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WHO’S COVERED FOR SHINGRIX?
MOST OF YOUR PATIENTS

You can recommend SHINGRIX with confidence for your patients 50 years and older with commercial insurance.¹

SHINGRIX
(ZOSTER VACCINE RECOMBINANT, ADJUVANTED)

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
For your patients 50 years and older with commercial insurance plans:

More than 9 out of 10 are covered, with average copays just $4 or less—making SHINGRIX cost less than a movie ticket.¹,²,*

Scan the QR code to SEE WHO YOU SHOULD VACCINATE

---

*SOURCE: Managed Markets Insight & Technology, LLC, Database as of February 2022. Coverage represents access to reimbursement from a health plan with restrictions appropriate to the Advisory Committee on Immunization Practices recommendation(s) and/or prescribing information, which means no accompanying step edits. Veterans Affairs and Indian Health Service lives have been omitted when calculating the percentage of lives.

- 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.

References: 1. Managed Markets Insight & Technology, LLC, Database as of February 2022. 2. Data on file, GSK.

You are encouraged to report vaccine adverse events to the US Department of Health and Human Services. Visit www.vaers.hhs.gov to file a report, or call 1-800-822-7967.

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SGXJRNA220009 June 2022
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°C and 8°C (36°F 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 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 = 14,645) 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 (38%), and swelling (26%); 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 1. Percentage of Subjects with Solicited Local and General Adverse Reactions within 7 Days of Vaccination in Adults Aged 50 to 59 Years, 60 to 69 Years, and 70 Years and Older (Total Vaccinated Cohort with 7-Day Diary Card)

<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></td>
<td>SHINGRIX n = 1,315</td>
<td>Placebo n = 1,312</td>
<td>SHINGRIX n = 1,311</td>
</tr>
<tr>
<td>Local Reactions</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Pain</td>
<td>88</td>
<td>14</td>
<td>83</td>
</tr>
<tr>
<td>Pain, Grade 3*</td>
<td>10</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Redness</td>
<td>39</td>
<td>1</td>
<td>38</td>
</tr>
<tr>
<td>Redness, &gt;100 mm</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Swelling</td>
<td>31</td>
<td>1</td>
<td>27</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>General Reactions</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Myalgia</td>
<td>57</td>
<td>15</td>
<td>49</td>
</tr>
<tr>
<td>Myalgia, Grade 3*</td>
<td>9</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Fatigue</td>
<td>57</td>
<td>20</td>
<td>46</td>
</tr>
<tr>
<td>Fatigue, Grade 3*</td>
<td>9</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Headache</td>
<td>51</td>
<td>22</td>
<td>40</td>
</tr>
<tr>
<td>Headache, Grade 3*</td>
<td>6</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Shivering</td>
<td>36</td>
<td>7</td>
<td>30</td>
</tr>
<tr>
<td>Shivering, Grade 3*</td>
<td>7</td>
<td>0.2</td>
<td>5</td>
</tr>
<tr>
<td>Fever</td>
<td>28</td>
<td>3</td>
<td>24</td>
</tr>
<tr>
<td>Fever, Grade 3*</td>
<td>0.4</td>
<td>0.2</td>
<td>1</td>
</tr>
<tr>
<td>GI</td>
<td>24</td>
<td>11</td>
<td>17</td>
</tr>
<tr>
<td>GI, Grade 3*</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).

• 7 days included day of vaccination and the subsequent 6 days.
• 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.
• Placebo was a saline solution.
• Grade 3 pain: Defined as significant pain at rest; prevents normal everyday activities.
• Grade 3 myalgia, fatigue, headache, shivering, and GI: Defined as preventing normal activity.
• 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.
• GI = 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 (28% and 21%, 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 (2.7%, 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 2 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. 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 0.2%), 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%) or 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 lymphaedenitis 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. 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 of 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).

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Physician Bootcamp: Beyond the classroom education for physicians

For nearly 100 years, Medical Economics® has served as the leading business magazine for physicians. Our staff prides itself on providing useful tips and advice on all things related to running a medical practice, the business-side of medicine that physicians don’t learn in medical school.

To that end, in 2022, Medical Economics® launched a four-part Physician Bootcamp series of live, virtual, educational events focused on practice management and personal finance. Our second event, the Summer 2022 Physician Bootcamp, was held in late June. The four educational sessions were excellent, featuring best practices in dealing with administrative burdens, physician burnout, remote patient monitoring and tax planning.

“I have been a family physician for over 40 years, and I know that practicing medicine now is more challenging than ever,” says L. Allen Dobson, M.D., a family physician and editor-in-chief of Medical Economics®. “Our mission is to educate physicians far beyond the training they received in medical school, so that all physicians can make the most of their medical career.

If you missed it, don’t worry. This edition of Medical Economics®, our August issue, contains recaps of the four events along with links to further resources on MedicalEconomics.com, including the full, on-demand sessions (free registration is required to view the videos). Flip to page 28 to check out the recaps.

We still have two more live events scheduled for this year, on Sept. 15 and Nov. 17, which will feature at least eight more educational sessions to help physicians stay at the top of their game. Stay tuned for more details!

As always, we want to hear from our readers what you think about our content, and what ideas you have to help us serve the physician community better. Reach out to our editorial director Chris Mazzolini at cmazzolini@mjlifesciences.com with any feedback. 

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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:

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- 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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I am concerned. There is a brewing storm within the normally collaborative and professional family of medicine as nursing organizations and other nonphysician associations advocate in state legislatures across the country to be allowed to practice independently and without restriction or supervision. Although I understand their motivation in advocating for their profession, I fear for the unintended consequences of this movement that will ultimately undermine the public trust in the entire medical system.

I have practiced and been partners with many nurse practitioners (NPs) and physician assistants (PAs) during my career, many of whom are very capable of seeing patients independently — after years of experience. I have also seen firsthand that most new graduates are far from prepared to practice outside a structured environment with mentors and experienced physicians.

Additionally, I have been critical of the inadequate supervision requirements that have been in place for decades, being neither protective of the public nor designed to improve the knowledge or skills of those supervised. In essence, supervision should be the version of advanced training that residencies are for physicians.

As a family physician, I totally understand having to prove my competence. When I entered practice, as is still true today, doing obstetrics or managing complex hospital patients was not standard in my hospital for family physicians, nor was such training assured simply by graduating a residency. (There is a difference between experiential vs hands-on practical training).

Despite training as a resident, I was required to consult and be supervised to prove my knowledge and ability, and I ultimately gained full obstetrical privileges and admitting privileges to the intensive care unit and coronary care unit. It felt demeaning, but with time and wisdom, I realized it did more for my specialty and my own standing in the medical community.

Traditionally, state medical boards are set up to license physicians and regulate the practice of medicine. They are required to set the minimum standards of practicing medicine in the state, broadly defined as diagnosis and treatment of disease, prescribing medication and performing surgery. Almost without exception, states have moved away from their own certification exams to requiring physicians pass each part of the extensive three-part United States Medical Licensing Examination; part three being taken during the first year of residency training, and licensure coming after completing one year of post-medical school residency training.

New physicians can then get their medical license, but almost all complete a residency before entering independent practice. With state legislatures granting full independent practice to advanced practice nurses and PAs and each board granting their own licenses, we are on the way to having multiple standards of the practice of medicine. I am afraid the long-term effect of this move will play out over time and, unfortunately, in the courts.

I am also concerned about the increasing lack of public transparency regarding the training and credentials of the clinician who is caring for them. There is a trend by many hospitals and other corporate clinics to staff their urgent care centers, primary care clinics with NPs or PAs, often without an onsite physician.

Although the motivation seems to be greater availability of staff and lower costs, there is concern about whether new hires at these sites are ready for such independent practice. I believe the public still expects physician care as the primary option when seeking care, particularly in the emergency department or urgent care setting. If that is no longer the standard of practice, then the public should be made aware.

There is more to unpack on the subject of physician, NP and PA workforce, as well as the many aspects of the growing conflict within the house of medicine. We at Medical Economics® will begin to examine the conflict and take a deeper dive into training differences, data regarding the claim that NP or PA care is equal to physician care, and whether the growing numbers of NPs and PAs is solving our geographic distribution problem. We’ll also look at who is hiring NPs and PAs, the economic drivers of this movement and emerging examples of places and policies that assure patients receive the best possible care from these practitioners.

L. Allen Dobson Jr., M.D., FAAFP, is a family physician and editor-in-chief of Medical Economics®.
Informing your perspective on the bear market

By David S. Gilreath, CFP

The stock market has performed so well over the past 13 years that, based on personal experience alone, investors would probably have to be at least 50 years old to not be surprised by the onset of the bear market this year. Even so, many investors older than this have been taken aback by the market’s decline. Not surprisingly, many younger investors, having experienced nothing but a galloping bull (albeit with a couple brief naps), are still shaking their heads and asking: What the heck happened?

Much of this dismay stems from a sharp contrast between expectations and actual events. If you expect corrections and bear markets as normal parts of the market, they’re much less unsettling. However, if all you know is (on average) a rising market, that’s another story.

Many older investors don’t view the bear market as the rude surprise that many younger investors do, but they are concerned about its impact on their retirement resources. This is true even of older investors with solid investment plans that anticipate market declines. Yet, for most physicians near retirement who have been investing wisely long term, even if the bear lasts for years (and this is unlikely), its personal impact will probably be quite limited. This is assuming a gradual withdrawal of assets to pay retirement expenses rather than cashing in a big chunk of a portfolio anytime soon.

**Perspective is paramount**

What investors of all ages have in common is that their investing expectations are influenced not only by life experience but also, more profoundly, by how they view the market. My 40-plus years as an advisor has taught me that investing success is all about this perspective.

Different views of the market may go a long way toward answering this question: How is it that over their lifetimes, some people make a tremendous amount of money in the stock market, whereas others, who are investing the same amounts, struggle with repeated disappointment, many of them giving up? Regardless of your personal experience, your perspective can change — usually for the better — if you learn more about market history, and these changes may make you a better investor.

Since I got into this business in 1981, the slope of the S&P 500 has edged jaggedly upward from a miniscule 125 to peak at 4,818 in January 2022. Although this year, the market just had the worst first half of any year since 1970, as of May, the index had still doubled five times in 40 years: 125 to 250 to 500 to 1,000 to 2,000 to 4,000. That’s a lot of doubling of doubling.

Along the way, of course, there have been many ups and downs, but there have mostly been ups. A chart that displays the S&P 500 over four decades depicts its jagged, upward course — higher and higher peaks continuing after various valleys. Looking at this chart, some investors focus on the peaks, whereas others see only valleys. Investors who focus on the peaks not only sleep better but are also more likely to have more investing success, primarily because they’re less inclined to do something rash, such as pulling money out when their accounts decline. They’re also more inclined to do something smart, such as buying on dips when appropriate.

**Eye of the beholder**

Those who see mainly peaks are by no means immune to investing mistakes, but those who see only the valleys may have what psychologists call a success inhibitor. Too much fear leads to a reluctance to take advantage of, or even see, opportunities the market may be presenting. Yet, those who see mainly peaks are more inclined to think: If these opportunities underperform and/or acquire too much risk, money can be moved to new ones with less risk and better performance prospects.

Successful long-term investors know higher peaks will always come after valleys, because they always have. Using history as a guide, they assume (thus far, correctly) that the U.S. economic engine will keep pushing corporate profits higher and higher, creating new market highs over time.

Some people think I’m crazy when I say the S&P 500 will probably double, reaching 7,700 in less than 10 years. They cite various countervailing factors: the problems of war, crime,
ADVICE YOU CAN INVEST IN

Despite all these troubles, the stock market doubled in price again and again.

To illustrate the power of the compounded growth of equities resulting from this market performance, a $500,000 portfolio doubling five times grows to 32 times its original value — to $16,000,000, not including dividends, which would add a few million bucks more. This is why Albert Einstein called compound interest the eighth wonder of the world, adding, “He who understands it, collects it. He who doesn’t, pays it.”

Conviction and self-discipline
People who make a lot of money in the stock market are steadfast in their conviction and self-discipline. They know there will be turbulence, but they don’t bail out when things get shaky. Using a long-term horizon, they let growth and compounding work its magic.

People who are chronically disappointed with their investing results tend to have the opposite perspective. By obsessing over the valleys and cliffs, these investors try to pick a perfect time to invest and get scared into inaction when the time isn’t perfect. This mindset is inherently self-defeating, because there’s never a perfect time. Sir John Templeton, one of the most successful long-term investors ever, said it best, “The perfect time to invest is when you have the money.” That way, you can better position to reap rewards from the market’s long-term growth.

Many investors who fixate on market valleys don’t understand that their behavior really isn’t investing. It’s more like gambling, because instead of positioning for eventual growth, they’re betting that they know various things that can’t be known.

An inordinate amount of time is wasted, with incessant head-scratching, by people in the financial industry who are trying to predict the unpredictable. Emotions aside, we know the S&P 500 has always hit new highs eventually, but there’s no way to predict when these peaks will be reached. Thus, it’s far better to have a long-term investing plan that accounts for inevitable corrections — and stick to it. No matter what your age or risk tolerance, investing is a lot easier and likely more successful if your perspective is informed by market history.

Dave S. Gilreath, a Certified Financial Planner, is a 40-year veteran of the financial services industry. He is a partner and chief investment officer of Sheaff Brock Investment Advisors, LLC, a portfolio management firm for individual investors, and Innovative Portfolios, LLC, an institutional money management firm. Based in Indianapolis, the firms manage about $1.4 billion in assets nationwide.
A strategy for investing during a recession

By Jim Sloan

There is a difference between investing during a recession and investing in anticipation of a recession. When a recession is already underway, the options are limited. The best options are things you can do in anticipation of a recession. The very best options are those you can undertake to prepare your portfolio to ride out challenging economic environments of all kinds, recognizing that a recession is an event that can occur at any time. Here are some strategic suggestions, including both dos and don’ts.

SUGGESTION 1: Don’t panic and sell
Panic selling almost always turns out to be wrong. If you own well-chosen stocks, a recession and bear market aren’t the end of the world. Your portfolio will eventually come back. And who knows? If it does turn out to be the end of the world, there’s not much you can do about it. Eat all the ice cream with chocolate sauce you want, I suppose. Panicking can be bad for your health. Instead, try working out, reading a book or embracing stoicism. It’s not so much what happens to you as how you deal with it. Detaching yourself from what is going on around you is the first principle of successful investing.

SUGGESTION 2: Do nothing at all
Don’t do anything, just sit there. Try to not look at your portfolio for a while.

This is the John Bogle approach, suggesting that you establish a proper mix of an index stock fund or exchange-traded funds (ETFs) combined with an index bond fund or ETF. As the founder of Vanguard and the first to popularized index funds, Bogle would naturally prefer the Vanguard Total Stock Market ETF (VTI) and the Vanguard Total Bond Market ETF. Both have minuscule expense ratios (.02% and .03%) and include everything in proportional weights, which provides natural diversification. You don’t attempt to outsmart the market by focusing on a particular sector at a particular time.

The John Bogle approach is hard to beat for individuals who don’t spend a lot of time studying the market. Those who have followed Bogle have done well. Although I subscribe to the approach of doing little or nothing, index investing hasn’t been my personal approach. The S&P 500 or VTI has the virtue of automatically increasing your exposure to the best growth stocks as they grow to be an ever larger portions of the index (adjusted daily). There is also the downside of periods, such as the past two years, when high flyers come back to earth and drag down the index. My own portfolio consists of individual stocks put together in a way that seeks to avoid that extra volatility. It’s not necessary to beat the index to do very well and achieve your personal goals. One goal of a stock portfolio is to avoid catastrophes by staying away from high-risk stocks. The indexes are required to own them. You don’t have to. A sensible goal is to beat the index in risk-adjusted terms. Most of the stocks I own are low beta and are selected to perform well enough in a variety of environments, including inflation, deflation and recession. I have also bought I bonds regularly since 2000. Most purchases came when inflation wasn’t a major issue, but they have recently served very well as an insurance policy against inflation.

Remember that the most important actions dealing with a recession are taken before the recession begins. Being prepared is always the way to go. Don’t let yourself go into a recession with an undiversified portfolio full of risk. When I was a financial advisor, the saddest thing I ever thought was, “The solution to your problem is to have not gotten yourself into that position in the first place.”

SUGGESTION 3: Don’t chase individual sectors unless you are a skilled trader
It doesn’t make much sense to me to make long-term buys on the basis of your expectations for short-term outperformance. Even if you manage to get it right, what do you do when the cycle moves on to the next stage? My preference is to own a mixture of quality stocks, which as a group will provide good returns over the long run. I realize many analysts emphasize particular sectors for various market stages, both on Wall Street and Seeking Alpha. The focus is often on sectors with high dividends. Owning some stocks that pay good dividends is fine. Among other things, it reduces the duration of your equity portfolio because high dividends
accelerate return of your capital. They may also go down less than the market in the early stage of recessions.

Two examples of such holdings in my portfolio are Johnson & Johnson and McKesson Corp. Both are good companies in the health care area, which are largely uncorrelated to the rest of my portfolio. It’s important for you to know I bought them when no recession was on the horizon. Two other areas that protect in recessions are insurance, where I own Traders Companies, Inc., and Markel Corp., as well as aerospace/defense, where I own Raytheon Technologies Corp. I might also add Lockheed Martin Corp., if it becomes cheaper in the course of a further market decline. Both insurance and aerospace/defense have customers who will not reduce their spending because of a recession. I knew that when I bought them, but it was not the only reason I bought them. I had no expectation of nailing the timing of a recession, they are simply part of a diversified portfolio.

**Suggestion 4: Take advantage of opportunities in fixed income**

In an economic contraction, bonds rally first, then stocks and then commodities. As I said in the third suggestion, trying to time stock sector buying occasionally works for skilled traders but is not a sound policy for long-term investors. The same holds for commodity stocks — the closest most investors come to actual commodities. Most are too cyclical.

Think of fixed income (i.e., bonds) as an asset class that extends all the way out from cash in money market funds to maturities of 30 years. The thing you can sometimes do in a timely fashion is shorten or lengthen maturities.

The current situation is ambiguous. The Federal Reserve is committed to increasing rates sharply; meanwhile, the behavior of many rates and other indicators point toward a recession, which might move the Federal Reserve to reverse its position and cause rates to fall. My solution was to move half of my cash reserve to a short-term Treasury ladder starting at six months, with steps of every six months out to two years. This plus the 50% still in cash produces a Treasury average rate of over 3%. Longer Treasuries offer little if anything more. It also maintains the flexibility for adding to the ladder if the Federal Reserve keeps increasing rates. On the other hand, you can buy and lock in longer Treasuries if it becomes clear that the Federal Reserve is about to lower rates to fight the recession. You can also use cash at that time to buy stocks, which have the longest duration of any financial asset. This nuanced strategy using Treasuries is the only thing I see that can take advantage of market cycles and economic cycles.

**Suggestion 5: Take advantage of tax losses**

Over the years, I have taken every opportunity to sell stock positions that are in the red. This is one of the advantages of having a stock portfolio instead of owning stocks through an index. If I have a stock or a tranche of a stock position that is in the red, I generally sell it toward the end of the year. Most of the time, I have been able to buy it back after 31 days without paying more. I do try to time my tax loss sales so as not to be doing it at the same time everybody else is.

The beauty of this strategy is that it makes your losses work for you. If you have a stock you are hesitant to trim because of embedded capital gains, a tax loss can be used to offset the gains. If you have no gains to offset, you can use up to $3,000 to offset ordinary income. You can also keep a tax-loss bank indefinitely. In most recent years, I haven’t had much to sell for a tax loss because most portfolio positions have very long-term capital gains. However, this year, I did a quick sale of two small positions that I had been too early to buy. I’ll buy them back in good time.

Bear markets frequently provide opportunities for tax-loss selling. People don’t like to sell losers and are often too quick to take profits. This turns the best strategy upside down. Another market adage is: “Sell your losers and let your winners ride.” Many of my winners have been riding for over a decade. Along with keeping your expenses down, taking tax losses is one of the few freebies in investing.

I urge you to take advantage of these opportunities before it’s too late!
CONTRAINDICATIONS:
- Screen patients at risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to starting KRYSTEXXA.
- Premedicate with antihistamines and corticosteroids and closely monitor for anaphylaxis for an appropriate period.
- Anaphylaxis may occur with any infusion, including a first infusion, and generally manifests within 2 hours of the infusion.
- Anaphylaxis and infusion reactions have been reported to occur during and after administration of KRYSTEXXA.

METHEMOGLOBINEMIA
WARNING: ANAPHYLAXIS AND INFUSION REACTIONS, G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND IMPORTANT SAFETY INFORMATION

Limitations of Use: KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

INDICATION
KRYSTEXXA® (pegloticase) is indicated for the treatment of chronic gout in adult patients who have failed to normalize serum uric acid and whose signs and symptoms are inadequately controlled with xanthine oxidase inhibitors at the maximum medically appropriate dose or for whom these drugs are contraindicated.

IMPORTANT SAFETY INFORMATION
WARNING: ANAPHYLAXIS AND INFUSION REACTIONS, G6PD DEFICIENCY ASSOCIATED HEMOLYSIS AND
METHEMOGLOBINEMIA
- Anaphylaxis and infusion reactions have been reported to occur during and after administration of KRYSTEXXA.
- Anaphylaxis may occur with any infusion, including a first infusion, and generally manifests within 2 hours of the infusion. Delayed hypersensitivity reactions have also been reported.
- KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions.
- Premedicate with antihistamines and corticosteroids and closely monitor for anaphylaxis for an appropriate period after administration of KRYSTEXXA.
- Monitor serum uric acid levels prior to each infusion and discontinue treatment if levels increase to above 6 mg/dL, particularly when 2 consecutive levels above 6 mg/dL are observed.
- Screen patients at risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to starting KRYSTEXXA.

Hemolysis and methemoglobinemia have been reported with KRYSTEXXA in patients with G6PD deficiency. KRYSTEXXA is contraindicated in patients with G6PD deficiency.

CONTRAINDICATIONS:
- In patients with G6PD deficiency.
- In patients with history of serious hypersensitivity reactions, including anaphylaxis, to KRYSTEXXA or any of its components.
CONTRAINDICATIONS:

• Screen patients at risk for glucose-6-phosphate dehydrogenase (G6PD) deficiency prior to starting KRYSTEXXA.
• Premedicate with antihistamines and corticosteroids and closely monitor for anaphylaxis for an appropriate period. Anaphylaxis may occur with any infusion, including a first infusion, and generally manifests within 2 hours of the infusion. Delayed hypersensitivity reactions have also been reported.

LIMITATIONS OF USE: KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

ADVERSE REACTIONS

The most commonly reported adverse reactions (≥5%) are:

KRYSTEXXA with methotrexate trial:
KRYSTEXXA with methotrexate: gout flares, arthralgia, COVID-19, nausea, and fatigue; KRYSTEXXA alone: gout flares, arthralgia, COVID-19, nausea, fatigue, infusion reaction, pain in extremity, hypertension, and vomiting.

KRYSTEXXA pre-marketing placebo-controlled trials:
gout flares, infusion reactions, nausea, constipation or ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis, and vomiting.

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

**INDICATIONS AND USAGE**

• Monitor serum uric acid levels prior to each infusion

• KRYSTEXXA should be administered in healthcare settings and by healthcare providers prepared to manage anaphylaxis and infusion reactions.

• Pre-medicate with antihistamines and corticosteroids and closely monitor for anaphylaxis for an appropriate period of time after administration of KRYSTEXXA.

• Monitor serum uric acid levels prior to each infusion and generally monitor within 2 hours of the infusion. However, delayed hypersensitivity reactions have also been reported.

• KRYSTEXXA should be administered in healthcare settings by and under the supervision of a qualified healthcare professional. If KRYSTEXXA is given by an intravenous route, it should be given over 2 hours according to the approved labeling. Use cartridges and vials with an expiration date that is no more than 18 months in the future.

**WARNINGS AND PRECAUTIONS**

• Patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency. Because methotrexate has been associated with methemoglobinemia, use KRYSTEXXA in patients with G6PD deficiency with caution. Methemoglobinemia has been reported with KRYSTEXXA. If methemoglobinemia occurs, discontinue KRYSTEXXA administration.

• Patients with asymptomatic hyperuricemia. KRYSTEXXA is not recommended for the treatment of asymptomatic hyperuricemia.

• Asymptomatic hyperuricemia. KRYSTEXXA is contraindicated in patients with asymptomatic hyperuricemia.

**CONTRAINDICATIONS**

KRYSTEXXA is contraindicated in:

• Patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency (see Warnings and Precautions)

• Patients with history of serious hypersensitivity reactions, including anaphylaxis, to KRYSTEXXA or any of its components

**WARNINGS AND PRECAUTIONS**

**Anaphylaxis**

In a 52-week, controlled trial, which evaluated KRYSTEXXA co-administered with methotrexate compared to KRYSTEXXA alone (see Adverse Reactions), patients were pre-treated with standardized infusion reaction prophylaxis and were discontinued from treatment with KRYSTEXXA if serum uric acid levels increased to above 6 mg/dL. Infusion reactions were reported in 26% of patients treated with KRYSTEXXA 8 mg every 2 weeks, and 41% of patients treated with KRYSTEXXA 8 mg every 4 weeks, compared to 5% of patients treated with placebo. Infusion reactions occurred in patients being pre-treated with an oral antihistamine, intravenous corticosteroid, and anxiolytic. In the first or second KRYSTEXXA infusion, patients who had undetectable or low antibody titers.

**Infusion Reactions**

In a 52-week, controlled trial which evaluated KRYSTEXXA co-administered with methotrexate compared to KRYSTEXXA alone (see Adverse Reactions), patients were pre-treated with standardized infusion reaction prophylaxis and were discontinued from treatment with KRYSTEXXA if serum uric acid levels increased to above 6 mg/dL. Infusion reactions were reported in 26% of patients treated with KRYSTEXXA 8 mg every 2 weeks, and 41% of patients treated with KRYSTEXXA 8 mg every 4 weeks, compared to 5% of patients treated with placebo. Infusion reactions occurred in patients being pre-treated with an oral antihistamine, intravenous corticosteroid, and anxiolytic. In the first or second KRYSTEXXA infusion, patients who had undetectable or low antibody titers.

**Methemoglobinemia**

In a 52-week, randomized, double-blind study conducted in patients with gout, 4% of patients experienced methemoglobinemia. Methemoglobinemia has been reported with KRYSTEXXA. If methemoglobinemia occurs, discontinue KRYSTEXXA administration.

**Drug Interactions**

Overdosage

**Adverse Reactions**

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

• Anaphylaxis (see Warnings and Precautions)

• Infusion Reactions (see Warnings and Precautions)

• G6PD Deficiency Associated with Hemolysis and Methemoglobinemia (see Warnings and Precautions)

• Gout Flares (see Warnings and Precautions)

• Congestive Heart Failure (see Warnings and Precautions)

Clinical Trials Experience

Because clinical studies are conducted under widely varying and controlled conditions, adverse reaction rates observed in clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug, or in the general population, observed in a broader patient population in clinical practice.

Co-administration with Methotrexate

A 52-week, randomized, double-blind trial conducted in adult patients with chronic gouty refractory to conventional therapy to evaluate administration of KRYSTEXXA 8 mg every 2 weeks co-administered with weekly administration of oral methotrexate 15 mg, compared to KRYSTEXXA alone. In this trial, patients who were able to tolerate two weeks on methotrexate 15 mg were then randomized to receive four additional weeks on either methotrexate 15 mg or methotrexate 15 mg co-administered with KRYSTEXXA. A total of 125 patients were randomized, and of these, 145 subjects completed the 4-week methotrexate run-in period and received KRYSTEXXA. Among the patients who started KRYSTEXXA co-administered with methotrexate and 49 received KRYSTEXXA plus placebo during the treatment period. All patients received pre-treatment with an oral antihistamine, intravenous corticosteroid and acetaminophen. These patients were between the ages of 24 and 83 years (average 55 years); 153 patients were male and 17 were female. 105 patients were White, 10 African American, 2 were Asian, and 8 were other.

In this trial, the percentages of patients with any flare for the first 3 months were 66% and 69% for the group treated with KRYSTEXXA co-administered with methotrexate and the group treated with KRYSTEXXA alone, respectively. The percentages of patients with any flare for the subsequent 3 months in patients treated with methotrexate and KRYSTEXXA were 41.5% and 41% during Month 9 and 9% during Month 12. In the group treated with KRYSTEXXA alone, the percentages of patients with any flare were 14% during Month 6, 9% during Month 9 and 21% during Month 12. During pre-marketing, 2-week controlled clinical trials with KRYSTEXXA alone, the frequencies of gout flares were higher in all treatment groups, but no patients experienced anaphylaxis in the group treated with KRYSTEXXA co-administered with methotrexate. The percentages of patients with any flare for the first 3 months were 74%, 81%, and 51%, for KRYSTEXXA 8 mg every 2 weeks, KRYSTEXXA 8 mg every 4 weeks, and placebo, respectively. The percentages of patients with any flare for the subsequent 3 months were 41%, 57%, and 67%, for KRYSTEXXA 8 mg every 2 weeks, KRYSTEXXA 8 mg every 4 weeks, and placebo, respectively. Patients received gout flare prophylaxis with colchicine and/or nonsteroidal anti-inflammatory drugs (NSAIDs) starting at least one week before receiving KRYSTEXXA.

Gout flares may occur after initiation of KRYSTEXXA. An increase in gout flares is frequently observed upon initiation of anti-hyperuricemic therapy, due to changing serum uric acid levels resultant from mobilization of urate from joints and soft tissues. Gout flares prophylaxis with a non-steroidal anti-inflammatory drug (NSAID) or colchicine is recommended starting at least 1 week before initiation of KRYSTEXXA therapy and continued until unless medically contraindicated or not tolerated. KRYSTEXXA does not need to be discontinued because of a gout flare. The gout flares should be managed concurrently as appropriate for the individual patient (see Dosage and Administration).

**CONGESTIVE HEART FAILURE**

KRYSTEXXA has not been formally studied in patients with congestive heart failure, but some have been reported in the pre-marketing, 24-week controlled clinical trials experienced exacerbation of congestive heart failure. Two cases of congestive heart failure exacerbation occurred during the trials in patients receiving treatment with KRYSTEXXA 8 mg every 2 weeks. No cases were reported in placebo-treated patients. Four subjects had exacerbations of pre-existing congestive heart failure while receiving KRYSTEXXA 8 mg every 2 weeks during the open-label extension study. Exercise caution when using KRYSTEXXA in patients who have congestive heart failure and monitor patients closely following infusion.

**Re-treatment with KRYSTEXXA**

No controlled trial data are available on the safety and efficacy of re-treatment with KRYSTEXXA after stopping treatment for longer than 4 weeks. Due to the immuno-genicity of KRYSTEXXA, patients receiving re-treatment may be at increased risk of anaphylaxis and infusion reactions. Therefore, patients receiving re-treatment after a drug-free interval should be monitored carefully (see Adverse Reactions).

**ADVERSE REACTIONS**

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

• Anaphylaxis (see Warnings and Precautions)

• Infusion Reactions (see Warnings and Precautions)

• G6PD Deficiency Associated with Hemolysis and Methemoglobinemia (see Warnings and Precautions)

• Gout Flares (see Warnings and Precautions)

• Congestive Heart Failure (see Warnings and Precautions)
Anaphylaxis may occur with any infusion, including a KRYSTEXXA co-administered with methotrexate or KRYSTEXXA alone period are provided in Table 1.

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>KRYSTEXXA with Methotrexate (N=86) n (%)</th>
<th>KRYSTEXXA Alone (N=80) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gout flare</td>
<td>64 (76%)</td>
<td>35 (71%)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>13 (14%)</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>COVID-19</td>
<td>9 (9%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>5 (5%)</td>
<td>6 (12%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>5 (5%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Infusion reaction</td>
<td>4 (4%)*</td>
<td>15 (31%)</td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>1 (1%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1 (1%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>0 (0%)</td>
<td>4 (8%)</td>
</tr>
</tbody>
</table>

* Included one case of anaphylaxis

The safety and effectiveness of KRYSTEXXA in pediatric patients less than 18 years of age have not been established.

**Lactation**

Risk Summary

It is not known whether this drug is excreted in human milk. Therefore, KRYSTEXXA should also be used when breastfeeding unless the clear benefit to the mother can overcome the unknown risk to the newborn/infant.

**Pediatric Use**

The safety and effectiveness of KRYSTEXXA® in children younger than 18 years have not been established.

**Renal Impairment**

No dose adjustment is required for patients with renal impairment.

**Overdosage**

No reports of overdose with KRYSTEXXA have been reported. The maximum dose that has been administered as a single intravenous dose is 12 mg as uricase protein. Patients suspected of receiving an overdose should be monitored, and general supportive measures should be initiated if no specific antidote has been identified.

**Patient Counseling Information**

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

**Anaphylaxis and Infusion Reactions**

- Anaphylaxis and infusion reactions can occur at any infusion while on therapy. Counsel patients on the importance of adhering to any pre-dispensing instructions to help prevent or lessen the severity of these reactions.
- Educate patients on the signs and symptoms of anaphylaxis, including wheezing, per-oral or lingual edema, hemodynamic instability, and rash or urticaria, nausea or vomiting.
- Educate patients on the most common signs and symptoms of an infusion reaction, including urticaria (skin rash), erythema (redness of the skin), dyspnea (difficult breathing), flushing, chest discomfort, chest pain, and rash.
- Advise patients to seek medical care immediately if they experience any symptoms of an allergic reaction during or at any time after the infusion of KRYSTEXXA (see Warnings and Precautions, Adverse Reactions).
- Advise patients to discontinue any oral urate-lowering agents before starting on KRYSTEXXA and not to take any oral urate-lowering agents while on KRYSTEXXA.

**Glucose-6-phosphate dehydrogenase (G6PD) Deficiency**

Inform patients not to take KRYSTEXXA if they have a condition known as G6PD deficiency. Explain to patients that G6PD deficiency is more frequently found in individuals of African, Mediterranean, or Southern Asian ancestry and that they may be tested to determine if they have G6PD deficiency; unless already known (see Warnings and Precautions, Contraindications).

**Gout Flares**

Explain to patients that gout flares may initially increase when starting treatment with KRYSTEXXA, but that medications to help reduce flares may need to be taken regularly for the first few months after KRYSTEXXA is started (see Warnings and Precautions, Adverse Reactions). Advise patients that they should not stop KRYSTEXXA therapy if they have a flare.

Manufactured by: Horizon Therapeutics Ireland DAC
Dublin, Ireland

US License Number 2022

**Horizon Therapeutics USA, Inc.**

Dermoid, IL 60015

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Despite your best efforts to follow billing guidelines, payers still deny your claims. Or in some cases, they pay you and then take the money back. Experts say you can’t ever eliminate denials and post-payment recoupments entirely, but you can reduce them by focusing on coding and documentation compliance. Listed below are eight of the most common reasons for denials and how to avoid them.

By Lisa A. Eramo, M.A.
1 Incorrect patient status (i.e., new versus established)

HOW TO GET PAID: Don’t make assumptions. A patient who is new to you isn’t necessarily a new patient per official definitions. For example, did the patient have an audio-visual telehealth appointment within the past three years? If so, they’re considered an established patient even if they’ve never been seen in person, according to Victoria Moll, CPC, owner and founder of Contempo Coding, LLC, in Fleetwood, Pennsylvania.

Was the patient who was seen within three years by another physician in the same clinic? If so, they’re also an established patient, according to Toni Ellhoms, CCS, CPC, chief executive officer of Alpha Coding Experts, LLC, in Orlando, Florida. “If taxonomy codes (aren’t) set up correctly, this will impact coding,” she says.

Be mindful of non-physician providers who see new patients and bill under their own nation provider identifier. If a physician sees those same patients within three years, the patients are considered established, Ellhoms explains.

2 Incorrect application of prolonged services codes with office visit evaluation and management (E/M) codes

HOW TO GET PAID: Know the rules. In the past, physicians could report a prolonged services E/M code in addition to any other E/M office visit code. However, in 2021, Medicare and current procedural terminology (CPT) rules and codes changed. What do you need to know? Consider the following:

- **Report the right codes.**
  
  For Medicare, the prolonged services code is G2212. For non-Medicare, it’s 99417.

- **Know when to report**

- **Note minimum time thresholds for Medicare versus non-Medicare.** See the chart below for more information.

- **Be sure to document the total face-to-face or non-face-to-face time spent with the patient on the date of the encounter.**

<table>
<thead>
<tr>
<th>Non-Medicare Prolonged Services</th>
<th>Code(s) to report for non-Medicare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total duration of new patient office visit (99205)</td>
<td></td>
</tr>
<tr>
<td>Less than 75 minutes</td>
<td>Not reported separately</td>
</tr>
<tr>
<td>75-89 minutes</td>
<td>99205 (x1) and 99417 (x1)</td>
</tr>
<tr>
<td>90-104 minutes</td>
<td>99205 (x1) and 99417 (x2)</td>
</tr>
<tr>
<td>105-119 minutes (or more)</td>
<td>99205 (x1) and 99417 (x3 or more for each additional 15 minutes)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total duration of established patient office visit (99215)</th>
<th>Code(s) to report for non-Medicare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 55 minutes</td>
<td>Not reported separately</td>
</tr>
<tr>
<td>55-69 minutes</td>
<td>99215 (x1) and 99417 (x1)</td>
</tr>
<tr>
<td>70-84 minutes</td>
<td>99215 (x1) and 99417 (x2)</td>
</tr>
<tr>
<td>85-99 minutes (or more)</td>
<td>99215 (x1) and 99417 (x3 or more for each additional 15 minutes)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medicare Prolonged Services</th>
<th>Codes to report for Medicare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total duration of new patient office visit (99205)</td>
<td></td>
</tr>
<tr>
<td>Less than 89 minutes</td>
<td>Not reported separately</td>
</tr>
<tr>
<td>89-103 minutes</td>
<td>99205 (x1) and G2212 (x1)</td>
</tr>
<tr>
<td>104-118 minutes</td>
<td>99205 (x1) and G2212 (x2)</td>
</tr>
<tr>
<td>119-133 minutes</td>
<td>99205 (x1) and G2212 (x3 or more for each additional 15 minutes)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total duration of established patient office visit (99215)</th>
<th>Codes to report for Medicare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 69 minutes</td>
<td>Not reported separately</td>
</tr>
<tr>
<td>69-83 minutes</td>
<td>99215 (x1) and G2212 (x1)</td>
</tr>
<tr>
<td>84-98 minutes</td>
<td>99215 (x1) and G2212 (x2)</td>
</tr>
<tr>
<td>99-113 minutes</td>
<td>99215 (x1) and G2212 (x3 or more for each additional 15 minutes)</td>
</tr>
</tbody>
</table>
Denial avoidance: Consider this critical tip

What’s the most important thing practices can do to avoid denials now and in the future? Track them. “It’s not that hard to develop an Excel spreadsheet so you can start noticing trends,” says Victoria Moll, CPC, owner and founder of Contempo Coding, LLC, in Fleetwood, Pennsylvania. “So many practices don’t keep up with the coding changes,” she says. “They file a claim on October 1, and the claim is denied because the code is invalid.”

What are some recently updated diagnoses? Consider the following:
- Headache. Report R51.0 or R51.9.
- Low back pain. Report M54.50, M54.51 or M54.59.
- Cough. Report R05.1, R05.2, R05.3, R05.4, R05.8 or R05.9.

Similarly, physicians who don’t stay on top of coding changes also run the risk of reporting invalid procedure codes, Huey explains. She provides the example of G0297 for lung cancer screening; this code was deleted in 2021 and replaced by 71271. In addition, in 2022, Centers for Medicare & Medicaid Services (CMS) finalized the addition of proposed CPT code 99X21 as new CPT code 99437 (chronic care management services, each additional 30 minutes, by a physician or other qualified health care professional, per calendar month). CMS also adopted new guidelines for musculoskeletal procedures, including nonmanipulative care, and continues to publish new vaccine codes for COVID-19.

Another helpful pointer is to know when a singular combination code (rather than multiple diagnosis codes) is required, explains Sarah Ragan, CPC, certified coder in Daytona Beach, Florida. For example, when a patient has type 2 diabetes with chronic kidney disease, report E11.22. When a patient has hypertension with chronic kidney disease, report I12-. When a patient has heart failure with hypertension and chronic kidney disease, report I13-. Physicians will deny claims when physicians don’t follow these coding rules, Ragan says.

4 Unspecified diagnosis codes

HOW TO GET PAID: Avoid unspecified diagnosis codes when possible, as they are on most payers’ non-covered lists, Moll explains. She provides the example of a vitamin B12 shot for vitamin B12-deficiency anemia. If physicians report D50.9 (unspecified iron deficiency anemia) rather than D51- (vitamin B12-deficiency anemia), many payers will deny the claim.

5 Lack of medical necessity

HOW TO GET PAID: It all comes down to specific payer policies for medical necessity, some of which may be stricter than the clinical criteria physicians use, says Tammy Tipton, owner of Appeal Solutions, Inc., in Oklahoma City. “These are the cases you (must) appeal to escalate to your provider rep,” she says. “You should also address these issues when you renegotiate your contract.”

However, payers may not negotiate in some cases, and patients need to understand they could be responsible for the bill, Huey explains. Consider a vitamin D deficiency screening. “Most payers won’t cover this test unless you have a history of a vitamin D deficiency,” she says. “What I see too many practices doing is coding it incorrectly — coding it as if the patient has the condition when we don’t know (whether) they do. This could be considered fraudulent coding.”

6 Coordination of benefits error

HOW TO GET PAID: Leverage front desk staff, Tipton says. More specifically, educate them on verification of benefits, policy language, and precertification so they help avoid denials on the front end of the billing process.

Huey agrees. Well-educated front desk staff can sort out
whether Medicare should be primary or secondary, for example. (Note: Medicare provides a scenario-based guide to help practices identify cases where Medicare should be reported as secondary. To view this guide, scan the QR code below with your smart phone camera app.

Front desk staff can also help determine whether the reason for the visit pertains to an injury that worker’s compensation or auto insurance might cover as primary, Huey explains. When this is the case, they can collect information about the injury itself, including how, where and when (as well as the specific time of day — yes, some payers require it) the accident or injury happened. “They can also remind physicians to document all this information so you aren’t facing a potential denial,” she says.

Use these two CPT modifiers to get paid correctly

By Lisa A. Eramo, M.A.

**DURING A TYPICAL OFFICE VISIT,** physicians may provide evaluation and management (E/M) services, minor procedures and more. The question is: Can they bill for each one separately? In some cases, the answer is yes. In others, though, the answer is no — but they must know what current procedural terminology (CPT) modifier to append. Modifiers communicate this important message to payers: Pay me for services that wouldn’t normally warrant separate reimbursement.

However, incorrectly appending these modifiers can lead to payment denials and open practices up for greater payer scrutiny. Consider these two important modifiers and the advice below on how you can use them to get paid correctly.

**Modifier -25**

**WHAT IT MEANS:**
A physician performed a significant, separately identifiable E/M service on the same day of a procedure or other service.

**HOW TO USE IT CORRECTLY:**

“This is how I always explain it: If the presenting problem is entirely resolved by the procedure, you just bill the procedure,” says Victoria Moll, CPC, owner and founder of Contempo Coding, LLC, in Fleetwood, Pennsylvania.

For example, a patient presents with hearing loss, so a physician examines their ears, sees impacted cerumen and decides to remove it. After the removal, the patient can hear again. In this case, only the cerumen removal is billable, Moll says. However, if the patient also had a sore throat that required treatment, a separate E/M with modifier -25 may be warranted. The same is true if the patient still couldn’t hear after the cerumen removal, and the physician ordered a hearing test.

Here’s another common scenario: A patient presents for a flu shot. If the physician only administers the vaccine, only the vaccine is billable, Moll explains. However, if the patient also mentions they’ve had a rash on their abdomen during the encounter, the physician may be able to bill a separate E/M service with modifier -25 for addressing the rash, she adds.

Similarly, when a physician performs a steroid injection for knee pain, they shouldn’t bill a separate E/M code, explains Toni Elhoms, CCS, CPC, CPMA, CRC, chief executive officer of Alpha Coding Experts, LLC, in Orlando, Florida. “This is a big issue in primary care,” she says. “The decision to perform a minor procedure is included in the procedure. You can’t just automatically tack on an E/M code and bill it with a modifier -25.”

However, there are always exceptions. Elhoms provides this example: A patient presents with knee pain, and a physician gives them a steroid injection. However, during the encounter, the physician also decides to prescribe medication and considers ordering an MRI because they suspect there could be a larger injury. In this case, there may be a separately identifiable E/M service.

Weight management or obesity screening and counseling (i.e., CPT codes 99401-99404) with an E/M office visit is another area of confusion, says Rozmin Bapat, CCS-P, CPB, CPC, CPCO, CPMA, founder and CEO of CodeRite Healthcare Consulting in Dallas. “If the patient is coming in for weight management and that’s all you’re doing, that doesn’t justify an office visit code,” she says. An exception would be if the patient presents for weight management and complains of leg pain. In this case, a separate E/M visit code may be warranted, she explains.

When using modifier -25, the best practice is to separate documentation for the E/M service
incident-to billing errors that could result in a denial:

- Billing incident-to when the payer doesn’t permit it under any circumstances
- Billing incident-to services for a new patient
- Billing incident-to for an established patient when a change to the plan of care occurs
- Billing incident-to for an established patient when the supervising physician is not present in the office suite and immediately available to provide assistance and direction

**8 Billing for a related E/M service within seven days of a virtual service (i.e., a virtual check-in or e-visit).**

**HOW TO GET PAID:** Consider waiting seven days before billing a virtual service to ensure the practice doesn’t provide a related E/M service during that same time frame, Elhoms says. If the physician doesn’t provide a related E/M service within seven days of providing the virtual service, practices can bill the virtual service. If the physician does provide a related E/M service within seven days, practices can only bill one or the other — not both. Elhoms advises physicians to work with their practice management vendor to include built-in edits for virtual services codes to ensure proper billing.

**Did you know?**

**Omitting laterality modifiers could cause denials**

Laterality modifiers include -RT (right), -LT (left) and modifier -50 (bilateral). For certain types of procedures (e.g., ear lavage or injection), payers expect to see a laterality modifier. If you don’t provide this information, they’ll deny the claim, says Sarah Ragan, CPC, certified coder in Daytona Beach, Florida.

from documentation for the separate procedure, according to Deborah Grider, CDIP, CPC, senior healthcare consultant at KarenZupko & Associates, Inc., in Chicago. “There should be two separate procedure notes. It shouldn’t all be rolled into the E/M service,” she says.

However, knowing your payer policies is also critical. For example, some commercial payers have policies stating you can’t ever bill a level two E/M service on the same day as a minor procedure, Moll explains. “A minor procedure includes some component of E/M,” she says. “Often, a level two E/M service is not significant and separately identifiable.”

Other times, payers deny claims with modifier -25 as a matter of policy, or they automatically require additional documentation before paying the claim, Grider explains. Similarly, payers may never cover weight management counseling separately, or they may require a specific body mass index, Bapat says.

There’s also the issue of diagnosis codes. Although two different diagnosis codes aren’t required to report modifier -25, some payers might automatically deny claims when physicians only report one diagnosis code, Grider explains. “Providers may need to appeal these cases and submit documentation to prove they did the separate evaluation,” she says.

In many cases — but not all — two different diagnoses may be warranted, Bapat says. She provides the example of an E/M service with an annual wellness visit (AWV). When a physician performs a separate E/M service, they should report one or more diagnosis codes for the separate problem, along with a Z00.01 for the AWV with abnormal findings. For example, if the physician discovers the patient has hypertension and decides to prescribe a medication, they should report the E/M service with 10.

**Modifier -24**

**WHAT IT MEANS:**

A physician performed an unrelated E/M service during a postoperative period.

**HOW TO USE IT CORRECTLY:**

It is important to understand global periods for minor procedures, Elhoms says. Each code in the surgery section of CPT has a global period indicator. This means all services related to the procedure are included in those days and cannot be billed separately. More specifically, some procedures have a 90-day global period, whereas others have a 10-day or zero-day period, meaning nothing related to the procedure is separately billable on the day of the procedure.

Consider the following global day designations for common minor procedures:

<table>
<thead>
<tr>
<th>Minor procedure</th>
<th>CPT code</th>
<th>Global day designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerumen removal</td>
<td>69209-69210</td>
<td>0</td>
</tr>
<tr>
<td>Joint aspiration and/or injection</td>
<td>20610</td>
<td>0</td>
</tr>
<tr>
<td>Foreign body removal</td>
<td>10120-10121</td>
<td>10</td>
</tr>
<tr>
<td>Laceration repair</td>
<td>12031-12057</td>
<td>10</td>
</tr>
<tr>
<td>Incision and drainage</td>
<td>10140</td>
<td>10</td>
</tr>
</tbody>
</table>

Here’s where modifier -24 comes in. If the service is within the global period but unrelated to the procedure, physicians may be able to append modifier -24 to the E/M code so they can get paid separately. Elhoms advises to ask this question before separately reporting an E/M code with modifier -24: Is the service standard pre- and postoperative care for the procedure? “If the answer is yes, that’s not enough for a separate E/M service,” she says.

Another question to ask is: Am I reporting two different diagnosis codes? If so, modifier -24 may be warranted, Grider explains. She provides this example: A patient has a laceration repair, then presents with a sinus infection three days later. “Even though you’re within the global period, it’s clear why a separate E/M service was warranted,” she says.
LEARNING OBJECTIVES

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- Evaluate the potential impact of recent clinical trial data on clinical decision-making and care of patients

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Current economic conditions have created uncertainty for physicians and their portfolios. Inflation is rising and, as the Federal Reserve tries to keep it under control, so are interest rates. These uncertain times are new to many investors who are used to decades of stable financial conditions and may be wondering what moves are needed to protect their investments.

Medical Economics® spoke with Jeff Pratt, CRC, about how physicians should approach investing. Pratt is a financial adviser for Finity Group, a Portland, Oregon-based financial planning firm that specializes in working with medical professionals. Responses have been edited for length and clarity.

Medical Economics® (ME): How big a threat can high inflation be to an investment portfolio?

Jeff Pratt: Real returns are where the rubber hits the road. An investor might see a return of 7% on their portfolio in a given year. However, what if inflation for the same year was measured by the consumer price index at 9%? On paper, that’s a real return loss of 2% since the portfolio growth didn’t keep pace with inflation for the same year. Another thing to consider with inflation is overall consumer spending habits. In our current environment with inflation running a little hotter, let’s take a pound of coffee from the store as an example (of a) good that can be purchased. More likely than not, that pound of coffee from the store is more expensive today than it was six, nine, or 12 months ago. At the same time, most people are probably still buying the pound of coffee from the store even though it’s a little more expensive in the moment. Folks might not be happy with that, but the good is still being purchased. What if inflation gets to a point where instead of simply being unhappy with the price of such a good, consumers shift their spending altogether as to not purchase the pound of coffee from the store anymore because it becomes too expensive? Inflation can only outpace wage growth for so long before consumer spending is negatively impacted, and drop-off in consumer spending could lead to an economic slowdown.

ME: With inflation on the rise, what should physicians do to protect their investments, particularly if they are nearing retirement?

JP: Whether it’s inflation or any other factor, investors should remain focused on their long-term goals and be cognizant of not taking on risk — or too much risk, at the very least — they can’t handle. Let’s contextualize this. Say physician No. 1 is nearing retirement with a $5 million investment portfolio. Let’s also assume they anticipate only needing to draw $100,000 per year from their investment portfolio to meet their retirement lifestyle needs due to other income sources. Using just this vacuum of a scenario, this hypothetical physician No. 1 may not need to adjust much in their portfolio even with inflation on the rise.

We’ll continue in a vacuum scenario with only two inputs. Physician No. 2 has the same dollar amount investment portfolio at $5 million. To support their retirement lifestyle, though, they need...
to draw $500,000 per year from the portfolio. This is quite a faster drawdown and, if we saw a down-turn in portfolio balance, would likely have a larger overall impact on retirement planning than (in the case of) physician No. 1. It could be possible that with physician No. 2, their portfolio needs to be repositioned but what if they say they only want to plan around a life expectancy of another five years with no preferences on leaving wealth to heirs and/or charities?

Going back to physician No. 1, let’s say their life expectancy is 25 years but they also have huge goals of wanting to preserve as much wealth as possible to be passed on to their heirs/future generations? Any number of scenarios can be painted on paper as to address what physicians can do to protect their investments in a higher inflation environment. How to go about doing that, though, is going to depend on circumstances surrounding each person’s situation and goals.

**ME: What are some investment types that can help protect against inflation?**

**JP:** First thing that comes to mind is Government Series I Savings Bonds. Individuals can purchase these at the Treasury Direct website. The main things to be aware of with I Bonds is that each person is limited to purchasing a total of $15,000 per calendar year ($10,000 maximum electronic and $5,000 in paper bonds can be purchased). Once the I Bond is purchased, the money must be left in the bond for at least a year. Also, if cashed out in less than five years, then the previous three months’ accrued interest is forfeited. Because of this, Series I Bonds are most likely to be considered by folks with cash needs between one and five years out.

From a portfolio standpoint, it is important to remember that each inflationary environment is driven by a different series of factors or catalysts. There is no one-stop shop to inflation-proof a portfolio. However, within equities, investors may want to consider more of a focus on high-quality companies with competitive advantages that provide them with pricing power in their industries. The idea here is that these companies will be able to pass along price increases to consumers without significantly affecting demand or their profit margins. Fixed income typically struggles in an inflationary environment, but as an asset class it can still be an essential risk-management tool despite potential headwinds. Investors may want to look at shifting toward lower-duration bonds, which have less exposure to inflation and rising interest rates. As with any investment portfolio-related approach, though, it’s important to consider the whole puzzle and not just one piece of it. Some folks may be more impacted in their investment portfolio by inflation; others, not so much.

Every investor likely has goals, time horizons, risk tolerances and investment preferences unique to them. Take these considerations into account and be sure to maintain proper diversification that matches the investors’ specific time horizons and risk tolerance. With such an approach, folks might find they need to rebalance their portfolios back to their target asset allocation.

**ME: With inflation rising quickly, some physicians might be tempted to start shifting around investments from stocks to bonds — is this type of movement a good idea?**

**JP:** (It) depends on the goals and time horizons being considered. A physician approaching retirement who has continued to stay more heavily invested in stocks may want to consider reducing risk in their portfolio by increasing bond exposure. A physician who is young and doesn’t plan on retiring for 30-plus years may not need to do the same. Risk tolerance is always something that should be considered as well. The shorter time horizon a physician has on their money, the more conservative savings vehicle they might want to consider and vice versa. Someone with a long time horizon on an investment portfolio might find on paper they can or should be more aggressive with their investment strategy but if that’s not something they’re comfortable with, it may not be suitable to do so.

**ME: If a physician was looking at retiring in the next three years, should they continue on that path or keep working so they can offset some of the losses to inflation they are likely to incur?**

**JP:** A few questions to answer the question: If there are some losses in an investment portfolio due to inflation, are the losses projected to have a material negative impact on the retiring physician’s retirement income distribution strategy they want to start in the next three years? Is this hypothetical retiring physician at a typical retirement age of early to mid-60s? Older? Younger? What life expectancy are we planning around once the retirement distribution income strategy is started? The unique circumstances surrounding this hypothetical retiring physician could lead to both answers. It could be found that continuing on the current path is suitable. It could also be found that continuing to work is what’ll keep us on the highest probability path of success in relation to creating the retirement income distribution stream desired. *
Selling your practice? Avoid these four mistakes

Often, private practice physicians make drastic mistakes when selling their medical practice and lose thousands of dollars in the process. All their hard work and long-term investment goes down the drain.

However, these mistakes are often easily avoidable. As small business owners, these physicians had once dreamed of owning their own medical practice and building it to success. As times goes on, they hope to reap the rewards in the form of a successful business sale. This sounds like a great plan, but making the sale is not as easy as it may appear. Here are four tips to help you avoid a practice sale pitfalls, disappointment and lost money.

**MISTAKE 1**
**Not planning ahead or waiting too long to sell**

Waiting too long or not planning in advance can cause many physician practice owners to miss their window of opportunity. It takes a considerable amount of time to prepare for and execute a medical practice sale, therefore long-term planning is key to any successful medical practice sale. Physicians looking to retire quickly and sell their practice within 12 months are way behind the power curve, and these scenarios are often a long-shot endeavor. It pays to plan ahead — you never know when that perfect buyer may approach you and make you an offer you just can’t refuse.

Succession planning is a major consideration, especially for solo physician practices. Again, waiting until the last minute (less than 12 months) to plan for your exit puts you at a severe disadvantage. Additionally, the physician succeeding you must be set up for success. If they see you have been planning and considering this sale for quite some time, your price will be much higher.

**MISTAKE 2**
**Not finding the right person to assist you**

Finding the right transactional consultant to help you with succession planning and to assist you with the sale of your medical practice is crucial to your success. Often, physician practice owners go with the first person they meet just to “list their practice” and get the process going. This can cost you time and money in the long run. Within a few months, you may see no results and have to go on the search all over again. Taking the time to interview professionals and looking at a realistic outcome of what is expected will get you going in the right direction. Also keep in mind that no one is more motivated, passionate and knowledgeable about your medical practice than you.

**MISTAKE 3**
**Asking too much or too little**

Setting a very high or unrealistic price tag on a medical practice can lead to a dead-end street. Expecting to get top dollar for a practice that generates little or no profit is simply using bad business sense. Consider your specialty, similar practices, the current economy and your marketplace when pricing your practice to sell. Remember it is business, so don’t take it personally. Look for the most valuable opportunities for your medical practice.

Another mistake is to price the medical practice too low. Sometimes physician owners will price their practices low because they are burned out, suffer from an illness or did not get good advice. Do your homework first; listen to your professionals, such as a transactional consultant; and do research about other medical practice sales before jumping in with both feet.

**MISTAKE 4**
**Selling to the wrong person**

Taking the first offer may not be a wise choice, as this may not necessarily be your best offer. Selling your practice for top dollar with little or no money down along with an extended contract may lead you to lose it all. Medical practice sales can go bad after the new owner takes over. The new owner may lack business experience, have a closed mind or be a poor leader — the list goes on. A successful medical practice owner makes it look easy, but change that mix and disaster may strike. When this happens, the new owner may quickly end up in the red, which is why you want to get all or most of the money up front and leave little to escrow.

Evaluate your options and make the best selection for the long term. Ask yourself: Is this the best physician to buy and run my practice? Can they quickly connect with my patients and referring physicians and learn how to market effectively?

**FINAL THOUGHTS**

The more planning you put into your sale, the better the price you will be able to obtain. Keep in mind that the prospective buyer will be very suspect of your reason for selling. Have your plan and strategy in place to eliminate any fears.

Nick Hernandez, M.B.A., FACHE, is the founder and CEO of ABISA LLC. Send your medical practice management questions to medec@mjhlifesciences.com.
In the initial phase of the COVID-19 pandemic, patients were afraid to go to the doctor in person. As a result, the number of face-to-face encounters plummeted. Many nonurgent issues were delayed, but acute issues needed to be addressed and telehealth was the main way to deliver that care.

Even as patients have returned to in-person care, there is still a widespread demand for telehealth. “Patients got a taste of the convenience, lower cost, ease of access and efficiency of telehealth,” says David Cameron, M.D., a family medicine physician in Denver. “Also, during the subsequent COVID-19 delta and omicron surges, telemedicine was able to assist in managing the unprecedented spike in volume of patient visits.”

During the pandemic, many practices embraced telehealth for the first time. A big factor in this was that insurers were widely reimbursing for telehealth care — it wasn’t that physicians and patients didn’t want it before, it’s just that a clinic couldn’t easily get paid for a telehealth visit.

Monique White-Dominguez, M.D., an internist and lead physician consultant at Sameday Health, a personalized care provider with more than 50 clinics in 15 states, says sterile medical offices and the coldness of the space can make patients uncomfortable when they seek care. Telehealth solves this issue and, in her view, was a long time coming.

“At its core, telehealth is about access. Everyone should be able to access quality, personalized care when they need it — whether they live five minutes from [a clinic] or somewhere rural where the closest medical office is hours away,” she says. “Telehealth enables this to become a reality by creating a new touchpoint between patients and providers and ensuring that patients’ whole-body needs are being cared for.”

David Maleh, M.D., an internist with MDVIP in Wilmington, Delaware, notes that virtual visits provide some advantages over telephone and even in-person visits. “Being able to read a patient’s face and body language, which you cannot do over the phone or when a patient is wearing a mask in the exam room, is important,” he says. “Some other benefits have been the ability to assess a patient’s living arrangement for fall risks, for instance, and having a patient’s family members, such as their adult children, participate in the visit. They give another perspective, which can provide a better sense of what’s going on with the patient.”

Telemedicine is here to stay and many physicians are wisely investing in better platforms in an effort to take their telehealth care to the next level. Christina Chen, M.D., a family medicine physician and medical director at Bright.md, a leading company in asynchronous telehealth, says one thing that the pandemic made clear is that there really isn’t much that can’t be done virtually or online. Patients want the technology that powers their daily lives to power their health care as well, she says.

Recent strides in integrating various telehealth tools are certainly making work flows more seamless, but there is still work to be done. “Out of necessity during the early days of the
pandemic, health systems scrambled to adopt digital solutions, but now that the dust has settled a bit, we need to make sure that those solutions play well with each other and with each organization’s EHR (electronic health record),” Chen says. “Your digital front door needs to connect seamlessly with your chatbot and online scheduling systems. Your video visit vendor should communicate well with your EHR, and so on and so forth. Ideally, all of these tools working together leads to a better experience not only for patients, but also for the providers caring for those patients.”

Unfortunately, the industry isn’t there yet. Results of a recent study by telehealth company Amwell showed that nearly 1 in 4 clinicians say video visit work flows are not at all or hardly integrated with their organization’s existing systems.

“With all of the advancements we’re making in technology, integration with EHRs and existing clinical work flows is a must-have for telehealth solutions — and those platforms and digital tools that aren’t addressing this are going to be left behind,” Chen says. “With all of the advancements we’re making in technology, integration with EHRs and existing clinical work flows is a must-have for telehealth solutions.”

Advancing telehealth
The pandemic disrupted health care delivery and forced health care systems to develop and integrate telehealth into the rest of their system. Some advancements include the ordering of studies such as laboratory tests, radiology tests and the ordering of studies such as lab tests, radiology tests and proctored COVID-19 testing.

Additionally, home telehealth equipment has allowed for a more robust telehealth offering because providers can obtain vital signs, examine patients’ ears, and listen to their heart and lungs.

Technological advancements have been key in pushing telehealth forward.

“Patients are the best experts on what feels normal for their bodies, and coming off a global pandemic, they’re more attuned to these feelings than ever before,” White-Dominguez says. “Many of them have even begun to use wearable devices that enable them to track aspects of their health in real time. As a result, patients are more empowered to seek out care when they deem it necessary through convenient telehealth opportunities, and they can share any pertinent information that has been unveiled through their wearable devices.”

Allison Edwards, M.D., family physician and medical director of Sesame Care, notes that higher-quality video and audio and better software have made visits easier to conduct and allow better insights than a platform such as Skype.

“Software has blossomed to recognize that we need both security and usability, and the crucible of COVID-19 has accelerated the development of great telehealth platforms,” she says. “Plus, more tech is in the home as technology continues to pervade our daily lives — from remote patient monitoring tools to simpler items (such as blood-pressure) cuffs, thermometers and pulse oximeters.”

Maleh sees telehealth becoming a bigger part of how medical practices function and how patients receive health care on a regular basis.

“We saw during the pandemic that many of them don’t have a computer (and some don’t have) Wi-Fi,” Maleh says. “There is a steeper learning curve for a patient in their 80s versus one in their 50s, and it takes additional time and encouragement to increase telehealth adoption among older patient populations.”

Also, although there are federal laws around telemedicine and reimbursement, there are also state-specific policies. This can be challenging and confusing for patients who see multiple providers in different states.

And unlike years ago when there were limited options, today patients have multiple virtual care options such as asynchronous visits, scheduled video visits, on-demand video visits and messaging with a provider.

“As a patient, the abundance of choice can be confusing and overwhelming,” Chen says. “(Although) technology is changing health care as we know it and expanding more immediate access to medical services, we need to be wary of not introducing new barriers to seeking care. Providers can mitigate this risk by educating their patients with all relevant information and directions that will lead to a seamless patient experience via telehealth.”

Overcoming challenges
One of the biggest challenges with telehealth is getting elderly patients to utilize the platforms.

“We saw during the pandemic that many of them don’t have a computer (and some don’t have) Wi-Fi,” Maleh says. “There is a steeper learning curve for a patient in their 80s versus one in their 50s, and it takes additional time and encouragement to increase telehealth adoption among older patient populations.”

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Maleh sees telehealth becoming a bigger part of how medical practices function and how patients receive health care on a regular basis.

“For example, my patients come in to the office for the MDVIP Wellness Program, which is their extensive annual physical,” he says. “However, follow-up care, such as blood pressure checks for a (patient with hypertension), weight checks to monitor weight loss, and reviewing laboratory reports, could be done virtually.”

“With all of the advancements we’re making in technology, integration with EHRs and existing clinical work flows is a must-have for telehealth solutions.”

— Christina Chen, M.D.,
a family physician, Bright.md
ome practices may consider transitioning to a concierge model, which is sometimes called a subscription or retainer practice. A concierge practice is a direct contract between a doctor and patient, where the patient pays for an agreed menu of health care services. Patients pay a fixed fee, whether the fee is monthly or annually, to receive medical services administered by a provider. The concierge medicine business model is expected to reach $10 billion by 2028 and is expected to continue to expand.

Some providers find concierge medicine appealing because they can spend more time with their patients listening and understanding their needs, ultimately offering better care to them. Additionally, in a concierge model, providers manage to earn more, despite a smaller number of patients, and establish a work-life balance. The idea of controlling work, avoiding provider burnout, allocating more family time and pursuing personal and professional interests offers an attractive choice for all providers. But despite this, there are still several legal and compliance hurdles.

A concierge practice can be a lucrative way for a provider to achieve work-life balance by reducing the number of patients, increasing time with patients and making great profits. But before you transition, speak with an experienced attorney who can help the transition.

**PITFALL**

**Patient agreements**

The provider will create and enter a patient agreement, where the patient agrees to pay all fee schedule charges at the time of service for access to a specific menu of enhanced services.

- Some patients cannot afford the services under the patient agreement.
- Some patients will still try to pay with insurance instead of the patient agreement.
- Understand and review the payor agreement to avoid breaching the contract, and refrain from offering concierge services that may be covered by a third-party payor agreement.

**Insurance licensure**

Spend time with your attorney reviewing your patient agreement to ensure it does not violate state law.

- Some provider arrangements may appear less like patient-provider contracts and more like an insurance agreement. In most states, insurance laws have several requirements before any person can offer this to any patient. Thus, it’s important your attorney reviews your state’s insurance licensure laws and provides you a summary of this review before drafting a provider-patient agreement.

**Kickbacks**

Review the ways you are marketing and convincing patients to use your concierge services.

- An issue that arises is that of illegal kickbacks and fee-splitting legal rules. When concierge practices offer free services, this raises concerns under the federal antikickback statute, if Medicare is involved, or state antikickback laws. Enforcement authorities can view the free service as an illegal inducement for clinical services.

**Medicare**

Understand how Medicare addresses concierge medicine.

- As for governmental health care programs, Medicare providers may engage in concierge services if the provider complies with Medicare regulations and the terms of assignment agreements, most notably the requirement to not charge Medicare beneficiaries extra for services already covered by Medicare.
- Medicare’s concerns about concierge medicine and assignment agreements are outlined in a 2004 Office of Inspector General (OIG) advisory opinion alert titled “OIG Alerts Physicians About Added Charges for Covered Services—Extra Contractual Charges Beyond Medicare’s Deductible, Coinsurance: A Potential Assignment Violation.” Medicare providers should also review federal authorities for civil monetary penalties.

**Patient abandonment**

Review the way in which you are separating from patients who do not join your concierge services.

- When providers switch over to a concierge model, some patients will not follow your practice. Provide adequate notice to patients of your new business model, and provide patients enough time to find another health care provider if they choose not to follow your new business model. Review state patient abandonment laws to ensure you remain in compliance with any state regulation.

Doris Dike, Esq., is the managing partner of Dike Law Group. Dike is a business lawyer for health care clients. Send your legal questions to medec@myhlifesciences.com.
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The next event is September 15th, pre-register for the Fall Physician Bootcamp below!

PRE-REGISTER

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Reducing administrative burdens at your practice through clinical-first technology

INTRODUCTION
Electronic health records (EHRs), clinical documentation for billing and meeting administrative and regulatory requirements are among the major sources of frustration for primary care doctors. A 2018 study in *Annals of Family Medicine* found that physicians spend an average of 90 minutes per day outside of work hours on EHR-related tasks. For growing numbers of clinicians, these are the reasons for giving up the practice of medicine entirely.

Fortunately, there is now a wide array of technological tools and services physicians can use to ease the burden of documentation and other billing and administrative tasks while also improving practice workflow and clinical decision-making. However, obtaining the right tools and maximizing their benefits requires planning and understanding what technology can and can’t do for your practice.

LEARNING OBJECTIVES
- Identify best practices to alleviate the most common clinical and administrative burdens in your practice.
- Understand the role of technology in building an optimized clinical workflow and delivering more effective patient care.
- Discuss with Robert Wolf, M.D., at Wolf Medical Group how his practice reduced administrative burden and achieved a more effective clinical workflow by leveraging a clinical-first EHR and associated technology.

MEET THE PANELISTS
Sara Pastoor, M.D., director, primary care advancement, Elation Health
Robert Wolf, M.D., Wolf Medical Group, Rising Sun, Maryland

From billing and documentation to responding to messages in patient portals, doctors today — especially those practicing primary care — face an avalanche of paperwork, and much of it is tied to EHRs. A technology that was supposed to make clinicians’ lives easier instead has created frustration and feelings of alienation from the practice of medicine and contributed to worrisome levels of burnout.

In a 2020 Medical Economics® survey, 31% of respondents cited paperwork as the leading cause of their feelings of burnout, which is more than twice the percentage of the second-leading cause. A 2016 survey of 6,375 primary care physicians that was published in Mayo Clinic Proceedings found that EHR users faced a higher risk of burnout than nonusers.

However, even as one new technology has heightened professional dissatisfaction among clinicians, other tools are emerging to help alleviate it. Family physician Robert Wolf, M.D., described how he uses some of these tools in his practice during a discussion with Sarah Pastoor, M.D., director of primary care advancement for EHR manufacturer Elation Health.

“I’m obsessed with efficiency. (I’m) always asking: How can we do this faster? How can we pare this process down?” Wolf said. One of the most important steps he’s taken to become more efficient has been to automate the clinical note-taking process.

“With computers, anything you have to do repeatedly can be automated, and I realized I was repeating the same instructions for simple things like urinary tract or upper respiratory infections,” he said. “If I could find a way to insert text explaining what I’ve done for a patient into the progress notes, I’d get credit for it and not have to keep retyping it.”

To achieve those ends, Wolf has developed templates in his EHR for common conditions and automated elements of the text software with tools such as dictation and text expansion software. “When patients come to see me, I’m already thinking about what template I’m going to use and what text I’ll put in there,” he said. “The
software is set up so I can document quickly and for maximum reimbursement. In many cases, I can meet the criteria for a 99214-level visit, even for something simple.” Doing so, he adds, has led to “a significant improvement in the quality of my life. I no longer feel like I’m on that hamster wheel, where I have to see more and more patients.”

Wolf stressed the importance of using the latest technology and obtaining devices from the same vendor so they integrate seamlessly. His vendor of choice is Apple, because its products work well with each other and with his EHR. Among other advantages, Apple enables him to take notes on an iPad rather than a computer during patient visits. “It’s important to me not to have a computer monitor and keyboard between me and the patient,” he said.

Before he sees patients, a medical assistant gathers and enters the patient’s vitals and other basic information in the EHR. “That means when I come in the room, I basically just have to make the clinical decisions that only I, as the physician, can make,” he said. In addition, rather than have patients wait for any follow-up handouts, he emails them or communicates via the patient portal. “I try to keep things as simple as possible, because simplicity is good for patients and for me. I feel like I’m doing things that really matter,” he said.

The practice uses Slack for internal communication. Wolf says his staff uses this platform to notify him of tasks he needs to accomplish before the end of the day, which is something they formerly did using paper slips. Using Slack makes it easier to prioritize and track the tasks so none of them get overlooked or forgotten.

Wolf said his focus on technology for streamlining and simplifying his practice has changed his attitude about practicing medicine. “I know people get discouraged and feel like medicine is set so it’s impossible to both make a living and enjoy what you’re doing,” he said. “But now, at age 55, I’m finding there are ways to use technology so you can restore joy to what you’re doing.”

Technology should free up physicians to focus on the patient and create a more patient-centered experience.

Look for tools that automate time-consuming and redundant tasks.

Strive to create a digital ecosystem that enables seamless flow of information throughout the practice, anchored by an EHR that integrates well with other technologies and functions and the way clinicians think.

Technology should make the work of capturing and reporting tasks tied to reporting and billing as simple as possible.

Using digital technology for internal communication better enables prioritization of tasks and reduces the possibility of tasks being overlooked or forgotten.

In a 2020 Medical Economics® survey, 31% of respondents cited paperwork as the leading cause of their feelings of burnout, which is more than twice the percentage of the second-leading cause.
The clinical-first EHR platform powering the future of primary care

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“I’ve used electronic health records for 25 years, and I’ve had some real clunkers. Elation is pretty seamless.”

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Burnout, COVID-19 and the ‘Great Reset’

KEN NAZEMETZ: Do you think the psychological impact of COVID-19 will continue to affect physicians as they learn how to live in this next normal?

JOHN KELLO, PH.D.: Yes, the COVID-19 pandemic is not something that happened once, then went away. It is similar to the Great Depression. The Great Depression changed the people who grew up during that time, so we will not be the same people we were. We cannot just be carried along by the next fad or wait to deal with the next crisis; it’s up to us to design how we want our future to be in the remaining chapters of our lives. I’m going to sound like a psychologist here: The remaining chapters of our lives have not yet been written. Physicians should ask themselves, “What can I control? What can I do differently so I’m not, once again, dealing with all this bureaucratic work that’s impacting my autonomy?” Doctors need to take care of their body and mind, and that often requires rethinking their business model, rethinking how they do what they do.

NAZEMETZ: You brought up how physicians should consider recrafting their careers, but these days, physicians have been conditioned to be strong and persevere. Why is it so difficult for physicians to take care of themselves the same way they look to take care of their patients?

KELLO: It’s their sacred mission to take care of others. Physicians are the best of the best, but they’re susceptible to breaking down as much as anyone else. When that happens, it’s horrible for them, and it’s hard for their patients. Physicians tend to think they can tough it out. Nearly half of all the responding physicians in a national survey said, “My strategy for managing stress is to isolate myself and not burden others with it.” They would never advise this to one of their patients.

NAZEMETZ: In your presentation, you talked about how a crisis can be the right time for someone to explore something new, possibly a new business model. In the midst of ongoing uncertainty in healthcare, how is this applicable to physicians?

KELLO: You can experience a crisis and the aftermath of a crisis in a variety of ways. You can think, “Poor me. Life is bad. I lost two years of my life. I’m not happy.” Or you can say, “I’m going to sound like a psychologist here: The remaining chapters of our lives have not yet been written. Physicians should ask themselves, “What can I control? What can I do differently so I’m not, once again, dealing with all this bureaucratic work that’s impacting my autonomy?” Doctors need to take care of their body and mind, and that often requires rethinking their business model, rethinking how they do what they do.”
NOW IS THE RIGHT TIME TO PICTURE A BETTER FUTURE

COVID-19 has left many primary care physicians in a worse position than before the pandemic. With alarmingly increasing levels of burnout and no relief in sight, now is the time to assess your next step. Imagine what your life could look like with more time for all the people you care for and care about the most... patients, family, friends.

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“This is an opportunity.” Again, I would not have chosen this as the trigger for the Great Reset, but now physicians can be empowered to look at their own life and redefine how they want it to be. If you go back to the same version of your old normal, you’re missing a tremendous opportunity. This is your chance to take action and find a solution that allows you to have more control and autonomy over your life, in whatever form that is. Some physicians are leaving the profession. I am not recommending that, but we’re seeing a potential nurse and doctor shortage in several areas. I want physicians to recognize that they’ve been on the hamster wheel, running harder and faster, and running the risk of wearing themselves down and burning themselves out. Instead, doctors should be asking themselves, “How do I get back to providing quality care for my patients in a way that nurtures them, cares for them and allows me to have work-life balance?” It’s not out of reach.

NAZEMETZ: Let’s say you have a physician who’s recognizing some signs of burnout, recognizing that things need to change and recognizing that they are not practicing medicine the way they would want to because of stress. It’s human nature to avoid change. How can physicians get past barriers they set for themselves?

NAZEMETZ: Let’s say you have a physician who’s recognizing some signs of burnout, recognizing that things need to change and recognizing that they are not practicing medicine the way they would want to because of stress. It’s human nature to avoid change. How can physicians get past barriers they set for themselves?

KELLO: Think about it like this: Change has been imposed on us by the pandemic, so it might be difficult for physicians to want to make a change if they feel they’ve been successful with their current strategy and believe their life is good and they’re okay. Maybe they don’t see reasons to change. But if you’re constantly running on the hamster wheel or the pandemic has increased your stress level dramatically, you don’t have a constructive choice. You’re on the burning platform, and you have to make a change. It’s time to self-reflect: What’s your vision if you make a change? Where does that take you? What are your goals? Maybe the answer is work-life balance, taking care of your family, having enough income and making a positive difference. So, now that you know what’s driving you to change and have directional clarity, how are you going to get started? What are your first few steps?

NAZEMETZ: With your research, you’ve had a unique opportunity to take an objective eye and observe what’s happening in the business of medicine and what’s influencing physicians both positively and negatively. In your professional opinion, do you recommend doctors explore other practice models that might better meet their needs?

KELLO: The short answer is yes. A lot of the physicians we interviewed, and some I have read opinion pieces from, have said they simply had to get out of a huge hospital practice or another gigantic system to get more control, manage their workload and be able to continue to deliver the kind of healthcare they want to provide. There are alternative business models available. Again, one of the primary culprits that impacts a lot of primary care physicians is the prevailing volume-based, fee-for-service business model. That’s not a business model anyone with a blank sheet of paper would have ever designed, but it’s now the standard for primary care, and it unfortunately keeps doctors in the cycle of having to see more patients with less time per patient to maintain their income. It is a chief underlying contributor to the stress everyone’s experiencing. So, while we’re waiting for the government to change regulations to make it easier for physicians to manage their load, physicians have to look at their own business model.

60% of physicians surveyed said “too many bureaucratic tasks” was the primary contributor to burnout.
Remote patient monitoring economics

INTRODUCTION
In 2019 and 2020, the Centers for Medicare & Medicaid Services created new reimbursement codes for providers to monitor and manage patient care remotely. Patients wear small monitoring devices connected to an app on a smartphone that sends data to the physician. Monitoring patients remotely can generate over $150 per patient per month. Remote patient monitoring (RPM) has been shown to improve outcomes for patients while much of the work is done by clinical staff, and it doesn’t require an excessive amount of time from the physician. With inflation hitting record highs and payers focusing more on positive patient outcomes, RPM is the perfect way to both boost revenue and improve patient outcomes. Not every patient is eligible for remote monitoring, but those with a diagnosis of obesity, diabetes or chronic pain usually are, along with patients who require pre- or postsurgical management. Now is the perfect time to see whether RPM makes economic sense for your practice.

LEARNING OBJECTIVES
- Understand the available codes for RPM and the proper way to use them.
- Learn about the benefits of RPM for both physicians and their patients.
- Gain a full appreciation for the reimbursement/revenue potential of a successful RPM program.

MEET THE PANELIST
Shari Kappell, CPCO, CPPM, CPC

How remote patient monitoring can boost your practice revenue and improve patient outcomes

In a time when inflation is rising, medical practices must look at every way possible to boost revenue. When you can accomplish that with existing patients in a way that also improves their outcomes, you have a solution that is helping both patient and practice health. Remote patient monitoring (RPM) provides exactly that. “(RPM) is a revenue stream that is remarkably untapped, despite how CMS (Centers for Medicare & Medicaid Services) backs it,” Shari Kappell, CPCO, CPPM, CPC, implementation and billing manager at CoachCare, says.

RPM is when a patient uses a wireless device that’s able to upload data in real time to a health care provider so they can track and monitor their condition from their practice. The data are relayed using a mobile app.

“RPM has a lot of great benefits for the provider,” Kappell says. “You can improve your patient care (and) connectivity with patients, and it’s flexible and efficient. You can monitor your patients before their health conditions get out of control, which is one of the huge benefits of having a (RPM) program.”
Another bonus is that once the physician orders RPM, a junior staffer can monitor the data and only involve the doctor when necessary. “Patients feel like there is more of a connection with their doctor, even though they are not actually speaking to the provider face-to-face,” Kappell says. “Having that connectivity to your provider and your care team is promoting that next level of care for patients. Accountability is driving patients to have better outcomes by having them become more active participants in their health care decisions.”

For example, one CoachCare study on patients who are obese found 86% more weight loss at the patient level for those using RPM compared with those who were not, and those using RPM stayed on the obesity program 30% longer.

Most patients are eligible for RPM, and although those with chronic conditions are often the best candidates, acute patients can also benefit. An RPM patient will need to have had a face-to-face visit over the past 12 months, with telehealth visits also qualifying.

“It’s really based on insurance coverage, to get a basic understanding of where coverage is for your key payers, but for the most part, insurances are covering RPM,” Kappell says.

If staffing is tight or already overburdened, the monitoring function can be outsourced. Kappell says all devices must be FDA approved, so consumer products such as Apple watches are not eligible for use in a RPM program.

As CMS and other payers move to more value-based care contracts, RPM is the perfect tool for physicians. “It’s intervening prior to a medical catastrophe,” Kappell says. “It’s low cost to patients (and is) creating consistent revenue streams for providers. It greatly reduces the chances of patients having to go undiagnosed for months by giving real-time data to providers in their care teams.”

$150

RPM can provide more than $150 per patient per month.
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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The first part of developing an effective tax strategy is finding out which tax bracket you fall into and how much more you can earn before you move up to the next bracket. Most doctors will find themselves paying around 35% and possibly up to 37%, according to David Auer, CPA, MS, PFS, CGMA, president and founder of Physician Tax Solutions. If you have a C-corporation, the tax is a flat 21%, whereas self-employed physicians have a 12.4% and employed physicians have a 6.2% Social Security tax. Physicians should also factor in their capital gains taxes, as well as state income and corporate tax liability.

President Joe Biden has proposed increasing taxes, but legislators are running out of time to make the changes into law before the end of this year. Auer doesn’t believe taxes on the highest earners will rise to the historical high of 94%. “Depending on what state you live in and what other taxes you might be subject to, (your tax rate) could very well be into the 60% to 70% range, and that becomes very important when it comes to tax planning,” he said.

Auer recommends that doctors maximize their retirement plan contributions, which lowers their taxable income and moves them to a lower tax bracket. He also recommends considering a Roth conversion, which involves rolling over transferring funds from a traditional IRA or plan funds to a Roth IRA. This maneuver can be done by individuals who own a traditional IRA, a SEP IRA or those who’ve had a SIMPLE IRA for at least two years. It is also available to those with a 401(k), 403(b) or a government 457(b) plan eligible for distribution.

Roth IRA funds can be withdrawn tax-free so long as the funds have been held for at least five years and the holder is 59.5 years or older. There

Continued on page 40
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A Modern Parable of Financial Independence

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Angie O'Dea
Client Success Manager
“Depending on what state you live in and what other taxes you might be subject to, (your tax rate) could very well be into the 60% to 70% range, and that becomes very important when it comes to tax planning.”

Physicians can put away an additional $66,000 by funding a “back door” Roth IRA and a Mega Roth 401(k).

Continued from page 38

is also no lifetime required minimum distributions for Roth IRA owners.

Auer also recommends considering funding a “back door” Roth IRA and a Mega Roth 401(k) to further lower your taxable income. If properly utilized, these can enable physicians to put away an additional $66,000 and lower their taxable income.

When it comes to investments, Auer recommends harvesting capital losses, which can offset current and future capital, plus an addition $3,000 a year. However, beware of the capital wash rules that say you can’t buy the same assets, which leads to the initial loss for 30 days.

Physicians should also consider converting W-2 income to 1099 income either in part or entirety. This is helpful, especially if the physician has locum tenens income in addition to their regular job. This also adds the ability to claim business expenses as deductibles.

To those physicians who already have Schedule C/1099 income, Auer recommends considering converting that income to an S-Corporation LLC. This will lower self-employment taxes and reduce the risk of an audit. “Based on the most recent published statistics the IRS has provided, generally speaking, if you have a Schedule C income of over $250,000, you currently have about a 2.5% chance of an IRS audit,” he said. “If you have that same income going through an S-Corporation, statistically, that drops your audit risk down to 0.7% — a fairly significant drop in the risk of an audit, everything else being the same.”

With an S-Corporation in place, Auer recommends considering employing family members by putting them on the payroll and assigning responsibilities. This shifts income from being subject to your tax bracket to being subject to their tax bracket.

A physician can also maximize their home office and automobile deductions. There are acceptable ways to do this, so it’s best to work with a tax planner to ensure you’re getting the most out of your vehicle and workspace. Physicians should also consider the per diem allowances for lodging and meals as opposed to the actual expenses.

Finally, physicians should consider making a pass-through entity (PTE), such as an S-Corporation or partnership, to pay individual state income taxes at the PTE level. You would be able to deduct the cost of that tax dollar for dollar. This is available in 40 states.”
The No Surprises Act (NSA) is complicated. Certain requirements became effective January 2022. Others don’t go into effect until next January.

We’ve been assessing the NSA since late 2020 and have made necessary modifications to our billing policies and procedures to support compliance with the NSA provisions that have taken effect. We will be monitoring proposed additional requirements that may become effective next January.

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Things You Should Know About Managing Anemia in CKD

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Nurse Practitioner
UAB Medicine
University of Alabama at Birmingham
Birmingham, AL

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Disclosures (Dr. Davis): Speakers Bureau: Amgen, Bayer.

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To learn more about this topic, including information on the underlying pathophysiology of anemia in CKD, go to www.gotoper.com/tysk22ckd-art

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3. Answer the evaluation questions.
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You may immediately download your certificate.
Anemia, which is a common complication of chronic kidney disease (CKD), is linked to adverse renal and cardiovascular (CV) outcomes, an increased risk for hospitalization and poor quality of life (QOL) in patients with CKD. Decreased production of erythropoietin (EPO) is the primary cause of anemia in CKD, but inflammation, iron deficiency, bleeding abnormalities and malnutrition may also play a role. Here are 3 things you should know about managing anemia in CKD.

1. Initial assessment of anemia is similar for patients with and without CKD.

National Kidney Foundation clinical practice guidelines recommend that all patients with a glomerular filtration rate of less than 60 mL/min/1.73 m² be evaluated for anemia via hemoglobin (Hb) level assessment. The World Health Organization defines anemia as an Hb level of less than 13.0 g/dL in men and less than 12.0 g/dL in women. In addition to a complete blood count, the evaluation of anemia in CKD should include measures that help determine any underlying causes.

Red blood cell (RBC) parameters that may be used to evaluate and classify anemia are listed in the Table. Reticulocyte counts, used to evaluate bone marrow production of RBCs, are useful in determining contributing factors, such as hemolysis. Measurement of serum folate and cobalamin levels, as well as testing for fecal occult blood, may also be performed.

Table. Red Blood Cell Parameters in the Evaluation of Anemia

<table>
<thead>
<tr>
<th>PARAMETER</th>
<th>DEFINITION</th>
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<tbody>
<tr>
<td>RBC count</td>
<td>Number of RBCs in a specified volume of whole blood</td>
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<tr>
<td>Mean cell volume</td>
<td>Average size of RBCs</td>
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<tr>
<td>Mean cell Hb</td>
<td>Amount of Hb per RBC</td>
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<tr>
<td>Mean cell Hb</td>
<td>Amount of Hb per unit volume</td>
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<tr>
<td>RBC distribution width</td>
<td>Variability of the size of RBCs</td>
</tr>
<tr>
<td>RBC morphology</td>
<td>Assessment of RBCs via blood smear</td>
</tr>
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</table>

Hb, hemoglobin; RBC, red blood cell.

Iron deficiency and inflammation are common contributing factors to anemia in CKD. The serum iron level, a measure of the iron bound to transferrin that is available for erythropoiesis, is low in both iron deficiency anemia and anemia of inflammation. Transferin saturation (TSAT), calculated from the serum iron level and total iron binding capacity of transferrin, is also generally low in both types of anemia. The ferritin level, a measure of the body’s iron stores, is low in absolute iron deficiencies, but levels may be elevated in chronic inflammation and should be interpreted with caution.

2. Iron supplements and erythropoiesis-stimulating agents are typically used to treat anemia in CKD.

Iron supplementation, given orally or intravenously (IV), is used to treat iron deficiency and/or maximize response to therapy with erythropoiesis-stimulating agents (ESAs). The Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guideline for anemia in CKD recommends that patients who are not receiving treatment with iron be given a trial of iron therapy when TSAT levels are below 30% and ferritin levels are below 500 ng/mL if improving Hb levels is preferred based on patient symptoms and clinical goals. In non-dialysis-dependent patients, the route of iron administration can be chosen based on the severity of iron deficiency, presence of venous access, prior response to therapy, adherence and cost. Oral iron may cause gastrointestinal effects, which may include constipation, a metallic taste, cramping and, sometimes, diarrhea.

IV iron supplementation is recommended in dialysis-dependent patients, because parenteral iron replaces iron stores rapidly and improves adherence. In the PIVOTAL trial, monthly, proactive high-dose IV iron given to patients with dialysis-dependent CKD was associated with a decrease in the risk of CV events and death, ESA dose and incidence of transfusions compared with use of low-dose iron.

ESAs can be used to raise Hb levels, but the benefits and risks of treatment must be carefully weighed when initiating or maintaining these agents. Although they are efficacious at reducing transfusion requirements, ESAs are associated with CV risks at higher Hb targets with minimal improvements in QOL, and optimal Hb target levels have not been established.
KDIGO guidelines recommend that all underlying causes of anemia be addressed before beginning treatment with ESAs.5 ESA initiation is recommended in patients with dialysis-dependent stage 5 CKD when Hb levels fall between 9 and 10 g/dL, but ESA therapy may be started in some individuals when Hb levels are above 10 g/dL based on assessment of benefits and risks. The guidelines suggest that ESAs should not be used to maintain Hb concentrations above 11.5 g/dL, although individualization of therapy above these levels may be necessary.3 The guidelines recommend against initiating ESA therapy in non–dialysis-dependent patients who have an Hb level greater than 10 g/dL; in those with an Hb level less than 10 g/dL, the decision to initiate ESA therapy should be based on individual patient factors.

Emerging agents may provide new mechanisms for treatment.

Optimal management of anemia in CKD with traditional therapies has not been established, potentially contributing to its undertreatment.1 Hypoxia-inducible factor (HIF) prolyl hydroxylase (PH) inhibitors are investigational agents for anemia in CKD that act via the HIF pathway.16 This pathway is used by cells throughout the body to sense tissue oxygenation and, during hypoxia, stimulate the EPO gene, among other genes involved in iron transport and angiogenesis. By acting through this pathway, HIF-PH inhibitors can stimulate the production of endogenous EPO while also potentially modulating iron homeostasis.12 These agents, which have the advantage of oral administration, are in various stages of clinical development, and they have been studied in both dialysis-dependent and non–dialysis-dependent populations.17-22 Major adverse CV events have been the key safety concern in trials.

HIF-PH inhibitors prevent the destruction of the protein HIF-1α, a key component of the transcription factor HIF-1, which activates the EPO gene.

If I have a person who is iron deficient and who also has a low Hb level, I will initiate both [iron and ESA] together. We know [that] by giving the ESA, we are going to be utilizing more iron.”

—Jane S. Davis, CRNP, DNP

KEY REFERENCES

For a full list of references go to www.gotoper.com/tysk22ckd-art
1. Your new patient is a 59-year-old man with a long history of type 2 diabetes and hypertension. He has stage 3 chronic kidney disease (CKD), and he has retired early. He complains of fatigue, saying that he needs to rest more frequently when he goes on his daily walk. He takes nightly insulin, daily ferrous sulfate and twice daily carvedilol. His blood pressure is 135/83 mm Hg, and his heart rate is 82 beats/min. The remainder of his physical examination is unremarkable. Which of the following would be an appropriate test to order at this time?
   A. Complete blood count
   B. Reticulocyte count
   C. Serum iron level
   D. Transferrin saturation
   E. Serum ferritin level
   F. All of the above

2. The patient from the previous question has the following laboratory values: hemoglobin, 8.9 g/dL (normal, 12-16 g/dL), hematocrit, 27% (normal, 36%-45%); mean corpuscular volume, 72 µm³ (normal, 80-100 µm³); transferrin saturation, 14% (normal, > 20%); and ferritin, 80 ng/ml (normal, 100-500 ng/mL). What would be the best next step in his management?
   A. Obtain a bone marrow sample for analysis.
   B. Increase his dose of oral ferrous sulfate, and start darbepoetin.
   C. Discuss the risks and benefits of red blood cell transfusion.
   D. Start a second antihypertensive medication.

To learn more about this topic, including information on the underlying pathophysiology of anemia in CKD, go to www.gotoper.com/tysk22ckd-art
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Public Vaccine: 1.5
Private Vaccine: 3.25

3. Add the number of doses required for the operating room

4. Add the number of doses required for the floor

5. Add the number of doses required for the off-site

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7. Add the number of doses required for the backup

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Better Together program helps extinguish burnout for female physicians

By Logan Lutton, Associate Editor

Better Together is a professional, structured coaching program designed by female physicians to address the burnout that is disproportionately experienced by women in medicine. What started out as a clinical trial has transformed into a full program that has coached more than 100 women, many of whom have found personal and professional success.

Medical World News® spoke with Better Together cofounders Adrienne Mann, M.D., and Tyra Fainstad, M.D., via Zoom. The transcript below was edited for length and clarity.

Medical World News®: Can you describe the Better Together program?
Adrienne Mann, M.D.: Better Together is a six-month online group coaching program that was designed for women residents. It was delivered to women residents at the University of Colorado in 2021. In our program, participants get invited to a members-only website, where they can engage with us in three different ways. We have weekly content over six months that covers a whole bunch of stuff, starting from vision and values, setting big goals, to dealing with perfectionism, impostor syndrome and envisioning your future self. We have weekly modules that people can work through on their own. They can also be coached by Tyra and I or live on a Zoom call, where we host two calls a week. They can raise their hand and come up and say, “Hey, I would like coaching today on some bad feedback I got in the operating room,” and we’ll go back and forth with them on a Zoom call in front of a group of their peers, and then send them back when they’re done. We usually coach about four people per call. They can also engage in coaching on our website in a written way. They write to us, we respond, and it gets posted on a forum on the website for all the participants to read and benefit from. Throughout all this, our objective is to help show people what’s going on in their mind and get them curious about their thinking.

MWN: What makes today’s physician culture so toxic?
Tyra Fainstad, MD: Physician culture rests on this idea that a physician is a hero. With that comes an idea of pure altruism, which unfortunately has gotten translated into putting yourself last. It even creeps into martyrdom a little bit.

MANN: This is a pattern I’ve seen get worse over my career. It’s been brought to light with recent events, especially the pandemic. People are starting to talk more about the toxic culture. Unfortunately, instead of talking about the culture itself, what ends up happening is this battle between the system and the individual, which leaves room for someone to be at fault and someone to blame. You’ve got the system on one side, blaming the individual employees or health care providers, saying, “Here, try a free yoga session. Are you happy now?” You can get physicians as resilient as possible, and there is still going to be this awful culture (and) this mindset of perfectionism.

MWN: Why does burnout disproportionately affect women?
FAINSTAD: There are issues women deal with disproportionately in the workplace — outright sexism, macroaggressions and daily microaggressions. It’s creating this huge cognitive load to have to deal with the additional stress of not being taken seriously or constantly being asked what your age is. I get asked all the time, “Who’s taking care of your kids?” by my patients. Certainly, people who are underrepresented in medicine deal with that to a magnificently bigger degree. Adding to this is the fact that people who are socialized as women are often the ones (who) are the default caregiver outside of work. There isn’t a place for rest or to let your guard down. The pandemic brought that to a head, also. When kids couldn’t go to school anymore, data (have) shown the work fell disproportionately onto those (who) identify as women at home.
MWN: The demographics of this study were primarily White, cis-gendered women. Would you consider introducing this program to communities of color or nonbinary individuals?

MANN: Those demographics are representative of the population we have here at the University of Colorado. We plan to expand this program in the fall of this year to 27 sites across the country, with a focus to serve many other populations.

FAINSTAD: We’re hoping to get an adequate representation of all the people we’re serving — so all the trainees in medicine — and then find out (whether) there is a difference in those (who) are underrepresented. Do people of color get more out of this? Do nonbinary people get more out of coaching? Then also having the representation amongst coaches. We are still in the early planning stages of all that, but that’s a goal of this program.

MWN: Was there a specific moment when you decided this program needed to happen?

MANN: For me, it was when I hired my first coach. I have experienced three waves of burnout over the course of my medical training. One little blip in medical school, one blip in residency, then another blip, (which was the most severe) when I was early faculty. I had just had my second kid and was trying to figure out how to come back to work in several leadership roles and just really struggled to find my feet, and I hired a coach to help me get some perspective.

FAINSTAD: My story is the same. Adrienne and I sort of had these parallel experiences, which are not that rare.

MWN: What do you think led to the success of this program?

FAINSTAD: At the base of it, physicians and physicians in training are just not OK right now. The data show many of us are burned out, many of us are barely keeping our heads above water. We, of course, didn’t plan the pandemic to coincide with the release of Better Together, but it really was right there when the residents needed it. It was easy to get into it in a socially distanced way. It addressed at the core, the reasons why we’re not OK. The reason we’re not OK is because we haven’t learned how to manage our feelings and our minds. [Participants] see Adrienne and I as medical educators they know and respect. We talk about this journey we’ve been through, and I think it’s accessible to them in a way that perhaps other mental health modalities are not. Coaching is not stigmatized in the way other mental health resources are.

MANN: The tools we teach them are practical. They can apply these metacognitive tools immediately and see the traps they get themselves stuck in, in their thinking. The other thing that was powerful about our intervention was that they were not doing this alone. They’re able to see (they’re) not the only one who shows up to work, thinking people are going to find out (they) don’t know everything. We also offer three different ways for folks to engage. These are busy women, (and) their days are long. We’re able to offer a bunch of different ways to participate meaningfully in the program.
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