up to 30 days post-last vaccination, deaths were reported for 0.04% of subjects who received SHINGRIX and 0.05% of subjects who received placebo in the 2 studies. From the first administered dose up to 1 year post-last vaccination, deaths were reported for 0.8% of subjects who received SHINGRIX and for 0.9% of subjects who received placebo. Causes of death among subjects were consistent with those generally reported in adult and elderly populations.

**Potential Immune-Mediated Diseases:** In the 2 studies, new onset potential immune-mediated diseases (pIMDs) or exacerbation of existing pIMDs were reported for 0.6% of subjects who received SHINGRIX and 0.7% of subjects who received placebo from the first administered dose up to 1 year post-last vaccination. The most frequently reported pIMDs occurred with comparable frequencies in the group receiving SHINGRIX and the placebo group.

**Dosing Schedule:** In an open-label clinical study, 238 subjects 50 years and older received SHINGRIX as a 0- and 2-month or 0- and 6-month schedule and was consistent with that observed in Studies 1 and 2. The safety profile of SHINGRIX was similar when administered according to a 0- and 2-month or 0- and 6-month schedule and was consistent with that observed in Studies 1 and 2.

### 6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of SHINGRIX. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

**General Disorders and Administration Site Conditions**

- Decreased mobility of the injected arm which may persist for 1 or more weeks.
- **Immune System Disorders**

- Hypersensitivity reactions, including angioedema, rash, and urticaria.
- **Nervous System Disorders**

- Guillain-Barré syndrome.

**Postmarketing Observational Study of the Risk of Guillain-Barré Syndrome Following Vaccination with SHINGRIX**

The association between vaccination with SHINGRIX and GBS was evaluated among Medicare beneficiaries aged 65 years or older. Using Medicare Claims data, from October 2017 through February 2020, vaccinations with SHINGRIX among beneficiaries were identified through National Drug Codes, and potential cases of hospitalized GBS among recipients of SHINGRIX were identified through International Classification of Diseases codes.

The risk of GBS following vaccination with SHINGRIX was assessed in self-controlled case series analyses using a risk window of 1 to 42 days post-vaccination and a control window of 43 to 183 days post-vaccination. The primary analysis (claims-based, all doses) found an increased risk of GBS during the 42 days following vaccination with SHINGRIX, with an estimated 3 excess cases of GBS per million doses administered to adults aged 65 years or older. In secondary analyses, an increased risk of GBS was observed during the 42 days following the first dose of SHINGRIX, with an estimated 6 excess cases of GBS per million doses administered to adults aged 65 years or older, and no increased risk of GBS was observed following the second dose of SHINGRIX. These analyses were based on GBS diagnoses in claims data were supported by analyses of GBS cases confirmed by medical record review. While the results of this observational study suggest a causal association of GBS with SHINGRIX, available evidence is insufficient to establish a causal relationship.

### 8 USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

The data are insufficient to establish if there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

#### 8.2 Lactation

**Risk Summary**

It is not known whether SHINGRIX is excreted in human milk. Data are not available to assess the effects of SHINGRIX on the breastfed infant or on milk production/excretion [see Use in Specific Populations (8.2) of full prescribing information].

#### 8.5 Geriatric Use

**Adults Aged 60 Years and Older**

Of the total number of subjects who received at least 1 dose of SHINGRIX in Studies 1 and 2 (n = 14,645), 2,243 (15%) were aged 60 to 69 years, 6,837 (47%) were aged 70 to 79 years, and 1,921 (13%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

The frequencies of solicited local and general adverse reactions in subjects aged 70 years and older were lower than in younger adults (aged 50 through 69 years). [See Adverse Reactions (6.1).]

### 17 PATIENT COUNSELING INFORMATION

- Inform patients of the potential benefits and risks of immunization with SHINGRIX and of the importance of completing the 2-dose immunization series according to the schedule.
- Inform patients about the potential for adverse reactions that have been temporally associated with administration of SHINGRIX.
- Provide the Vaccine Information Statements, which are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).
PUBLISHER’S NOTE

HIRING IN THE GREAT RESIGNATION

The COVID-19 pandemic has changed many things about health care. One of the things the pandemic has made more difficult is hiring and retaining staff members.

We’ve all read and heard about the “Great Resignation” and how workers are quitting their jobs and being more stingy about the type of employment they accept. Medical practices are not immune to this trend when it comes to support staff, administrators and clinicians.

So what can practices do to keep the excellent staff members they have and fill those open positions as quickly as possible? That’s the subject of our cover story in this, our May issue of Medical Economics®.

We also have other great content in this issue, including investing advice when it comes to cryptocurrency and an article about how practices can better negotiate payer contracts. We also have a great interview with Tammie Chang, MD, a physician and author who wrote a book about the challenges of being a woman while practicing medicine and what female physicians can do to band together and support each other.

I’d like to take the rest of this note to preview our upcoming June issue. In it we will have the latest installment of the Medical Economics® Physician Report, our annual survey where we explore trends in physician compensation, malpractice insurance costs, productivity and much more. It’s the 93rd year for the report, so make sure you check out next month’s issue and MedicalEconomics.com for tons of useful data on the state of medicine today.

As always, we value our readers’ feedback. If you have any story ideas, comments on our content or anything else, please reach out to Editorial Director Chris Mazzolini at cmazzolini@mjhlifesciences.com. Thanks for reading!

Mike Hennessy Jr.
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of MJH Life Sciences®
Physician’s Financial News®

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Check out this month’s edition of our Investing Intelligence column.

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Should you invest in Bitcoin?

Practice Management

16  Hiring and retaining staff  
Don’t let the “Great Resignation” negatively affect your practice.

Physician’s Money Digest®

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Medical World News

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An interview with author Tammie Chang, M.D.
COVID-19 COVERAGE CENTRAL

Medical Economics® editors are covering what you need to know during the ongoing novel coronavirus (COVID-19) pandemic. Our ongoing coverage of COVID-19 features:

- Breaking news on the latest developments.
- Tips for physicians to extend the life of N95 respirators.
- Mental health tips for doctors and other providers.
- How physicians can protect themselves from COVID-19.
- Strategies for using telehealth.

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Tabassum Salam, M.D., the ACP’s vice president of medical education, discusses what physicians need to know to get started with telehealth right away.

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Apretude

cabotegravir 200 mg/mL
extended-release injectable suspension

Please see the following pages for Brief Summary of full Prescribing Information, including Boxed Warning, for APRETUDE.

LEARN MORE ABOUT APRETUDE AT

APRETUDEHCP.COM
BRIEF SUMMARY

APRETUDE (cabotegravir extended-release injectable suspension) for intramuscular use

The following is a brief summary only; see full Prescribing Information, including Boxed Warning, for complete product information.

WARNING: RISK OF DRUG RESISTANCE WITH USE OF APRETUDE FOR HIV-1 PRE-EXPOSURE PROPHYLAXIS (PrEP) IN UNDIAGNOSED HIV-1 INFECTION

Individuals must be tested for HIV-1 infection prior to initiating APRETUDE or oral cabotegravir, and with each subsequent injection of APRETUDE, using a test approved or cleared by the FDA for the diagnosis of acute or primary HIV-1 infection. Drug-resistant HIV-1 variants have been identified with use of APRETUDE by individuals with undiagnosed HIV-1 infection. Do not initiate APRETUDE for HIV-1 PrEP unless negative infection status is confirmed. Individuals who become infected with HIV-1 while receiving APRETUDE for PrEP must transition to a complete HIV-1 treatment regimen.

CONTRAINDICATIONS

APRETUDE is contraindicated in individuals: with unknown or positive HIV-1 status; with previous hypersensitivity reaction to cabotegravir; receiving the following coadministered drugs for which significant decreases in cabotegravir plasma concentrations may occur due to uridine diphosphate glucuronosyltransferase (UGT1A1) – Anticonvulsants: carbamazepine, oxcarbazepine, phenobarbital, phenytoin; Antimycobacterials: rifampin, rifapentine.

WARNINGS AND PRECAUTIONS

Comprehensive Management to Reduce the Risk of HIV-1 Infection: Use APRETUDE for HIV-1 PrEP to reduce the risk of HIV-1 infection as part of a comprehensive prevention strategy including adherence to the administration schedule and safer sex practices, including condoms, to reduce the risk of sexually transmitted infections (STIs). APRETUDE is not always effective in preventing HIV-1 acquisition. The time from initiation of APRETUDE for HIV-1 PrEP to maximal protection against HIV-1 infection is unknown. Risk for HIV-1 acquisition includes behavioral, biological, or epidemiologic factors including, but not limited to, condomless sex, past or current STIs, self-identified HIV risk, having sexual partners of unknown HIV-1 viremic status, or sexual activity in a high prevalence area or network. Counsel individuals on the use of other prevention measures (e.g., consistent and correct condom use; knowledge of partner(s)’ HIV-1 status, including viral suppression status; regular testing for STIs that can facilitate HIV-1 transmission). Inform individuals about and support their efforts in reducing sexual risk behavior. Use APRETUDE to reduce the risk of acquiring HIV-1 only in individuals confirmed to be HIV-1 negative. HIV-1 resistance substitutions may emerge in individuals with undiagnosed HIV-1 infection who are taking only APRETUDE, because APRETUDE alone does not constitute a complete regimen for HIV-1 treatment; therefore, care should be taken to minimize the risk of initiating or continuing APRETUDE before confirming the individual is HIV-1 negative. Prior to initiating APRETUDE for HIV-1 PrEP, ask seronegative individuals about recent (in past month) potential exposure events (e.g., condomless sex or condom breaking during sex with a partner of unknown HIV-1 status or unknown viremic status, a recent STI), and evaluate for current or recent signs or symptoms consistent with acute HIV-1 infection (e.g., fever, fatigue, myalgia, skin rash). If recent (<1 month) exposures to HIV-1 are suspected or clinical symptoms consistent with acute HIV-1 infection are present, use a test approved or cleared by the FDA as an aid in the diagnosis of acute or primary HIV-1 infection. When using APRETUDE for HIV-1 PrEP, HIV-1 testing should be repeated prior to each injection and upon diagnosis of any other STIs. If an HIV-1 test indicates possible HIV-1 infection, or if symptoms consistent with acute HIV-1 infection develop following an exposure event, additional HIV testing to determine HIV-1 status is needed. If an individual has confirmed HIV-1 infection, the individual must be transitioned to a complete HIV-1 treatment regimen. Counsel HIV-1 uninfected individuals to strictly adhere to the recommended dosing and testing schedule for APRETUDE in order to reduce the risk of HIV-1 acquisition and the potential development of resistance. Some individuals, such as adolescents, may benefit from frequent visits and counseling to support adherence to the dosing and testing schedule. Potential Risk of Resistance with APRETUDE: There is a potential risk of developing resistance to APRETUDE if an individual acquires HIV-1 either before or while taking APRETUDE or following discontinuation of APRETUDE. To minimize this risk, it is essential to clinically reassess individuals for risk of HIV-1 acquisition and to test before each injection to confirm HIV-1 negative status. Individuals who are confirmed to have HIV-1 infection must transition to a complete HIV-1 treatment regimen. Alternative forms of PrEP should be considered following discontinuation of APRETUDE for those individuals at continuing risk of HIV-1 acquisition and initiated within 2 months of the final injection of APRETUDE.

Long-Acting Properties and Potential Associated Risks with APRETUDE: Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). It is important that healthcare providers take the prolonged-release characteristics of cabotegravir into consideration when APRETUDE is prescribed. Hypersensitivity Reactions: Serious or severe hypersensitivity reactions have been reported in association with other integrase inhibitors and could occur with APRETUDE. Administration of cabotegravir oral lead-in dosing was used in clinical studies to help identify participants who may be at risk of a hypersensitivity reaction. Remain vigilant and discontinue APRETUDE if a hypersensitivity reaction is suspected. Discontinue APRETUDE immediately if signs or symptoms of hypersensitivity reactions develop (including, but not limited to, severe rash, or rash accompanied by fever, general malaise, fatigue, muscle or joint aches, blisters, mucosal involvement [oral blisters or lesions], conjunctivitis, facial edema, hepatitis, eosinophilia, angioedema, difficulty breathing). Clinical status, including liver transaminases, should be monitored and appropriate therapy initiated if a long-acting property or hypersensitivity reaction is suspected. See previous section. Hepatotoxicity: Hepatotoxicity has been reported in a limited number of individuals receiving cabotegravir with or without known pre-existing hepatic disease or identifiable risk factors. Clinical and laboratory monitoring should be considered and APRETUDE should be discontinued if hepatotoxicity is suspected and individuals managed as clinically indicated. For information regarding long-acting properties of APRETUDE, see previous section. Depressive Disorders: Depressive disorders (including depression, depressed mood, major depression, persistent depressive disorder, suicide ideation or attempt) have been reported with APRETUDE. Promptly evaluate individuals with depressive symptoms to assess whether the symptoms are related to APRETUDE and to determine whether the risks of continued therapy outweigh the benefits. Risk of Reduced Drug Concentration of APRETUDE Due to Drug Interactions: The concomitant use of APRETUDE and other drugs may result in reduced drug concentration of APRETUDE. See Drug INTERACTIONS section below for steps to prevent or manage these possible and known significant drug interactions, including dosing recommendations. Consider the potential for drug interactions prior to and during use of, and after discontinuation of APRETUDE; review concomitant medications during use of APRETUDE.

ADVERSE REACTIONS

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect rates observed in practice. Clinical Trials Experience in Adults: The safety assessment of APRETUDE is based on the analysis of data from 2 international, multicenter, double-blind trials, HPTN 083 and HPTN 084. Adverse reactions were reported while on blinded study product following exposure to APRETUDE extended-release injectable suspension and oral cabotegravir tablets as oral lead-in. The median time on blinded study product in HPTN 083 was 65 weeks and 2 days (range: 1 day to 156 weeks and 1 day), with a total exposure on cabotegravir of 3,231 person-years. The median time on blinded study product in HPTN 084 was 64 weeks and 1 day (range: 1 day to 153 weeks and 1 day), with a total exposure on cabotegravir of 2,009 person-years. The most common adverse reactions regardless of severity reported in at least 1% of participants in HPTN 083 or HPTN 084 are presented in Table 4. In HPTN 083, 6% of participants in the group receiving APRETUDE intramuscular injection every 2 months and 4% of participants receiving oral TRUVADA (emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF)) once daily discontinued due to adverse events (all causality). Non-injection-site–associated adverse events leading to discontinuation and occurring in >1% of participants were increased alanine aminotransferase with APRETUDE and TRUVADA. In HPTN 084, 1% of participants receiving APRETUDE and 1% of participants receiving TRUVADA discontinued due to adverse events. The most commonly reported adverse event (all causality) leading to discontinuation was increased alanine aminotransferase (<1%) with APRETUDE and TRUVADA. The side-by-side tabulation is to simplify presentation; direct comparison across trials should not be made due to differing trials.

(cont’d on next page)
BRIEF SUMMARY for APRETUDE (cabotegravir extended-release injectable suspension), for intramuscular use (cont’d)

Table 4. Adverse Drug Reactions* (All Grades) Reported in at Least 1% of Participants Receiving APRETUDE in Either HPTN 083 or HPTN 084

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>HPTN 083</th>
<th>HPTN 084</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site reactions b</td>
<td>82% (n = 2,281)</td>
<td>38% (n = 1,610)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4% (n = 2,285)</td>
<td>4% (n = 1,614)</td>
</tr>
<tr>
<td>Headache</td>
<td>4% (n = 2,285)</td>
<td>12% (n = 1,614)</td>
</tr>
<tr>
<td>Pyrexia c</td>
<td>4% (n = 2,285)</td>
<td>&lt;1% (n = 1,614)</td>
</tr>
<tr>
<td>Fatigue d</td>
<td>4% (n = 2,285)</td>
<td>3% (n = 1,614)</td>
</tr>
<tr>
<td>Sleep disorders e</td>
<td>3% (n = 2,285)</td>
<td>1% (n = 1,614)</td>
</tr>
<tr>
<td>Nausea</td>
<td>3% (n = 2,285)</td>
<td>4% (n = 1,614)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2% (n = 2,285)</td>
<td>4% (n = 1,614)</td>
</tr>
<tr>
<td>Flatulence</td>
<td>1% (n = 2,285)</td>
<td>&lt;1% (n = 1,614)</td>
</tr>
<tr>
<td>Abdominal pain f</td>
<td>1% (n = 2,285)</td>
<td>2% (n = 1,614)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>&lt;1% (n = 2,285)</td>
<td>2% (n = 1,614)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>&lt;1% (n = 2,285)</td>
<td>2% (n = 1,614)</td>
</tr>
<tr>
<td>Rash g</td>
<td>&lt;1% (n = 2,285)</td>
<td>2% (n = 1,614)</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>&lt;1% (n = 2,285)</td>
<td>2% (n = 1,614)</td>
</tr>
<tr>
<td>Somnolence</td>
<td>&lt;1% (n = 2,285)</td>
<td>2% (n = 1,614)</td>
</tr>
<tr>
<td>Back pain</td>
<td>&lt;1% (n = 2,285)</td>
<td>1% (n = 1,614)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>0 (n = 2,285)</td>
<td>4% (n = 1,614)</td>
</tr>
</tbody>
</table>

*Adverse reactions defined as “treatment-related” as assessed by the investigator, with exception of injection site reactions, where all injection site reactions were reported regardless of causality.

b Participants who received injection: HPTN 083, APRETUDE (n = 2,117) and TRUVADA (n = 2,081); HPTN 084, APRETUDE (n = 1,519) and TRUVADA (n = 1,516).

c Pyrexia includes pyrexia, feeling hot, chills, influenza-like illness.

d Fatigue includes fatigue, malaise.

*Other injection-associated adverse reactions: In the HPTN 083 clinical trial, an increased incidence of pyrexia (including pyrexia, feeling hot, chills, influenza-like illness) (4%) was reported by participants receiving APRETUDE compared with participants receiving TRUVADA (<1%). There were no differences reported in the incidence of pyrexia between groups in HPTN 084. Vasovagal or pre-syncope reactions considered treatment related were reported in <1% of participants after injection with APRETUDE in HPTN 083. None were reported as treatment related by the investigators in HPTN 084.

Less Common Adverse Reactions: The following select adverse reactions (regardless of severity) occurred in <1% of participants receiving APRETUDE in HPTN 083 or HPTN 084: Hepatobiliary Disorders: Hepatotoxicity. Investigations: Weight increase (see below). Psychiatric Disorders: Depression.

Weight Increase: At the Week 41 and Week 97 timepoints in HPTN 083, participants who received APRETUDE gained a median of 1.2 kg (Interquartile Range [IQR]: -1.0, 3.5; n = 1,623) and 2.1 kg (IQR: -0.9, 5.9; n = 601) in weight from baseline. Those who received TRUVADA gained a median of 0 kg (IQR: -2.1, 2.4; n = 1,611) and 1 kg (IQR: -1.9, 4.0; n = 598) in weight from baseline, respectively. Those who received TRUVADA gained a median of 1 kg (IQR: -1.0, 4.0; n = 1,131) and 3 kg (IQR: -1.0, 6.0; n = 218) in weight from baseline, respectively. Laboratory Abnormalities: Grade 3 or 4 post-baseline maximum toxicity laboratory abnormalities for HPTN 083 or HPTN 084 are summarized in Table 6.

(cont’d on next page)
Table 6. Laboratory Abnormalities (Grades 3 to 4) in >1% of Participants in Either HPTN 083 or HPTN 084

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>HPTN 083</th>
<th>HPTN 084</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>APRETUDE Every 2 Months (n = 2,281)</td>
<td>TRUVADA Once Daily (n = 2,285)</td>
</tr>
<tr>
<td>ALT (≥5.0 x ULN)</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>AST (≥5.0 x ULN)</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Creatine phosphokinase (≥10.0 x ULN)</td>
<td>15%</td>
<td>14%</td>
</tr>
<tr>
<td>Lipase (≥3.0 x ULN)</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Creatinine (≥1.8 x ULN or increase to ≥1.5 x baseline)</td>
<td>3%</td>
<td>3%</td>
</tr>
</tbody>
</table>

ALT = Alanine transaminase, ULN = Upper limit of normal, AST = Aspartate aminotransferase.

Serum Lipids: Changes from baseline to Month 15 in total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, and total cholesterol to HDL ratio in HPTN 083 and HPTN 084 are presented in Table 7.

Table 7. Fasting Lipid Values, Median Change from Baseline* at Week 57, Reported in HPTN 083 and HPTN 084

<table>
<thead>
<tr>
<th></th>
<th>HPTN 083</th>
<th>HPTN 084</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>APRETUDE</td>
<td>TRUVADA</td>
</tr>
<tr>
<td>Total cholesterol (mg/dL)</td>
<td>+1.0</td>
<td>-10.0</td>
</tr>
<tr>
<td>LDL cholesterol (mg/dL)</td>
<td>+1.0</td>
<td>-6.0</td>
</tr>
<tr>
<td>HDL cholesterol (mg/dL)</td>
<td>-0.2</td>
<td>-3.0</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)</td>
<td>+2.7</td>
<td>0.0</td>
</tr>
<tr>
<td>Total cholesterol: HDL cholesterol ratio</td>
<td>+0.1</td>
<td>+0.0</td>
</tr>
</tbody>
</table>

*Nearly 60% of participants with baseline data available had Week 57 data available in both arms of both trials. Within each trial, baseline values were comparable among participants receiving APRETUDE and TRUVADA.

Clinical Trials Experience in Adolescents: In adolescents receiving APRETUDE for HIV-1 PrEP, the safety data were comparable to the safety data reported in adults receiving APRETUDE for HIV-1 PrEP.

Drug Interactions

Use of Other Antiretroviral Drugs after Discontinuation of APRETUDE: Residual concentrations of cabotegravir may remain in the systemic circulation of individuals for prolonged periods (up to 12 months or longer). These residual concentrations are not expected to affect the exposures of antiretroviral drugs that are initiated after discontinuation of APRETUDE. Potential for Other Drugs to Affect APRETUDE: Cabotegravir is primarily metabolized by UGT1A1 with some contribution from UGT1A9. Drugs that are strong inducers of UGT1A1 or UGT1A9 are expected to decrease cabotegravir plasma concentrations; therefore, coadministration of APRETUDE with these drugs is contraindicated. Established and Other Potentially Significant Drug Interactions: Information regarding potential drug interactions with cabotegravir is provided below. These recommendations are based on either drug interaction trials following oral administration of cabotegravir or predicted interactions due to the expected magnitude of the interaction. The information below includes potentially significant interactions but is not all inclusive.

- Anticonvulsants: carbamazepine, oxcarbazepine, phenobarbital, phenytoin – coadministration is contraindicated with APRETUDE due to potential for significant decreases in plasma concentration of APRETUDE
- Antimycobacterials: rifampin, rifapentine – coadministration is contraindicated with APRETUDE due to potential for significant decreases in plasma concentration of APRETUDE
- Antimycobacterial: rifabutin – when rifabutin is started before or concomitantly with the first initiation injection of APRETUDE, the recommended dosing of APRETUDE is one 600-mg (3-mL) injection, followed 2 weeks later by a second 600-mg (3-mL) initiation injection and monthly thereafter while on rifabutin. When rifabutin is started at the time of the second initiation injection or later, the recommended dosing schedule of APRETUDE is 600 mg (3 mL) monthly while on rifabutin. After stopping rifabutin, the recommended dosing schedule of APRETUDE is 600 mg (3 mL) every 2 months
- Narcotic analgesics: methadone – no dose adjustment of methadone is required when starting coadministration of methadone with APRETUDE. However, clinical monitoring is recommended as methadone maintenance therapy may need to be adjusted in some individuals

Drugs without Clinically Significant Interactions with Cabotegravir: Based on data from studies reported in the APR, the following drugs can be coadministered with cabotegravir (non-antiretrovirals) or given after discontinuation of cabotegravir (antiretrovirals and non-antiretrovirals) without a dose adjustment: etravirine, midazolam, oral contraceptives containing levonorgestrel and ethinyl estradiol, and rilpirine.

Consult the full Prescribing Information for potential drug interactions; this list is not all inclusive.

Use in Specific Populations

Pregnancy: Pregnancy Exposure Registry: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to APRETUDE during pregnancy. Healthcare providers are encouraged to register individuals by calling the Antiretroviral Registry (APR) at 1-800-258-4263. Risk Summary: There are insufficient human data on the use of APRETUDE during pregnancy to adequately assess a drug-associated risk of birth defects and miscarriage. While there are insufficient human data to assess the risk of neural tube defects (NTDs) with exposure to APRETUDE during pregnancy, NTDs were associated with dolutegravir, another integrase inhibitor. Healthcare providers should discuss the benefit-risk of using APRETUDE with individuals of childbearing potential or during pregnancy. Cabotegravir use in pregnant women has not been evaluated. APRETUDE should be used during pregnancy only if the expected benefit justifies the potential risk to the fetus. For cases of anticipated pregnancy, the APR has been established to monitor for birth defects following exposure to antiretrovirals. The rate of miscarriage is not reported in the APR. The background rate for major birth defects in a U.S. reference population of the Metropolitan Atlanta Congenital Defects Program (MACDP) is 2.7%. The estimated background rate of miscarriage in clinically recognized pregnancies in the U.S. general population is 15% to 20%. The APR uses the MACDP as the U.S. reference population for birth defects in the general population. The MACDP evaluates women and infants from a limited geographic area and does not include outcomes for births that occurred at <20 weeks’ gestation. In animal reproduction studies with oral cabotegravir, a delay in the onset of parturition and increased stillbirths and neonatal deaths were observed in pregnant rats. In a rat pre- and postnatal development study at >28 times the exposure at the recommended human dose (RHD), no evidence of adverse developmental outcomes was observed with oral cabotegravir in rats or rabbits (>28 times or similar to the exposure at the RHD).
BRIEF SUMMARY for APRETUDE (cabotegravir extended-release injectable suspension), for intramuscular use (cont’d)

respectively) given during organogenesis (see Data). Clinical Considerations: Cabotegravir is detected in systemic circulation for up to 12 months or longer after discontinuing injections of APRETUDE; therefore, consideration should be given to the potential for fetal exposure during pregnancy. Data: Human Data: Data from a birth outcome surveillance study in Botswana showed that dolutegravir, another integrase inhibitor, was associated with increased risk of NTDs when administered at the time of conception and in early pregnancy. Data from clinical trials are included in the section Risk with cabotegravir. Animal Data: Cabotegravir was administered orally to pregnant rats at 0, 0.5, 5, or 1,000 mg/kg/day from 15 days before cohabitation, during cohabitation, and from Gestation Days 0 to 17. There were no effects on fetal viability when fetuses were delivered by caesarian, although a minor decrease in fetal body weight was observed at 1,000 mg/kg/day (>28 times the exposure in humans at the RHD). No drug-related fetal toxicities were observed at 5 mg/kg/day (approximately 13 times the exposure in humans at the RHD), and no drug-related fetal malformations were observed at any dose. Cabotegravir was administered orally to pregnant rabbits at 0, 30, 500, or 2,000 mg/kg/day from Gestation Days 7 to 19. No drug-related fetal toxicities were observed at 2,000 mg/kg/day (approximately 0.7 times the exposure in humans at the RHD). In a rat pre- and postnatal development study, cabotegravir was administered orally to pregnant rats at 0, 0.5, 5, or 1,000 mg/kg/day from Gestation Day 6 to Lactation Day 21. A delay in the onset of parturition and increases in the number of stillbirths and neonatal deaths by Lactation Day 4 were observed at 1,000 mg/kg/day (>28 times the exposure in humans at the RHD); there were no alterations to growth and development of surviving offspring. In a cross-fostering study, similar incidences of stillbirths and early postnatal deaths were observed when rat pups born to cabotegravir-treated mothers were nursed from birth by control mothers. There was no effect on neonatal survival of control pups nursed from birth by cabotegravir-treated mothers. A lower dose of 5 mg/kg/day (13 times the exposure at the RHD) was not associated with delayed parturition or neonatal mortality in rats. Studies in pregnant rats showed that cabotegravir crosses the placenta and can be detected in fetal tissue. Lactation: Risk Summary: It is not known if cabotegravir is present in human breast milk, affects human milk production, or has effects on the breastfed infant. When administered to lactating rats, cabotegravir was present in milk (see Data). If cabotegravir is present in human milk, residual exposures may remain for 12 months or longer after the last injections have been administered. Because of detectable cabotegravir concentrations in systemic circulation for up to 12 months or longer after discontinuing injections of APRETUDE, it is recommended that women breastfeed only if the expected benefit justifies the potential risk to the infant. Data: Animal Data: Animal lactation studies with cabotegravir have not been conducted. However, cabotegravir was detected in the plasma of nursing pups on Lactation Day 10 in the rat pre- and postnatal development study. Pediatric Use: The safety and effectiveness of APRETUDE for HIV-1 PEP in at-risk adolescents weighing at least 35 kg is supported by data from 2 adequate and well-controlled trials of APRETUDE for HIV-1 PEP in adults with additional safety and pharmacokinetic data from studies in HIV-1 infected adults who were administered CABENUVA, and in HIV-1 infected pediatric subjects who were administered separate components of CABENUVA in addition to their current antiretroviral therapy. APRETUDE for HIV-1 PEP is being evaluated in 2 open-label multicenter clinical trials in adolescent individuals. Fifty-nine adolescents have been enrolled. Of these, 54 adolescent participants received one or more injections. In adolescents receiving APRETUDE for HIV-1 PEP, the safety data were comparable to the safety data reported in adults receiving APRETUDE for HIV-1 PEP. While using APRETUDE, HIV-1 testing should be conducted prior to initiating APRETUDE (with or without an oral lead-in with oral cabotegravir) and prior to each injection of APRETUDE. Adolescents may benefit from more frequent visits and counseling to support adherence to the dosing and testing schedule. The safety, efficacy, and pharmacokinetics of APRETUDE in pediatric participants younger than 12 years of age or weighing <35 kg has not been established. No dose adjustment is required in elderly individuals. There are limited data available on the use of APRETUDE in individuals aged 65 years and older. In general, caution should be exercised in administration of APRETUDE in elderly individuals reflecting greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. Renal Impairment: Based on studies with oral cabotegravir, no dosage adjustment of APRETUDE is necessary for individuals with mild (creatinine clearance ≥60 to <90 mL/min) or moderate renal impairment (creatinine clearance ≥30 to <60 mL/min). In individuals with severe renal impairment (creatinine clearance 15 to <30 mL/min) or end-stage renal disease (creatinine clearance <15 mL/min), increased monitoring for adverse effects is recommended. In individuals with end-stage renal disease not on dialysis, effects on the pharmacokinetics of cabotegravir are unknown. As cabotegravir is >99% protein bound, dialysis is not expected to alter exposures of cabotegravir. Hepatic Impairment: Based on studies with oral cabotegravir, no dosage adjustment of APRETUDE is necessary for individuals with mild or moderate hepatic impairment (Child-Pugh A or B). The effect of severe hepatic impairment (Child-Pugh C) on the pharmacokinetics of cabotegravir is unknown. OVERDOSE There is no known specific treatment for overdose with APRETUDE. If overdose occurs, monitor the individual and apply standard supportive treatment as required as well as observation of the clinical status of the individual. As APRETUDE is highly bound to plasma proteins, it is unlikely that it will be significantly removed by dialysis. Consider the prolonged exposure to APRETUDE following an injection when assessing treatment needs and recovery.
High Stock Volatility Signals Investor Opportunity

BY DAVID S. GILREATH, CFP

High volatility is widely viewed as the Grim Reaper of stock returns, but nothing could be further from the truth. This misconception underlies incorrect assumptions about the volatility index (VIX), a useful tool that ratings-hungry broadcasters and click-craving websites like to call the fear index.

Individual investors have been conditioned to believe that high readings in this index signal the dreaded reaper’s approaching footsteps with seismograph-like reliability. Not only do we know that doom is approaching, but we also know when it is arriving.

Of course, with such sensationalistic reports, financial media get the kind of rapt attention that only scared audiences can give. “The fear index is up,” talking heads intone, giving people the willies.

But investors should not be scared. They would be glad if they understood volatility and the VIX. Yet, because many do not, reports that the index is rising are considered bad news — and choice media fodder.

Contrary to popular belief, high volatility is not a terrorist threat to investors. Rather, it is a natural part of the stock market. Nor is the VIX a measure of fear; it is a gauge that can be used for gain.

The VIX measures the projected speed of up and down stock price movements. It reflects changes in levels of option premiums — the current market price of option contracts, which are agreements for the prospective sale or purchase of stocks for a set price within set time periods.

The index was created by the Chicago Board Options Exchange in the 1990s to anticipate volatility as indicated by the near-term (within 30 days) expiration of options on the S&P 500. The VIX is not an opinion. Instead, it is a formulaic and mechanical 30-day projection of stock price volatility.

Although some view the VIX as a measure of investor sentiment, there is no factual basis for the notion that the VIX turns on fear, nor any reason to believe that fear can be inferred from high VIX readings. Investors (primarily institutional investors) trade options to make money by anticipating stock price changes within set ranges. The index measures changes in price expectations, not fear.

Many people think that when the VIX is high they should reduce equity exposure, but they have things reversed: a high VIX signals opportunity. High VIX readings signal when you might want to buy stocks, not sell them, because these high readings are usually followed by good market returns in ensuing months. If you buy when the VIX rises above 30, then over the next six to 12 months the odds are high that you will have gains.

My firm recently did a study on the market’s behavior in the nearly 8,100 trading days that the VIX has existed. The average level has historically been 19.5. On nearly 700 days, it has been above 30. Six months after those 30-plus readings, the average price of stocks in the S&P 500 increased 85% of the time, and the index’s average return was 13.4%. And 12 months after a VIX of 30 or higher, the index gained in price 90% of the time, with an average return of 23.4%.
In October 2021, the VIX was around 19. If you held the popular misconception about the index, saying ‘the water’s calm so let’s jump in,’ you wouldn’t have done well on those purchases. At that time the S&P 500 was at 4,600. In late March, it was at 4,500.

But if you had invested in late January 2021, the last over-six-month-ago time the VIX was over 30, the S&P 500 had dropped to 3,800 from fears about the COVID-19 Delta variant, and the VIX popped to 37. By late July 2021 (six months later), the S&P 500 was at 4,400 was up 17.4%, like 85% of periods after previous VIX spikes.

“A growing array of exchange-traded funds is making options strategies highly accessible to individuals, enabling them to effectively hedge risk, produce income or both.”

So much for the perils of high volatility. For those who understand its consequences, a high VIX is an opportunity to position for growth. Instead of the fear index, it should be called the opportunity index.

Volatility in the market is as natural as wind in Earth’s atmosphere. If there is air, there will be wind, and if stock prices are subject to change (which will be forever), we will have volatility. Stock prices do not go up or down in smooth, even patterns. Instead, these lines on charts are always jagged to some degree.

Individual investors seeking to profit from these fluctuations directly by trading options have long faced the obstacle that this is a highly complex undertaking best left to pros (i.e., don’t try this at home). But now, a growing array of exchange-traded funds is making options strategies highly accessible to individuals, enabling them to effectively hedge risk, produce income or both.

Hospitals off to a poor financial start in 2022

Declining revenue and inpatient volumes have followed the COVID-19 omicron surge

By Todd Shroyock
Managing Editor

U.S. hospitals and health systems are off to a poor start in 2022, according to a report from Kaufman Hall.

Hospitals have seen two consecutive months of negative operating margins, with most organizations seeing declining margins, revenue, and inpatient volumes following the COVID-19 omicron surge.

Outpatient care volumes have been slow to recover, despite a steep decline in COVID-19 cases. Similar to past surges, delays in nonurgent care led to decline in outpatient metrics during omicron, while a moderate rise in surgery volume showed some patients returned in February, but overall patient volumes remained low.

The 7-day moving average of new cases dropped 92% from an all-time high of 809,621 at the apex of omicron on Jan. 15 to 66,195 on Feb. 28. The 7-day moving average of new daily admissions dropped 79% from a peak of 21,622 on Jan. 15 to 4,515 on Feb. 28.

Also affecting hospital revenue were receding inpatient volumes at the end of the omicron surge. COVID-19-related hospitalizations declined, leading to lower inpatient volume and drop in the average length of stay in February as fewer patients required care for severe symptoms.

There was some good news, as many hospitals saw some relief from rising expenses. Expenses decreased across most metrics from January to February, but nationwide labor shortages and global supply chain issues continue to drive up expenses compared to prior years.

The median Kaufman Hall Operating Margin Index reflecting actual margins for the month was -3.45%, up from -4.52% in January but still well below sustainable levels. Recovery from the omicron surge likely will continue to be slow in the coming months, and hospitals could face additional setbacks if other variants lead to new surges.

Poor volume performance led to month-over-month revenue declines in February. Gross Operating revenue was down 7.4% and Outpatient revenue dropped 5% from January levels. Inpatient revenue had the biggest decrease, down 19.3% following a nearly 3% increase the prior month due to January’s spike in hospitalizations.

Compared to prior years, gross operating revenue rose 7.8% versus February 2021 and 5.7% versus the same month in 2020. Inpatient revenue was up just 0.9% compared to February 2021 but down 1.2% from February 2020. Outpatient revenue increased 9.3% year-over-year versus 2021 but decreased 2.8% versus February 2020.
The Biden administration issued an executive order on March 9, 2022, outlining its objectives for the responsible development of cryptocurrency. Brookings described the order as “non-controversial.” But five years ago, it wasn’t certain whether Western governments would even tolerate digital assets. Today, they overwhelmingly allow them, subject to the same tax and legal framework as property. While the order shouldn’t cause any dramatic changes to crypto, it shows how far the world has come in a short period of time. Even pro-sports leagues are getting in on the action, aiming for ways to issue their own cryptocurrencies.

The U.S. Treasury likely had a legal opportunity to tax crypto as a collectible (at a higher 28% rate) as it does gold and art, but it didn’t. In college, one professor taught us how the media and popular culture tended to assimilate new ideas that were a threat to it, as did the government. Dislike the people in power? Great, we’ve got some rock albums and T-shirts you can buy for $19.99 a pop!

Bitcoin (BTC-USD) was envisioned by some of its early supporters as a tool that could completely upturn the political system. The political establishment has dealt with bitcoin not by outlawing it but by allowing regulated exchanges where people can speculate on the price and pay huge amounts of short-term capital gains tax to the government. I think this is actually a reasonable approach; I don’t know if I would want to live in the anarcho-capitalist world that some early bitcoin supporters envisaged. What bitcoin does do amazingly well is allow for a store of wealth that won’t be affected by the lousy political decisions of various central bankers.

How will the executive order affect bitcoin?
The key takeaway from the Biden administration’s executive order is that crypto is here to stay. The Feds don’t want people laundering drug money with crypto, they don’t want oligarchs evading sanctions with it, and they want the tax situation for domestic investors to be equal to other asset classes, not better or worse. The order also directed the Federal Reserve to research a central bank digital currency, but I’ve yet to see any compelling use for one, so researching is probably all it will do. Biden’s executive order on crypto is interesting in light of the ongoing campaign to get the Grayscale Bitcoin Trust (OTC:GBTC) approval to convert to an exchange-traded fund (ETF). The SEC solicited comments last month from the public on the ETF conversion. Over 2600 people have written in, with the overwhelming majority in support (I wrote in, too; here’s mine). There are still issues that might need to be worked through before the first ETF approval, but with the support of the public, I’d imagine that it’s a matter of “when,” not “if,” and that the regulatory framework will develop so people can invest easily in bitcoin with exchange-traded products without fear of losing their keys or getting hacked.

There also are interesting new developments such as El Salvador’s push to sell bitcoin-linked bonds (a gimmick, but it’s smart). Also, both sides of the war in Ukraine have used bitcoin to help their efforts. I don’t see any real negatives with bitcoin here other than that it’s a neutral store of value a lot like the dollar with respect to moving money in and out of warring countries. It’s not really optimal for people to burn coal to mine bitcoin either, but the world is already taking steps to address this.

Will bitcoin go back up in 2022?
2022 has shown that Bitcoin is clearly a risk asset and it isn’t immune to the changing risk appetites of traders. Going forward, I would expect crypto to be more correlated with stocks than it was in the past. In the long run, the fundamentals for bitcoin remain sound with increasing adop-
tion and nearly endless potential for people in developing countries to put their savings in something that won’t lose value because of the actions of their central banks.

I’m bearish on the NASDAQ (QQQ) and on the market in general right now because of the unwinding of stimulus and what I believe are unrealistic earnings expectations. Whether this remains a correction or develops into a bear market is yet to be seen, but bitcoin is likely to see some short-term pressure. I do expect bitcoin to challenge its all-time high this year, but the equity markets falling could slow this process down to a crawl. Bitcoin has been range-bound between roughly $30,000 and $60,000 for the last year.

**Is bitcoin now a buy, sell or hold?**

One way of thinking about asset classes was developed in the Black-Litterman model by the late Fischer Black (who also created the Black-Scholes model) and Robert Litterman, then quant strategists at Goldman Sachs. The idea is to match the global market-cap weight of assets as a starting point and then increase or decrease your allocations based on your opinions of what is likely to return well.

Bitcoin now represents between 0.5% and 1% of global assets, so that’s the starting point under this model. Then there are graphs that tell you how much to invest based on your opinions of what is likely to return well.

The trends suggest an allocation somewhere between 0.5% and 10% based on how optimistic you are on bitcoin. Also note that the model suggests is also to rebalance some of your gains into other asset classes if crypto skyrockets. You could also certainly hold onto the bitcoin and not rebalance, but you don’t want to be all in on one asset class. It’s a first-world problem to have when you’ve become concentrated in one asset because it’s gone up so much, but it’s not mathematically optimal from a risk-management standpoint. I’ve seen both approaches with people who got into crypto relatively early and made a bunch of money but would prefer diversifying at this point.

I’d say if you don’t own it, bitcoin is a buy, and if you do own some bitcoin in the recommended range and your position matches up with the return expectations above, then I’d hold it. GBTC is my favorite vehicle for owning bitcoin at the moment.
Hiring Staff During the Great Resignation

Strategies practices can use to attract skilled workers to their open positions

by Aine Cryts Contributing Author

Low pay, no opportunities for advancement and feeling disrespected at work: Those are the three top reasons American workers said “I quit” as part of the “Great Resignation,” according to a Pew survey conducted in March 2022. Other experts have referred to this wave of resignations, which rose to a 20-year high in November 2021, as the “Great Reshuffling,” indicating that these workers simply chose better jobs.

While physicians and nurses are more likely to stick around, your front desk staff may have one foot out the door. Experts provide a wealth of advice to hire and retain employees—including offering salaries that compete with local retailers, conducting “stay interviews” and offering four-day work weeks.

Chris Garofalo, M.D., a physician in North Attleboro, Massachusetts, agrees that this is one of the most challenging hiring environments his practice has faced. “There are people who are looking for more flexibility. I know when I talk to my patients. Most people don’t want to go back to the office full time, but they don’t necessarily want to stay home full time.”

Still, one of the issues with a medical practice is that it’s difficult to have people working from home. “We need to take care of our patients in the office setting,” said Garofalo.

He addresses employees’ need for flexibility by letting them take a half a day if they’re sick or want to go to their child’s soccer game. “Most of the time we can accommodate that. They don’t necessarily need to take it as sick time. If someone needs to go, we will deal with it later.”

Hiring strategies for front desk and medical assistant staff

Seeking candidates to fill front desk and medical assistant roles is never easy. According to Garofalo, online job boards can be hit or miss. “About 60% to 70% of the people who respond and make an appointment for an interview no-show the interview. Of the people who show up, 30% to 40% don’t have the medical assistant qualification, and we can’t train on the job,” he said.

Recently, Garofalo needed to hire a medical assistant at his practice so he posted the job opening on Everything North Attleboro, a community Facebook.

“My thought was this was more local,” he said. “It’s not just people who are going to apply generically to job postings. I put a more personal
touch, and we got some really good responses. That’s how we hired our most recent medical assistant, who has 15 years of experience.”

Another option is to actively recruit employees who want to work as part-timers, according to Andy Swanson, CMPE, vice president of industry insights at Medical Group Management Association (MGMA). “Medical practices have gotten better at flexible staffing in the last 10 to 15 years,” he said.

Swanson expects that many of the people who recently left jobs will run out of money and need to pursue part-time work. At a medical practice, that could look like a 9 a.m.-to-2 p.m. shift three days a week for one front desk staffer, and another team member takes that shift the other two days.

“Not everyone wants full-time work....Maybe they don’t want to stop driving for Uber or they want something while the kids are in preschool,” he said. Another benefit of this flexible staffing model: The practice can save money that it would have spent on health insurance and other benefits, added Swanson.

Hiring and retention strategies for administrative staff

The average hourly rate for a Target employee in Sunnyvale, California, is $21.80, while a Target employee in Washington, DC, earns $20.24 an hour, according to San Francisco-based Zippia, which tracks salary information for job seekers.

But understanding the local labor market is one area where medical practices fall short, said Swanson. “You’re competing with fast food services and retail. That means your pay has to be at or above [those workplaces], and you can’t pay the median rate of $18 an hour that MGMA says you should pay for your state or region. “

His advice to the practice’s human resources person: “You need to mind-shift and benchmark pay rates to your market, not just to the national average.”

Jennifer Brull, M.D., FAAFP, a family medicine physician in Plainville, Kansas, doesn’t have to compete with Target’s hourly rate because the retailer is a two-hour drive from her practice. But she can offer her front desk staff some lifestyle benefits that are tough to beat: Minimal physical labor is required and the outpatient practice doesn’t require staff to work evening or weekend hours.

It’s just as important to create a work environment where employees want to stay. Many among Brull’s team have remained at the practice for 10 to 25 years. “We have a reputation for being a culturally good place [to work] where people care about you....If you need to be out for a family event, you

“About 60% to 70% of the people who respond and make an appointment for an interview no-show the interview. Of the people who show up, 30% to 40% don’t have the medical assistant qualification, and we can’t train on the job.”

Chris Garofalo, M.D., North Attleboro, Massachusetts
can do that. You have health care coverage as a benefit. That’s how we try to make ourselves attractive as an employer.”

**Hiring and retention strategies for clinical staff**

In addition to hiring and retaining administrative staff, physician practices have to recruit and retain physicians and nurses. Twenty-eight percent of health care leaders reported losing a physician to an unexpected retirement, according to a March 2021 poll by MGMA. Meanwhile, the U.S. Bureau of Labor Statistics projects a 9% employment growth for RNs from 2020 to 2030; the fastest growth is expected for nurses in outpatient settings.

This is a real-world challenge for Brull, who has decided to leave her practice in November 2022 and hopes to hire two doctors before she leaves. She owns her practice and collaborates with a nearby practice; together they’re recruiting the new physicians.

In addition, a nurse practitioner is leaving the practice in June, so Brull needed to recruit another new clinician. In July, the practice will welcome a new physician assistant who is on course to graduate this spring.

Brull credits her practice’s work precepting physician assistants and nurse practitioners with creating “a pretty big pipeline” for the recent physician assistant hire. “They know who we are. They’re in our practice for a month or more, which is a great way to know if they like us and vice versa. That’s much better than an interview,” she said.

But the practices still need to recruit two physicians. Early on, she and her physician colleagues decided that one of the new physicians should specialize in family medicine with a focus on obstetrics. Besides that, one of the physicians — she’s “an amazing networker,” said Brull — is actively recruiting two new physicians.

She had to work with the nearby hospital to ensure an “income guarantee” for the new physicians and the recruitment process requires “getting us plugged into residency programs across the state,” said Brull.

There are two selling points she’s leaning into as her team recruits two new physicians: Plainville is a rural area with low crime and a good education system, and physicians who choose to practice in the area for four years can have their medical school tuition refunded.

“I grew up in this part of the state,” said Brull, who has practiced medicine in the Plainville area for 20 years. “I moved to the big city for 10 years for training and then I moved back. The only things I miss are the shopping and the food. Now there’s online shopping, which means I only miss the food. And my husband is a great cook.”

Tom Florence, executive vice president of recruiting at Merritt Hawkins, said the company’s physician recruiting business has seen “a tremendous uptick in demand.”

Typically, about 15% of physicians will move or change jobs each year, he explained, but that’s now “hovering in the 25% range.” Florence credits the pandemic with prompting physicians to reconsider what’s important to them. That could be a different location, a different practice setting, different work hours, or the need for flexibility, he said.

When Florence coaches hiring managers, he suggests that they start with a market analysis, much the same way a real estate agent does with a property that comes on the market.

“You want to make sure that the (physician) opportunity they’re providing is viable compared to other physician roles...which includes looking at compensation for a primary care doctor in Boston, for example. If we can’t find a candidate locally, that’s now a national search,” he said.

Beyond salary, flexibility for physicians is critical, according to Florence. “Anytime you can give them set hours or set schedules, they really appreciate that. Four-day work weeks—that’s an opportunity that stands out as well.”

Still, he encourages practices to retain physicians by consistently checking in to see how they’re doing. “Some companies do exit interviews. I encourage clients to do ‘stay interviews.’”
Stay interviews are meetings once or twice a quarter where physicians are engaged in a conversation with the lead physician who asks these questions:
1. How are things going?
2. What can we do to keep you happy?
3. What things do you like here?
4. What would encourage you to stay here?

Professional information services company Wolters Kluwer also offers advice on recruiting nurses, including the following tips:
- Emphasize career advancement by offering new-graduate residency programs and transition-to-practice programs to attract new talent.
- Focus on work-life balance, not just the job.
- Compensate appropriately, realizing that tuition reimbursement and loan repayment programs are attractive perks.
- Offer flexible schedules, which will may help with work-life balance.
- Create “nurse ambassadors” who can connect emotionally with their peers in video testimonials.
- Create a sense of community where nurses feel they have a voice.

Build and sustain a ‘kind culture’
Garofalo is candid about his practice’s inability to compete with larger practices or hospitals that can pay employees more. His strategy: Build and sustain a “kind culture.” For him that means letting an employee leave for the day if their child is sick and backing up an employee if a patient treats them rudely.

Building and sustaining a culture where employees want to work “starts at the top,” said Garofalo. “It starts with the physician-owner and our practice manager. I think we have to model that kind of behavior...We are very protective of our employees. We certainly have had episodes where patients were getting very upset (at employees). We as doctors aren’t afraid to step into that, rather than just delegating it to our employees.”

“It’s important for employees to know we have their backs and we’re there to support them,” added Garofalo.

Here’s some language he has used with a patient who had treated a staffer poorly: “You don’t get to treat employees one way and me another way. You can’t be all ‘nickey nice’ with me (and rude to staff).”

Getting the workplace culture right seems to work as a retention tool, he said. “Over the past four years, we have had three people leave who came back. They got more money elsewhere but they came back here to get paid less. But we provide a better atmosphere for people.”

Successfully navigating conflict among employees also helps, advised Garofalo. His approach to building a “family-type” atmosphere at the practice is twofold. The practice is very careful to ensure the people it hires are a good fit and, he says: “We really try to keep drama to a minimum. We address it. We have our HR person who has no problem addressing it. We make sure that people understand what behaviors will and won’t be tolerated.”

MGMA’s Swanson advises medical practices to think long and hard about the employee value proposition. “That outlines a handful of key drivers in which employees find value, for example, pay, benefits, and vacation, in addition to the career benefit, learning and development, and flexibility with the ability to work from home,” he said.

It can be as simple as practice leaders asking this question: “What are we going to offer on a spectrum of value creators?”

“We’re either going to pay you more...or offer flexibility or better hours. What can we do...to really stand out for the majority of candidates?” Those are the questions every practice leader should be asking, said Swanson. »
Donor-advised funds
FIVE BENEFITS FOR PHYSICIANS

by Julianne F. Andrews, MBA, CFP, AIF
Contributing Author

Would you like to make a donation that supports a cause you believe in and reduces your taxes? Maybe you would like to get the tax benefits now but take more time determining which charities should get your money. Many high-earning physicians find that taking advantage of a donor-advised fund is often a simple, tax-savvy way to make charitable contributions.

What is a donor-advised fund?
A donor-advised fund (DAF) is a special type of account used specifically for making charitable donations. You (the donor) make contributions to a nonprofit, third-party entity that hosts the account (the sponsor). You then recommend to the sponsor which charities should receive your donations.

Your contributions to the DAF can be made in the form of:
- **Cash.**
- **Securities (stocks, mutual funds, exchange-traded funds).**
- **Real estate.**
- **Private equity interests.**
- **C corp and S corp shares.**
- **Cryptocurrencies.**

Once a contribution has been made to the DAF, the transfer is irrevocable. Always consult your financial adviser before funding your DAF to discuss the option most beneficial to you.

What are the benefits of DAFs?
DAFs offer a variety of benefits for high-earning physicians looking to reduce taxes, support their favorite charities and simplify their giving strategy.

1. **TAX EFFICIENCY**
One of the biggest reasons wealth managers recommend DAFs involves the tax benefits they offer. Normally when you donate to a charity, the funding comes from earned income on which you have already paid taxes. Or it might come from the sale of securities, which could trigger taxes on the capital gains.

By contrast, when you contribute to a DAF using an appreciated asset, you can avoid paying capital gains on the contribution (if the asset was held for more than one year). Instead of gifting assets that would otherwise incur a tax event, you can strategically use the DAF to reduce your tax burden.

Contributions to a DAF can also be particularly beneficial for individuals with concentrated positions in company stock. Rather than trying to sell their shares and attempting to rebalance their portfolio, they could instead gift those shares to the DAF by making a tax-exempt transfer.

Your federal tax return could benefit as well. When donating securities to a DAF, your contribution could serve as a possible above-the-line tax deduction worth up to 30% of your adjusted gross income, and up to 60% when donating cash.

2. **Bunching contributions**
In recent years, many high net worth taxpayers have witnessed the unfortunate removal of a substantial number of itemized deductions from their Schedule A worksheets. The standard
deduction was raised substantially, but *unless your itemized deductions exceed the standard deduction, your charitable gifts will not help to reduce your taxable income*. Many charitably inclined physicians, then, are receiving little or no tax benefit from their generous contributions. For those individuals who regularly donate to the same charities each year, bunching deductions with a DAF could help physicians exceed the standard deduction threshold amount and receive a larger tax benefit for their charitable contributions.

Instead of making individual donations over the next two to four years, you combine them into one larger DAF contribution. You will get the tax benefit of the full, larger contribution for that year, which will help your itemized deductions. In the interim years, you would then take the standard deduction. It can be particularly helpful to “bunch” in years when you anticipate that income will be higher to offset a potentially higher tax liability.

### 3. Tax-Free Growth Potential

Once you contribute assets to the DAF, they will grow tax free within the fund (like a Roth IRA). Generally, the assets will be converted to a limited group of investment offerings like a 401(k). Depending on the organization, they may even be managed by a financial adviser. Ultimately, this will increase the potential for your contributions to grow in value and could lead to larger grants to charities of your choice.

### 4. Delayed Distributions to Charities

Suppose you would like to take advantage of these tax benefits or have a cause you would really like to support, but you are uncertain as to which charitable organizations are the right ones for your donations. A DAF can serve as an intermediate holding account. Large contributions can be made to your DAF all in one year and dispersed to the charities of your choice months or even years later. Meanwhile, your contributions are still tax deductible in the year they were made.

### 5. Less Recordkeeping

Rather than making multiple donations to several charities and then trying to keep track of them, a DAF can be used to simplify the process. You only need to contribute to the DAF and then let the DAF manage the logistics of distributing your grants. To your benefit, you will receive one consolidated statement that you can easily submit to your tax professional.

#### How do I contribute to a DAF?

Chances are that if you are already investing with a major full-service brokerage, you will have the opportunity to contribute to a DAF. Many reputable services like Vanguard, Fidelity and Charles Schwab each have charitable arms that qualify as a section 501(c)(3) organization according to the IRS. For some of these institutions, the minimum starting amount can be as little as $5,000.

Several public and community foundations also serve as DAF sponsors. These organizations will typically cater to specific social, regional and faith-based causes.

#### Make the most of your charitable donations

Donating to charity is a noble act, but it can also be done in a way that is beneficial to your bottom line. After all, if you can save in taxes, you will ultimately have more wealth with which to make an impact. A DAF can be a great way to avoid paying taxable capital gains and to have more flexibility over when charities will receive your grants. »

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PLANNING TIP

This gifting strategy can even be incorporated into your estate plan. Proceeds from a retirement plan or life insurance policy can be gifted to the sponsor to reduce or even eliminate the potential tax burden on your heirs.
Cost segregation
Use this tax deferral method to front-load depreciation deductions

For many physicians, owning property is a key part of their business planning. Having your practice in a building you own gives you control over the property and, potentially, additional income. For instance, owning a building that is larger than you need for your own practice allows you to rent the extra space to someone else and then make the passive income from the rental. However, there are expenses that go along with that, including maintenance, repairs and taxes. Taxes are inevitable, as the saying goes, but there are ways to mitigate some of the high taxation that can come with property ownership. One such solution is cost segregation, which takes advantage of depreciation to analyze a property in a way that can save an owner money.

What is depreciation in real estate?
Everything involved in a property has a natural loss of value due to normal use — think the wear and tear that an office will take on a daily basis over the years, from thinning carpets to aging plumbing. Depreciation allows the property owner to write off more for taxes by considering that regular wear as loss of property value. For commercial property, depreciation is measured over 39 years, a considerable length of time. When looking at depreciation of property, the entirety of the property is considered, from that thinning carpet to the building itself.

What is cost segregation?
Cost segregation is a tax deferral method that front-loads the depreciation deductions by breaking the property down into different asset classifications that are subject to their own depreciation timelines rather than taking the property as a whole. Considering the components’ shorter depreciation schedules, cost segregation lowers the taxable income of a property at a quicker rate, which can maximize tax savings. This is helpful to increase cash flow and reduce taxes, which is especially beneficial in the early years of ownership.

How does cost segregation work with depreciation?
To start the process, a cost segregation analysis must be done on the property. This study is conducted by engineers and CPAs, who consider the property and separate it out into components, including electrical and plumbing systems, carpeting and wall coverings, computers and other specialized equipment, which will vary by property type. Each of the components is measured against its own particular depreciation schedule rather than that of the whole property, differing from the usual way depreciation for a property is measured. The depreciation times for these individual components is considerably shorter than the 39-year commercial property depreciation timeline, in some cases, as short as five years. This shorter time is the result of those components being reclassified as personal property. For property owners, this means writing off more and ultimately paying lower taxes on the property.

Since 2017, federal regulation has made the benefits even more attractive for property owners, allowing both businesses and individuals to deduct a certain percentage of costs the very first year they’re in service. This includes used as well as new property, and through 2022, the percentage is 100 percent. With these savings and the resulting increased cash flow, it may be a good time to purchase property.

How much does it cost?
While anyone could identify separate assets in a property, because the final report is subject to IRS review, it’s important to ensure you have professionals conducting the survey and creating the reports to make sure things are identified correctly for their true value. The fees associated with cost segregation stem from the analysis itself. Depending on the type of property and its size, the costs can vary, but the general cost will range between $3,500 and $7,500 per property and will likely take two to three months to complete. This should include the engineer walk-through as well as the final report.

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Medical Economics
SMARTER BUSINESS. BETTER PATIENT CARE.
10 tips for successfully negotiating payer contracts

by Lisa A. Eramo, M.A. Contributing Author

Before her practice joined an accountable care organization (ACO), payer contract negotiations seemed impossible, according to Karen Smith, M.D. Her family medicine practice in Raeford, North Carolina, couldn’t compete with large multispecialty clinics and hospital corporations.

“We accepted what we were given,” Smith says. “Contract negotiations were definitely one-sided.”

Since her practice joined the ACO, however, payment rates have gone up. There’s also the potential for shared savings — additional money that ACO members receive for providing cost-effective, high-quality care.

“Now we get paid in a manner that supports our practice, including our overhead,” she says. “That makes life a little easier and it allows me to invest back into my practice.”

The struggle is real

Many physicians struggle with fee-for-service payer contract negotiations because asking for higher payments can feel like a futile effort, says Andrew Harding, co-founder and vice president of customer success at Rivet, a healthcare billing and payment company that works with practices. “Payers invest millions of dollars into modeling software,” he says. “They hold the data and they basically hold all of the cards. They have a lot of power.”

Still, negotiating a successful payer contract is possible for those willing to craft a thoughtful, data-driven argument for why they deserve more money, Rivet says.

“I think this is an often-overlooked revenue generator,” he says. “Physicians think it will be really stressful or not yield any results, but if it’s been more than a few years, chances are your payers haven’t kept up with industry changes and inflation.”

What’s a reasonable payment increase?

Harding says he often helps physicians successfully negotiate a 3% to 5% increase every few years.

Consider these strategies to negotiate favorable payer contracts:

1. Obtain copies of payer contracts and fee schedules.
   “You can’t negotiate if you don’t know the baseline,” Harding says. “Use those contracts and fee schedules to forecast a 3% or 5% increase. How much actual revenue will that bring to your practice?”

Another reason to review current contracts is to identify and address payment variances that are below your contractually agreed-upon rate. Harding worked with one practice that hadn’t realized a payer never implemented a 5% increase negotiated five years previously.

2. Explore alternative payment models.
   If an independent physician isn’t already part of an ACO or clinically integrated network (CIN), they should consider joining, says Faisal Khan, senior counsel at Nixon Gwilt Law. “You can still be a standalone practice,” he says. “It’s about taking advantage of opportunities to partner with a larger entity to demonstrate quality.”

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www.medicalworldnews.com
Smith agrees. “Our payment models are going to continue to change,” she says. “It’s so important for practices to be prepared to move and shift in the direction that will keep the business alive.”

3. **Provide cost and quality data.** Even if you’re not part of an ACO, CIN or other type of value-based contract that requires you to capture certain quality and cost metrics, you’re probably participating in Medicare’s Merit-based Incentive Payment System, which does require some of this data collection. What do Medicare data say about the care you provide, and how might you use those data to your advantage when negotiating with commercial payers? Use those results as leverage. “It’s beneficial for payers to have these high-quality independent practices in their network,” Harding says.

4. **Differentiate yourself.** When you ask for a payment rate increase, show the payer what value you provide compared with your local peers, Harding says. For example, is yours the only practice that offers extended business hours during the week or telehealth appointments on the weekends? Are you the only primary care physician in a 5-mile radius? Harding says it’s easy to obtain this information by going to a payer’s website or an online booking service such as Zocdoc and performing a search using your ZIP code to see how many physicians practice nearby. Physicians may have market dominance within a few-mile radius and not realize it.

5. **Identify your volume of active patients.** This is the number of unique patients you’ve seen in the past two years, Harding says. Remind the payer know that if you go out of network, the payer will need to notify patients that their designated primary care physician is no longer in network, which potentially will make patients unhappy about having to switch physicians. “It’s a lot of administrative headaches for payers and for patients,” he says.

6. **Consider an escalator clause.** An escalator clause is a contract provision that guarantees a specific payment increase during a defined period. For example, practices could negotiate a three-year contract but build in automatic increases of 1% each year.

7. **Perform a payer analysis.** How does one payer’s payment rates compare with others? Is that payer paying below-market rates? If so, use deidentified information (either the average or rate by rate) to build a case for higher rates, Harding says. Talk with other physicians in your local area to get a sense of their contracted rates, says Boyd Stewart, vice president of payer/provider collaboration at KLAS Enterprises. KLAS is working with various practice management vendors to obtain blinded data it can use to publish benchmarks for payment rates, denial rates and more.

8. **Negotiate carve-outs for high-utilization services.** For example, your practice may be able to negotiate higher rates specifically for office visits to maximum revenue impact, Harding says.

9. **Add services to your fee schedule.** Many physicians perform COVID-19 immunizations and laboratory tests, the codes for which may not be on their fee schedule with a specific pre-negotiated contracted rate, Harding says. Instead, they’re paid a percentage of charges, which is often lower. “All you need to do is add these services to your fee schedule and you’ll be paid more money for performing the same service,” he says.

10. **Know where you’ll draw the line.** “If a payer isn’t going to pay comparable rates or increases, you always have the option to leave the network,” Harding says.

**Words of caution**

When you do negotiate an increased payment rate, doublecheck that it will benefit your practice. “A payer might provide a 5% increase, but when a physician looks at the services they provide most often, they might see those are actually getting a 2% cut,” Harding says.

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**Sample contract language**

**Contract review checklist**

**Examples of significant payer unilateral policy changes**
Trusts 101 for physicians

Trusts can be effective and important legal tools, but they are not all the same and they are not universally interchangeable. We examine some of the trust law basics and terms every successful physician should know when evaluating their own legal planning needs.

WHAT IS A ‘TRUST’?

For the purposes of our discussion, a trust is a formal, binding, legal document that allows an individual to create and transfer title to property or value of any kind to the control of another for the benefit of a third party.

- The entity that creates and funds a trust is known as a “grantor” or “settlor.” If there is more than one, they are known as “co-grantors”; e.g., husband and wife as co-grantors.

- The trust is under the control of a “trustee.” If more than one trustee is serving at the same time, they are known as “co-trustees”.

- The trustee manages the trust in accordance with the terms it provides, most commonly for the benefit of a third party, known as the “beneficiary.”

- There may be one or more beneficiaries and some trusts name “primary” and “contingent” beneficiaries; e.g., a wife leaves her estate to her husband as primary and to her three children as contingent beneficiaries if he predeceases her.

Two key trust terms: ‘revocable’ and ‘irrevocable’

These are key terms in any trust. Understanding them is especially important to those who are using a trust as part of an asset protection plan. A revocable trust can be revoked at any time up until your last breath, allowing you to change the trust details, including the trust’s assets and beneficiaries. As such, a revocable trust is defective against your creditors and liabilities, during your lifetime. An irrevocable trust, on the other hand, makes a permanent transfer of assets away from yourself to the trust so that the assets are trust property and not available for your personal or professional liability. With these basics in mind, we will look at specific types of trusts in greater detail.

Trust situs – jurisdictional issues

The term “situs” refers to the jurisdiction and choice of law selected for the trust. Trusts may be established under the law of your state, another U.S. state, or the laws of a foreign nation or “offshore.” Different jurisdictions may have significantly different laws, taxation, and compliance requirements, including which asset protection benefits they provide.

Some special purpose asset protection trusts don’t rely on specific creditor protection laws, but rather on other well-established legal principles, including arm’s length sales transactions (e.g., you sell an asset to a trust for fair market value) and gifts to trusts that are considered “completed gifts” by the IRS for tax purposes and of which you relinquish title and control.

The myth of trust ‘secrecy’

Any asset protection plan or planner that uses the term “secret” should be a red flag and most likely avoided. There is no such thing as secrecy in the law (as opposed to privacy, which does exist and can be a trust benefit) and any plan that relies on assets being held in a trust, limited liability company, etc., that you hope isn’t found will also require your willingness to actively lie to conceal it. Why? Because an experienced litigator will simply ask you, under oath in discovery, in a deposition, in a debtor’s exam, etc. to disclose “any trust, partnership, corporation, foundation or similar device that you are a grantor, trustee, beneficiary, officer, member or director of.” You’ll either answer honestly or you’ll be committing perjury.

Ike Devji, J.D., has practiced law exclusively in the areas of asset protection, risk management and wealth preservation for 16 years. Send your legal questions to Medec@mjhlifesciences.com.
Five ways digital health is reshaping patient care in 2022

by Gary Manning

If the last year and a half has taught us anything, it's that the future is rather unpredictable. That being said, it pays to take a clear-eyed look at the powerful potential that existing and emerging digital technologies offer for improving the quality of patient care in 2022 and beyond.

Here are five ways that digital health is reshaping the health care environment:

1. **Proactive, predictive, personalized digital health management enhances care**
   When patients think about digital health, they typically envision the opportunity to have a telehealth/virtual visit with a caregiver because they don't feel well or are experiencing symptoms that concern them. However, it's time to start thinking about digital health in a much broader perspective: the capability to anticipate and address issues before serious or life-threatening health concerns arise.

   Specifically, remote patient monitoring (RPM) — a key component of virtual care — will increasingly help clinicians proactively manage post-acute and chronic care using a highly personalized, data-informed approach. Step 1 is to establish a personalized profile for each at-risk patient using artificial intelligence (AI)-based analytics applied to continuous real-world patient data captured by wearable sensors. Step 2 is to identify and alert clinicians about anomalies specific to that individual patient that can signal potential health problems.

   For example, rather than comparing a patient with heart failure to millions of others living with the same condition, this technology can determine the baseline at which an individual patient has been functioning and safely living. By tracking changes in sleep, exercise, vital signs or other physiological measures, clinicians can intervene proactively to prevent or mitigate issues in a more personalized approach.

   The result is a win-win-win: Clinicians may improve quality of care, hospitals may reduce unnecessary and costly readmissions and patients may remain in their own homes longer, more comfortably and more confidently.

2. **Hospital-at-home options enable providers to maximize resources**
   The pandemic vividly underscores the challenges health systems face when seriously ill patients outnumber available hospital beds and exacerbate clinician shortages. Deploying digital health platforms that continuously monitor patients and use AI to extract clinical insights can significantly help stretch these limited resources.

   In some cases, patients who were believed to require hospital admission can be “admitted” to their home while clinicians remotely manage their care, freeing up hospital beds for the sickest individuals in need of such care. Providers then deliver commensurate quality of care in a lower-cost environment and patients recover or manage their condition in the comfort of a familiar environment. In other words, the hospital comes to the patient.

   Enhancing hospital-at-home options enables health systems to deliver the right care from the right clinician to the right patient at the right time. The expanded
and innovative virtual care payment models CMS implemented so hospitals can count on receiving reimbursement for this approach further support its viability.

3 **Continuous RPM and AI analytics help prevent avoidable, costly readmissions**

Unnecessary and avoidable readmissions continue to be a costly challenge for hospitals. For example, readmission rates are often as high as 25% for patients living with heart failure and chronic obstructive pulmonary disease. The ability to prevent just a handful of those readmissions provides significant savings.

Continuous RPM combined with AI to extract insights and provide context around the physiological data captured delivers a more complete picture of the patient. This, in turn, supports clinicians’ ability to intervene in a timely manner to prevent readmissions. To cite just one example, a clinician may need to understand whether a patient’s heart rate spiked because she just ran up the stairs or because her condition is deteriorating. On-demand access to near real-time data can guide decision-making and appropriate treatment.

4 **Disease- and device-agnostic RPM plus AI analytics provide valuable health insights**

Wearable sensors are becoming increasingly commonplace, with the global wearable medical devices market poised to expand at a compound annual growth rate of 26.8% from 2021 to 2028, according to Grand View Research. As consumers grow more comfortable wearing noninvasive devices as part of their daily routine, it has become easier to monitor a broad range of vital signs and physiological activity important to understanding wellness and illness.

But data alone are often insufficient for health management; the “magic” comes from applying AI-based analytics. Disease- and device-agnostic machine learning-based platforms can extract personalized clinical insights from volumes of data and trending, zeroing in on the specific health needs of each individual. Armed with this information, clinicians can partner with patients to create, implement and monitor health management plans tailored to patients’ unique requirements and goals.

5 **Digital health technology supports better medication dosing and adherence**

Poor medication adherence costs our health system billions of dollars each year. Digital health platforms using AI may improve medication adherence through increasing the touch points with patients to help them more easily stay on track with their medication regimen.

But even more exciting is the opportunity for life sciences companies and clinicians to collaborate with technology companies to help provide the information needed for clinicians to titrate medications according to specific patient needs. For many medications, adjusting the drug to the optimal dose requires multiple patient visits. This is burdensome for both patient and clinician and delays optimal treatment.

Remote monitoring of the patient’s physiological response to the current dose allows the clinician to track key vital signs that may make it safe and effective to adjust medication doses while the patient stays home. This home-based approach to medication management reduces the hurdles to optimal dosing for myriad diseases.

Digital technologies are increasingly redefining health care in multiple ways. They help patients take the right medications in the right dosages at the right time and enable clinicians to identify signs of decompensation and other clinical risk factors so they can proactively intervene to improve outcomes. They also support providers seeking cost-efficient ways to optimize finite health care resources. All of this bodes well for exciting opportunities for everyone to live their healthiest lives possible.

Gary Manning is senior vice president and general manager, healthcare, physIQ.
THE NEXT CHAPTER FOR INTEROPERABILITY IS UPON US

As health care leaders navigate our transition from life in a pandemic to a world where COVID-19 is an endemic disease, interoperability will likely be top of mind. As we enter the pandemic’s third year, we can expect four new drivers to propel interoperability:

1. **Trust and interoperability**
   Interoperability and the recent surge in support from health care leaders for Fast Healthcare Interoperability Resources (FHIR), spurred by federal mandates, have unlocked previously siloed data stored behind proprietary internal enterprise systems. By mandating that patient data be made accessible via Application Programming Interfaces (APIs) and standardized formats, health care is effectively liberating data resources, allowing parties beyond payers and providers to create value on behalf of patients.

   Now data have the potential to flow freely between stakeholders in health care, but questions remain: Is the information verifiable and can we trust it? Trust is a foundational element across the health care ecosystem, impacting quality of life and cost of care for millions of patients.

   For governments, health plans and providers to use the data now accessible, the pipelines providing the infrastructure for transport and aggregation of the data must be verified and certified. The expectation is for a push to develop and implement a nationwide fabric of policies, technologies and governance mechanisms to guarantee trust in quality of information, as well as the dependability of its delivery to and from digital end points. This would require the fully articulated consent of patients. The industry will be able to deliver on the vision of value-based care like never before, because ability to accurately report on quality of care and the impact of decisions on payments and premiums is now reality.

2. **The rise of digital health apps**
   Consumer apps that verify negative COVID-19 test results and vaccination status are quietly gaining significant support across political lines for many reasons. Already these apps have proven useful for international travel, cruises and increasingly for access to public event venues, conferences and even weddings and other private affairs. Domestically, and to some extent internationally, most of these apps are adopting the HL7 FHIR standards promoted by the VCI Initiative and using the SMART Health Card framework.

   Adoption of these digital tools by consumers and vendors will inevitably accelerate interoperability and the use of FHIR. Payers, providers and other stakeholders will continue to expand the use of SMART Health Cards to enable patients to become true agents of interoperability, carrying their information to every encounter where it might be required.

3. **Generation Z’s demand for a more personalized experience**
   Generation Z is the first to know only a world with the internet, smart devices and apps. As a result, its members have radically different views about privacy and trust in the digital world, as well as an understanding that convenience is often based in transparency. Having grown up with Google, Facebook, Amazon, Instagram and Yelp, Gen Z has become accustomed to the instant availability of information about anything while seemingly having little hesitation about sharing.

   With these patients, there is an emerging quid pro quo relationship between sharing information and receiving better access to great care. Add big data, machine learning, artificial intelligence, ubiquitous cloud access and REST (representational state transfer) APIs, and the expectations bar for Gen Z will be much higher than anything we have seen. Gen Z is pushing the industry to mirror the same consumer-centric experience as e-commerce at large. Interoperability will be key in reaching that level of personalization.

4. **More sticks with the carrots**
   The dangling carrots for interoperability have increasingly been the real dollars associated with reduced burden, reduced cost and fully engaged patients — all within the context of increased quality of and better access to care.

   Meanwhile, legislation such as the No Surprises Act and the 21st Century Cures Act that broadly cover payers, providers, and technology vendors act as sticks banging on the industry with which to further enhance interoperability.

   More than ever, payers, providers and now patients are realizing the value in interoperable data exchange. In 2022, we can expect interoperability discussions to transition from how we share data to how we trust data.

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**John Kelly** provides strategic consulting to Edifecs customers, specializing in information exchange and applying principles of supply chain integration to the health care delivery lifecycle. Previously he was CIO of health care network provider NavNet, director of eBusiness Architecture at Harvard Pilgrim Health Care, and managing director of his own health IT consulting firm.
The Foundations of a Great Tax Plan

INTRODUCTION
Doctors and consumers generally know it’s best to start saving for retirement as much as possible, as early as possible. A 2021 survey by the American College of Physicians member insurance program found about half of early-career physicians, those in their 30s and 40s, were behind where they would like their savings portfolio to be.

In 2021, inflation forced Americans to reconsider the value of a dollar, now and in the future. In the 12 months from January 2021 to January 2022, the Consumer Price Index for All Urban Consumers rose 7.5%, according to the federal Bureau of Labor Statistics. Doctors were left wondering how to put more money in their pockets to cover rising costs in the future.

Remarking on the ratification of the U.S. Constitution, Founding Father Benjamin Franklin noted that “in this world, nothing is certain except death and taxes.” Physicians spend their careers helping patients fight against the former. For their own financial health, they should consider ways to fend off the latter.

LEARNING OBJECTIVES
- Discover actionable tips to grow your retirement nest egg.
- Identify tax minimization strategies well suited for you and how to use them.
- Understand the benefits and steps required to personalize your financial planning.

MEET THE PANELIST
Alexis E. Gallati, EA, MBA, M.S. Tax, CTP, founder and lead tax strategist at Cerebral Tax Advisors of Knoxville, Tennessee. Gallati is the author of the book “Advanced Tax Planning for Medical Professionals” and has written for Medical Economics®.
1% of S corporations and partnerships were audited in 2019.
Managing money through retirement is a cycle with three phases: the seed, the growth, and the harvest.
The seed is the initial investment in an asset or an account. Growth happens over time.
The harvest is money used to live on during retirement.
“You can pay or avoid taxes at each of these points depending on the nature of the assets you buy or the account you invest in,” Gallati said. “Which place is the best? Well, it depends on a lot of factors, most importantly including where your personal tax rates are at any particular point in your cycle.”
Younger physicians may have situations different from those at retirement age or beyond it.
Different investments offer tax breaks at different times – some when they start as seeds at the time of investment, some when they are ready for harvest, or withdrawal.
Consider hiring children to maximize retirement savings for yourself and for them.

“It pays to be aggressive and that’s because overall audit odds are so low that most legitimate deductions aren’t likely to wave red flags.”
Alexis Gallati, Cerebral Tax Advisors, Knoxville, Tennessee.

Solutions & Takeaways

- Building a retirement nest egg consists of defense – cutting expenses – and offense – saving money to make money.
- Physicians should respect the IRS but shouldn’t be afraid of creating a legal tax plan that minimizes taxes to maximize retirement savings.
- Sole proprietorships, partnerships, and corporations are small businesses that can help physicians reduce their income tax burdens.
- Different investments offer tax breaks at different times – some when they start as seeds at the time of investment, some when they are ready for harvest, or withdrawal.
- Consider hiring children to maximize retirement savings for yourself and for them.

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Different investments offer tax breaks at different times – some when they start as seeds at the time of investment, some when they are ready for harvest, or withdrawal.
Different investments – taxable stocks, traditional or Roth IRAs, nonqualified annuities, cash value life insurance, health savings accounts – have different tax advantages at each stage.
For example, with a traditional IRA, the seed and growth are tax free. But withdrawals — the harvest — are taxable.
Gallati says health savings accounts are a personal favorite because the seed, growth and harvest all are tax free for paying for qualified medical expenses.
Each investment needs research, but tax breaks may be available on the seed, growth or harvest. Take the break when it’s the best, Gallati says.
“You basically have to figure out where you’re at in your finances and you have to play a little bit of mind reader and have your crystal ball to know what tax rates are going to be like,” Gallati says. “Different people have different philosophies when it comes to what would end up being best.”
A home office — with family as staff — can be part of a physician’s retirement savings plan.
Hiring children is a favorite strategy, Gallati says, because it allows doctors to put away money for retirement for themselves and for their children.
The employees, 7 years and older, must earn reasonable wages and have their own job descriptions, time sheets and bank accounts. With the right amount of savings, time and investment growth, children may be millionaires themselves when they retire, Gallati says.
Home offices, along with mileage and meals, can serve as tax deductions for physicians.

More Online
Check out the full video and materials of this session.

32 Medical Economics | May 2021
WE’RE NOT THE TAX PEOPLE YOU’RE USED TO HEARING ABOUT

When was the last time your tax advisor said: “Here’s an idea that will save you money?

- PROACTIVE TAX PLANNING SERVICES
- SPECIALIZED IN PHYSICIANS
- CLIENTS IN 40+ STATES
- SELECT NUMBER OF CLIENTS
- 20+ YEARS OF EXPERIENCE

Our clients see an average
100% - 250% RETURN ON INVESTMENT IN TAX PLANNING

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1-865-281-1461
Preventing coding and billing errors can reduce claims denials

INTRODUCTION
For primary care practices, earning enough revenue to meet overhead expenses and provide quality care has always been a challenge. But practices often make the challenge even greater through sloppy coding and billing, leading to delayed or incorrect reimbursements from payers. The Centers for Medicare & Medicaid Services estimates that in fiscal year 2021, Medicare made $6.25 billion in fee-for-service payments that were improper under its coverage, coding and billing rules.

Fortunately, there are steps doctors and practice administrators can take to ensure they receive all they are owed in a timely fashion. But it requires forethought, training, and commitment from everyone in the practice.

LEARNING OBJECTIVES
- Identify the most common reasons for denials and how to handle them differently to improve practice revenue.
- Audit your practice’s coding program and identify areas for improvement.
- Learn coding best practices and what changes may be in store.

MEET THE PANELIST
Nancy M. Enos, FACMPE, CPMA
Independent Consultant
MGMA Health Care Consulting Group

“Use audit feedback to learn, to protect your practice, and make sure that you’re optimizing your reimbursement and reducing your risk.”

“...didn’t go to medical school to become a medical coder or biller” is a common refrain among doctors unhappy with the time and resources those tasks require. Nevertheless, coding and billing are inescapable parts of practicing medicine, and doing them poorly can have severe financial consequences, either from frequent claims denials or overbillings that the practice must then repay.

Longtime coding consultant Nancy Enos, FACMPE, CPC, CPMA, says claims denials often are the result of errors in billing. Consequently, reducing denials requires identifying the source of the mistakes and providing feedback to staff on how to avoid them. “Without that feedback loop there’s no education and no stemming the tide,” she says.

Enos advises practices to focus on three areas for reducing billing errors and claims denials: front office, clinical staff and back office. Common front office-related reasons for denials include the following:
- Lack of coordination of patient benefits.
- Expired insurance coverage.
- Expenses not covered by a patient’s insurance.
- Expenses incurred prior to the patient’s coverage date.
- Lack of required precertification/authorization for an expense.

“The front office is where the revenue cycle begins,” Enos says. That means staff members need to verify eligibility up front so patients know their financial responsibilities and agree to meet them.

Clinicians can minimize claims denials by making sure their notes are concise, detailed and specific, Enos says. “Diagnosis lacking specificity is one of the biggest reasons for denials. Putting in the clinical details such as the problem’s severity and whether it’s chronic or acute will get you to the most specific diagnosis code and get your claim paid faster,” she explains.

Other problems she frequently sees in clinical notes include:
- The date of service doesn’t meet frequency limits.
- Time spent with the patient for time-based services is not documented.
The note is not signed.
The billing provider’s and service provider’s names don’t match.
The note doesn’t support the CPT codes reported for it.

In some ways, back office staff face the biggest challenges in the effort to reduce claims denials because many of the issues they deal with are ambiguous, Enos says. She cites the example of erroneous unbundling. “It’s difficult to completely prevent it because you don’t always know which payers will pay for lesser procedures at the same time as more comprehensive ones,” she says.

Other issues back offices frequently deal with include the following:
- CPT codes are inconsistent with the place of service.
- The patient has reached the benefit maximum for the time period.
- Claims are duplicated.
- Procedure/modification combinations are incompatible.
- Referral(s) are not listed on the claim.

When such mistakes occur, “it’s the back office’s responsibility to rectify them as quickly as possible, then share the feedback with the source of the errors,” Enos says.

The possibility of having to repay thousands of dollars following a payer audit is another reason for closely monitoring billing and coding procedures, Enos notes.

“Plan to be audited at some point, and don’t assume everything’s OK as long as you’re getting paid,” she advises. The best way for practices to prepare, especially individual and small group ones, is to follow the compliance program developed by the U.S. Department of Health and Human Service’s Office of Inspector General. Its recommendations include the following:
- Conduct internal monitoring and periodic audits.
- Implement compliance and practice standards by developing written standards and procedures.
- Designate a compliance officer or contact(s) to monitor compliance efforts and enforce practice standards.
- Conduct training and education on the standards and procedures.
- Investigate violations or allegations of violations and disclose any incidents to the appropriate government entity.
- Develop open lines of communication such as staff meetings on how to avoid erroneous or fraudulent conduct.

Enos recommends doing “benchmark” audits of five to 10 records per provider, followed by a minimum sample of 10 to 20 of the provider’s claims submissions, either retrospective or prospective. Departments or individuals of particular concern should undergo focused audits using at least 50 charts.

“Don’t look at auditing and monitoring as a form of punitive obligation, but as a way to ensure that you’re billing and coding properly,” Enos says. She says internal monitoring has the additional benefit of identifying and correcting undercoding, a problem common to most of the practices she works with.

After completing an audit, it’s critical to share the results throughout the practice. “It makes sense for a patient to see their doctor after getting an MRI, so why wouldn’t you want to provide feedback after an audit?” she says. Then she urges using the results to develop further training and education.

“Use that audit feedback to learn, to protect your practice and make sure that you’re optimizing your reimbursement and reducing your risk,” Enos says.

MORE ONLINE Check out the full video and materials of this session. 
https://medicaleconomics-377s8g0ne-mjhl5.vercel.app/view/coding-and-documentation?page=15
Another episode of overt hepatic encephalopathy (OHE) may be right around the corner. What can you do to reduce your patient’s risk of recurrence?

"I was oblivious to what was going on around me"

Align with the guidelines for patients at risk

XIFAXAN earned AASLD/EASL’s highest possible recommendation (GRADE I,A,1) as an add-on therapy to lactulose to reduce the risk of overt HE recurrence after a patient has a recurrence while on lactulose alone.1*

AASLD=American Association for the Study of Liver Diseases
EASL=European Association for the Study of the Liver

*Per the GRADE System for Evidence: Grade I=randomized, controlled trials; A=evidence is “high quality,” and further research is very unlikely to change our confidence in the estimated effect; and 1=recommendation is “strong,” with factors influencing strength of recommendation including the quality of evidence, presumed patient-important outcomes, and costs.

INDICATION

XIFAXAN® (rifaximin) 550 mg tablets are indicated for the reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults.

IMPORTANT SAFETY INFORMATION

- XIFAXAN is contraindicated in patients with a hypersensitivity to rifaximin, rifamycin antimicrobial agents, or any of the components in XIFAXAN. Hypersensitivity reactions have included exfoliative dermatitis, angioneurotic edema, and anaphylaxis.
- *Clostridium difficile*-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including XIFAXAN, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued.
- There is an increased systemic exposure in patients with severe (Child-Pugh Class C) hepatic impairment. Caution should be exercised when administering XIFAXAN to these patients.

XIFAXAN is the only FDA-approved agent indicated for the reduction in risk of OHE recurrence in adults.²

In a clinical trial of adults, XIFAXAN cut the risk of OHE recurrence and HE-related hospitalizations in half²

91% of patients in the placebo and XIFAXAN groups were on lactulose²

Study design²
- In a randomized, placebo-controlled, double-blind, multicenter, multinational, 6-month study, the efficacy of XIFAXAN 550 mg (taken orally twice a day) was evaluated in 299 adult subjects
- Inclusion criteria: Currently in remission (Conn score of 0 or 1) from HE and ≥2 episodes of HE associated with chronic liver disease in the previous 6 months
- Primary endpoint: Time to first breakthrough overt HE episode, defined as a marked deterioration in neurological function (an increase in Conn score to grade ≥2 or an increase in Conn score and asterixis grade of 1 each if subject entered study at grade 0)
- Key secondary endpoint: HE-related hospitalization

IMPORTANT SAFETY INFORMATION (continued)
- Caution should be exercised when concomitant use of XIFAXAN and P-glycoprotein (P-gp) and/or OATPs inhibitors is needed. Concomitant administration of cyclosporine, an inhibitor of P-gp and OATPs, significantly increased the systemic exposure of rifaximin. In patients with hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to rifaximin.
- In a clinical study, the most common adverse reactions for XIFAXAN in HE (≥10%) were peripheral edema (15%), nausea (14%), dizziness (13%), fatigue (12%), and ascites (11%).
- INR changes have been reported in patients receiving rifaximin and warfarin concomitantly. Monitor INR and prothrombin time. Dose adjustment of warfarin may be required.
- XIFAXAN may cause fetal harm. Advise pregnant women of the potential risk to a fetus.

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

“lt feels good to know XIFAXAN has my back”
1.2 Hepatic Encephalopathy

Rifaximin is indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults. Patients, including 265 exposed for 6 months and 202 for 18 months, experienced a lower incidence in XIFAXAN-treated subjects than in the placebo group in the 6-month trial (10). See table below for more detailed information:

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1.3 Drug Interactions

The following advers reactions, presented by body system, were reported in patients with a history of hepatic encephalopathy, the systemic exposure to rifaximin and a P-gp inhibitor such as cyclosporine is needed. See Warnings and Precautions (5.5). Clinical Pharmacology (12.3).

1.4 Overdosage

No specific information is available on the treatment of overt or subacute toxicity from rifaximin overdosage. In clinical studies at doses higher than the recommended dose and associated with symptoms of drug-induced liver disease, hepatic encephalopathy, and IBS were reduced in patients with hepatic encephalopathy who had rifaximin concentrations of 1.5-6 times the recommended dose for HE. The results of these studies suggest that rifaximin may be effective in reducing the risk of overt hepatic encephalopathy in patients with mild (Child-Pugh Class A), moderate (Child-Pugh Class B) and severe (Child-Pugh Class C) hepatic impairment, respectively, compared to that in healthy volunteers. No dosage adjustment is recommended because rifaximin is primarily acting locally. Nonetheless, caution should be exercised when XIFAXAN is administered to patients with severe hepatic impairment. See Warnings and Precautions (5.5). Clinical Pharmacology (12.3), Clinical Studies (14.2).

1.5 Concomitant Use with P-glycoprotein Inhibitors

Concomitant administration of cyclosporine, an inhibitor of P-gp and OATP significantly increased the systemic exposure of rifaximin. In patients with severe hepatic impairment, a potential additive effect of reduced metabolism and concomitant P-gp inhibitors may further increase the systemic exposure to rifaximin. See Drug Interactions (7.1). Clinical Pharmacology (12.3).

7.4 CYP3A4 Substrates

An in vitro study has suggested that rifaximin induces CYP3A4. [see Clinical Pharmacology (12.3)]. However, in patients with normal liver function, XIFAXAN at the recommended dosing regimen is not expected to induce CYP3A4. It is unknown whether rifaximin can have a significant effect on the pharmacokinetics of concomitantly administered CYP3A4 substrates in patients with reduced liver function who have elevated rifaximin-concentrations.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on XIFAXAN use in pregnant women to inform any drug-associated risks. Teratogenic effects were observed in animal reproduction studies following administration of rifaximin to pregnant rabbits and rats during organogenesis at doses approximately 0.9 to 5 times and 0.7 to 33 times, respectively of the recommended human doses of 600 mg to 1650 mg per day. In rabbits, oral, and maxillofacial, cardiac, and lumbal spine malformations were observed. Oral malformations were observed in both rats and rabbits at doses that caused reduced maternal body weight gain [see Data]. In the general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15% to 20%, respectively. Advise pregnant women of the potential risk to a fetus.

8.2 Lactation

Rifaximin is rapidly absorbed after oral administration and binds extensively to plasma proteins. Following a single 550 mg dose, approximately 2.6 times the recommended dose for HE [1,100 mg per day], and approximately 1.8 times the recommended dose for TD [600 mg per day] adjusted for body surface area).

8.3 Lactation

The safety and effectiveness of XIFAXAN has not been established in pediatric patients less than 18 years of age for HE.

8.4 Pediatric Use

The total number of patients in the clinical study of XIFAXAN for HE, 19% of patients were 65 and over, while 2.5% were and approximately 2.6 times the recommended dose for IBS-D [1,650 mg per day] adjusted for body surface area).

8.6 Renal Impairment

The pharmacokinetics of rifaximin in patients with impaired renal function has not been studied.

5.7 Hepatic Impairment

Following administration of XIFAXAN 550 mg twice daily to patients with normal hepatic function, 10% of patients had rifaximin concentrations of 1.5-6 times the recommended dose for HE. In the case of overdosage, discontinue XIFAXAN, treat symptomatically, and institute supportive measures as required.

13 NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Malignant schwannomas in the heart were significantly increased in male Crl:CD(SD) rats that received rifaximin by oral gavage for two years at 150 to 250 mg/kg per day (doses corresponding to 1.3 to 2.2 times the recommended dose for IBS-D [600 mg per day] twice daily for HE, based on relative body surface area comparisons). There was no increase in tumors in TgN2Rl rats dosed with rifaximin for 26 weeks at 150 to 2000 mg/kg per day (doses equivalent to 0.7 to 9 times the recommended daily dose for HE, based on relative body surface area comparisons).

13.1 Carcinogenesis

Rifaximin is a competitive inhibitor of the bacterial enzyme that synthesizes endotoxin. In the 2-year study, rifaximin caused a statistically significant increase in malignant schwannomas in male Crl:CD(SD) rats. Based on the low incidence of malignant schwannomas in control animals and the known capacity of rifaximin to inhibit the bacterial enzyme that synthesizes endotoxin, the tumors were interpreted as neoplastic. The tumors were characterized by a single layer of cells and were consistent with benign schwannomas, which are common in rats. The increase in malignant schwannomas was not dose-related, and there was no evidence of any adverse effect on pre and postnatal development.
Address Patient Needs in 2022 With a Membership-Based Model

INTRODUCTION
Health care consumers’ attitudes and expectations around primary care are rapidly evolving. In fact, 50% of patients have higher expectations of their doctors since before the COVID-19 pandemic, and nearly one in five patients considered changing physicians based on how they handled the pandemic. High-deductible plans and higher co-pays mean patients are paying more attention to how their health care dollars are spent and are looking for ways to get more for their money. Today’s health care consumers have many choices of where to go for care, and they are desiring better relationships with their doctors and requiring retail-like customer service. If they don’t get what they want, patients will simply switch providers. These shifting consumer attitudes can have negative implications for medical offices, but a membership model can help physicians deliver an enhanced service experience that yields an overall healthier practice.

LEARNING OBJECTIVES
- Understand how the COVID-19 pandemic influenced patient trends in primary care and how membership-based models can address these evolving needs.
- Learn how membership-based models can increase physician and patient satisfaction while generating predictable revenue for the practice.
- Hear from physicians who transitioned to membership models how it positively impacted their patients and their careers.

MEET THE PANELIST
Chris Lillich, Chief Marketing Officer, MDVIP
Lara Hitchcock, M.D., FAAFP, Family Medicine
MDVIP-Affiliated Physician
Michael Stevens, M.D., Internal Medicine
MDVIP-Affiliated Physician

Growing Patient Demands Require Innovative Care Models

Today’s health care consumers want more from their physicians than ever before. This trend has accelerated during the COVID-19 pandemic, and now patients desire the same level of service they receive from the nation’s top retail and hospitality companies.

Another reason patients expect more value from their primary care physicians is that more of the financial burden is falling on consumers’ shoulders. High co-pays and high-deductible health plans are more common and, as a result, patients are much more engaged in their care and what they are getting for every dollar. They want a closer relationship with their doctor that’s a two-way partnership for good health utilizing technology and data.

During the pandemic, many physicians struggled to meet these expectations. Almost a quarter of patients say their opinion of their doctor has changed since the COVID-19 pandemic began, and almost 20% of all patients are considering changing physicians based on how they handled communication and medical needs throughout the health care crisis.

Patients now want more individualized care and are willing to share more information about themselves to get it. “This means patients will gravitate toward practice models that are delivering the personalized experiences they want and that can provide convenient digital tools for tracking and communication,” explains Chris Lillich, chief marketing officer, MDVIP.

Practices must also have a strong web presence. Consumers are increasingly relying on digital avenues to get a sense of a physician without ever visiting the office. Even those patients who get a referral from a friend or family member will use the internet to do their own research. “One of the first things a consumer sees when Googling a physician or practice is their ratings and reviews, and a positive online reputation is the No. 1 deciding factor in a patient choosing one physician over another,” says Lillich.
For independent physicians to succeed in our consumer-centric health care landscape, they need a solution to volume-based medicine, a model that’s not dependent on seeing more patients. The ideal model allows for unrushed visits with time to build more meaningful doctor-patient relationships, a focus on prevention, and the ability to research and follow up on cases, while having a predictable income and a better work-life balance.

Physicians who converted to a membership medicine model noticed a huge difference in the experience and care they can offer in a smaller practice. “Before, you couldn’t keep up with phone calls, you couldn’t answer patient questions, you couldn’t get people in to see you,” says Michael Stevens, M.D., an MDVIP-affiliated internist. “The pandemic brought on a tsunami of patients wanting information and wanting your time, and there was no way to keep up with it. After the transition to MDVIP, I was able to send out emails to all my patients every week on the latest information that was coming out of the CDC, and I was doing phone calls in real time with same-day callbacks to patients.”

Lara Hitchcock, M.D., FAAFP, a family medicine physician affiliated with MDVIP, believes the tools MDVIP provides to both the doctor and patients make it possible to really personalize the experience. There’s not only a portal with an associated app, but also exercises and nutrition resources she ties into the annual exam and wellness plan. “We do a body composition analysis as part of the program, and if patients lost any muscle from the year before, I’m able to compare one year to the next where they lost it and tell them what to focus on,” explains Hitchcock. “Right at the point of care, I’m able to look up exercises to give them.”

MDVIP gives doctors and patients the time they both want and need. While membership medicine may not be right for every practice, those who moved away from traditional primary care can encourage other physicians to ask themselves if they can keep practicing the way they do now for another 5 to 10 years. If the answer is no, now might be the right time to look at a new practice model.

“Strong ratings and reviews are the No. 1 deciding factor in a patient choosing one physician over another.”

Chris Lillich, Chief Marketing Officer, MDVIP

Be aware of ongoing changes in health care that are driving patient expectations and choice.

Increase patient and physician satisfaction with a more personalized experience.

Spend more time with patients and less time on paperwork.

Focus on prevention and wellness, not just sick care.

Improve physicians’ work-life balance and financial stability.

Strong ratings and reviews are the No. 1 deciding factor in a patient choosing one physician over another.”

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Chris Lillich, Chief Marketing Officer, MDVIP
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Remote patient monitoring boosts patient outcomes and practice revenue

INTRODUCTION
Remote patient monitoring (RPM) harnesses technology to create better outcomes for patients. As RPM expands, there are more studies that show its effectiveness. For a weight-loss program, patients using RPM lost 86.3% more weight compared with those without RPM. And patients are not the only ones who benefit; practices using RPM see better revenue to boost their bottom line — in some cases doubling their revenue per patient. Instead of focusing on bringing in new patients to increase revenue, practices can boost how much they are making from each patient all while boosting health outcomes. Payers are also recognizing the effectiveness of RPM and offering full reimbursement rates for many services as they transition to more value-based care. In addition, offering RPM services does not require additional staff members to implement, only a few hours of training time. Practices looking to boost their revenue and patient outcomes should consider remote patient monitoring.

LEARNING OBJECTIVES
- Understand the benefits of RPM, how it works and which patients benefit.
- Develop talking points for persuading patients to use RPM services.
- Understand how to create an RPM, including revenue forecasts and patient outcome benchmarks.

MEET THE PANELIST
Wes Haydon
President and Co-Founder
CoachCare

Remote patient monitoring is starting to take off as technology allows physicians not only to boost patient health outcomes, but also to increase their practice revenue. In a study of 1,000 patients who received a diagnosis of obesity from across multiple practices, patients using RPM lost 86% more weight than patients who were not, and the RPM patients stayed on their weight-loss program 30.2% longer than non-RPM patients. The best news may be that getting these results doesn’t require an investment in additional personnel.

“None of these clients had to add staff to deliver these improved outcomes and engagement results,” says Wes Haydon, president and co-founder, CoachCare.

Now is a great time to start with RPM, says Haydon. CMS and commercial payers continue to expand their support for RPM services as they transition to more value-based care. Because physicians can now utilize auxiliary staffers and get reimbursed for additional diagnoses than previously, RPM is more cost effective than in prior years.

Haydon says RPM is for any physician looking to add revenue to their practice while building a best-in-class patient care program. “If you feel like you and your team are working hard every day, your staff is starting to get burned out and you just can’t seem to help patients enough, then RPM is for you.”

He says physicians who don’t accept insurance or are not comfortable with new technology should probably not look into an RPM program.

One of the advantages of remote patient monitoring is that practices are boosting revenue on the patients they already have rather than trying to market the practice to potential new patients.

“Adding patients is expensive and you are going to have to pay for marketing, and ultimately, it puts pressure on already overwhelmed staff,” says Haydon. “And so that ultimately makes it not scalable, because the maximum number of patients you can... Continued on page 44
RPM TO IMPROVE PATIENT OUTCOMES AND INCREASE CLINIC REVENUE

MORE WEIGHT LOSS

86.3%

App users lost 86.3% more weight than non-app users

HIGHER RETENTION RATE

30.2%

Retention rate of app users was 30.2% higher than non-app users

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• Improved engagement between clinic, coaches & patients
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Contact us at (737) 212-3183 or sales@coachcare.com for a demo of the CoachCare platform and for pricing
“If you feel like you and your team are working hard every day, your staff is starting to get burned out and you just can’t seem to help patients enough, then RPM is for you.”

Wes Haydon, President and Co-Founder, CoachCare

Continued from page 42

see is limited by the number of hours you work in a day. You also have to add a lot of new patients in order to have any meaningful impact in revenue.”

Instead of focusing on marketing to new patients, practices can prescribe reimbursable remote patient monitoring to existing chronic, at-risk and even post-acute patients. “You avoid all that wasted marketing spend and at the same time are also able to drastically improve the efficacy of the treatments,” says Haydon. “Your staff is able to focus on these value-added activities, and their morale is reinvigorated because they’re doing good for patients while also doing well for the practice financially.”

Another added benefit is that when staff have downtime, such as when there is a canceled appointment or between appointments, that’s normally not billable time. But with remote patient monitoring, it can be.

With the right system in place, a practice can generate double the revenue with half the patients, and the work isn’t really any different from what most practices are already doing. “If you’re doing any type of monitoring of patients, checking up on them or calling them in between visits, you’re probably not getting paid for that,” says Haydon. “That is remote monitoring.”

Without it, patients might be in a slow decline that might not be detected until their next visit, which might not be for a month or more. Remote monitoring offers the possibility of seeing the patient’s vitals, which are transmitted from home in real time, and getting reimbursed for having junior staff periodically review the data. If it falls outside predetermined ranges, then the physician is notified and can take appropriate action versus finding out when they come back to the office in a month.

86.3% more weight was lost by patients using RPM with a weight-loss program than those who weren’t.

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Approaches to Treatment of Systemic Lupus Erythematosus and Lupus Nephritis Are Evolving

Welcome to this special Lupus RheumView presentation, brought to you by Medical Economics® and Rheumatology Network™.

Lupus is an intangible, multisystem rheumatic disease that can present in an often-confusing manner. The following transcript focuses on a conversation between a practicing clinician and a professor discussing the epidemiology of lupus, risk factors, how rheumatologists can support their patients, the treatment advances in systemic lupus erythematosus (SLE) and pipeline drugs that may hold promise in treating lupus nephritis.

The guests for this special presentation of RheumView:

**Fotios Koumpouras, M.D., FACP**
Assistant professor of medicine (rheumatology), director of education and training, rheumatology, and director of the Yale Lupus Program at Yale School of Medicine, New Haven, Connecticut

**Ronald van Vollenhoven, Ph.D.**
Head of the Clinical Immunology and Rheumatology Department at the Academic Medical Center and of the Rheumatology Department at the VU University Medical Center, University of Amsterdam

**Classifying Lupus: A Spectrum Disorder**

**Fotios Koumpouras, M.D., FACP:** Our discussion today will focus on the practical considerations and approaches in diagnosis and management, particularly focusing on new advances in treatment targets and on new therapeutic advances in care for lupus and in lupus nephritis. The best place to start is...making the diagnosis for patients with lupus, and an overview of what [the] disease is. Can you tell the audience what populations are at risk for developing lupus...particularly systemic lupus?

**Ronald van Vollenhoven, Ph.D.:** This is a disease that...was described more than 100 years ago, and it has evolved...It is a disease where there are lots of autoantibodies. The clinical manifestations can be...very different from patient to patient. The American College of Rheumatology (ACR) and the Systemic Lupus Erythematosus International Collaborating Clinics group have some new criteria. The most recent updates come from the ACR and the European Alliance of Associations for Rheumatology (EULAR), working jointly to develop new criteria meant to classify lupus.

**Koumpouras:** You initially stated that the signs and symptoms of lupus are quite
variable, and lupus is a spectrum disease. We look at these clinical criteria to help (a) instruct rheumatologists about the diversity of clinical presentations that patients with lupus can have and (b) clue them in when multisystem complaints might actually be a connective tissue disease. As the criteria have evolved, they have encompassed the great spectrum of lupus.

van Vollenhoven: Clearly it has evolved, and it is better now than it was, but it’s still not perfect. We still need the clinician. We need them to look at the patient and the totality of the data. We can look at the list of the symptoms and the manifestations and the tests, but we also must use that feeling that we have as physicians.

Lupus Epidemiology and Risk Factors

Koumpouras: In the United States, and probably in Amsterdam, it’s very multicultural and multiethnic. Individuals of Hispanic origin or African American descent and Southeast Asian descent have an increased risk of lupus nephritis. Rheumatologists should be aware that particularly nephritis is occurring at a higher frequency in certain ethnic groups, and to be astute to follow abnormalities.

van Vollenhoven: We do see the dangerous manifestations of lupus in a bit more in certain ethnic groups. Indeed, lupus nephritis seems to be overrepresented. Treatment-wise, you’re guided by the symptoms, the manifestations and the (individual’s) background.

Screening Methods to Evaluate for Lupus

Koumpouras: In your patients with standard lupus, are you measuring urinalysis as a screen and are you following up if there’s mild hematuria or pyuria?

van Vollenhoven: In lupus, the patient will tell you. If they have a skin rash, they will tell you. If they have pleurisy, they will tell you. But there are two things that can happen that the patient won’t realize, and one is the cytopenias. (Individuals) can have dangerously low levels of thrombocytes or leukocytes without realizing it. The other thing is…the nephritis, which can be clinically totally silent. I think it is very good
practice to monitor for those things at frequent intervals, depending...on what kind of severity the patient has previously shown.

Support for Patients With Lupus

Koumpouras: What has become in the foreground of lupus care is the patient’s journey through this disease. Do you have any kind of a special program for patients?

van Vollenhoven: We do, yes. Lupus is a disease that can sometimes affect adolescents who go into adulthood. Patients can feel terrible but externally look fine (while) internally they’re having a lot of pain. They feel like a lot of physicians aren’t necessarily able to understand their symptoms. A lot of the symptoms can be broad and bizarre, but they’re real.

We have a program called the Lupus Wellness Program, and this is where our patients will come in a series of sessions. They meet with one of our nurse practitioners and they discuss the disease, the diagnosis and their medications. We incorporate preventive health strategies, management of hypertension, hyperlipidemia, fertility preservation, counseling around pregnancy, etc. This allows for patients to become more vested in their own self-care. They’re more educated about symptoms, because many of the symptoms that patients have are not from lupus. Certainly, we don’t want to treat them with steroids for things that don’t need that. It incorporates a lot of health strategies that are difficult when you’re primarily dealing with medications and flares during your limited clinical visit.

Systemic Lupus Erythematosus Treatment Advances: Belimumab

Koumpouras: What are exciting treatment advances for SLE?

van Vollenhoven: What’s exciting is the new treatments coming to the forefront for lupus. We’re seeing completely new therapies, but also very effective ways of using therapies that have been with us for a while. There’s also a lot in the pipeline. We’re at a watershed in the history of lupus therapeutics. We’re a little different in Europe from the United States; we’ve had belimumab available for about 10 years. It was available for treating general lupus, meaning not lupus nephritis specifically but other manifestations of lupus. It has slowly but surely become a staple of treatment of lupus.

For those cases where it works, we’re very happy also because it’s very well tolerated in the long term. This is a treatment that, if it helps the patient, it is something they can live with. We’re interested in long-term consequences of the disease, which can be quite devastating. The difference with the United States is that anifrolumab, which is new, has only very recently received approval from the European Medicines Agency.

Systemic Lupus Erythematosus Treatment Advances: Anifrolumab

Koumpouras: You touched on the brand-new drug anifrolumab, another breakthrough in lupus developed for SLE.

van Vollenhoven: I’m very curious because it’s been approved in the United States for several months. Are rheumatologists practicing in the United States gaining experience with anifrolumab? Is it available?

Koumpouras: We are. It’s becoming available in the community setting. Most academic centers are getting it on their formulary, but it’s still too early to know how important this may be in the treatment of lupus and when it should be employed in SLE.

van Vollenhoven: I’m still intrigued by how lupus may be several pathophysiologies. In some people, you have the high interferon signature or the low interferon signature. Going back to belimumab, you have patients for whom B-cell activity is very high, and they have all these other antibodies. Other patients might have lupus, but they may have only antinuclear antibodies and not the other ones. It might be that in the future, we’ll do these immunological analyses and (they) will tell us this patient should be treated with anifrolumab, this patient should be treated with belimumab, this patient will do best with a conventional therapy, etc. We’re not there yet by a long shot, but I want it for the future.

Lupus Nephritis Treatment Advances

van Vollenhoven: Some of these trials are also specific for lupus nephritis. Belimumab was only very recently approved for lupus nephritis, but it did seem to work very well in the clinical trial. We’re going to have to experience it in practice and see how we use it and how it works. In the United States, you have another new drug for lupus nephritis specifically, right?

Koumpouras: That’s right. It’s called voclosporin. It’s an old calcineurin inhibitor that has been repurposed and studied in lupus nephritis. It’s a calcineurin inhibitor that’s got very good pharmacokinetics, so it can be used safely at a wide dose range in most patients with varying levels of kidney disease. It
showed a very potent effect in rapidly reducing proteinuria. It’s a very promising therapy used in combination with mycophenolate.

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**Lupus Nephritis: Assessing Response to Novel Therapy**

**Koumpouras:** How long do you treat your patients who had lupus nephritis but otherwise had done well in induction and maintenance of remission? The traditional teaching was that if you withdrew immunosuppression before three years, there seemed to have been a fair amount of relapse. But if you had this treatment for three to five years and you withdrew, you seemed to have a more suppressive effect. For me, if they’re serologically active, and certainly if they’re young, I’m in favor of chronic suppression of the disease because it’s a genetic disease. The disease comes down to the genes in many instances. You’ve seen these withdrawal trials. When do you need the therapy? It’s not clear that they’re chronically active. I’m in favor of treating them long term, certainly for a good 10 years or so. Maybe if they’ve had quiescent disease and we’re tapering, but usually I treat long term.

**van Vollenhoven:** I agree with you, especially if you have serological activity. If they have anti-DNA, a low complement, or other strong associated antibodies, then I’d be very careful in tapering or stopping. But if the patient has been in remission and the serology looks good, I might be willing to try it. You have to have the conversation with the patient. Is this going to be totally safe? You can never promise that. There’s always a risk. But you can give them the promise that as soon as something starts happening, you’ll be there for them and hope that it can work. Patients do sometimes feel they want to give that possibility a chance in order to be free of treatment. That happens also. But I’d be very careful if I saw serological activity.

**Koumpouras:** We’re treating similarly. We have guidelines by your group, EULAR, for the treatment of lupus nephritis. They’re very helpful for the general rheumatologist who may not be as familiar with this. If you look at the guidelines, there’s emphasis on the adjunctive treatment and reducing steroids. What are the concepts? What are the goals? That can be very helpful even to folks who treat lupus. But as you know from the trials, not everyone with lupus nephritis gets better. You can give them all these medications, drug combination therapies, and you’re getting about 40% of the patient’s complete response. That means 60% of the patients still have some activity.

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**Lupus Treatment Advances: Agents in the Pipeline**

**Koumpouras:** What kind of pipeline drugs do you think or are you familiar with that hold promise potentially for lupus nephritis?

**van Vollenhoven:** That’s a great question. There is a very big number of drugs in the pipeline, but there are some that are more interesting than others. Some are building on mechanisms that we already know. For example, the mechanism of B cells, which are targeted by belimumab. There is a new drug being developed for the treatment of chronic lymphocytic leukemia, called acalabrutinib, also being developed for lupus. That would be quite interesting. It depletes B cells, so it isn’t like belimumab, which slows them down. It does that at a very high level in the tissues, which is...a new finding. The lupus trial with acalabrutinib was reported as positive and was published. It is one trial successful, but, of course, we know how it is with lupus nephritis. You have to keep doing the trials all over again.

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**Lupus Treatment Advances: Advice to Colleagues**

**Koumpouras:** Are there any last thoughts that you have in terms of the landscape for SLE treatment challenges that you’ve navigated or advice for the audience and for me?

**van Vollenhoven:** This is an exciting time when it comes to the therapies that are both now available and are going to be available for this disease. It’s been hard for our patients for so many years. They have shown tremendous patience...and they have also told us what’s really important to them. We should listen to them and be excited about the developments that are...taking place. “

*Editor’s note: This transcript has been edited for length and clarity.*
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— Mark J. Nelson, MD, FACC, MPH
Medical World News® (MWN): What are some challenges female physicians face?

Tammie Chang, M.D.: There are lots of challenges. I think one of the biggest ones is just the lack of support for women. For female physicians, there are very few accommodations. Typically, when women physicians are just coming out of training, they’re coming out during the peak child-bearing years, when they’re trying to start a family. They’re trying to juggle a lot of things: the home, the families, the workplace. The jobs themselves have very demanding work schedules and call schedules, and there just really isn’t a supportive culture. There are also few women making it to leadership. The leadership funnel narrows very early in the career. Only about 50% of leaders within health care are women even though women actually make up more than 80% of health care workforce when you look at all different fields, not just women physicians. So they’re not becoming decision makers, they’re not getting a seat at that table to really make change that’s conducive and supportive of women in the workforce. I think there’s still a lot of gender bias that women struggle with. It’s becoming more and more open and talked about now, thankfully, in health care and in this industry, but it impacts the daily lives of women physicians, because they are viewed as leaders, even though they don’t realize that they are. There is a double standard when it comes to how women are viewed in the workforce compared to their male physician colleagues. There’s a much tougher standard.

MWN: What are some of the challenges you were facing when you decided to write your book?

Chang: I was severely burned out. I had taken on all the responsibility because that’s all I knew how to do. I was suicidal and had to take a leave of absence and almost quit practicing medicine. More than 70% of physicians are now experiencing moderate to severe levels of burnout at this stage in the pandemic. That rate is even higher in women physicians. But we don’t talk about it much, so that’s why I’ve written this book. I’ve essentially written everything that I wish someone had told me.

MWN: Do you have any favorite moments or conversations you’ve had with fellow female physicians?

Chang: I’m running a five-day mini book club right now. We were talking about how hard it is to set some basic boundaries and we watch our male colleagues at work, and they don’t seem to struggle at all. It doesn’t seem to faze them. And so then it brought up questions about why. Is it biology? Is it how we’ve been raised or nurtured or socialized? Is it how we were raised with kids? Or another way to think about it is maybe it is actually bothering them, but they’re not showing it. We don’t really know what they’re experiencing on the inside, and
MWN: Why is it so important that we support women physicians?

Chang: We’re finally at a place where 51% of med school students are women. However, 40% of women physicians are either quitting or going part time within six years of finishing training. That’s a problem. We’re not keeping them in the workforce. There is also data showing better patient outcomes (with women physicians) that include higher patient satisfaction scores and decreased morbidity and mortality. It’s so important for us to continue to push forward and make things more equitable because we want to make things better for the next generation.

MWN: One of the biggest issues today is the conversation surrounding the pay gap between male and female physicians. What do you think society can do to bridge that gap?

Chang: I think it’s huge that it’s hit big headlines recently. There are still a lot of people, even in medicine, who don’t believe it. I think awareness is the first piece, and then also getting people to recognize that it’s actually happening in their own system. There’s a New York Times article that I shared and I got so much negative feedback from it. I had a few health care CEOs reach out to me and say, “Oh, we don’t have that in our system.” And I’m like, “Yeah, I bet you do — you just haven’t looked.” It’s about being honest and having the humility to go, “Oh, maybe this is happening within my organization that I’m in charge of and who is responsible for these things?” Maybe it’s not happening, and that would be amazing, right? Then share that data widely. Make it one of your metrics that you’re trying to follow each year. It shouldn’t matter what the role is; it should be the same, regardless of gender. Doing that on a local level at home, in our own organizations and institutions — that’s huge.

MWN: What are some ways female physicians can support each other?

Chang: There’s an unspoken understanding and bond when we’re a group that’s struggled together. It’s finding each other wherever we’re working. I call it a “raft of otters.” Female otters band together in stormy seas and create a raft with their paws. That’s what I strive to do in my daily work as the medical director of provider wellness for my health care system to which is trying to create little pockets of rafts for every single person working for our system. I tell people to reach out and connect with just one person, because the reality is that the other person probably needs a friend, too. »
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