Alternative Formulation Drizalma Sprinkle™

Drizalma Sprinkle™ is the first and only FDA-approved sprinkle formulation of delayed-release duloxetine—a selective serotonin and norepinephrine reuptake inhibitor designed to meet the needs of patients who cannot or will not swallow solid medication forms.

3 Administration Options for Your Patients

- Swallow whole
- Open and sprinkle over applesauce
- Open and administer via nasogastric tube

No need for crushing; just open, sprinkle, and serve

INDICATIONS AND USAGE

Drizalma Sprinkle™ (duloxetine) delayed-release capsules are indicated for the treatment of:

- Major depressive disorder in adults
- Generalized anxiety disorder in adults and pediatric patients aged 7 to 17 years
- Diabetic Peripheral Neuropathic Pain (DPNP) in adults
- Chronic musculoskeletal pain in adults

IMPORTANT SAFETY INFORMATION

WARNING: SUICIDAL THOUGHTS AND BEHAVIORS

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening and for emergence of suicidal thoughts and behaviors.

CONTRAINDICATIONS

Serotonin Syndrome and MAOIs: Do not use MAOIs intended to treat psychiatric disorders with Drizalma Sprinkle™ or within 5 days of stopping treatment with Drizalma Sprinkle™. Do not use Drizalma Sprinkle™ within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start Drizalma Sprinkle™ in a patient who is being treated with linezolid or intravenous methylene blue.

Please see additional Important Safety Information throughout this journal cover wrap, and Brief Summary of Full Prescribing Information, including Boxed Warning.
Addressing an Unmet Need for Patients With Difficulty Swallowing

Depression affects more than 6.5 million (approximately 20%) of the 35 million Americans aged 65 years and older. Approximately 40% of American adults cannot or will not swallow solid forms of medication.

Drizalma Sprinkle™ is indicated for Major Depressive Disorder (MDD) in adults.

IMPORTANT SAFETY INFORMATION [cont’d]

WARNINGs AND PRECAUTIONs

- **Hepatotoxicity:** Hepatic failure, sometimes fatal, has been reported in patients treated with duloxetine delayed-release capsules. Treatment should be discontinued in patients who develop jaundice or other evidence of clinically significant liver dysfunction and should not be resumed unless another cause can be established. Drizalma Sprinkle™ should not be prescribed for patients with substantial alcohol use or evidence of chronic liver disease.

- **Orthostatic Hypotension, Falls, and Syncope:** Syncope and orthostatic hypotension tend to occur within the first week of therapy but can occur at any time during treatment, particularly after dose increases.

- **Serotonin Syndrome:** There is increased risk when coadministered with other serotonergic agents (e.g., SSRIs, SNRIs, triptans), but also when taken alone. Monitor all patients taking Drizalma Sprinkle™ for the emergence of serotonin syndrome. If it occurs, discontinue Drizalma Sprinkle™ and initiate supportive treatment.

- **Increased Risk of Bleeding:** Duloxetine may increase the risk of bleeding events. A post-marketing study showed a higher incidence of postpartum hemorrhage in mothers taking duloxetine. Concomitant use of NSAIDs, aspirin, other antiplatelet drugs, warfarin, and anticoagulants may increase this risk.

- **Severe Skin Reactions:** Severe skin reactions, including erythema multiforme and Stevens-Johnson Syndrome, can occur with duloxetine. Drizalma Sprinkle™ should be discontinued at the first appearance of blisters, peeling rash, mucosal erosions, or any other sign of hypersensitivity if no other etiology can be identified.

- **Discontinuation Syndrome:** Adverse reactions after discontinuation of serotonergic antidepressants, particularly after abrupt discontinuation, include nausea, sweating, dysphoric mood, irritability, agitation, dizziness, sensory disturbances (e.g., paresthesias, such as electric shock sensations), tremor, anxiety, confusion, headache, lethargy, emotional lability, insomnia, hypomania, tinnitus, and seizures. A gradual reduction in dosage rather than abrupt cessation is recommended whenever possible.

- **Activation of Mania or Hypomania:** In patients with bipolar disorder, treating a depressive episode with duloxetine or another antidepressant may precipitate a mixed/manic episode. Use cautiously in patients with bipolar disorder. Prior to initiating treatment with Drizalma Sprinkle™, screen patients for any personal or family history of bipolar disorder, mania, or hypomania.

Please see additional Important Safety Information throughout this journal cover wrap, and Brief Summary of Full Prescribing Information, including Boxed Warning.
Drizalma Sprinkle™ Capsules Have Demonstrated Bioequivalence to Cymbalta® [duloxetine delayed-release capsules]1,4

- Because delayed-release duloxetine capsules are not able to be crushed, opened, or sprinkled, Drizalma Sprinkle™ provides the first and only once-daily, delayed-release dosing option for patients who cannot or will not swallow solid medication forms5,6
- Drizalma Sprinkle™ provides the same drug release whether it is swallowed whole in capsule form, sprinkled over applesauce, or administered via nasogastric tube7

The duloxetine your patients require—approved in a sprinkle formulation designed for those who cannot or will not swallow solid forms of medication1

Dosing and Administration

- Drizalma Sprinkle™ is available in 4 dosage strengths—20 mg, 30 mg, 40 mg, and 60 mg—for flexibility and easy titration1
- Drizalma Sprinkle™ can be administered with or without food. Capsules can be opened, and the contents sprinkled over applesauce1

IMPORTANT SAFETY INFORMATION (cont’d)
WARNINGs AND PRECAUTIONs (cont’d)
- Angle-Closure Glaucoma: Duloxetine may trigger an angle-closure attack in patients with anatomically narrow angles who do not have a patent iridectomy. Avoid use of Drizalma Sprinkle™ in patients with anatomically narrow angles
- Seizures: Drizalma Sprinkle™ should be prescribed with care in patients with a history of seizure disorder
- Blood Pressure: Monitor blood pressure prior to initiating treatment and periodically throughout treatment
- Hyponatremia: Can occur in association with SIADH. Cases of hyponatremia have been reported
- Glucose Control in Diabetes: In diabetic peripheral neuropathic pain patients, small increases in fasting blood glucose and HbA1c have been observed

ADVERSE REACTIONS
The most common adverse reactions [≥5% and at least twice the incidence of placebo patients] were nausea, dry mouth, somnolence, constipation, decreased appetite, and hyperhidrosis.

DOSING AND ADMINISTRATION
Drizalma Sprinkle™ may be taken with or without food. Drizalma Sprinkle™ may be swallowed whole (do not crush or chew capsule); opened and sprinkled over applesauce; or administered via nasogastric tube.

DRUG INTERACTIONS
- Avoid concomitant use with potent CYP1A2 inhibitors
- Consider dose reduction with concomitant use with CYP2D6 substrates

USE IN SPECIFIC POPULATIONS
- Hepatic Impairment: Avoid use in patients with mild, moderate, or severe hepatic impairment
- Renal Impairment: Avoid use in patients with severe renal impairment
- Pregnancy: Advise patients to notify their healthcare provider if they become pregnant or intend to become pregnant during treatment with Drizalma Sprinkle™. Third trimester use may increase risk of symptoms of poor adaptation [respiratory distress, temperature instability, feeding difficulty, hypotonia, tremor, irritability] in the neonate. Advise patients that Drizalma Sprinkle™ use during the month before delivery may lead to an increased risk for postpartum hemorrhage and may increase the risk of neonatal complications requiring prolonged hospitalization, respiratory support and tube feeding

Please see additional Important Safety Information throughout this journal cover wrap, and Brief Summary of Full Prescribing Information, including Boxed Warning.
Drizalma Sprinkle™ is Covered on Most Medicare Part D Plans

91% of lives on the top 10 Medicare Part D plans are offered coverage for Drizalma Sprinkle™.

Prescribe the Only Formulation of Duloxetine That is Designed to Be Opened and Sprinkled

Drizalma Sprinkle™ is designed for patients who cannot or will not swallow solid medication forms.

Drizalma Sprinkle™ provides effective therapy in one formulation for 4 different indications:

- Major Depressive Disorder (MDD) in adults
- Generalized Anxiety Disorder (GAD) in adults and pediatric patients aged 7 to 17 years
- Diabetic Peripheral Neuropathic Pain (DPNP) in adults
- Chronic musculoskeletal pain in adults

IMPORTANT SAFETY INFORMATION (cont’d)

USE IN SPECIFIC POPULATIONS (cont’d)

- Lactation: Advise breastfeeding women using duloxetine to monitor infants for sedation, poor feeding and poor weight gain and to seek medical care if they notice these signs

To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. at 1-800-818-4555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information throughout this journal cover wrap, and Brief Summary of Full Prescribing Information, including Boxed Warning.

To Learn More, Visit: drizalmasprinklehcp.com

References:
6. Cymbalta® (prescribing information). Indianapolis, IN: Lilly USA, LLC; 2020.

This promotional program was developed in conjunction with and sponsored by Sun Pharmaceutical Industries, Inc.

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INDICATIONS AND USAGE
Drizalma Sprinkle™ (duloxetine delayed-release capsules) is a serotonine and norepinephrine reuptake inhibitor (SNRI) indicated for:
- Major Depressive Disorder (MDD) in adults
- Generalized Anxiety Disorder (GAD) in adults and pediatric patients aged 7 to 17 years old
- Diabetic Peripheral Neuropathic Pain (DPNP) in adults
- Chronic Musculoskeletal Pain in adults

CONTRAINDICATIONS
Serotonin Syndrome and MAOIs: Do not use MAOIs intended to treat psychiatric disorders with Drizalma Sprinkle™ or within 5 days of stopping treatment with Drizalma Sprinkle™. Do not use Drizalma Sprinkle™ within 14 days of stopping an MAOI intended to treat psychiatric disorders. In addition, do not start Drizalma Sprinkle™ in a patient who is being treated with linezolid or intravenous methylene blue.

DOSEAGE AND ADMINISTRATION
- Drizalma Sprinkle™ can be taken with or without food. Drizalma Sprinkle™ may be swallowed whole (do not crush or chew capsule); opened and sprinkled over applesauce; or administered via nasogastric tube
- Missed doses should be taken as soon as it is remembered. Patients should not take two doses of Drizalma Sprinkle™ at the same time
- There is no evidence that doses greater than 60 mg/day confers additional benefit, while some adverse reactions were observed to be dose-dependent

WARNINGS AND PRECAUTIONS
- Hepatotoxicity: Hepatic failure, sometimes fatal, has been reported in patients treated with duloxetine delayed-release capsules. Duloxetine delayed-release capsules should be discontinued in patients who develop jaundice or other evidence of clinically significant liver dysfunction and should not be resumed unless another cause can be established. Drizalma Sprinkle™ should not be prescribed to patients with substantial alcohol use or evidence of chronic liver disease
- Orthostatic Hypotension, Falls, and Syncope: Cases have been reported with duloxetine delayed-release capsules therapy
- Serotonin Syndrome: Increased risk when coadministered with other serotonergic agents (eg, SSRI, SNRI, triptans), but also when taken alone. If it occurs, discontinue Drizalma Sprinkle™ and initiate supportive treatment
- Increased Risk of Bleeding: Duloxetine may increase the risk of bleeding events. A post-marketing study showed a higher incidence of postpartum hemorrhage in mothers taking duloxetine. Concomitant use of NSAIDs, aspirin, other antplatelet drugs, warfarin, and anticoagulants may increase this risk
- Severe Skin Reactions: Severe skin reactions, including erythema multiforme and Stevens-Johnson Syndrome, can occur with duloxetine. Drizalma Sprinkle™ should be discontinued at the first appearance of blisters, peeling rash, mucosal erosions, or any other sign of hypersensitivity if no other etiology can be identified
- Discontinuation Syndrome: Taper dose when possible and monitor for discontinuation symptoms
- Activation of Mania or Hypomania: Use cautiously in patients with bipolar disorder. Cautions patients about the risk of activation of mania/hypomania
- Angle-Closure Glaucoma: Avoid use of antidepressants, including Drizalma Sprinkle™, in patients with untreated anatomically narrow angles
- Seizures: Prescribe with care in patients with a history of seizure disorder
- Blood Pressure: Monitor blood pressure prior to initiating treatment and periodically throughout treatment
- Hyponatremia: Can occur in association with SIADH. Cases of hyponatremia have been reported
- Glucose Control in Diabetes: In diabetic peripheral neuropathic pain patients, small increases in fasting blood glucose and HbA1c have been observed

ADVERSE REACTIONS
Most common adverse reactions (≥5% and at least twice the incidence of placebo patients) include dry mouth, somnolence, constipation, decreased appetite, and hyperhidrosis.

DRUG INTERACTIONS
- Potent CYP1A2 Inhibitors: Avoid concomitant use
- CYP2D6 Substrates: Consider dose reduction with concomitant use

USE IN SPECIFIC POPULATIONS
- Hepatic Impairment: Avoid use in patients with mild, moderate, or severe hepatic impairment
- Renal Impairment: Avoid use in patients with severe renal impairment
- Pregnancy: Third trimester use may increase risk of symptoms of poor adaptation (respiratory distress, temperature instability, feeding difficulty, hypotonia, tremor, irritability) in the neonate. Advise patients that Drizalma Sprinkle™ use during the month before delivery may lead to an increased risk for postpartum hemorrhage and may increase the risk of neonatal complications requiring prolonged hospitalization, respiratory support and tube feeding.
- Lactation: Advise breastfeeding women using duloxetine to monitor infants for sedation, poor feeding and poor weight gain and to seek medical care if they notice these signs.

To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. at 1-800-818-4555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please read full Prescribing Information and Medication Guide for Drizalma Sprinkle™ and discuss any questions with your doctor.

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2021’s Top Challenges Facing Physicians

- Paperwork and administrative burdens
- Physician burnout and autonomy
- Saving for retirement
- Increased competition
- Getting paid
- EHR usability
- Hiring excellent staff
- Transitioning to value-based care

...and what to do about them

Mark McClellan, M.D., Ph.D., on the post-COVID-19 health care system
YOU CAN’T PROTECT THEM FROM ADOLESCENCE

The persons depicted here are models used for illustrative purposes only.
BUT YOU CAN HELP PROTECT THEM FROM MenB

Help protect appropriate patients by vaccinating against MenB.

There are many threats out there, but MenB is one you can help prevent. CDC recommends MenB vaccination for adolescents not at increased risk, aged 16-23 years [preferred age 16-18 years], based on shared clinical decision-making.1 Start the conversation with your patients and their parents about the importance of vaccinating against MenB.

Recommend that your appropriate patients start the MenB vaccination series.

Review what meningococcal disease is, as well as potential consequences, including death, and the rapid progression it may take.2,3

List the behavioral risk factors that can lead to contracting MenB.

Emphasize the importance of series completion and schedule their second dose.

Are you doing all you can to help protect your appropriate patients from MenB? Learn more at VaccinateForMeningitis.com

Vaccination may not protect all recipients.

CDC=Centers for Disease Control and Prevention; MenB=meningococcal serogroup B.


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The top challenges facing physicians in 2021

The major issues facing practitioners when it comes to money, practice management, legal issues, technology, and more.

Helping patients lose weight

Why approaching obesity as a chronic condition is the first step to effective patient management.

2021 payment outlook for physicians

What physicians need to know about fee schedule changes and private payer reimbursement.

The CARES Act implications

Tax benefits physicians need to know about.

Predicting the post-COVID-19 health care system

An in-depth interview with former FDA/CMS leader Mark McClellan, M.D., Ph.D.

CME

3 things you should know about HPV vaccination

3 things you should know about treating early rheumatoid arthritis

Don’t forget telehealth

As practices reopen, physicians should remember the benefits of telehealth.
CHAIRMAN’S LETTER

How pharmaceutical innovation is saving the world

Nine months.

In March 2020 the United States was in the early stages of the COVID-19 pandemic. We shut down the entire country and ground the economy to a halt to slow the spread of the virus. Think back to March and how much uncertainty we were living under.

Nine months later, the FDA approved two COVID-19 vaccines under emergency authorization. Before New Year’s Day, millions of Americans had received the vaccine, including frontline physicians and health care providers and nursing home patients, our most vulnerable citizens.

Nine months. Take a moment to let that sink in.

The mainstream media has crafted a narrative about the COVID-19 pandemic that’s almost entirely negative. For the purpose of ratings, they have described the U.S. response to the pandemic as blundering from one mistake to the next. This narrative is false.

There is another way — a more accurate and under-appreciate way — to tell the story of the past nine months. It is a story of heroism, innovation and precise science, performed under unbelievable pressure.

Let’s not mince words: The U.S. and the world must appreciate the role of the pharmaceutical industry — the researchers, physicians and business leaders — who are rescuing the world from COVID-19. It’s the medical breakthrough of our lifetime.

Instead of dwelling on why many in the media are ignoring this, let’s review some facts.

- Since the discovery of COVID-19, here is what scientists have accomplished: They identified a novel virus, unlocked and sequenced its genetic code, created new therapies to save lives, and developed multiple safe and effective vaccines using messenger RNA technology, a technology hopefully applicable to future vaccine development. Margaret Liu, M.D., a world-renowned expert in vaccines and gene therapy and a member of the MJH Life Sciences™ COVID Coalition, called it a breakthrough for mRNA vaccines.

- The United States has two vaccines approved for emergency use, one from Pfizer/BioNTech and another from Moderna, and the AstraZeneca/Oxford vaccine has been approved for emergency use in the UK. In addition, there are 64 vaccines undergoing clinical trial at the moment, including 20 in phase 3 trials. In the U.S. and throughout the world, the pharmaceutical industry has answered the call and invested heavily in this effort.

> Continued on Page 4
CHAIRMAN’S LETTER

This was the fastest vaccine development program in history, and it’s not even close. David Pride, M.D., Ph.D., a microbiologist at the University of California, San Diego, estimates that vaccines typically take 10 to 15 years to develop. Until the COVID-19 pandemic, the fastest development timeline was four years, for the mumps vaccine.

Many government systems moved quickly to lessen the burden of onerous regulations and provide funding so that vaccines could be developed quickly but with rigorous standards. Perhaps it should be a lesson to all of us that regulation and innovation can be calibrated more effectively during “normal” times as industry races to develop new therapies for other epidemics — cancer, diabetes, heart diseases and more.

The next step of the process — distribution of the vaccine — will be as challenging as the development phase, if not more so. But again, the pharmaceutical industry is rising to the occasion. Factories worldwide are working overtime to produce hundreds of millions of vaccine doses.

Less than a month after the Pfizer vaccine was approved, more than 15.4 million doses of vaccine have been distributed across the country, and more than 4.6 million people have received their first dose, according to CDC data. Many patients are already receiving their second dose.

Although 15.4 million doses are impressive, some expected 20 million doses. But that is moving the goal line, as six months ago many observers didn’t think a vaccine would be available until 2021.

Members of our COVID Coalition told us that the holidays slowed the rollout considerably. Nancy Messonnier, M.D., a physician with the National Center for Immunization and Respiratory Diseases at the CDC, expects a rapid increase in administered vaccines during the first few days of 2021.

Every day, more people will be vaccinated. After health care workers and our most vulnerable citizens, other frontline workers will be next. Teachers will be vaccinated so our children can return to school. And soon, all Americans will be able to receive the vaccine at their doctor’s office or at a CVS or Walgreens.

Remember, we accomplished this in nine months, with the help, dedication and expertise of our pharmaceutical industry heroes. Next time you turn on the TV and see negativity, turn it off. Imagine instead where we will be in nine months. «

Mike Hennessy Sr.
Chairman and Founder of MH Life Sciences™
I have long believed that Medical Economics® is the go-to journal for physicians to learn about the business of medicine.

And that’s why I’m thrilled to become the new Medical Economics® Editor-in-Chief.

My name is Dr. Allen Dobson. I’ve been a family physician and practiced in a small town in North Carolina for 35 years. Most recently, I was President and Chief Executive Officer of Community Care of North Carolina, and Chairman of the Board of Community Care Physician Network, a physician-led clinically integrated network of more than 2,500 independent primary care physicians across the state, treating more than 2.5 million patients.

Over the years, I’ve watched medicine change, and experienced the same challenges that have kept you up at night. I’ve shared both your worries and excitement about the potential future for primary care in this country.

So why have I taken on this role? To be your voice.

I believe the role of community-based physician practices in our health care system is too often unnoticed and overshadowed by the large corporate entities entering the health care arena. We will focus a spotlight on all the great work being done in communities across the U.S. by local physician practices.

You know that change has accelerated over the last decade — ACOs, value-based care, new care models, telehealth, risk based contracts, and so much more. We plan to examine these trends in detail along with the health policies and politics driving those changes.

Our goal is to provide the beyond-the-classroom information that physicians aren’t taught in medical school. We will provide you with compelling stories, clear information, and useful insights, no matter what stage of your career you are in. Whether you are closing in on retirement, in the heights of your career or just getting started as a medical student or resident, our goal is to provide the business and policy information you need, when you need it.

Despite the challenges confronting us, I remain hopeful. I believe the core values that have attracted some of our best and brightest into medicine are still present. Medical Economics® will be with you every step of the way as you take on what’s coming, and I’m excited about what we will do together.
2020 was one of the most challenging years in recent memory for physicians and the practices they manage. A pandemic and struggling economy put major strain on physicians and patients alike.

Because of the momentous events of last year, 2021 is a difficult year to predict, as rollout of the COVID-19 vaccine will go far in determining what kind of year it is for health care.

In late 2020, Medical Economics® asked our physician audience what they thought would be the most challenging issues they will face this year. This is what they told us. — by Medical Economics® Staff
If doctors had to chart their feelings about practicing medicine, many would list “paperwork” as their chief complaint.

In countless surveys and studies, and across specialties, physicians consistently cite the time and energy they must devote to filling out forms and other administrative tasks near or at the top of their list of grievances. The mantra repeatedly heard throughout the profession is, “This isn’t why I went into medicine.”

The problem is worsened by electronic health records (EHR), now used by close to 90% of office-based physicians. Once seen as a way to streamline documentation and data sharing, EHRs instead have become enormous time-sucks. A December 2016 study in *Annals of Internal Medicine* found that physicians in outpatient settings spent about 27% of their day on direct clinical face time with patients, but 49% on EHRs and desk work. Many also worked up to two hours every evening on EHR-related tasks.

More recently, the proliferation of quality metrics physicians must document, while well-intentioned, has resulted in another layer of time-consuming administrative tasks for doctors and their staff. “Payers and CMS with their reporting requirements are trying to do the right thing and reward quality care, but the process and metrics we have today are adding to the burden with little evidence it is helping quality,” David Gans, MHA, senior fellow of industry affairs for the Medical Group Management Association, told *Medical Economics*.

The growing number of treatments and medications requiring prior authorizations from payers are yet another source of administrative frustration for doctors and their staffs. In a 2020 American Medical Association survey, 86% of respondents described the administrative burden of prior authorizations as “high or extremely high.”

Similarly, respondents to the *Medical Economics* Physician Report said prior authorizations consumed, on average, more than 16 hours per week of practice time, including 11.6 hours for staff members and 4.6 hours for themselves.

Paperwork and administrative requirements are also linked to the alarming increase in physician burnout rates, especially among primary care doctors. When *Medical Economics* recently asked doctors what contributed most to their feelings of burnout, 31% cited “paperwork” — more than twice the percentage of the second-leading cause, poor work-life balance. “The data show that the things that cause burnout are the things that get in the way of why you went into medicine in the first place, such as being able to provide the kind of care you want to provide to your patients,” Jack Resneck, M.D., immediate past chairman of the American Medical Association board of trustees told *Medical Economics* in an interview this year.

Fortunately, there are steps physicians can take to reduce their administrative burden, starting with the EHR. Gans suggested that doctors and practices work with their EHR vendor on ways to automate data reporting, such as tailoring prompts according to patients’ specific requirements. For patients with diabetes, for example, the EHR might be programmed to provide reminders of the need for foot and eye exams, and report to payers that the patient received the reminder. In addition, some EHRs now offer the option of automatically reporting some quality data to CMS.
Employing scribes can also help to reduce paperwork and other administrative burdens. A 2018 study in JAMA Internal Medicine concluded that their use was associated with significant reductions in EHR documentation time and “significant improvements in productivity and job satisfaction.”

Ultimately, however, doctors probably need to accept that paperwork and administrative tasks will be an inescapable part of practicing medicine — particularly with the spread of value-based care models, which usually require detailed tracking and reporting of quality metrics.

“In the long run, value-based reporting is going to be a requirement from all payers,” Gans predicts. =

Reforming the prior authorization process

When it comes to top physician frustrations, prior authorizations rank near the top of the list, right next to poorly designed EHRs. Scan to read full article.

Getting paid and seeing enough patients

Generating enough revenue to keep a practice open requires knowing the intricacies of medical coding to make sure reimbursement is maximized while also recognizing trends that keep patients coming back.

Getting paid is regularly listed as a top challenge facing physicians, according to the 2020 Medical Economics® Physician Report.

The good news for physicians who primarily deliver office/outpatient services is that CMS has made significant changes to Evaluation and management (E/M) coding and documentation to make the process simpler.

For 2021, there are three areas physicians need to focus on to make sure they get paid.

Understand E/M changes

E/M codes are now much simpler, according to coding experts. Physicians will not select an E/M code based on total time spent during the encounter or medical decision making, whichever one pays more.

For medical decision making (MDM), gone is the complicated points system derived from the number of treatment options, complexity of data and morbidity risks. The new MDM table includes easy-to-understand requirements and compensates them for complex cases, regardless of time spent, as long as documentation supports medically necessary services.

In addition, physicians now get credit for many tasks, including reviewing and interpreting test results, speaking with family members if a patient cannot provide their own history, and discussing patient management with another health provider or other professional involved in their care.

For time-based billing, physicians can now count the total time on the date of the encounter that may or may not include counseling and care coordination. Doctors may also count, among other tasks, documenting clinical information in the EHR, ordering medications or tests, preparing to see the patient, and referring the patient to and communicating with other health care professionals.

Physicians should contact their payers to verify whether they will adopt Medicare’s changes. Some payers may continue to require code selection based on history, exam and MDM. They may also have requirements for individual codes.

“Reforming the prior authorization process When it comes to top physician frustrations, prior authorizations rank near the top of the list, right next to poorly designed EHRs. Scan to read full article.

Continued on Page 9
The most important thing is to ensure everything done matches the documentation. “Remember that if it’s not documented, it didn’t happen,” says Dreama Sloan-Kelly, M.D., CCS, president of Dr. Sloan-Kelly Consulting, a medical coding consulting company.

**Master telehealth payments**
The COVID-19 pandemic closed many primary care offices throughout the country, forcing physicians to quickly adopt telehealth as the only way to see patients and keep revenue coming into the practice. To say telehealth was a lifeline for practices is an understatement. According to *Medical Economics*® 2020 Technology Survey, more than 93% of physicians used telehealth to see patients during 2020, and 77% of them were using telehealth for the first time.

The Centers for Medicare & Medicaid Services (CMS) and private payers made a number of emergency exceptions to laws to make telehealth more accessible for both patients and physicians, and reimbursement for virtual visits was added or increased to match payment rates for in-office visits.

But the Medicare changes were made as part of the federal government’s public health emergency declaration, which will end whenever the pandemic has passed. While no one knows for sure when the pandemic will pass, doctors need to be ready for a sudden shift in telehealth reimbursement. In addition, some private payers have already rescinded reimbursement for certain telehealth visits as public confidence for in-office visits has increased.

Experts say physicians must balance keeping telehealth available for patients who are not comfortable coming into the office to capture as much revenue as possible with the fact that at some point in 2021, it’s likely that reimbursement for it may dry up.

Before the pandemic, telehealth reimbursement was extremely limited. Even if reimbursement remains for some services, it may not be at the same level as for an in-office visit, so doctors need to understand the return on their telehealth investment both now and when the public health emergency ends.

**Embrace the data**
Experts say fee for service isn’t going to vanish in 2021, but more contracts will be focused on value-based care, and the lifeblood of any value-based care contract is data. Payers want data to evaluate which physicians are the most effective, and the top performers get the best bonuses.

Participating in the most lucrative forms of value-based care requires that physicians have plenty of data on their outcomes and can show improvement and the ability to keep patients out of the hospital. An investment in software and equipment may be necessary to fully master all the data points within a practice, but without it, doctors will be at a disadvantage to both participate in and excel at value-based care.

“The key is for us to really break the fallacy that fee for service is a good way to pay for primary care,” says Farzad Mostashari, M.D., the former director of the Office of the National Coordinator for Health IT and currently CEO of Aledade, a company that assists small practices with transitioning to value-based care models. “We shouldn’t be basing primary care payments on that — it should be on the value created and we need to move towards more person-based rather than transactional.”

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**How should primary care physicians be paid?**
COVID-19 may have permanently changed the reimbursement landscape. *Scan to read full article.*
Physician burnout & autonomy

The perennial issue of physician burnout has only been intensified by the equipment shortages and shutdowns of the COVID-19 pandemic. Despite increased awareness in the health care system the same problem persists.

The 2020 Medical Economics® Physician Burnout Survey found that burnout is pervasive among physicians, with 91% of doctors saying they have felt burned out from practicing medicine at some point in their career. A further 71% of physicians reported feeling burned out at the time of the survey.

When asked what caused their burnout, 31% of physicians said too much paperwork and government/payer regulations, 15% cited poor work-life balance/work too many hours and 12% said the COVID-19 pandemic.

While little can be done on the ground with regard to increased stressors from pandemic, there are ways health care leaders can reduce the underlying issues.

Tips
Howard Baumgarten, LPC, has extensive experience working with physicians who feel burned out. He says there are three categories of burnout physicians should be on the lookout for: physiological, which can take the form of physical symptoms like headaches and high blood pressure; mental/emotional, which can take the form of anxiety and/or depression; and behavioral, which can take the form of increased alcohol use or smoking, overspending and not sleeping.

He says that once a physician starts feeling the symptoms of burnout, they should take steps to fight it. He gave some helpful tips for physicians to prevent feeling the heat of the health care system.

The first strategy is to aim for seven to eight hours of sleep, starting at the same time every night, and to avoid both drinking alcohol and screen time before bed. The next is to get 30 minutes of aerobic exercise four or five times a week with some muscle-building exercises mixed in. Physicians should also avoid sugary and fried foods and do something that makes them feel good, such as a hobby.

The National Academy of Medicine released a report early in 2020 saying personal stress management strategies are insufficient to tackle the burnout problem facing health care. While some of the suggestions the academy gave relate to structural issues, some can be adopted for independent practice leaders.

They are:

- Reduce tasks that do not improve patient care.
- Improve usability and relevance of health IT.
- Reduce stigma and improve burnout recovery services.

Autonomy
According to the 2020 Medical Economics® Physician Burnout Survey, 11% of physicians experience burnout due to a lack of autonomy or career control.

Wendy Dean, M.D., a psychiatrist and president and co-founder of Moral Injury of Healthcare, says that following the long period of rigorous training, focusing on independent, critical thinking with strict adherence to algorithms based on reimbursement policies can be grating.
Beyond the big systemic hurdles that must be crossed to bring this issue under control, Dean recommends that physicians learn how the incentives are aligned at their health care institution.

“Understand how reimbursement happens, what the incentives are at their entity,” she says, “and whether they can negotiate to build bridges with the administration. Build bridges with other licensees, so that everyone can work together to start fixing things at the local level.”

Dean says that by talking to their fellow physicians they can see what the patterns are and where the stumbling blocks may be.

“As you start to look into that more and more, you can quickly become an expert and can have the tools available to you to change what that problem is,” Dean says.

Resources
Susan T. Hingle, M.D., professor of medicine at Southern Illinois University School of Medicine, says there are burnout resources available on the websites of most major physician organizations, such as the American College of Physicians for internists.

She says many hospital systems also offer support phone lines to help deal with the increased stress from the COVID-19 pandemic.

“I want people to know that those are available and to know that there’s no shame in asking for help,” Hingle says. “That’s how we’re all going to get through this; by helping each other and getting through it together.”

Hiring & retaining clinical staff

A practice is only as good as the people who work there but finding and keeping the right people can seem like an insurmountable task. This can be compounded with the uncertainty and increased scrutiny introduced by the COVID-19 pandemic.

In a recent entry in weekly studies performed by the Larry A. Green Center and the Primary Care Collaborative on how COVID-19 has affected primary care practices, 35% of physicians say hiring new staff is a big obstacle to their practice.

With this perennial problem only getting worse, the question remains for physician leaders on how to hire, motivate and retain clinical staff.

Tips
Target the talent by looking for candidates from areas similar to those your practice is in. This familiarity can smooth over some of the wrinkles the staff member may feel starting at a new practice.

Another suggestion is to adjust your pay system to reward hard work or to boost the total compensation package. This can take the form of creating bonuses for staff members who meet productivity goals, giving employees a sense of how they can earn more without leaving the practice.

The practice leader can also consider offering staff members growth opportunities such as enabling them to pursue more education through training. Sometimes the cost of training and giving the employee a raise can be lower than the cost of hiring another employee to handle the same new duties.

Personalized benefits, such as flexible hours or more vacation time, can be a good recruitment tool and a motivator for current staff members. Allowing newly hired physicians the ability to hire their own care teams or set their own office hours can increase their motivation.

All these changes should be documented and formalized so that, even if employment packages are individualized, they do not appear to be capricious.

Millennials
An often-overlooked source for clinical staff is the newest batch of medical school graduates. While millennials may get a bad reputation in the media, they can be a key part of a health care team.

Andrew Hajde, CMPE, assistant director of association content at Medical Group Management Association in Englewood, Colorado, says the health care system is reaching a point where millennial physicians are becoming the only ones left to pick up the slack of retiring boomers and Generation Xers before Generation Z comes of age.

When hiring millennials it is important to remember that the cohort tends to put a premium on work-life balance and the feeling that their work has purpose.

Natasha Bhuyan, M.D., is a family physician and regional...
2021 TOP CHALLENGES

medical director with One Medical in Phoenix and a millennial. She says the members of her cohort no longer base their success on the hours they spend in the office or the number of patients seen.

“They’re measuring success based on fulfillment of purpose, based on developing meaningful relationships with patients and having time to connect with patients, improve their behaviors and see health results and outcomes change,” she says.

Millennial physicians are also aware that they need feedback and mentoring and can see the value in picking a senior employee’s brain to help them in their own work.

“[Millennial physicians are] measuring success based on fulfillment of purpose, based on developing meaningful relationships with patients.”

— Natasha Bhuyan, M.D., family physician, Phoenix

PHYSICIANS PRACTICE

Bhuyan says this new emphasis on mentorship is closer to coaching than in years past.

“How do we coach physicians to reach the top of their potential and beyond?” she asks. “How do we push people beyond what they think is their best?”

EHR usability

Electronic health record (EHR) systems remain a primary physician frustration. While the vendor market has matured, there is still a massive usability gap between what physicians want their systems to do and what their systems are capable of.

According to the 2020 Medical Economics® Technology Survey, about 70% of physicians have used the same EHR for more than five years and 71% say they have no plans to switch EHRs in the next year.

At the same time, physicians still feel EHRs leave them wanting. When asked in the survey about their primary complaints about the systems, 38% said they wanted a system that was easier to use and 33% said they wanted improved customization options.

“Frankly, I’ve never talked to a physician who said, ‘Boy, I just can’t wait to get on my EHR in the morning,’” says Rob Tennant, director of health information technology policy, Medical Group Management Association. “They understand their functionality, their utility, they know how important they are. They know, in some form, the capabilities that these software programs have, but they’re just not intuitive.”

Still, there remain effective ways physicians can reap more benefits from their existing systems, by optimizing them to improve practice efficiency and support physician workflow, says Mary O’Brien, FACHE, national practice director for Patina Solutions, a professional services organization in Chicago.

Here are four tips physicians should keep in mind.

Appoint a champion

Physician practices and hospitals should appoint what she calls a physician champion whose role is to support improvement in the utilization of the EHR through education, advocacy and training.

“There needs to be physician involvement in the design of workflows, in the design of how clinical decisions can be made,” O’Brien says. “Physicians always have to be talking to their administration about staying up to date on what their EHR’s highest capabilities are.”

This person can advocate for some key strategies to improve physician utilization and satisfaction of their EHR.

Personalize settings

The physician champion will
want to begin by making sure the EHR’s settings are personalized to the physicians using it.

“It’s very important that physicians can decide on their own what kind of alerts they want, what kind of education can come up next to some documentation or order they’re putting in,” she says.

Ideally, O’Brien says, physicians also have within their practice or hospital what she calls a clinical informaticist, someone whose role it is to make sure the information available in the EHR is actually used by the physician in the care of a patient. As an example she refers to an epidemiologist caring for a patient with diabetes. “The EHR needs to be capable of bringing up a patient’s past glucose level or past clinical visit.”

This is where those personalized settings are especially key.

Not every practice will have such a person on staff, however, so for smaller practices or private practices, she recommends partnering with other physician groups or large hospital systems or health plans to share services.

Add automated documentation tools
Next, she says, physicians should learn how to use the automated documentation tools within their EHR, such as text messages and voice-to-text dictation tools for documentation, which can include mobile device documentation tools.

These tools can reduce the amount of time the physician spends facing the computer instead of the patient, limiting the need for a scribe.

Emphasize training
Lastly, O’Brien emphasizes that no number of tools will make an EHR more useful without training, O’Brien says. And given how frequently CMS updates rules and regulations for EHRs, such as Meaningful Use and Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), it’s equally important that physicians have training resources available to them at all times to keep their knowledge and education about their EHR up to speed.

While most EHR companies put out regular addenda when new rules are released, she says it’s better to have someone who can stay on top of these changes just in case.

“All these new regulations require physicians to be trained constantly in how to use the technology to provide those metrics to the appropriate organization. “Constant training of physicians is very important,” she says.

The top EHRs, according to physicians
Physicians rated the EHR system on a number of factors ranging from usability to customer service. Scan to read full article.
2021 TOP CHALLENGES

Increased competition

Primary care doctors must adapt their practice to survive competitive pressure from every direction.

A primary care physician in many places can drive down the street and see competition on the rise, but it’s not from other doctors’ offices. Pharmacy chains and even some retailers are vying for the same patients but often have far more resources than the average primary care doctor. In addition, nonphysician providers are gaining increased independence, siphoning off low-acuity patients and their reimbursement.

In the past, nurse practitioners (NP) usually had to practice under a doctor’s supervision. Now, 29 states allow NPs to operate independently and the largest growth was in outpatient clinics. CMS reported that Medicare office visits provided by NPs and physician assistants rose from 4.6% to 12.3% between 2010 and 2017.

CVS Pharmacy, which already had more than 1,000 MinuteClinics focusing on basic care, is rolling out 1,500 HealthHUBs by 2021 that will focus on chronic disease management and blood draws. Amazon is testing clinics to provide care for its thousands of employees, Walgreens is planning to open more than 500 primary care clinics in or near its stores, and Walmart is increasing its commitment to health care clinics in or near its stores.

Experts say that if a primary care practice wants to survive, it must adapt to the realities of this hypercompetitive market.

“Health care delivery in traditional clinics really is going to have to evolve to be quicker, better, cheaper and faster in order for people to be satisfied with it,” says Hajde.

Here are the key strategies experts recommend:

**Availability**

Patients don’t get sick only during business hours and offering a few Saturday appointments no longer caters to their busy lifestyles. With urgent cares and retail clinics offering extended hours daily, if a practice doesn’t adapt its schedule to its patients, they’ll get their care from a place that does.

**Easy online appointment-setting**

Patients don’t want to spend 15 minutes on hold to make an appointment. Practices need to offer online scheduling to make it easier for patients to book an appointment.

**Minimized wait times**

Patients expect the doctor to see them within about 15 minutes of their appointment time. Consider implementing a system that texts patients updates on wait times, allowing them to adjust their arrival to reflect the doctor’s current schedule.

**Updated waiting rooms**

Free Wi-Fi, coffee and water are the minimum. A modern design with comfortable furniture and natural lighting will put patients at ease and make them feel valued. A dingy room plastered with warnings and payment notices isn’t exactly customer friendly.

**Streamlined paperwork**

The more forms that can be filled out electronically and in advance, the better. No one wants to sit in a waiting room filling out forms on a clipboard that could easily have been done the night before. Checkout should be just as easy, with little or no time spent standing in line.

**Quick responses to questions**

Patients expect a response to questions posed via email or an
Saving for retirement

Physicians have different financial concerns at different stages of their careers. Older physicians are keenly aware of retirement while younger physicians are focusing on getting their careers started and often staring down a pile of student debt.

What they share in common is a need to save money for their own future and the security of their family.

“Saving money takes hard work,” says Joel Greenwald, M.D., CFP, principal of Greenwald Wealth Management in St. Louis Park, Minnesota. “And the hard work that it takes is understanding where your money goes. A lot of doctors just don’t bother to take the time to understand where their spending is going. And they figure it’ll take care of itself or they’ll just continue to make a nice income.”

Finding the right financial adviser for you and your situation is key to developing the right savings and investment strategy. Here are some important questions to ask as you find the best adviser.

Are you a fiduciary 100% of the time?

Unlike most professionals, financial advisers have a choice of operating under one of two professional standards: suitability or fiduciary. The fiduciary standard requires advisers to act in their client’s best interests whereas the suitability standard does not.

Advisers fall into one of three camps: fiduciary all the time, suitability all the time or both. Those who do both “wear two hats,” switching back and forth between suitability and fiduciary standards.

Don’t settle for the part-time fiduciary. It’s best to verify they’re acting as a fiduciary all the time.
How many physicians do you work with?

Cutting-edge advisory firms are building niches to stay relevant and provide the best possible value to their clients. Industry experts say firms should target between 50 and 150 clients per adviser depending on the level of services provided. If they’re dedicated to a specific niche, at least 50% of those clients should be within it. The more specific their niche, the better. Ideally your adviser has a manageable number of clients with a very high percentage of physicians just like you.

How does your firm’s revenue percentage breakdown?

Today, most financial advisers are proudly beating the financial planning drum. Some firms offer “free” financial planning and use it as a backdoor sales tool to sell more financial products. Others bundle it with investment management services and consider it a value add. And then some firms charge for stand-alone financial planning services only or in combination with other services.

Are you fee-only or fee-based?

Fee-only advisers can accept fees only directly from clients. They’re not permitted to accept any referral fees, commissions or kickbacks from third parties. Fee-based advisers accept client fees and commissions or other types of compensation. Understand your adviser’s fee structure and you’ll be well equipped to identify conflicts.

How much exactly am I paying you for this service?

As uncomfortable as this question is, it’s legitimate. Financial advisers traditionally haven’t done a good job of explaining how their compensation and services work. Nonetheless, you have a right to know. As a client, how can you possibly measure the cost/benefit of working together if you’re not clear on services and costs?

Among its other effects, the COVID-19 pandemic has highlighted the growing importance of value-based payment models for primary care practices. Especially in the early stages of the crisis, when patient visits plummeted, value-based contracts provided a financial lifeline to practices that had them.

“Why enter into these contracts? First and foremost, it’s financial stability,” Tim Irvine, M.D., a physician at IKP Family Medicine in The Woodlands, Texas, told attendees of the Medical Group Management Association’s 2020 Medical Practice Excellence conference in October.

IKP has about 6,000 patients under capitated or pay-for-performance models. “The monthly capitation checks from these contracts are a dependable revenue stream that evens out the ups and downs of the revenue cycle,” he said.

Value-based contracts can also help practices obtain resources for improving patient outcomes, according to former CMS administrator Mark McClellan, M.D., PhD. Addressing the National Association of Accountable Care Organizations 2020 fall conference, McClellan cited a CMS study showing that the further along in transitioning to value-based care a practice was at the start of the
pandemic, the better its response in areas such as obtaining personal protective equipment and the ability to identify patients at high risk for complications if they contracted COVID-19.

But transitioning from traditional fee-for-service medicine to payment models based on outcomes and/or that include financial risk is a lot easier said than done. That’s especially true for small independent practices, many of which may not have the resources to operate successfully under value-based contracts.

“Effectively implementing a value-based model requires more than simply changing the payment methodology,” Norman Chenven, M.D., vice chairman for the Council of Accountable Physician Practices, wrote in a 2019 blog post for Physicians Practice. “Successful transformation requires realignment of providers in order to design and deliver proactive care and prevention.”

Moreover, even before the pandemic struck, practices were under escalating pressure from the federal government to adopt value-based contracts that include some downside risk, i.e., absorbing some of the losses if its care costs exceed targeted amounts or it doesn’t meet its quality goals. In 2018 CMS announced its Pathways to Success program which, among other features, limited how long accountable care organizations (ACO) could remain in a Medicare Shared Savings Program (MSSP) without taking on financial risk.

Following the program’s implementation in 2019, the number of MSSP participants fell nearly 8%, according to a report from the Medicare Payment Advisory Commission, an indication of the inability, or reluctance, of many ACOs to take on downside risk.

Even so, uncertainty over the long-term viability of fee-for-service medicine will likely cause more practices to participate in value-based contracts going forward. The challenge then becomes how to transition successfully between the two models. Writing in Physicians Practice, Joe Nicholson, D.O., chief medical officer of the consulting firm CareAllies, advises practices to start small and gradually increase the percentage of their revenue tied to risk-based contracts.

He further suggests focusing first on existing targets for clinical improvements, such as mammogram screenings or HbA1c testing for patients with diabetes. “Build on those programs to close any final gaps and then address more complex needs,” he advises.

An important benefit of some risk-based contracts, Nicholson adds, is providing incentives to address social determinants of health (SDoH), such as food insecurity or access to transportation, which have a significant impact on patient outcomes. Thus, practices should investigate a payer’s policies regarding SDoH before entering into a contract with them.

Nicholson also advises practices to ask:
- **Does the payer’s quality or population health reporting provide insights into**
- **nontraditional care gaps, such as behavioral health?**
- **Which payers have similar requirements for quality reporting, so that the practice can simplify testing and scale risk-based arrangements?**
- **Does the payer’s approach to utilization management empower the practice to make decisions about its service and treatment offerings?**

“At their core, risk-based models should inspire the flexibility to deliver care in the manner most effective for patients’ overall health,” Nicholson writes. —Norman Chenven, M.D., vice chairman, Council of Accountable Physician Practices

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**How value-based care can save your practice**

Why physician practices that have leaned into value-based care have weathered the COVID-19 pandemic successfully.

Scan to read full article.
Tackling obesity

How physicians are addressing obesity as a chronic condition and helping patients lose weight

by Keith Loria Contributing Author

The latest CDC National Health and Nutrition Examination Survey revealed that 39.6% of adults and 18.5% of children aged 2 to 19 in the U.S. have obesity.

Obesity can impact essentially every organ in the body. It increases the risk for cardiovascular disease, fatty liver disease and cirrhosis, cancer and, of course, diabetes. Type 2 diabetes rates have climbed along with obesity and diabetes represents an urgent public health crisis.

“There is a plethora of medical conditions that arise from unhealthy weight gain and they are categorized by metabolic changes and physical forces,” says Krishna Doniparthi, M.D., director and physician at Functional Medicine of Georgia in Milton, Georgia. “Metabolic changes entail elevated blood glucose, elevated blood pressure, dyslipidemia, cancer and other metabolic diseases.”

Obesity is a chronic condition that requires a strong physician-patient relationship, honest and direct conversation and personalized treatment plans to tackle.

In 2013, obesity was recognized as a disease by the American Medical Association. Since then, the medical world is beginning to view obesity less as a lifestyle choice and more as a multifactorial dysregulation of hunger and satiety hormones.

Lydia C. Alexander, M.D., an internist in San Francisco who has specialized in weight management and obesity treatment, says adipose tissue is not just an inert storage depot for excess energy but is metabolically active.

“When adiposopathy occurs — also known as ‘sick fat’ disease — inflammation in the body predisposes to other diseases such as metabolic syndrome, hypertension and Type 2 diabetes,” she says. “Given what we know about adiposopathy or obesity as a disease, it is not surprising that obesity is recognized as conferring excess risk for severe sickness from COVID-19.”

In fact, on July 17, the CDC added BMI under 30 kg/m2 as a risk factor for severe COVID-19. Untreated obesity predisposes to increased morbidity and mortality from COVID-19, just as it does for many other health conditions.

Alexander notes the best way to address obesity is through a multidisciplinary treatment approach based on the four pillars of obesity treatment: behavioral modification, nutrition, physical activity and pharmacotherapy, with bariatric surgery as an important adjunct modality for a subset of patients.

“Beyond structuring treatment on these foundational elements, taking a ‘partnership’ approach with patients is key,” she says. “This involves asking open-ended questions, listening, summarizing health
goals, collaborating on the treatment and informing the treatment with one’s medical expertise.”

**Navigating sensitive conversations**

“Would you like to talk about your weight?”

This is considered the first step outlined by the Obesity Medicine Association when approaching a patient about the subject of obesity.

“The language should not be offensive or blaming/shaming,” Doniparthi says.

Sarah Hallberg, D.O., M.S., medical director of the medically supervised weight loss department at Indiana University Health Arnett, notes the most important things to have with you when approaching a patient about the issue of obesity are compassion, evidence and no judgment.

“Being nonjudgmental may seem easy to many physicians, but I ask them to really have a good look in the mirror when it comes to passing judgment,” she says. “It is very easy for us to think that we are acting nonjudgmental, but if it is really an act instead of something that you truly believe, it is easy for patients to see right through that.”

For that reason, Hallberg says evidence is important to bring to a conversation. It is also important for the physician to review the evidence themselves when questioning if they are truly nonjudgmental when facing a patient struggling with obesity.

“Obesity is a disease, not a choice or lack of willpower,” Hallberg says. “Evidence in a patient conversation needs to be centered on the impact that obesity has on morbidity and mortality.”

After speaking to a patient about evidence that supports acting on the disease of obesity, the next thing to discuss is food.

“I can’t tell you how many patient discussions I have been in and how many lectures on obesity I have listened to where food is not brought up. This is so frustrating,” Hallberg says. “You have to know what your patient is eating to understand how best to help them.”

Alexander notes that unlike many chronic conditions or diseases, obesity cannot be hidden from others. Patients often come into their physician’s office embarrassed and self-conscious about their weight.

“First and foremost, it is important to begin any conversation about weight by asking permission,” she says. “An example of what this looks like may be, ‘Would it be OK to discuss your weight today during our visit?’”

Most patients will welcome the opportunity to talk about their weight concerns with the doctor.

When discussing weight, Alexander suggests using patient-first language, which makes a distinction between the disease and the individual.

“For example, we would not refer to a patient with stomach carcinoma as cancerous,” she says. “We discuss them in the context of having cancer, a disease. They are not the disease. Similarly, it is important to address obesity and a patient as having obesity rather than being obese. Lastly, I think it is helpful to discuss the science behind obesity.”

Tips to offer

Physicians who have been able to help patients with obesity often rely on solid motivational interviewing and developing personalized treatment plans.

For most patients, the key to losing weight is to assess their total carbohydrate consumption. As weight has increased in this country over the last few decades, calorie consumption has increased as well. However, the increased

**“Sometimes patients are not ready to make a change. Consider using the stages of behavior change to determine where a patient lies: precontemplation, contemplation, preparation, action and maintenance.”**

—Krishna Doniparthi, M.D., director, Functional Medicine of Georgia, Milton, Georgia
“Obesity is a disease, not a choice or lack of willpower. Evidence in a patient conversation needs to be centered on the impact that obesity has on morbidity and mortality.”

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Obesity is a disease, not a choice or lack of willpower. Evidence in a patient conversation needs to be centered on the impact that obesity has on morbidity and mortality.

Sarah Hallberg, D.O., M.S., medical director, medically supervised weight loss department, Indiana University Health Arnett

Calories have all been in the form of carbohydrates.

“The push to get patients to eat a low-fat diet has had unintended consequences as it has resulted in many low-fat, but highly processed high-carbohydrate/sugar products coming to the marketplace,” Hallberg says. “This can be seen in everything from low-fat yogurt to low-fat crackers. For most people suffering from obesity, it is the carbohydrates that need to be cut and not the fat. In fact, fat is incredibly satiating which can be a big help when trying to lose weight.”

Alexander uses a six-point model of “ask, listen, affirm, summarize, inform and treat” when approaching patients about this sensitive topic. “I think the most important tenants for motivational interviewing include asking permission, patient-first language and taking a collaborative approach to arrive at a treatment plan to improve obesity and the concomitant chronic conditions associated with it such as sleep apnea, diabetes, high blood pressure, GERD, depression and more,” she says. “As part of motivational interviewing, it is important to address internalized weight bias and educate patients on appetite regulation.”

She starts with an open-ended question such as “Tell me more about what’s been going on for you weightwise?” and listens to their response so she understands the root problems.

A patient may mention: “I’ve gained 25 pounds since COVID began in March because the gym closed and I’m more sedentary working from home. I barely get out of my chair. I’ve also been under a lot of stress taking extra precautions to protect my husband’s mom who is living with us from getting COVID.”

That’s when Alexander goes into affirm mode, responding with something like, “It sounds like you have a lot of stressors right now and feel time-constrained to care for yourself in the way you would like,” moving to summarize the problem to make the patient understand she’s been listening.

Next, she informs the patient of what she knows, stressing that a lot has recently been learned about obesity and how to treat it and asking if they would be interested in hearing about the newest and best understanding of why some patients struggle with their weight, how effective treatment now exists and how it works.

“An example of a personalized treatment plan would take into account patient preferences and reality,” Alexander says. She suggests “incorporating NEAT — nonexercise activity time — into daily routine on days when formal exercise isn’t possible, managing work and/or school expectations, meditation to manage stress and anti-obesity medication to modulate appetite signaling.”

Good advice

When physicians see that their patients are not losing weight, it might not be that they are not listening, but that perhaps the advice they were given was wrong.

“Health care providers have consistently been telling patients that the key to weight loss and improvement for almost every other health condition is a low-fat diet. What we know now through increased research and research review is that there is no evidence to support this advice as a broad recommendation,” Hallberg says. “In many cases, this approach has worsened medical conditions and certainly frustrated people attempting to lose weight.”

Some reliable evidence-based sources that she recommends to patients are the Obesity Medicine Association, Obesity Action Coalition and Virta Health.

For those who are unsure how to begin changing their nutrition, Doniphan suggests starting by eliminating easily digestible foods such as sweetened sodas, which tend to be a source of sugars for many people.

Furthermore, he notes to respect the patient’s wishes and don’t force change on them; try to guide them toward the decision to make a healthier lifestyle change.

“Sometimes patients are not ready to make a change,” he says. “Consider using the stages of behavior change to determine where a patient lies: precontemplation, contemplation, preparation, action and maintenance.”

Additional material and resources are available from the Obesity Medicine Association, including a free copy of the Obesity Algorithm, a quick reference guide to understanding the four aspects of obesity medicine: behavior, nutrition, pharmacology and physical activity.”
Physicians are facing a variety of reimbursement trends in 2021 that range from how they code office visits to payers emphasizing more value-based care. With 2020 being a tough year for many practices, doctors need to understand what’s happening with payments so they can earn every penny possible to help make up for losses suffered during the pandemic and prepare their practices for the future.

Here’s a look at the biggest changes.

E/M codes and the physician fee schedule
The biggest fundamental shifts in reimbursement are the changes to the physician fee schedule and evaluation and management (E/M) codes. For example, there will no longer be an E/M requirement for a specific level of history and exam. Under the new guidelines, history and exam need to be relevant and pertinent based only on the reason for the visit, with a new focus on the level of medical decision or time as defined by the code.

Physicians need to make sure they understand the new coding criteria or they might miss out on revenue, says Anders Gilberg, senior vice president, government affairs, Medical Group Management Association. “It’s something that could potentially impact reimbursement if they’re not prepared,” says Gilberg, adding that it’s important to make sure all the practice workflows and staff training are set up to account for the changes.

The other big change is the reduction in the Medicare conversion factor from $36.09 in 2020 to $32.26 in 2021, which means practices with a large Medicare population need to plan for a likely reduction in revenue.

Telehealth reimbursement trends
The pandemic forced many practices to embrace telehealth as a means to keep seeing patients, and the Centers for Medicare & Medicaid Services (CMS) responded by lifting many restrictions and reimbursing telehealth visits at the same rates as in-person visits. Most private payers also made telehealth reimbursement equal to office visits for common ailments. CMS’s actions are directly tied to the public health emergency declared by Congress, and what happens to telehealth reimbursement post-pandemic remains unknown. Some private payers have already rolled back some of their telehealth payments as patients have begun returning to practices.

Experts say this leaves physicians who may have invested significant sums into telehealth wondering if they will still be reimbursed for virtual visits once the pandemic wanes.

“It’s not that private payers would assume the answer is they shouldn’t pay them more or increase the rates for telehealth, but they want to make certain that what they’re paying for results in changed outcomes,” says Mark Bethke, FSA, managing director, Deloitte Consulting. “My understanding is there is not a whole lot of data out there that really illustrates how effective telehealth is. You need multiple years of data to truly see outcomes, and
MONEY / 2021 PAYMENT OUTLOOK

while telehealth has been around for a long time, it wasn’t adopted by many until very recently. You can’t really trust the last six months of claims data to say this is the long-term impact because we’re affected much more by a pandemic.”

Gilberg says he expects most private payers to revert to their original agreements in 2021, so whatever aspects of telehealth were covered before the pandemic will continue to be covered, but any special exceptions will likely be removed. On the public payer side, Gilberg says CMS’s changes are covered by the public health emergency, and if that legislation expires, so, too, will all the special telehealth payment rules.

“There are some modest changes in the fee schedule for 2021, adding a couple of codes to the telehealth coverage categories, but largely, CMS can’t do that much without Congress,” Gilberg says. “That’s important, because prior to the public health emergency, Medicare didn’t even cover telehealth outside of rural areas, and there were significant geographic restrictions and other administrative restrictions on telehealth. Unless Congress intervenes, all that will change, including the loss of any type of payment parity.”

**Payer trends to watch**

Value-based care is expected to continue growing as more payers embrace it as a means to control costs and have data that proves improved outcomes, but fee-for-service isn’t going away — at least not yet.

“I can’t say value-based care is going to be all here in three years because it’s a claim we’ve been saying for many, many years and we’ve been wrong every time,” Bethke says. But even though fee-for-service is hanging around, physicians need to embrace value-based care for their long-term success, he adds.

Gilberg says to expect more hybrid types of approaches to payment models, similar to shared savings programs where fee-for-service is the underlying payment methodology, but then there are bonuses or penalties for cost and quality.

The transition away from FFS takes time, because to be successful, it requires more than just a new payment model where physicians take on more risk. “You have to make changes to the care model and that requires a big change for people to essentially be told they have to operate differently than they have historically done,” Bethke says. “It might require changing physician compensation structures, it might be taking on new claims data, or new analytics that a provider has not had to do and think about before. But the people who can organize and have scale, and they can do it competitively, will have an advantage.”

Medicare, through its Quality Payment Program (QPP), is already measuring doctors in various categories as it tries to identify — and reward — the doctors who achieve the best patient outcomes. But whether it’s for QPP or a private payer value-based care contract, scale is important to protect a practice. Without enough patients, a few chronic ones that have major health problems at one time could wreck a physician’s overall score, resulting in missed bonuses or even a payment penalty.

“I think that you can still be independent, but be part of something, whether it’s an ACO (accountable care organization) or some clinically integrated network,” Bethke says. “I absolutely believe independence can still work if they’re willing to take a portion of their business and partner up in some aggregated fashion with some entity. I think it’s important to be in the driver’s seat versus having it forced upon you.”

Physicians who have the data to show payers they are improving quality, improving efficiency and delivering better outcomes with lower costs will be in a position to negotiate the best contracts in 2021 and beyond.

“Data is everything when it comes to value-based care,” Gilberg says. “The most effective value-based arrangements between physicians and payers are those in which the payers provide data back to the physicians.”

“The most effective value-based arrangements between physicians and payers are those in which the payers provide data back to the physicians.”

— Anders Gilberg, MGMA
With stay at home and shelter in place orders, it is safe to assume many practices have seen a significant decline in visits and revenue. It is probably also safe to assume that many practices will suffer a loss this year. While this is undoubtedly an unfortunate event, Congress passed the CARES Act in an attempt to provide relief.

As you can imagine from an 880-page bill, there are many tax and nontax provisions in the bill. This article will focus solely on the changes made to net operating losses (NOL). We will start with defining an NOL, discussing the legislative history of NOLs, and finish up with some examples of the benefits of the new rules.

**Background**

According to IRS Publication 536, an NOL occurs when deductions exceed income. In 2020, losses are generally caused by deductions from a trade or business, casualty and theft losses from a federally declared disaster, or rental property. Business losses are the most common cause of an NOL. Even though partnerships and S corporations generally cannot use NOLs, partners and shareholders can use their portion of the business’s income and deductions to calculate their own NOL.

Prior to the passage of the Tax Cuts and Jobs Act (TCJA) in late 2017, NOLs could be carried back two years and carried forward 20 years. The TCJA generally disallowed NOLs from being carried back and allowed them to be carried forward indefinitely. There was also an 80% of taxable income limitation placed on NOLs.

Enter pandemic. Stay at home orders and social distancing guidelines have decimated small businesses. In an effort to blunt the effects, Congress passed the CARES Act. The act now allows losses arising in 2018, 2019, and 2020 to be carried back five years. This means that a 2018 NOL can be carried back to 2013. Taxpayers can, however, elect to forgo the carryback and carry the loss forward, instead. The CARES Act also allows losses carried to 2019 and 2020 to offset 100% of taxable income.

**Benefit**

Taxpayers are encouraged to consult their tax preparers to see if carrying back or forward is more beneficial. If one decides to carry back a loss, they can either amend a return or file an application for tentative refund depending on deadlines. If a carryforward is decided upon, taxpayers must file an election to waive the carryback period.

Given the TCJA’s decrease in marginal tax rates, carrying back a loss to years with higher brackets could provide a tax rate arbitrage. For example, a married filing joint taxpayer with $150,000 of taxable income in 2019 would be in the 22% bracket. If the same were true in 2013, they would be in the 28% tax bracket. So, assume this taxpayer had an unusually bad year in 2018 and experienced a $50,000 net operating loss. The taxpayer could carry that back to 2013 to offset their income or carry it forward to offset 2019 income.

Additionally, there could be an even greater tax benefit for higher income earners choosing to carryback an NOL to pre-TCJA years. Some high-income earners were subject to an exemption and itemized deduction phase out due to the Pease limitation before 2018, both of which are currently nonexistent. Lastly, some practitioners could be currently eligible for the new 199A deduction possibly reducing their effective rate even further compared to pre TCJA years with higher marginal rates and no 199A deduction.

**Conclusion**

While our current circumstances are dire, the new NOL rules could provide some financial solace. Practitioners should consider how these new rules affect them. 

James Enriquez is a partner at Adaptive Tax Planning, LLC. Send your financial questions to medec@mjhlifesciences.com.
Creating a post-COVID health care system

by Chris Mazzolini, Editorial Director

The COVID-19 pandemic is a monumental challenge for the U.S. health care system. But it’s also a once-in-a-lifetime opportunity to shake up the status quo, which relies on a fee-for-service system that is outdated and leaves both physicians and patients wanting more.

What should a post-pandemic health care delivery system look like? And what role should primary care physicians hold in this system?

Medical Economics® sat down recently via Zoom with Mark McClellan, M.D., Ph.D., to discuss that opportunity. McClellan is a former CMS administrator and FDA commissioner, and now serves as director of the Duke-Margolis Center for Health Policy at Duke University. This transcript was edited for length and clarity.

Medical Economics®: How would you assess the performance of the health care system during COVID-19?

Mark McClellan: I think it’s been mixed. First of all, health professionals in this country have done an incredible job working under often very difficult conditions and a pandemic where we never seem to be able to get to full containment. So it’s continuing to be a heavy burden on health care workers all over the country as we keep seeing recurrent cases and continued heavy burdens on our health care system throughout hospitals and detecting cases and managing patients with COVID-19.

I’ve also been impressed with the progress that we’ve made on therapeutics. I’m glad that Remdesivir seems to be moving beyond a shortage, limited access stage and becoming more broadly available. And we’ve clearly learned a lot about how to manage severe cases. Where it’s been tougher is in just how well prepared and robust our health care systems are. At the beginning of the pandemic, we just weren’t well prepared for this. We faced shortages in everything from diagnostic testing to PPE, and that had big consequences for our ability to contain the spread.

Now, people have commented a lot about the relative weakness of the U.S. public health system. I’ve seen a lot of examples of health care organizations moving upstream and doing more testing and at-risk communities helping integrate with public health. That may be the best path forward for our country for the future, since we just don’t have a well-developed public health system.

And then finally, in terms of the way our health care system has responded, I’ve been particularly impressed with organizations that have already moved away from fee-for-service payments. Some of the organizations that are more advanced in capitated type models, those organizations didn’t have their revenue floor fall out from under them when utilization fell in March and April. They were already engaged in a lot of telehealth and longitudinal data management to monitor their higher risk patients. They had a relatively easy time adapting to what was needed in the pandemic, which was a shift towards early intervention with patients, managing risks, redesigning care to put an emphasis on sites of service that were more community- and home-based.
I hope those features of our health care system, the interaction with public health, the building on population-based, value-based care models are something that we can develop further as we get through the rest of this pandemic and move beyond. It would make for a much more resilient health care system, one that’s much easier on health professionals the next time around.

ME: What should that post-COVID-19 health care delivery system look like? And how do we take the next step with value-based care?

McClellan: In Duke Margolis, we’ve been collaborating with a lot of organizations and experts around the country, including six former CMS administrators who have worked from different perspectives, Republican and Democrat, on value-based care and payment reforms, including organizations like Families USA that are very concerned about the well-being of lower- and middle-income families that have really struggled during the pandemic.

And it all comes back to changing the way that we support our health professionals so they have an easier job not only responding to the pandemic but delivering care that reflects the opportunities for keeping people out of the hospital, for early diagnosis, and for dealing with the root causes of health problems much better than we have in the past. You know, people have been talking about value-based care for a while and it I think the evidence confirms that it does support paying differently by designing care differently.

Working as teams, using longitudinal data systems, we can do a better job of keeping people out of the hospital, improving patient experience, avoiding complications, and even get some savings at the same time. It’s been slow going, but I’m hoping that this will be a time for some further progress. I think it’s something that health care providers are maybe a bit more open to after seeing their fee-for-service revenues go down.

From a patient standpoint, people really have appreciated not just the ability to set up a telehealth visit, but all these services being reorganized around them and meeting their needs. Things like phone calls to let them know their risk. Or if they do have symptoms or a problem, connecting 24/7 to a nurse practitioner who knows their care and their records. It’s just a better way of delivering care. Here in North Carolina, Blue Cross of North Carolina has implemented a program where they’re giving some of their primary care groups some additional payments to help them get through the pandemic, who haven’t had as much assistance as some of the hospitals from the CARES Act and other emergency funding.

So they’re getting some financial help right now. And in conjunction with that they’re planning to move into so-called advanced medical home models over the next couple of years. This was a strategic direction that Blue Cross wanted to move in anyway, to get to better care. But it’s a special opportunity to do it now with some of the savings from reduced utilization that we’ve seen over the last few months, channeled directly into strengthening the practices and helping them move into these better models.

And we’re seeing some other examples like that around the country. CMS is starting some new programs that permit some upfront payments to physicians as part of their direct contracting and primary care first models and retooled oncology care model and kidney care model. Many other private insurers are interested in the same kinds of approaches. So it does seem like an opportune time to reflect on what went wrong, and really try to advance some of these value-based care models.
ME: I’m wondering what you think the correct approach is to getting providers to embrace value-based care? There’s the carrot and there’s the stick, and we sort of applied both of them in different ways. I’m wondering what you think is the way to really get physicians and health systems to leap with both feet into value-based care?

McClellan: Yeah, there are carrots and sticks. And from my time at CMS, a lot of providers complained about too much paperwork. So obviously, the more this is carrot-incentive oriented, the better. I actually think that the challenge with MIPS is that it puts a lot of emphasis on some minor adjustments in fee-for-service. You still get paid on a fee-for-service basis. You still have to do all the billing, all the paperwork, and on top of that, you’ve got to make sure you’re reporting on all the measures and things like that. And some of the things that the metrics are intended to do, like avoid readmissions, or improve other aspects of quality, the fee-for-service system doesn’t really pay you that well to support.

So the kinds of reforms I think are more promising, and the ones that in recent CMS reports they’ve shown have led to more savings and bigger measurable improvements in care, are ones that do move a bit more away from fee-for-service. So for a primary care group, giving them a payment per person, as a medical home or direct contract payment, that they get up front, and that they can use to make new kinds of investments, restructuring their practice, moving towards more of a team-based approach to care, investing in new IT capabilities that they can use in collaboration with health plans and other community organizations to augment the scope of services they can provide to keep people healthy.

And it’s those shifts away from the fee-for-service hamster wheel that give providers a chance to take a step back and say, okay, how do I really want to design my practice, that I think can make the most difference. And we’re seeing those kinds of models, not just in primary care, but in oncology, and kidney care. Getting kidney patients out of the dialysis clinics, which are generally not associated with the best outcomes and instead using models that enable more dialysis at home. That just wasn’t possible under the old here’s-your-payment-for-each-dialysis-service approach. And same thing true for other areas of specialized care and for accountable care organizations, as well.

CMS has tried to take a step in a number of their major Alternative Payment Model programs recently, pushing a bit more towards bigger shifts away from fee-for-service. I get nervous when I hear terms like downside risk, but really the flip side of that is money that you get up front that you can spend on what you think is most important, not just money where you have to ask, “do I have to do this procedure, this visit, and document this MIPS measure in order to get it?”

So it’s those bigger shifts that I think are more promising. And the good news here too, is that there are more supports and more experience available for all types of providers, small and large, primary care and specialty, to understand better how they can succeed in these approaches. It’s something that we work on a lot at Duke Margolis. There are other large collaborations producing more examples of successes. Other programs that really can help providers that are interested in these models look at and understand what they need to do. It is some work but in terms of provider experience—the quality part of the quadruple aim that’s very important for practice sustainability, as well as patient experience and quality of care and outcomes — these really are, it is increasingly clear, better ways of delivering care.

ME: Primary care physicians often feel very undervalued. And they feel like they’re on the hamster wheel, maybe more than a lot of other specialties. What do you see as the ideal role for primary care in the health care system?

McClellan: They need to have a bigger role. That means more support for more enhanced kinds of primary care programs, the kinds of things I’ve just been talking about. They involve primary care physicians not just doing a couple of office visits a year, but really being the coordinators, or the integrators of better care models that include working with a team, a nurse who can help with ongoing chronic care management, a social worker who can help with root causes of patients not taking their medication, or having some kind of issue that keeps them from getting into the office when a checkup is needed. Working with someone in the community who can help them as well as be sort of a trusted voice.

What we’re really talking about is an enhanced primary care model that costs more money. And that’s why I think some of the major payers for value-based care models are trying to get there by really creating significant payments to the enhanced primary care groups that are more than what they would have gotten before. But it’s also not linked to fee-for-service, because all those things I just mentioned are not things that are paid for in fee for service but instead are related to additional capabilities for helping to manage patients more effectively, getting better
results, keeping them at home more. And they typically come with some accountability around health outcomes for their population or experience for their population. And getting total cost of care down.

We saw a number of models tried in the 2000s and 2010s, that were kind of additional payments for primary care. And those were helpful, and they made a difference in terms of supporting these kinds of additional capabilities, strengthening the primary care offices. Unfortunately, especially if you count the additional payments to primary care, they didn't generally show overall health care savings, at least in the first few years after they were implemented.

The models that have shown more of an effect are these kinds of direct contracting or advanced primary care models that are more like physician led ACOs where the physician groups do take on at least some limited accountability for the total cost of care for their patients. It gives them more opportunities for additional revenues when they keep patients out of the hospital, get them into more effective care models, use specialty care more efficiently. Bring costs down as well as improving outcomes.

There are more programs available that physicians can get engaged in, like Aledade Health or Agilon, to provide support for some of these additional capabilities. Or they can work with health plans and Medicare Advantage and the Blue Cross plan that I mentioned earlier. So those kinds of opportunities look very promising as a realistic path available increasingly now to primary care docs to take primary care reimbursement from the really low 5% or thereabouts of spending in the US, up to 10% or more. If you count all the integrated services, the coordination with behavioral health, and so forth, it makes for what should be a much stronger, enhanced primary care for the future.

Check out Medical Economics Pulse. This interview was transcribed from a video interview that was recorded as part of Medical Economics® Pulse video program.

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Q&A

Keep using telehealth to boost your practice

Virtual visits will remain important part of engaging with patients even after the pandemic.

by Todd Shryock Managing Editor

The COVID-19 pandemic brought telehealth into the mainstream for many physicians and patients. Usage rates have declined from highs in April, but experts say that telehealth will play a much bigger role in health care moving forward and that physicians need to embrace it to succeed.

Medical Economics® spoke with Caroline Brennan, Ph.D., vice president of the health division of Escalent, a health care research firm, to learn more about telehealth strategies and trends. The transcript has been edited for clarity and brevity.

Medical Economics® (ME): How can doctors encourage people to use telehealth for the first time?

Brennan: I believe that it’s about communication at every stage of the interaction between the patient, the office and the doctor. So right away, when a patient calls the doctor’s office looking for an appointment, the office can offer telehealth as an option and provide a little bit of background about how that visit would work. Another way to encourage usage is to have a lot of information on the practice’s website. It should explain how telehealth works, not just the technological aspects of it, but what to expect, how these visits go, what conditions are appropriate for it, what are inappropriate for it. Also, include frequently asked questions or things such as anonymized patient testimonials to help put people at ease and make them more interested in giving it a try.

ME: How much of the reluctance to use telehealth comes from not having a comfort level with the technology? And how can doctors help patients overcome that?

Brennan: What’s interesting is when we started our research on this, we thought that the technology barrier would be significant. And what we found is that not many people expressed concern about technology, about not being tech savvy, or not having some tools at home. But nonetheless, any time any of us goes to a new website, logs in and uses technology for the first time, there’s always some apprehension. Doctors’ offices can provide very detailed login information, explain exactly what needs to be downloaded, give instructions on how it will work, maybe even provide some test runs, so that people can get more comfortable with it before their first telehealth appointment.

ME: What are some best practices doctors should use during a telehealth visit?
**Brennan:** One thing that we did hear loud and clear, it wasn’t technology ... what people were really concerned about was the face-to-face interaction and missing out on that. Anything the doctor can do to re-create it or simulate what an in-person visit would be like would go a long way in putting the patient at ease. So things such as small talk and eye contact with the patient set the expectations of how that visit might go. Doctors also should explain how they will make a diagnosis and acknowledge some of the limitations of telehealth because patients aren’t right there with them. At the same time, assure patients that they can still get a quality diagnosis, that they will still have good quality of care through this telehealth experience.

**ME:** Why should doctors continue to use telehealth once the pandemic is over, even if many of them are more comfortable with in-person visits?

**Brennan:** I think everybody is probably more comfortable with in-person visits. But the opportunity to have telehealth continuing after this pandemic ... there are a lot of convenience factors here, and it’s also opening up health care to people who might not be as likely to go to the doctor’s office. Maybe they’re very busy, they don’t have reliable transportation to get there, or maybe a doctor’s office is very far away, so it takes a lot of time. Continuing to offer telehealth as a robust alternative to the in-person visit would improve the opportunity for people to get health care that they might not otherwise be accessing.

**ME:** Telehealth usage rates have dropped from the initial highs in April — how can physicians encourage patients to keep using it when appropriate?

**Brennan:** I think it all comes down to bringing it up when they’re making the appointment, whether that’s on the phone or even if they’re booking the appointment online, offering that as an option. I think word of mouth is very persuasive, so as people slowly get more experience with it, and they tell their friends and family that, no, it actually wasn’t so bad and they had a good experience, I think that would go a long way in encouraging people to continue using it.

**ME:** What does the long-term future of telehealth look like in the United States?

**Brennan:** Based on what we’re hearing, it certainly is not going to replace in-person visits. But I do think it will remain as a viable option in a lot of cases for a lot of people. At first, it will be for very specific conditions and situations. But I think telehealth is here to stay, and anything that will increase people’s access to health care is a win in my book.

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Release Date: January 1, 2021
Expiration Date: January 1, 2022

Learning Objectives
Upon successful completion of this activity, you should be better prepared to:
• Review recommendations for human papillomavirus (HPV) vaccination with patients and caregivers to increase informed decision-making
• Identify appropriate candidates for HPV vaccination, including the recently expanded group of patients aged 27 to 45 years

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1. Read this activity in its entirety.
2. Go to gotoper.com/go/HPV2021print to access and complete the post-test.
3. Answer the evaluation questions.
4. Request credit using the drop-down menu.
You may immediately download your certificate.
Approximately 15 years after the first routine human papillomavirus (HPV) vaccination recommendations were issued, vaccination rates remain suboptimal. Data from a 2019 national survey found that only 54.2% of adolescents aged 13 to 17 years had completed the vaccination series, and the Healthy People 2030 target is for 80% of adolescents to be vaccinated. Given recently updated HPV vaccination recommendations, and the need for clear communication to promote patient and parent acceptance of the vaccine, here are 3 things you should know about HPV vaccination and prevention.

1. The burden of HPV is growing.
   Although the rate of cervical carcinoma diagnoses in the United States fell between 1999 and 2015, the annual incidence of HPV-associated cancers increased from 30,115 to 43,371 during this period, with numbers rising in both men and women.

   

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<thead>
<tr>
<th>Year</th>
<th>HPV-ASSOCIATED CANCERS</th>
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<tr>
<td>1999</td>
<td>30,115</td>
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<td>2015</td>
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   In the United States, HPV is the most common sexually transmitted infection. Almost all individuals who are not vaccinated against HPV will become infected with it upon initiating sexual activity, with approximately half of infections involving a high-risk HPV genotype. In most cases, the immune system clears the infection within a few years, and cancer does not result. However, if the infection persists latently, the individual’s risk of developing epithelial cell abnormalities and resulting cancer at the site of infection rises.

2. Patients aged 9 to 45 years may be eligible for HPV vaccine.
   In 2019, the Advisory Committee on Immunization Practices (ACIP) expanded its HPV vaccination recommendations to include more adults. Though the vaccination is routinely recommended for ages 11 through 26, the Centers for Disease Control and Prevention (CDC) recommends starting at age 9 for children with a history of sexual assault or abuse, and ACIP recommends shared decision-making for adults aged 27 through 45 who are not adequately vaccinated.

   Key HPV vaccination points for clinicians to remember include the following:
   - The vaccination is most effective when given before initiation of sexual activity.
   - Patients initiating vaccination before their 15th birthday should receive 2 doses of vaccine, with the second administered 6 to 12 months after the first.
   - Those initiating on or after their 15th birthday should receive 3 doses of vaccine, with the second at month 1 or 2 and the third at month 6; this schedule also applies to patients with certain immunocompromising conditions.
   - For patients aged 9 through 26 years who were not adequately vaccinated, the ACIP recommends catch-up vaccination; if the vaccination schedule is interrupted, vaccine doses do not need to be repeated.
   - In adults aged 27 to 45 years, the shared decision-making discussion is intended to target those who are most likely to benefit from HPV vaccination. Adults in a long-term mutually monogamous relationship are at low risk of new HPV infections, but having new sex partners raises the risk of new HPV infection. Currently, only a 9-valent vaccine is distributed in the United States. It is indicated for male and female individuals aged 9 through 45 years for preventing the following conditions related to specific HPV genotypes:
     - Cervical, vulvar, vaginal and anal cancer; oropharyngeal and other head and neck cancers
     - Cervical intraepithelial neoplasia grades 1 and 2 to 3;
cervical adenocarcinoma in situ; vulvar and vaginal intraepithelial neoplasia grades 2 and 3; anal intraepithelial neoplasia grades 1, 2 and 3
Genital warts caused by HPV types 6 and 11

3

Short, simple messages can improve vaccine acceptance.

The CDC recommends that clinicians check their patients’ vaccination status at each visit, then recommend and provide necessary vaccinations. It also suggests that clinicians provide a “bundled” recommendation for all adolescent vaccines for eligible patients (e.g., meningococcal, pertussis and HPV).

“I like to keep it simple. When patients are 9 and 10 years old, I start to give guidance about what to expect when they get to their 11-year-old visit. When that visit comes, I say, ‘Today is the day we need to do your Tdap, HPV and meningitis shots,’ and there are no surprises or many questions by that point.”

— Margot Savoy, MD, MPH

Other CDC suggestions include the following:

- Ensuring that all office staff who interact with patients are aligned in the communication they provide to patients and parents about HPV vaccination
- Preparing brief responses to common parent questions, such as the purpose of vaccination, the risk and implications of HPV infection in both female and male adolescents, vaccine effectiveness and safety, and its potential effect on the adolescent’s decision to initiate sexual activity

The CDC has additional information on HPV-related communication for clinicians at: cdc.gov/hpv/hcp/boosting-vacc-rates.html.

KEY REFERENCES


For a full list of references go to gotoper.com/go/HPV2021print
CME POST-TEST QUESTIONS

1. A mother brings her 11-year-old son and 12-year-old daughter to primary care for their well-child visits. The mother, who is 42 years old and dating female partners but is not in a long-term relationship, initiates a discussion about HPV vaccination for her children and herself.

Which of the following is an appropriate vaccination recommendation to provide to the family?

A. As preteens, neither child is yet eligible for HPV vaccination.
B. Because she is engaged in lesbian relationships, the mother is at minimal risk of HPV infection and would gain little benefit from vaccination.
C. Both children are eligible for a 2-dose HPV vaccination series, and the mother is eligible for shared decision-making regarding a 3-dose series.
D. Male adolescents, including the son, require a 2-dose HPV vaccination series and female adolescents, including the daughter, require a 3-dose series.

2. Which of the following steps is less likely to help health care providers resolve HPV vaccination stigma and other barriers with patients during a clinic visit?

A. Aligning expectations on vaccine messaging with clinic nurses and medical assistants
B. “Bundling” the HPV vaccination with other necessary vaccine recommendations
C. Practicing making their recommendation “pitch” using guidance from the CDC
D. Thoroughly explaining HPV-related cancer incidence, citing data from the federal government

To learn more about this topic, including information on how to provide patient-motivating communication on HPV vaccination, go to gotoper.com/online-cme-activities/cpc/cpc-fmx20hpv

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Things You Should Know About Treating Early Rheumatoid Arthritis

Release Date: January 1, 2021
Expiration Date: January 1, 2022

Learning Objectives
Upon successful completion of this activity, you should be better prepared to:

• Review current American College of Rheumatology (ACR) guidelines regarding rheumatoid arthritis (RA) disease activity measures to guide treatment decisions in patients with RA.
• Evaluate clinical efficacy, safety and tolerability of current and emerging disease-modifying antirheumatic drugs (DMARDs) for the treatment of RA.

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You may immediately download your certificate.
Given the availability of disease-modifying antirheumatic drugs (DMARDs) with multiple mechanisms of action and recent advances in optimizing their use, clinicians can achieve low disease activity or remission in the majority of patients with rheumatoid arthritis (RA). Here are 3 things you should know about providing treatment in early RA, based on the latest guideline strategies.

1 **Start DMARD treatment quickly.**

The 2019 European League Against Rheumatism (EULAR) guidelines for DMARDs recommend initiating DMARD therapy in patients upon RA diagnosis. The 2015 American College of Rheumatology (ACR) guidelines recommend initiating DMARD therapy in DMARD-naive patients with early symptomatic RA. DMARDs, unlike therapies that treat symptoms, such as NSAIDs, limit erosive damage to joints.

Both guidelines recommend methotrexate (MTX) as the preferred initial DMARD in most patients with early RA. Considered a conventional synthetic DMARD (csDMARD) along with leflunomide (LEF), sulfasalazine (SSZ), hydroxychloroquine (HCQ) and a few less commonly used agents, MTX is the most common first-line therapy for RA worldwide. MTX is also used in more advanced RA, and it can be used as monotherapy or combined with other csDMARDs, biologic DMARDs (bDMARDs) or targeted synthetic DMARDs (tsDMARDs).

At its annual meeting in November 2020, the ACR released information from its draft recommendations for the pharmacologic treatment of RA. It strongly recommends MTX monotherapy over HCQ or SSZ for patients with moderate to high disease activity who are DMARD-naive. For these patients, the draft recommendations conditionally recommend MTX over LEF, and strongly recommend MTX over biologic or tsDMARD monotherapy.

2 **Set a target and treat to it.**

A decade after the treat-to-target concept was formally introduced in RA management, its adoption in clinical practice remains inconsistent. In a 2018 survey of 439 U.S. rheumatologists, only 44% reported “always” practicing in a treat-to-target manner.

Both EULAR and ACR guidelines recommend disease remission or low disease activity (LDA) as the ideal treatment targets. In a 2018 survey of 439 U.S. rheumatologists, only 44% reported “always” practicing in a treat-to-target manner.

Both EULAR and ACR guidelines recommend disease remission or low disease activity (LDA) as the ideal treatment targets. Remission is considered the appropriate target in patients with early disease, and LDA may be more appropriate in patients with established disease or a history of failed therapies. For patients not at target, the 2020 draft ACR recommendations conditionally recommend LDA over remission as the minimal initial treatment goal. The ACR/EULAR definitions of remission require the patient to be in one of the following categories at any given time:

- Tender joint count and swollen joint count 1 or less; C-reactive protein 1 mg/dL or less; and patient global assessment of 1 or less on a 0 to 10 scale.
- A Simplified Disease Activity Index (SDAI) of 3.3 or less.

3 **Discontinue MTX within a year due to toxicity.**

However, patient nonadherence to MTX is common, and 7% to 38% have been found to discontinue treatment within a year due to toxicity. The use of injectable rather than oral MTX, as well as folic or folinic acid supplementation, may improve tolerability and adherence.

“Rheumatologists have a lot of options for treatment choices for RA patients now, and having carefully considered evidence-based guidance is important for designing a treatment plan with patients. There are always patient factors that influence decision-making, and the new guidelines make allowances for these and address specific scenarios.”

— Jon T. Giles, MD, MPH
Know when and how to switch therapies in early RA.

The 2019 EULAR guidelines, which focus on DMARD therapy, recommend adjusting therapies in patients with active disease who have shown no improvement by at most three months of treatment or who have not reached their target by six months.²

For patients whose disease activity remains moderate or high on initial DMARD monotherapy, the next recommended therapies in the ACR 2015 guidelines are combination csDMARDs; a tumor necrosis factor (TNF) inhibitor with or without MTX; or a non-TNF biologic with or without MTX.

Approximately 50% to 60% of patients do not reach treatment goals with the first DMARD course, and more than 60% of these patients will require a third DMARD. Currently, no laboratory markers are available to predict which patients will respond to a particular drug, although interest in this type of personalized medicine is high.¹ Treatment selection should be based on shared decision-making that includes patient preferences, comorbidities, potential contraindications and treatment costs, both to the patient and to society.²,³

### ACR70 Response Rates for DMARDS¹

<table>
<thead>
<tr>
<th>Category</th>
<th>Drug</th>
<th>Response Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSDMARDS</td>
<td>Methotrexate</td>
<td>20% to 40%</td>
</tr>
<tr>
<td>Leflunomide</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>TSDMARDS*</td>
<td>Tofacitinib</td>
<td>20%</td>
</tr>
<tr>
<td>Baricitinib</td>
<td>24%</td>
<td></td>
</tr>
<tr>
<td>BDMARD TNF INHIBITORS*</td>
<td>Etanercept</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Infliximab</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Adalimumab</td>
<td>20%</td>
</tr>
<tr>
<td></td>
<td>Golimumab</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Certolizumab</td>
<td></td>
</tr>
<tr>
<td>BDMARD IL-6 RECEPTOR ANTAGONISTS*</td>
<td>Tocilizumab</td>
<td>22%</td>
</tr>
<tr>
<td></td>
<td>Sarilumab</td>
<td></td>
</tr>
<tr>
<td>OTHER BDMARDS*</td>
<td>Rituximab</td>
<td>22%</td>
</tr>
<tr>
<td></td>
<td>Abatacept</td>
<td></td>
</tr>
</tbody>
</table>

ACR, American College of Rheumatology; b, biologic; cs, conventional synthetic; DMARD, disease-modifying antirheumatic drug; IL-6, interleukin 6; ts, targeted synthetic.

* Among methotrexate insufficient responders

### Key References


For a full list of references go to gotoper.com/go/ai-ra-management2021
A 43-year-old woman with a two-month history of swollen, painful joints with positive rheumatoid factor and elevated levels of C-reactive protein receives a diagnosis of rheumatoid arthritis. Which of the following steps would be most appropriate for you to take as part of a guideline-supported treat-to-target strategy for this patient?

A. Select a disease-modifying antirheumatic drug (DMARD) based solely on efficacy and safety
B. Immediately initiate biologic DMARD monotherapy
C. Assess the efficacy of the patient’s DMARD therapy at six months
D. Set a goal for the patient to attain a Simplified Disease Activity Index (SDAI) of 3.3 or less

Which of the following is a true statement about DMARD therapies?

A. Well-established biomarkers are available to predict patient response to specific DMARD classes
B. Among patients with insufficient methotrexate response, ACR70 response rates are approximately 20% to 22% with tofacitinib, adalimumab or sarilumab
C. Methotrexate is associated with a high level of patient satisfaction and adherence
D. Three-quarters of patients with RA reach their treatment goals with their first DMARD

To learn more about this topic, including information on providing optimal diagnosis and choosing initial and subsequent DMARD therapy, go to gotoper.com/online-cme-activities/ai/ai-dm20
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ARS15PV 15 cu.ft. 33.75" 23.5" 25" Glass $1,204.00
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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 (shingles) in adults aged 50 years and older.

Limitations of Use:

SHINGRIX is not indicated for prevention of primary varicella infection (chickenpox).

2 DOSAGE AND ADMINISTRATION

2.2 Administration Instructions

For intramuscular injection only.

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

2.3 Dose and Schedule

Two doses (0.5 mL each) administered intramuscularly according to the following schedule: A first dose at Month 0 followed by a second dose administered anytime between 2 and 6 months later.

4 CONTRAINDICATIONS

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

5 WARNINGS AND PRECAUTIONS

5.1 Preventing and Managing Allergic Vaccine Reactions

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

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.

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 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 (24.9%) subjects were aged 50 to 59 years, 4,488 (15.3%) subjects were aged 60 to 69 years, and 17,531 (59.8%) 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 (74.3%), followed by Asian (18.3%), black (1.4%), and other racial/ethnic groups (6.0%); 58% were female.

Solicited Adverse Events

In Studies 1 and 2, data on solicited local and general adverse events 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 adverse reaction and each solicited general adverse event following administration of SHINGRIX (both doses combined) were pain (78.0%), redness (38.1%), and swelling (25.9%); and myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (20.5%), and gastrointestinal symptoms (17.3%), respectively.

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 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, GI: Defined as >39.0°C/102.2°F.

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

### Table 1. Percentage of Subjects with Solicited Local Adverse Reactions and General Adverse Events 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>Age Group</th>
<th>Solicited Local Adverse Reactions</th>
<th>Solicited General Adverse Events</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SHINGRIX %</td>
<td>Placebo %</td>
</tr>
<tr>
<td>Aged 50-59 Years</td>
<td>n = 1,315</td>
<td>n = 1,312</td>
</tr>
<tr>
<td>Pain</td>
<td>88.4</td>
<td>14.4</td>
</tr>
<tr>
<td>Pain, Grade 3d</td>
<td>10.3</td>
<td>0.5</td>
</tr>
<tr>
<td>Redness</td>
<td>38.7</td>
<td>1.2</td>
</tr>
<tr>
<td>Redness, &gt;100 mm</td>
<td>2.8</td>
<td>0.0</td>
</tr>
<tr>
<td>Swelling</td>
<td>30.5</td>
<td>0.8</td>
</tr>
<tr>
<td>Swelling, &gt;100 mm</td>
<td>1.1</td>
<td>0.0</td>
</tr>
<tr>
<td>Myalgia</td>
<td>56.9</td>
<td>15.2</td>
</tr>
<tr>
<td>Myalgia, Grade 3e</td>
<td>8.9</td>
<td>0.9</td>
</tr>
<tr>
<td>Fatigue</td>
<td>57.0</td>
<td>19.8</td>
</tr>
<tr>
<td>Fatigue, Grade 3e</td>
<td>8.5</td>
<td>1.8</td>
</tr>
<tr>
<td>Headache</td>
<td>50.6</td>
<td>21.6</td>
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<tr>
<td>Headache, Grade 3e</td>
<td>6.0</td>
<td>1.7</td>
</tr>
<tr>
<td>Shivering</td>
<td>35.8</td>
<td>7.4</td>
</tr>
<tr>
<td>Shivering, Grade 3e</td>
<td>6.8</td>
<td>0.2</td>
</tr>
<tr>
<td>Fever</td>
<td>27.8</td>
<td>3.0</td>
</tr>
<tr>
<td>Fever, Grade 3e</td>
<td>0.4</td>
<td>0.2</td>
</tr>
<tr>
<td>GIa</td>
<td>24.3</td>
<td>10.7</td>
</tr>
<tr>
<td>GI, Grade 3e</td>
<td>2.1</td>
<td>0.7</td>
</tr>
</tbody>
</table>

(continued on next page)
The incidence of solicited local and general symptoms was lower in subjects aged 70 years and older compared with those aged 50 to 69 years.

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

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 (28.2% and 21.4%, respectively) compared with Dose 1 (24.4% and 18.8%, respectively). Grade 3 solicited general adverse events (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3.1%, 3.6%, and 3.5%, 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 1 (1.4%, 1.4%, 2.3%, and 2.4%, respectively). Grade 3 solicited general adverse events (headache, shivering, myalgia, and fatigue) were reported more frequently by subjects after Dose 2 (2.3%, 3.1%, 3.6%, and 3.5%, respectively) compared with Dose 1 (1.4%, 1.4%, 2.3%, and 2.4%, respectively). 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.

7 DRUG INTERACTIONS

7.1 Concomitant Vaccine Administration

For concomitant administration of SHINGRIX with inactivated influenza vaccine [see Clinical Studies (14.5) of full prescribing information].

7.2 Immunosuppressive Therapies

Immunosuppressive therapies may reduce the effectiveness of SHINGRIX.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

There are no available human data to establish whether there is vaccine-associated risk with SHINGRIX in pregnant women [see Use in Specific Populations (8.1) of full prescribing information].

8.2 Lactation

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

Of the total number of subjects who received at least 1 dose of SHINGRIX in the 2 efficacy trials (n = 14,645), 2,243 (15.3%) were aged 60 to 69 years, 6,837 (46.7%) were aged 70 to 79 years, and 1,921 (13.1%) were 80 years and older. There were no clinically meaningful differences in efficacy across the age groups or between these subjects and younger subjects [see Clinical Studies (14.1, 14.2, 14.3) of full prescribing information].

The frequencies of solicited local and general adverse events 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).

Storage:

Store vials of Lyophilized eG Antigen and Adjuvant Suspension Components refrigerated between 2° and 8°C (36° and 46°F). Protect vials from light. Do not freeze. Discard if the vials have been frozen.

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Produced in USA.
**Important Safety Information (cont’d)***

- Solicited local adverse reactions in subjects aged 50 years and older were pain (78.0%), redness (38.1%), and swelling (25.9%).
- Solicited general adverse reactions in subjects aged 50 years and older were myalgia (44.7%), fatigue (44.5%), headache (37.7%), shivering (26.8%), fever (20.5%), and gastrointestinal symptoms (17.3%).
- SHINGRIX was not studied in pregnant or lactating women, and it is unknown if it is excreted in human milk. Therefore, it cannot be established whether there is vaccine-associated risk with SHINGRIX in pregnant women or if there are effects on breastfed infants or milk production/excretion.

### SHINGRIX DELIVERED >90% EFFICACY AGAINST SHINGLES REGARDLESS OF AGE IN THOSE 50 YEARS AND OLDER

<table>
<thead>
<tr>
<th>AGE</th>
<th>Efficacy (95% CI)</th>
<th>Shingles cases (n) in SHINGRIX group (N)</th>
<th>Shingles cases (n) in placebo group (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>50–59†</td>
<td>96.6% (89.6, 99.3)</td>
<td>3 (3492)</td>
<td>87 (3525)</td>
</tr>
<tr>
<td>60–69†</td>
<td>97.4% (90.1, 99.7)</td>
<td>2 (2141)</td>
<td>75 (2166)</td>
</tr>
<tr>
<td>70–79‡</td>
<td>91.3% (86.0, 94.9)</td>
<td>19 (6468)</td>
<td>216 (6554)</td>
</tr>
<tr>
<td>≥80‡</td>
<td>91.4% (80.2, 96.9)</td>
<td>6 (1782)</td>
<td>68 (1792)</td>
</tr>
</tbody>
</table>

Images do not depict actual patients

*Data from the phase 3 ZOE-50 (≥50 years of age) trial and pooled data in individuals ≥70 years of age from the phase 3 ZOE-50 and ZOE-70 trials in subjects who received 2 doses of SHINGRIX (N=7344 and 8250, respectively) or placebo (N=7415 and 8346, respectively) and did not develop a confirmed case of herpes zoster within 1 month after the second dose.‡

Data from the phase 3 ZOE-50 (≥50 years of age) trial and pooled data in individuals ≥70 years of age from the phase 3 ZOE-50 and ZOE-70 trials in subjects who received 2 doses of SHINGRIX (N=7344 and 8250, respectively) or placebo (N=7415 and 8346, respectively) and did not develop a confirmed case of herpes zoster within 1 month after the second dose.‡

Study 1 Design: Data from ZOE-50—a placebo-controlled, observer-blind, phase 3 trial conducted in 18 countries in which subjects ≥50 years old were randomized to receive 2 doses (0 and 2 months) of either SHINGRIX (N=7698) or placebo (N=7713). A total of 7344 and 7415 subjects who received SHINGRIX and placebo, respectively, were included in the modified Total Vaccinated Cohort (mTVC) analysis.‡

Study 2 Design: Data from ZOE-70—a placebo-controlled, observer-blind, phase 3 trial conducted in 18 countries in which subjects ≥70 years old were randomized to receive 2 doses (0 and 2 months) of either SHINGRIX (N=6950) or placebo (N=6950). A total of 6541 and 6622 subjects who received SHINGRIX and placebo, respectively, were included in the mTVC analysis.‡

The primary efficacy analysis (mTVC) in Studies 1 and 2 included all subjects who did not develop a confirmed case of herpes zoster (HZ) within 1 month after the second dose.‡

Pooled Analysis: Data from ZOE-50 and ZOE-70 were combined in a pre-specified pooled analysis. A total of 8250 and 8346 subjects ≥70 years of age who received SHINGRIX and placebo, respectively, were included.‡

The studies excluded subjects who were immunocompromised, had a previous history of HZ, were previously vaccinated against varicella or HZ, and patients whose survival was not expected to be at least 4 years, or with conditions that might interfere with study evaluations.‡
SAFETY PROFILE

SOLICITED ADVERSE REACTIONS\textsuperscript{1,4}

<table>
<thead>
<tr>
<th>LOCAL ADVERSE EVENTS*</th>
<th>SHINGRIX (N=4884)</th>
<th>Placebo (N=4880)</th>
<th>%</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>78.0</td>
<td>10.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain, Grade 3'</td>
<td>6.4</td>
<td>0.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Redness</td>
<td>38.1</td>
<td>1.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Redness, Grade 3'</td>
<td>2.9</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swelling</td>
<td>25.9</td>
<td>1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swelling, Grade 3'</td>
<td>1.0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>GENERAL ADVERSE EVENTS*</th>
<th>SHINGRIX (N=4876)</th>
<th>Placebo (N=4881)</th>
<th>%</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Myalgia</td>
<td>44.7</td>
<td>11.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia, Grade 3\textsuperscript{3}</td>
<td>5.1</td>
<td>0.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>44.5</td>
<td>16.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue, Grade 3\textsuperscript{3}</td>
<td>5.3</td>
<td>1.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>37.7</td>
<td>15.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache, Grade 3\textsuperscript{6}</td>
<td>3.3</td>
<td>0.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shivering</td>
<td>26.8</td>
<td>5.8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shivering, Grade 3\textsuperscript{6}</td>
<td>4.1</td>
<td>0.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever\textsuperscript{II}</td>
<td>20.5</td>
<td>3.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever, Grade 3\textsuperscript{3}</td>
<td>0.3</td>
<td>0.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal Symptoms\textsuperscript{GA}</td>
<td>17.3</td>
<td>8.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal Symptoms, Grade 3\textsuperscript{3}</td>
<td>1.4</td>
<td>0.6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\*Main safety pooling analysis, ZOE-50 and ZOE-70 studies. Incidence of solicited general symptoms reported during the 7-day (ie, day of vaccination and subsequent 6 days) post-vaccination period, overall/subject (total vaccinated cohort with 7-day diary card; subjects ≥50 YOA).

\textsuperscript{1}Significant pain at rest; prevented normal everyday activities.

\textsuperscript{2}Temperature ≥99.5°F (≥37.5°C) for oral, axillary, or tympanic route, or ≥100.4°F (≥38°C) for rectal route.

\textsuperscript{3}Includes nausea, vomiting, diarrhea, and/or abdominal pain.

\textsuperscript{4}Number of subjects with at least 1 documented dose; YOA=years of age.

To see the CDC Recommendations about vaccination, visit us at RecoSHINGRIX.com

Important Safety Information (cont’d)

- Vaccination with SHINGRIX may not result in protection of all vaccine recipients

Please see additional Important Safety Information throughout and Brief Summary of Prescribing Information for SHINGRIX on the previous pages.


Trademark ownership information is included.
EVALUATE THE DATA. 
EDUCATE YOUR PATIENTS.

YOU CAN BE CONFIDENT WHEN DISCUSSING SHINGRIX WITH PATIENTS 50 YEARS AND OLDER

SHINGRIX
(ZOSTER VACCINE RECOMBINANT, ADJUVANTED)

In the pivotal clinical trials, the most common solicited adverse reactions observed were pain, redness, and swelling at the injection site, myalgia, fatigue, headache, shivering, fever, and gastrointestinal symptoms.1

>90% EFFICACY1,*

*Data from the phase 3 ZOE-50 (≥50 years of age) trial and pooled data in individuals ≥70 years of age from the phase 3 ZOE-50 and ZOE-70 trials. See study designs inside for more details.1

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

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